ANNEXURE A

Sodium hydroxide (18%) buffered solution was prepared according to the following formula:

Compound		Quantity
NaOH		18.0 g
Deionized water	ad	100 ml

Method:

1. Weigh the exact amount of Sodium hydroxide powder on a calibrated balance.
2. Add the powder to a Class A calibrated glass volumetric vase.
3. Fill to volume with deionised water.
4. An exothermic reaction takes places, do not put cap on to tight. Leave to cool.
5. Fill up to final volume.
6. Shake well and use within 24 hours.

ANNEXURE B

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	13/10/2008	Batch No:	Carbopol® 934P 0.10%
Requested by:	Charlene		

Product description: 0.10% Carbopol® emulgel formulation without co-solvent

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign					

Raw material	Batch nr	Quantity %	Quantity 200 g	Weight	Action Sign	Check sign
Vit F ethyl ester	308E009	2.8	5.6g	5.61g		
Cremophor EL®	04517856PO	1.0	2.0g	2.00g		
dl-α- Tocopherol	707090036	0.2	0.4g	0.42g		
Butylated Hydroxyanisole	07115PG-475	0.04	0.08g	0.0807g		
Butylated Hydroxytoluene	04416KD-076	0.2	0.4g	0.4005g		
TBHQ	1254992	0.2	0.4g	0.4008g		
Nipastat®	GBG0001069	0.175	0.35g	0.3500g		
Carbopol® 934P	CC67JBB139	0.10	0.2g	0.2005g		
N_2O . H_2O	NO8021	95.05	190.11g	190.21		
NaOH (18%)	1028176	0.23	0.46g	0.47g		
Total		100	200g	200.14g		

Method:

1. Weigh off $N_2O.H_2O$ and Nipastat®. Add the Nipastat® to the water. Stir well.
   Heat mixture until 60 °C on hotplate with probe. Temp: 57 °C
2. Weigh off the Carbopol® and add it to the heated water mixture at 800 rpm.
3. Add the sodium hydroxide buffer slowly to the mixture at 300 rpm while stirring continuously.

Page 1 of 2

4. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑
   Butylated Hydroxyanisole ☑, Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat the oil mixture on hotplate to 60 °C. Temp: 57 ° C
5. Weigh off dl-α-Tocopherol and add to 4.
6. Immediately add 5 to 1 and homogenize at 13500 rpm for 5 minutes.

		Sign	Date
Prepared:	CHARLENE		2008/10/13
Checked:	CARLIE		2008/10/13

Packaging:

Describe containers: 1 x 50ml Clear glass for visible detection
1 x 100ml Amber glass for viscosity, pH, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Two by
Volume of each 50ml and 100ml

Example of label:

Product Name : CARBOPOL 0.1%
Batch Number : CAR 0.1%
Packaging Date : 13/10/2008
Expiry Date : 13/11/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document

Date: 06/10/2006	Batch No:	Carbopol® 934P 0.10% (PG)
Requested by: Charlene		

Product description: 0.10% Carbopol® emulgel formulation with co-solvent

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign					

Raw material	Batch nr	Quantity %	Quantity 200 g	Weight	Action Sign	Check sign
Vit F ethyl ester	308E009	2.8	5.6g	5.62g		
Cremophor EL®	04517856PO	1.0	2.0g	2.01g		
dl-α- Tocopherol	707090036	0.2	0.4g	0.43g		
Butylated Hydroxyanisole	07115PG-475	0.04	0.08g	0.0805g		
Butylated Hydroxytoluene	04416KD-076	0.2	0.4g	0.4003g		
TBHQ	1254992	0.2	0.4g	0.4002g		
Nipastat®	GBG0001069	0.175	0.35g	0.350g		
Carbopol® 934P	CC67JBB139	0.10	0.2g	0.2007g		
Proylene glycol	52560	10.0	20.0	20.0g		
N_2O . H_2O	NO8021	85.055	170.11	170.11g		
NaOH (18%)	1028176	0.23	0.46g	0.47g		
Total		100	200g	200.08g		

Method:

1. Weigh off $N_2O.H_2O$, propylene glycol and Nipastat®. Add the Nipastat® to the propylene glycol. Stir well. Add the Nipastat® mixture to the $N_2O.H_2O$ Heat mixture until 60 °C on hotplate with probe. Temp: 60 °C

2. Weigh off the Carbopol® and add it to the heated water mixture at 800 rpm.
3. Add the sodium hydroxide buffer slowly to the mixture at 300 rpm while stirring continuously.
4. Weigh off and heat together: Vit F ethyl ester [✓], Cremophor EL [✓],
   Butylated Hydroxyanisole [✓] Butylated Hydroxytoluene [✓] and TBHQ [✓]
   Heat the oil mixture on hotplate to 60 °C. Temp: 61 °C
5. Weigh off dl-α-Tocopherol and add to 4.
6. Immediately add 5 to 1 while stirring at 13500 rpm with the homogenizer for 5 minutes.

		Sign	Date
Prepared:	CHARLENE		2008/10/06
Checked:	CARLIE		2008/10/06

Packaging:

Describe containers: 1 x 5oml Clear glass for visible detection
1x 100ml Amber glass for viscosity, ptl, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign			

Quantity filled: Two by

Volume of each 5oml and 100ml

Example of label:

Product Name : CARBOPOL 0.1% PG 10%
Batch Number : CAR 0.1% PG 10%
Packaging Date : 06/10/2008
Expiry Date : 06/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	13/10/2008	Batch No:	Carbopol® 934P 0.20%
Requested by:	Charlene		

Product description: 0.20% Carbopol® emulgel formulation without co-solvent

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign					

Raw material	Batch nr	Quantity %	Quantity 200 g	Weight	Action Sign	Check sign
Vit F ethyl ester	308E009	2.8	5.6g	5.62g		
Cremophor EL®	04517856PO	1.0	2.0g	2.02g		
dl-α- Tocopherol	707090036	0.2	0.4g	0.41g		
Butylated Hydroxyanisole	07115PG-475	0.04	0.08g	0.0808g		
Butylated Hydroxytoluene	04416KD-076	0.2	0.4g	0.4008g		
TBHQ	1254992	0.2	0.4g	0.4007g		
Nipastat®	GBG0001069	0.175	0.35g	0.3501g		
Carbopol® 934P	CC67JBB139	0.20	0.4g	0.4001g		
N_2O . H_2O	NO8021	94.725	189.45g	189.46g		
NaOH (18%)	1028176	0.46	0.92g	0.92g		
Total		100	200g	200.06g		

Method:

1. Weigh off $N_2O.H_2O$ and Nipastat®. Add the Nipastat® to the water. Stir well. Heat mixture until 60 °C on hotplate with probe. Temp: 60 °C
2. Weigh off the Carbopol® and add it to the heated water mixture at 800 rpm.
3. Add the sodium hydroxide buffer slowly to the mixture at 300 rpm while stirring continuously.

4. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,
   Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat the oil mixture on hotplate to 60 °C. Temp: 68 °C
5. Weigh off dl-α-Tocopherol and add to 4.
6. Immediately add 5 to 1 while stirring at 13500 rpm with the homogenizer for 5 minutes.

		Sign	Date
Prepared:	CHARLENE		2008/10/13
Checked:	CARLIE	CMBritz	2008/10/13

Packaging:

Describe containers: 1x 50ml Clear glass for visible detection
1x 100ml Amber glass for viscosity, pH, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Two by

Volume of each 50ml and 100ml

Example of label:

Product Name : CARBOPOL 0.2%
Batch Number : CAR 0.2%
Packaging Date : 13/10/2008
Expiry Date : 13/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document

Date:	13/10/2008	Batch No:	Carbopol® 934P 0.2% (PG)
Requested by:	Charlene		

Product description: 0.2% Carbopol® emulgel formulation with co-solvent

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	JE	JE	JE	JE	JE

Raw material	Batch nr	Quantity %	Quantity 200 g	Weight	Action Sign	Check sign
Vit F ethyl ester	308E009	2.8	5.6g	5.63g	JE	CMB
Cremophor EL®	04517856PO	1.0	2.0g	2.00g	JE	CMB
dl-α- Tocopherol	707090036	0.2	0.4g	0.40g	JE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.08g	0.0807g	JE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.4g	0.4001g	JE	CMB
TBHQ	1254992	0.2	0.4g	0.4006g	JE	CMB
Nipastat®	GBG0001069	0.175	0.35g	0.3500g	JE	CMB
Carbopol® 934P	CC67JBB139	0.2	0.4g	0.4004g	JE	CMB
Propylene glycol	52560	10.0	20.0g	20.03g	JE	CMB
N_2O . H_2O	NO8021	84.72	169.44g	169.45g	JE	CMB
NaOH (18%)	1028176	0.46	0.92g	0.92g	JE	CMB
Total		100	200g	200.06g	JE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Nipastat®. Add the Nipastat® to the water. Stir well. Heat mixture until 60 °C on hotplate with probe. Temp: 60 °C
2. Weigh off the Carbopol® and add it slowly to the heated water mixture at 800 rpm.
3. Add the sodium hydroxide buffer slowly to the mixture at 300 rpm while stirring continuously.

4. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑ ,
   Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat the oil mixture on hotplate to 60 °C. Temp: 58 °C
5. Weigh off dl-α-Tocopherol and add to 4.
6. Immediately add 5 to 1 while stirring at 13500 rpm with the homogenizer for 5 minutes.

		Sign	Date
Prepared:	CHARLENE		2008/10/13
Checked:	CARLIE	CMBritz	2008/10/13

Packaging:

Describe containers: 1 x 50ml Clear glass for visible detection
1 x 100ml Amber glass for viscosity, pH, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Two by

Volume of each 50ml and 100ml

Example of label:

Product Name : CARBOPOL 0.2%. PG 10%.
Batch Number : CAR 0.2%. PG 10%.
Packaging Date : 13/10/2008
Expiry Date : 13/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	13/10/2008	Batch No:	Carbopol® 934P 0.3%
Requested by:	Charlene		

Product description: 0.3% Carbopol® emulgel formulation without co-solvent

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	JE	JE	JE	JE	JE

Raw material	Batch nr	Quantity %	Quantity 200 g	Weight	Action Sign	Check sign
Vit F ethyl ester	308E009	2.8	5.6g	5.60g	JE	CMB
Cremophor EL®	04517856PO	1.0	2.0g	2.01g	JE	CMB
dl-α- Tocopherol	707090036	0.2	0.4g	0.42g	JE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.08g	0.0802g	JE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.4g	0.4007g	JE	CMB
TBHQ	1254992	0.2	0.4g	0.4001g	JE	CMB
Nipastat®	GBG0001069	0.175	0.35g	0.3502g	JE	CMB
Carbopol® 934P	CC67JBB139	0.3	0.6g	0.6008g	JE	CMB
N_2O . H_2O	NO8021	94.39	188.78g	188.80g	JE	CMB
NaOH (18%)	1028176	0.69	1.36g	1.37g	JE	CMB
Total		100	200g	200.03g	JE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Nipastat®. Add the Nipastat® to the water. Stir well. Heat mixture until 60 °C on hotplate with probe. Temp: 60 °C
2. Weigh off the Carbopol® and add it slowly to the heated water mixture at 800 rpm.
3. Add the sodium hydroxide buffer slowly to the mixture at 300 rpm while stirring continuously.

4. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,
   Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat the oil phase on hotplate to 60 °C. Temp: 68 °C
5. Weigh off dl-α-Tocopherol and add to 4.
6. Immediately add 5 to 1 and homogenize at 13500 rpm for 5 minutes.

.

		Sign	Date
Prepared:	CHARLENE		2008/10/13
Checked:	CARLIE	CMBritz	2008/10/13

Packaging:

Describe containers: 1X 5ml Clear glass for visible detection
1X 100ml Amber glass for viscosity, pH, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Two by

Volume of each 5ml and 100ml

Example of label:

Product Name : CARBOPOL 0.3%.
Batch Number : CAR 0.3%.
Packaging Date : 13/10/2008
Expiry Date : 13/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	13/10/2008	Batch No:	Carbopol® 934P 0.3% (PG)
Requested by:	Charlene		

Product description: 0.3% Carbopol® emulgel formulation with co-solvent

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	JE	JE	JE	JE	JE

Raw material	Batch nr	Quantity %	Quantity 200 g	Weight	Action Sign	Check sign
Vit F ethyl ester	308E009	2.8	5.6g	5.61g	JE	CMB
Cremophor EL®	04517856PO	1.0	2.0g	2.02g	JE	CMB
dl-α- Tocopherol	707090036	0.2	0.4g	0.4g	JE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.08g	0.808g	JE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.4g	0.4008g	JE	CMB
TBHQ	1254992	0.2	0.4g	0.4003g	JE	CMB
Nipastat®	GBG0001069	0.175	0.35g	0.3501g	JE	CMB
Carbopol® 934P	CC67JBB139	0.3	0.6g	0.6000g	JE	CMB
Propylene glycol	52560	10.0	20.0g	20.01g	JE	CMB
N_2O . H_2O	NO8021	84.39	168.78g	168.78g	JE	CMB
NaOH (18%)	1028176	0.69	1.36g	1.37g	JE	CMB
Total		100	200g	200.75g	JE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Nipastat®. Add the Nipastat® to the water. Stir well. Heat mixture until 60 °C on hotplate with probe. Temp: 60 °C
2. Weigh off the Carbopol® and add it slowly to the heated water mixture at 800 rpm.

3. Add the sodium hydroxide buffer slowly to the mixture at 300 rpm while stirring continuously.
4. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑ ,

   Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑

   Heat the oil mixture on hotplate to 60 °C. Temp: 60 °C
5. Weigh off dl-α-Tocopherol and add to 4.
6. Immediately add 5 to 1 and homogenize at13500 rpm for 5 minutes.

		Sign	Date
Prepared:	CHARLENE		2008/10/13
Checked:	CARLIE	CMBritz	2008/10/13

Packaging:

Describe containers: 1X 5oml Clear glass for visible detection
1X 100ml Amber glass for viscosity, ptl, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Two by

Volume of each 5oml and 100ml

Example of label:

Product Name : CARBOPOL 0.3% PG 10%
Batch Number : CAR 0.3% PG 10%
Packaging Date : 13/10/2008
Expiry Date : 13/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	14/07/2008	Batch No:	HPMC2.00A
Requested by:	Charlene		

Product description: 2.00% Hydroxypropylmethyl cellulose emulgel formulation without co-solvent according to method A

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	JE	JE	JE	JE	JE

Raw material	Batch nr	Quantity %	Quantity 200 g	Weight	Action Sign	Check sign
Vit F ethyl ester	308E009	2.8	5.6g	5.60g	JE	CMB
Cremophor EL®	04517856PO	1.0	2.0g	2.00g	JE	CMB
dl-α- Tocopherol	U707090036	0.2	0.4g	0.43g	JE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.08g	0.0805g	JE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.4g	0.4017g	JE	CMB
TBHQ	1254992	0.2	0.4g	0.4002g	JE	CMB
Nipastat®	GBG0001069	0.175	0.35g	0.3500g	JE	CMB
HPMC	4456908	2.0	4g	4.0023g	JE	CMB
N_2O . H_2O	NO8021	93.385	186.76g	186.77g	JE	CMB
Total		100	200g	200.03g	JE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Nipastat®. Use a 400ml glass beaker and add the Nipastat® to the water. Stir well. Add the HPMC to the water mixture while stirring with overhead stirrer at 300 rpm for 10 minutes or until fully hydrated. Heat the water mixture to 70 °C on hotplate.
   Temp: 71 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑.

Butylated Hydroxyanisole ☑, Butylated Hydroxytoluene ☑ and TBHQ ☑

Heat to 60 °C. Temp: 59 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 2 minutes.
5. Continue stirring with overhead stirrer at 300rpm until room temperature is reached.

		Sign	Date
Prepared:	CHARLENE		2008/07/14
Checked:	CARLIE		2008/07/14

Packaging:

Describe containers: 1x 50ml Clear glass for visible detection
1x 100ml Amber glass for viscosity, pH, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Two by

Volume of each 50ml and 100ml

Example of label:

Product Name : HPMC 2.00% Method A
Batch Number : HPMC 2.00% A
Packaging Date : 14/07/2008
Expiry Date : 14/07/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	14/07/2008	Batch No:	HPMC2.00A(PG)
Requested by:	Charlene		

Product description: 2.00% Hydroxypropylmethyl cellulose emulgel formulation with co-solvent according to method A

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	200 g			
Vit F ethyl ester	308E009	2.8	5.6g	5.61g	CE	CMB
Cremophor EL®	04517856PO	1.0	2.0g	2.00g	CE	CMB
dl-α- Tocopherol	U707090036	0.2	0.4g	0.39g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.08g	0.0809g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.4g	0.4016g	CE	CMB
TBHQ	1254992	0.2	0.4g	0.4017g	CE	CMB
Nipastat®	GBG0001069	0.175	0.35g	0.3505g	CE	CMB
HPMC	4456908	2.0	4g	4.0011g	CE	CMB
Propylene glycol	52560	10	20g	20.03g	CE	CMB
N_2O . H_2O	NO8021	83.39	166.78g	166.77g	CE	CMB
Total		100	200g	200.04g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$, propylene glycol, HPMC and Nipastat®. Use a 400ml glass beaker and add the HPMC and Nipastat® to the propylene glycol. Stir well. Add the propylene glycol mixture slowly to the water mixture while stirring with an overhead stirrer at 300 rpm for 10 minutes or until fully hydrated. Heat the water mixture to 70 °C on hotplate.

Temp: 68 °C

2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,
   Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat to 60 °C. Temp: 61 °C
3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 2 minutes.
5. Continue stirring with overhead stirrer at 300 rpm until room temperature is reached.

		Sign	Date
Prepared:	CHARLENE		14/07/2008
Checked:	CARLIE	CMBritz	14/07/2008

Packaging:

Describe containers: 1x 50ml Clear glass for visible detection
1x 100ml Amber Glass for viscosity, ptl, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: _____

Volume of each _____

Example of label:

Product Name : HPMC 2.00% Method A(PG)
Batch Number : HPMC 2.00% A (PG)
Packaging Date : 14/07/2008
Expiry Date : 14/07/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	27/10/2008	Batch No:	HPMC2.00B
Requested by:	Charlene		

Product description: 2.00% Hydroxypropylmethyl cellulose emulgel formulation without co-solvent according to method B

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	200 g			
Vit F ethyl ester	308E009	2.8	5.6g	5.60g	CE	CMB
Cremophor EL®	04517856PO	1.0	2.0g	2.02g	CE	CMB
dl-α- Tocopherol	U707090036	0.2	0.4g	0.41g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.08g	0.0801g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.4g	0.4003g	CE	CMB
TBHQ	1254992	0.2	0.4g	0.4005g	CE	CMB
Nipastat®	GBG0001069	0.175	0.35g	0.3500g	CE	CMB
HPMC	4456908	2.0	4g	4.0001g	CE	CMB
N_2O . H_2O	NO8021	93.385	186.77g	186.77g	CE	CMB
Total		100	200g	200.03g	CE	CMB

Method:

1. Weigh off and heat together: Vit F ethyl ester ☑ Cremophor EL ☑, Butylated Hydroxyanisole ☑, Butylated Hydroxytoluene ☑ and TBHQ ☑

   Mix well together with spatula.
2. Weigh off the HPMC and at it slowly to the oil phase while stirring with spatula.

Heat to 60 °C. Temp: 60 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Weigh off Nipastat®, $N_2O.H_2O$ and mix well together. Heat on hotplate until 70 °C. Temp: 80 °C
5. Immediately add 3 to 4 while homogenizing @ 13500 rpm for 3 minutes and a further 2 minutes @ 1838 rpm.
6. Continue stirring with overhead stirrer until room temperature is reached.

		Sign	Date
Prepared:	CHARLENE		27/10/2008
Checked:	CARLIE	CMBritz	27/10/2008

Packaging:

Describe containers: 1 X 50ml Clear glass for visible detection
1X 100ml Amber glass for viscosity, pH, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Two by

Volume of each 50ml and 100ml

Example of label:

Product Name : HPMC 2.00% Method B
Batch Number : HPMC 2.00% B
Packaging Date : 27/10/2008
Expiry Date : 27/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	27/10/2008	Batch No:	HPMC2.00B (PG)
Requested by:	Charlene		

Product description: 2.00% Hydroxypropylmethyl cellulose emulgel formulation with co-solvent according to method B

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	200 g			
Vit F ethyl ester	308E009	2.8	5.6g	5.60g	CE	CMB
Cremophor EL®	04517856PO	1.0	2.0g	2.00g	CE	CMB
dl-α- Tocopherol	U707090036	0.2	0.4g	0.47g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.08g	0.0804g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.4g	0.4005g	CE	CMB
TBHQ	1254992	0.2	0.4g	0.4000g	CE	CMB
Nipastat®	GBG0001069	0.175	0.35g	0.3500g	CE	CMB
Propylene glycol	52560	10.0	20g	20.00g	CE	CMB
HPMC	4456908	2.0	4g	4.0007g	CE	CMB
N_2O . H_2O	NO8021	83.385	166.77g	166.67g	CE	CMB
Total		100	200g	200.08g	CE	CMB

Method:

1. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑
   Butylated Hydroxyanisole ☑, Butylated Hydroxytoluene ☑ and TBHQ ☑
   Mix well together with spatula.

2. Weigh off the HPMC and add it slowly to the oil phase while stirring with spatula. Heat to 60 °C. Temp: 64 °C
3. Weigh off dl-α-Tocopherol and add to 2.
4. Weigh off the propylene glycol, Nipastat® and $N_2O.H_2O$. Add the Nipastat® to the propylene glycol and mix well. Add the mixture to the $N_2O.H_2O$ and heat on hotplate until 70 °C. Temp: 65 °C
5. Immediately add 3 to 4 while homogenizing @ 13500 rpm for 3 minutes and a further 2 minutes at 1815 rpm.
6. Continue stirring with overhead stirrer until room temperature is reached.

		Sign	Date
Prepared:	CHARLENE		27/10/2008
Checked:	CARLIE	CMBritz	27/10/2008

Packaging:

Describe containers: 1x 5ml Clear glass for visible detection
1x 100ml Amber glass for viscosity, pH, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign			

Quantity filled: Two by

Volume of each 5ml and 100ml

Example of label:

Product Name : HPMC 2.00% Method B(PG)
Batch Number : HPMC 2.00% B(PG)
Packaging Date : 27/10/2008
Expiry Date : 27/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	14/07/2008	Batch No:	HPMC3.00A
Requested by:	Charlene		

Product description: 3.00% Hydroxypropylmethyl cellulose emulgel formulation without co-solvent according to method A

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	200 g			
Vit F ethyl ester	308E009	2.8	5.6g	5.61g	CE	CMB
Cremophor EL®	04517856PO	1.0	2.0g	2.03g	CE	CMB
dl-α- Tocopherol	U707090036	0.2	0.4g	0.40g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.08g	0.0804g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.4g	0.4014g	CE	CMB
TBHQ	1254992	0.2	0.4g	0.4014g	CE	CMB
Nipastat®	GBG0001069	0.175	0.35g	0.3505g	CE	CMB
HPMC	4456908	3.0	6.0g	6.0005g	CE	CMB
N_2O . H_2O	NO8021	92.385	184.77g	184.79g	CE	CMB
Total		100	200g	200.06g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Nipastat®. Use a 400ml glass beaker and add the Nipastat® to the water. Stir well. Add the HPMC to the water mixture while stirring with overhead stirrer at 300 rpm for 10 minutes or until fully hydrated. Heat the water mixture to 70 °C on hotplate. Temp: 64 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,

Butylated Hydroxyanisole [✓], Butylated Hydroxytoluene [✓] and TBHQ [✓]

Heat to 60 °C. Temp: 62 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500rpm for 5 minutes.
5. Continue stirring with overhead stirrer at 300rpm until room temperature is reached.

		Sign	Date
Prepared:	CHARLENE		14/07/2008
Checked:	CARLIE	CMBritz	14/07/2008

Packaging:

Describe containers: 1X 50ml Clear glass for visible detection
1X 100ml Amber glass for viscosity, pH, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Two by

Volume of each 50ml and 100ml

Example of label:

Product Name : HPMC 3.00%. Method A
Batch Number : HPMC 3.00%. A
Packaging Date : 14/07/2008
Expiry Date : 14/07/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	14/07/2008	Batch No:	HPMC3.00A(PG)
Requested by:	Charlene		

Product description: 3.00% Hydroxypropylmethyl cellulose emulgel formulation with co-solvent according to method A

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	200 g			
Vit F ethyl ester	308E009	2.8	5.6g	5.61g	CE	CMB
Cremophor EL®	04517856PO	1.0	2.0g	2.02g	CE	CMB
dl-α- Tocopherol	U707090036	0.2	0.4g	0.42g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.08g	0.0807g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.4g	0.4008g	CE	CMB
TBHQ	1254992	0.2	0.4g	0.4009g	CE	CMB
Nipastat®	GBG0001069	0.175	0.35g	0.3507g	CE	CMB
HPMC	4456908	3.0	6.0g	6.0003g	CE	CMB
Propylene glycol	52560	10	20g	20.00g	CE	CMB
N_2O . H_2O	NO8021	82.385	164.77g	164.77g	CE	CMB
Total		100	200g	200.05g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$, propylene glycol, HPMC and Nipastat®. Use a 400ml glass beaker and add the HPMC and Nipastat to® the propylene glycol. Stir well. Add the propylene glycol mixture slowly to the water mixture while stirring with an overhead stirrer at 1200 rpm for 10 minutes or until fully hydrated. Heat the water mixture to 70 °C on hotplate.

Temp: 60 °C

2. Weigh off and heat together: Vit F ethyl ester [✓], Cremophor EL [✓],
   Butylated Hydroxyanisole [✓], Butylated Hydroxytoluene [✓] and TBHQ [✓]
   Heat to 60 °C. Temp: 63 °C
3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5minutes.
5. Continue stirring with overhead stirrer at 300rpm until room temperature is reached.

		Sign	Date
Prepared:	CHARLENE		14/07/2008
Checked:	CARLIE		14/07/2008

Packaging:

Describe containers: 1x 50ml Clear glass for visible detection
1x 100ml Amber glass for viscosity, pH, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign			

Quantity filled: Two by

Volume of each 50ml and 100ml

Example of label:

Product Name : HPMC 3.00% Method A (PG)
Batch Number : HPMC 3.00% A (PG)
Packaging Date : 14/07/2008
Expiry Date : 14/07/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	27/10/2008	Batch No:	HPMC 3.00B
Requested by:	Charlene		

Product description: 3.00% Hydroxypropylmethyl cellulose emulgel formulation without co-solvent according to method B

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	200 g			
Vit F ethyl ester	308E009	2.8	5.6g	5.60g	CE	CMB
Cremophor EL®	04517856PO	1.0	2.0g	2.00g	CE	CMB
dl-α- Tocopherol	U707090036	0.2	0.4g	0.51g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.08g	0.0808g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.4g	0.4004g	CE	CMB
TBHQ	1254992	0.2	0.4g	0.4001g	CE	CMB
Nipastat®	GBG0001069	0.175	0.35g	0.3502g	CE	CMB
HPMC	4456908	3.0	6.0g	6.0006g	CE	CMB
N_2O . H_2O	NO8021	92.385	184.77g	184.77g	CE	CMB
Total		100	200g	200.11g	CE	CMB

Method:

1. Weigh off and heat together: Vit F ethyl ester ☑ Cremophor EL ☑, Butylated Hydroxyanisole ☑, Butylated Hydroxytoluene ☑ and TBHQ ☑

   Mix well together with spatula.
2. Weigh off the HPMC and add it slowly to the oil phase while stirring with spatula.

Heat to 60 °C. Temp: 65 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Weigh off Nipastat®, $N_2O.H_2O$ and mix well together. Heat on hotplate until 70 °C. Temp: 75 °C
5. Immediately add 3 to 4 while homogenizing @ 13500 rpm for 3 minutes and a further 2 minutes @ 1787 rpm.
6. Continue stirring with overhead stirrer until room temperature is reached.

		Sign	Date
Prepared:	CHARLENE		27/10/2008
Checked:	CARLIE		27/10/2008

Packaging:

Describe containers: 1x 50ml Clear glass for visible detection
1x 100ml Amber glass for viscosity, pH, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Two by

Volume of each 50ml and 100ml

Example of label:

Product Name : HPMC 3.00% Method B
Batch Number : HPMC 3.00% B
Packaging Date : 27/10/2008
Expiry Date : 27/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	27/10/2008	Batch No:	HPMC3.00B (PG)
Requested by:	Charlene		

Product description: 3.00% Hydroxypropylmethyl cellulose emulgel formulation with co-solvent according to method B

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	200 g			
Vit F ethyl ester	308E009	2.8	5.6g	5.60g	CE	CMB
Cremophor EL®	04517856PO	1.0	2.0g	2.00g	CE	CMB
dl-α- Tocopherol	U707090036	0.2	0.4g	0.50g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.08g	0.0809g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.4g	0.4002g	CE	CMB
TBHQ	1254992	0.2	0.4g	0.4003g	CE	CMB
Nipastat®	GBG0001069	0.175	0.35g	0.3507g	CE	CMB
Propylene glycol	52560	10.0	20g	20.00g	CE	CMB
HPMC	4456908	3.0	6.0g	6.0008g	CE	CMB
N_2O . H_2O	NO8021	82.385	164.77g	164.78g	CE	CMB
Total		100	200g	200.11g	CE	CMB

Method:

1. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑, Butylated Hydroxyanisole ☑, Butylated Hydroxytoluene ☑ and TBHQ ☑

   Mix well together with spatula.

2. Weigh off the HPMC and add it slowly to the oil phase while stirring with spatula. Heat to 60 °C. Temp: 62 °C
3. Weigh off dl-α-Tocopherol and add to 2.
4. Weigh off the propylene glycol, Nipastat® and $N_2O.H_2O$. Add the Nipastat® to the propylene glycol and mix well. Add the mixture to the $N_2O.H_2O$ and heat on hotplate until 70 °C. Temp: 77 °C
5. Immediately add 3 to 4 while homogenizing @ 13500 rpm for 3 minutes and a further 2 minutes at 1816 rpm.
6. Continue stirring with overhead stirrer until room temperature is reached.

	Sign	Date
Prepared: CHARLENE		27/10/2008
Checked: CARLIE	CMBritz	27/10/2008

Packaging:

Describe containers: 1X50ml Clear glass for visible detection
1x 100ml Amber glass for Viscosity, pH, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Two by

Volume of each 50ml and 100ml

Example of label:

Product Name : HPMC 3.00% Method B (PG)
Batch Number : HPMC 3.00% B (PG)
Packaging Date : 27/10/2008
Expiry Date : 27/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	22/09/2008	Batch No:	XG1.00A
Requested by:	Charlene		

Product description: 1.00% Xanthangum emulgel formulation without co-solvent according to method A

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	150 g			
Vit F ethyl ester	308E009	2.8	4.2g	4.20g	CE	CMB
Cremophor EL®	04517856PO	1.0	1.5g	1.51g	CE	CMB
dl-α- Tocopherol	U707090036	0.2	0.3g	0.32g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.06g	0.605g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.3g	0.3006g	CE	CMB
TBHQ	1254992	0.2	0.3g	0.3011g	CE	CMB
Nipastat®	GBG0001069	0.175	0.263g	0.2630g	CE	CMB
Xanthangum	2509089	1.0	1.5g	1.5009g	CE	CMB
N_2O . H_2O	NO8020	94.39	141.58g	141.59g	CE	CMB
Total		100	150g	150.05g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Nipastat®. Add the Nipastat® to the water. Stir well. Add the xanthangum to the water mixture while stirring with overhead stirrer at 1200 rpm for 10 minutes or until fully hydrated. Heat the water mixture to 70 °C on hotplate.
   Temp: 72 °C

2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,
   Butylated Hydroxyanisole ☑, Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat the oil mixture to 60 °C on hotplate. Temp: 62 °C
3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Continue stirring with overhead stirrer at 300 rpm until room temperature is reached.

		Sign	Date
Prepared:	CHARLENE		22/09/2008
Checked:	CARLIE	CMBritz	22/09/2008

Packaging:

Describe containers: 1X 50ml Clear glass for visible detection
1X 100ml Amber glass for viscosity, pH, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Two by

Volume of each 50ml and 100ml

Example of label:

Product Name : Xanthangum 1.00% Method A
Batch Number : XG 1,00% A
Packaging Date : 22/09/2008
Expiry Date : 22/09/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	22/09/2008	Batch No:	XG1.00A (PG)
Requested by:	Charlene		

Product description: 1.00% Xanthangum emulgel formulation with co-solvent according to method A

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	150 g			
Vit F ethyl ester	308E009	2.8	4.2g	4.21g	CE	CMB
Cremophor EL®	04517856PO	1.0	1.5g	1.53g	CE	CMB
dl-α- Tocopherol	U707090036	0.2	0.3g	0.32g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.06g	0.0604g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.3g	0.3001g	CE	CMB
TBHQ	1254992	0.2	0.3g	0.3010g	CE	CMB
Nipastat®	GBG0001069	0.175	0.263g	0.2636g	CE	CMB
Propylene glycol	52560	10.0	15.0g	15.00g	CE	CMB
Xanthangum	2509089	1.0	1.5g	1.5002g	CE	CMB
N_2O . H_2O	NO8020	84.39	126.58g	126.59g	CE	CMB
Total		100	150.0g	150.08g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$, propylene glycol and Nipastat®. Add the Nipastat® to the propylene glycol, use water to rinse all the Nipastat® into container and add rest of the water. Add the xanthangum to the water mixture while stirring with overhead stirrer at 1200 rpm for 10 minutes or until fully hydrated. Heat the water mixture to 70 °C on hotplate. Temp: 68 °C

2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,
   Butylated Hydroxyanisole ☑, Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat the oil mixture to 60 °C on hotplate. Temp: 58 °C
3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Continue stirring with overhead stirrer at 300 rpm until room temperature is reached.

		Sign	Date
Prepared:	CHARLENE		22/09/2008
Checked:	CARLIE	CMBritz	22/09/2008

Packaging:

Describe containers: 1x 50ml Clear glass for visible detection
1x 100ml Amber glass for viscosity, pH and confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign			

Quantity filled: Two by

Volume of each 50ml and 100ml

Example of label:

Product Name : Xanthangum 1% Method A (PG)
Batch Number : XG 100% A (PG)
Packaging Date : 22/09/2008
Expiry Date : 22/09/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	29/09/2008	Batch No:	XG1.00B
Requested by:	Charlene		

Product description: 1.00% Xanthangum emulgel formulation without co-solvent according to method B

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	150 g			
Vit F ethyl ester	308E009	2.8	4.2g	4.20g	CE	CMB
Cremophor EL®	04517856PO	1.0	1.5g	1.51g	CE	CMB
dl-α- Tocopherol	U707090036	0.2	0.3g	0.33g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.06g	0.609g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.3g	0.3007g	CE	CMB
TBHQ	154992	0.2	0.3g	0.3007g	CE	CMB
Nipastat®	GBG0001069	0.175	0.263g	0.2634g	CE	CMB
Xanthangum	2509089	1.0	1.5g	1.50g	CE	CMB
N_2O . H_2O	NO8020	94.385	141.578g	141.58g	CE	CMB
Total		100	150g	150.59g	CE	CMB

Method:

1. Weigh off and heat together: Vit F ethyl ester ☑ Cremophor EL ☑,
   Butylated Hydroxyanisole ☑, Butylated Hydroxytoluene ☑ and TBHQ ☑
   Mix well together with spatula.
2. Weigh off the xanthangum and add it slowly to the oil phase while stirring with spatula.
   Heat to 60 °C. Temp: 63 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Weigh off Nipastat®, $N_2O.H_2O$ and mix well together. Heat on hotplate until 70 °C.
   Temp: 78 °C
5. Immediately add 3 to 4 while homogenizing @ 13500 rpm for 5 minutes.
6. Continue stirring with overhead stirrer at 400 rpm until room temperature is reached.

		Sign	Date
Prepared:	CHARLENE		29/09/2008
Checked:	CARLIE	CMBritz	29/09/2008

Packaging:

Describe containers: 1 x 50ml Clear glass for visible detection
1 x 100ml Amber glass for viscosity, ptl, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Two by

Volume of each 50ml and 100ml

Example of label:

Product Name : Xanthangum 1.00% Method B
Batch Number : XG 1.00% B
Packaging Date : 29/09/2008
Expiry Date 29/09/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	29/09/2008	Batch No:	XG1.00B (PG)
Requested by:	Charlene		

Product description: 1.00% Xanthangum emulgel formulation with co-solvent according to method B

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	150 g			
Vit F ethyl ester	308E009	2.8	4.2g	4.20g	CE	CMB
Cremophor EL®	04517856PO	1.0	1.5g	1.51g	CE	CMB
dl-α- Tocopherol	U707090036	0.2	0.3g	0.31g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.06g	0.0601g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.3g	0.3005g	CE	CMB
TBHQ	1254992	0.2	0.3g	0.3001g	CE	CMB
Nipastat®	GBG0001069	0.175	0.263g	0.2635g	CE	CMB
Propylene glycol	52560	10.0	15.0g	15.1g	CE	CMB
Xanthangum	2509089	1.0	1.5g	1.5016g	CE	CMB
N_2O . H_2O	NO8020	84.39	126.58g	126.58g	CE	CMB
Total		100	150.0g	150.13g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$, propylene glycol and Nipastat®. Add the Nipastat® to the propylene glycol, use water to rinse all the Nipastat® into container and add rest of the water. Heat the water mixture to 70 °C on hotplate. Temp: 73 °C

2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,
   Butylated Hydroxyanisole ☑, Butylated Hydroxytoluene ☑ and TBHQ ☑
   Mix well together with spatula.
3. Weigh off the xanthangum and add it slowly to the oil phase while stirring with spatula.
   Heat to 60 °C. Temp: 65 °C
4. Weigh off dl-α-Tocopherol and add to 3. Mix well together.
5. Immediately add 4 to 1 while homogenizing @ 13500 rpm for 5 minutes.
6. Continue stirring with overhead stirrer at 400 rpm until room temperature is reached.

		Sign	Date
Prepared:	CHARLENE	Cwp	29/09/2008
Checked:	CARLIE	CmBritz	29/09/2008

Packaging:

Describe containers: 1 x 50ml Clear glass for visible detection
1 x 100ml Amber glass for viscosity, pH, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign	CL	CL	CL

Quantity filled: Two by

Volume of each 50ml and 100ml

Example of label:

Product Name : Xanthangum 1.00% Method B (CPG)
Batch Number : XG 1.00% B (CPG)
Packaging Date : 29/09/2010
Expiry Date : 29/09/2010

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	06/10/2008	Batch No:	XG1.50A

Requested by:	Charlene		

Product description: 1.50% Xanthangum emulgel formulation without co-solvent according to method A

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	150 g			
Vit F ethyl ester	308E009	2.8	4.2g	4.20g	CE	CMB
Cremophor EL®	04517856PO	1.0	1.5g	1.51g	CE	CMB
dl-α- Tocopherol	U707090036	0.2	0.3g	0.34g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.06g	0.609g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.3g	0.3009g	CE	CMB
TBHQ	1254992	0.2	0.3g	0.2633g	CE	CMB
Nipastat®	GBG0001069	0.175	0.263g	2.2503g	CE	CMB
Xanthangum	2509089	1.5	2.25g	2.2503g	CE	CMB
N_2O . H_2O	NO8020	93.89	140.835g	140.85g	CE	CMB
Total		100	150g	150.08g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Nipastat®. Add the Nipastat® to the water. Stir well. Add the xanthangum to the water mixture while stirring with overhead stirrer at 1200 rpm for 10 minutes or until fully hydrated. Heat the water mixture to 70 °C on hotplate.
   Temp: 78 °C

2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,
   Butylated Hydroxyanisole ☑, Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat the oil mixture on hotplate to 60 °C. Temp: 65 °C
3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Continue stirring with overhead stirrer at 400 rpm until room temperature is reached.

		Sign	Date
Prepared:	CHARLENE		06/10/2008
Checked:	CARLIE		06/10/2008

Packaging:

Describe containers: 1x 50ml Clear glass for visible detection
1x 100ml Amber glass for viscosity, pH, Confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Two by

Volume of each 50ml and 100ml

Example of label:

Product Name : Xanthangum 1.50% Method A
Batch Number : XG 1.50% A
Packaging Date : 06/10/2008
Expiry Date : 06/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	06/10/2008	Batch No:	XG1.50A (PG)

Requested by:	Charlene		

Product description: 1.50% Xanthangum emulgel formulation with co-solvent according to method A

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	150 g			
Vit F ethyl ester	308E009	2.8	4.2g	4.19g	CE	CMB
Cremophor EL®	04517856PO	1.0	1.5g	1.51g	CE	CMB
dl-α- Tocopherol	U707090036	0.2	0.3g	0.33g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.06g	0.0607g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.3g	0.3003g	CE	CMB
TBHQ	1254992	0.2	0.3g	0.3003g	CE	CMB
Nipastat®	GBG0001069	0.175	0.263g	0.2632g	CE	CMB
Propylene glycol	52560	10.0	15.0g	14.99g	CE	CMB
Xanthangum	2509089	1.5	2.25g	2.2509g	CE	CMB
N_2O . H_2O	NO8020	83.89	125.835g	125.83g	CE	CMB
Total		100	150.0g	150.03g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$, propylene glycol and Nipastat®. Add the Nipastat® to the propylene glycol, use water to rinse all the Nipastat® into container and add rest of the water. Add the xanthangum to the water mixture while stirring with overhead stirrer at 1200 rpm for 10 minutes or until fully hydrated. Heat the water mixture to 70 °C on hotplate.

Temp: 70 °C

2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,
   Butylated Hydroxyanisole ☑, Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat the oil mixture on hotplate to 60 °C. Temp: 60 °C
3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Continue stirring with overhead stirrer at 400 rpm until room temperature is reached.

	Sign	Date
Prepared: CHARLENE		06/10/2008
Checked: CARLIE		06/10/2008

Packaging:

Describe containers: 1X 50ml Clear glass for visible detection
1X 100ml Amber glass for Viscosity, pH, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign			

Quantity filled: Two by

Volume of each 50ml and 100ml

Example of label:

Product Name : Xanthangum 1.50% Method A(PG)
Batch Number : XG 1.50% A (PG)
Packaging Date : 06/10/2008
Expiry Date : 06/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	06/10/2008	Batch No:	XG1.50B

Requested by:	Charlene		

Product description: 1.50% Xanthangum emulgel formulation without co-solvent according to method B

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	150 g			
Vit F ethyl ester	308E009	2.8	4.2g	4.20g	CE	CMB
Cremophor EL®	04517856PO	1.0	1.5g	1.50g	CE	CMB
dl-α- Tocopherol	U707090036	0.2	0.3g	0.32g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.06g	0.0608g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.3g	0.3011	CE	CMB
TBHQ	1254992	0.2	0.3g	0.3006g	CE	CMB
Nipastat®	GBG0001069	0.175	0.263g	0.2638g	CE	CMB
Xanthangum	2509089	1.5	2.25g	2.2505g	CE	CMB
N_2O . H_2O	NO8020	93.885	140.828g	140.83g	CE	CMB
Total		100	150g	150.03g	CE	CMB

Method:

1. Weigh off and heat together: Vit F ethyl ester ☑ Cremophor EL ☑,
   Butylated Hydroxyanisole ☑, Butylated Hydroxytoluene ☑ and TBHQ ☑
   Mix well together with spatula.
2. Weigh off the xanthangum and add it slowly to the oil phase while stirring with spatula.
   Heat to 60 °C. Temp: 66 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Weigh off Nipastat®, $N_2O.H_2O$ and mix well together. Heat on hotplate until 70 °C.
   Temp: 75 °C
5. Immediately add 3 to 4 while homogenizing @ 13500 rpm for 5 minutes.
6. Continue stirring with overhead stirrer at 400 rpm until room temperature is reached.

		Sign	Date
Prepared:	CHARLENE		06/10/2008
Checked:	CARLIE	CMBritz	06/10/2008

Packaging:

Describe containers: 1 X 50ml Clear glass for visible detection
1X100ml Amber glass for viscosity, pH, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Two by
Volume of each 50ml and 100ml

Example of label:

Product Name : Xanthangum 1.50% MethodB
Batch Number : XG1.50% B
Packaging Date : 06/10/2008
Expiry Date :06/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	06/10/2008	Batch No:	XG1.50B (PG)
Requested by:	Charlene		

Product description: 1.50% Xanthangum emulgel formulation with co-solvent according to method B

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign					

Raw material	Batch nr	Quantity %	Quantity 150 g	Weight	Action Sign	Check sign
Vit F ethyl ester	308E009	2.8	4.2g	4.20g		
Cremophor EL®	04517856PO	1.0	1.5g	1.51g		
dl-α- Tocopherol	U707090036	0.2	0.3g	0.31g		
Butylated Hydroxyanisole	07115PG-475	0.04	0.06g	0.0599g		
Butylated Hydroxytoluene	04416KD-076	0.2	0.3g	0.3004g		
TBHQ	1254992	0.2	0.3g	0.3010g		
Nipastat	GBG0001089	0.175	0.263g	0.2639g		
Propylene glycol	52560	10.0	15.0g	15.04g		
Xanthangum	2509089	1.5	2.25g	2.2505g		
N_2O . H_2O	NO8020	83.89	125.835g	125.84g		
Total		100	150.0g	149.77g		

Method:

1. Weigh off $N_2O.H_2O$, propylene glycol and Nipastat®. Add the Nipastat® to the propylene glycol, use water to rinse all the Nipastat® into container and add rest of the water. Heat the water mixture to 70 °C on hotplate. Temp: 75 °C

2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,
   Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑
   Mix well together with spatula.
3. Weigh off the xanthangum and add it slowly to the oil phase while stirring with spatula.
   Heat the oil mixture on hotplate to 60 °C. Temp: 64 °C
4. Weigh off dl-α-Tocopherol and add to 3. Mix well together.
5. Immediately add 4 to 1 while homogenizing @ 13500 rpm for 5 minutes.
6. Continue stirring with overhead stirrer at 300 rpm until room temperature is reached.

		Sign	Date
Prepared:	CHARLENE		06/10/2008
Checked:	CARLIE	CMBritz	06/10/2008

Packaging:

Describe containers: 1x 50ml Clear glass for visible detection
1x 100ml Amber glass for viscosity, pH, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Two by

Volume of each 50ml and 100ml

Example of label:

Product Name : Xanthangum 1.50% Method B(PG)
Batch Number : XG 150% B (PG)
Packaging Date : 06/10/2008
Expiry Date :06/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	22/09/2008	Batch No:	XG2.00A
Requested by:	Charlene		

Product description: 2.00% Xanthangum emulgel formulation without co-solvent according to method A

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	150 g			
Vit F ethyl ester	308E009	2.8	4.2g	4.21g	CE	CMB
Cremophor EL®	04517856PO	1.0	1.5g	1.52g	CE	CMB
dl-α- Tocopherol	U707090036	0.2	0.3g	0.31g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.06g	0.0603g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.3g	0.3001g	CE	CMB
TBHQ	1254992	0.2	0.3g	0.3002g	CE	CMB
Nipastat®	GBG0001069	0.175	0.263g	0.2636g	CE	CMB
Xanthangum	2509089	2.0	3.0g	3.0003g	CE	CMB
N_2O . H_2O	NO8020	93.39	140.077g	140.08g	CE	CMB
Total		100	150g	150.05g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Nipastat®. Add the Nipastat® to the water. Stir well. Add the xanthangum to the water mixture while stirring with overhead stirrer at 1200 rpm for 10 minutes or until fully hydrated. Heat the water mixture to 70 °C on hotplate.
   Temp: 71 °C

2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,
   Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat the oil mixture on hotplate to 60 °C. Temp: 61 °C
3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Continue stirring with overhead stirrer at 900 rpm until room temperature is reached.

		Sign	Date
Prepared:	CHARLENE		22/09/2008
Checked:	CARLIE	CMBritz	22/09/2008

Packaging:

Describe containers: 1x 50ml Clear glass for visible detection
1x 100ml Amber glass for viscosity, pH, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: two by

Volume of each 50ml and 100ml

Example of label:

Product Name : Xanthangum 2.00% Method A
Batch Number : XG 2.00% A
Packaging Date : 22/09/2008
Expiry Date : 22/09/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	22/09/2008	Batch No:	XG2.00A (PG)
Requested by:	Charlene		

Product description: 2.00% Xanthangum emulgel formulation with co-solvent according to method A

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	150 g			
Vit F ethyl ester	308E009	2.8	4.2g	4.20g	CE	CMB
Cremophor EL®	04517856PO	1.0	1.5g	1.51g	CE	CMB
dl-α- Tocopherol	U707090036	0.2	0.3g	0.31g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.06g	0.0606g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.3g	0.3011g	CE	CMB
TBHQ	1254992	0.2	0.3g	0.3001g	CE	CMB
Nipastat®	GBG0001069	0.175	0.263g	0.2634g	CE	CMB
Propylene glycol	52560	10.0	15.0g	15.02g	CE	CMB
Xanthangum	2509089	2.0	3.0g	3.0009g	CE	CMB
N_2O . H_2O	NO8020	83.39	125.085g	125.08g	CE	CMB
Total		100	150.0g	150.59g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$, propylene glycol and Nipastat®. Add the Nipastat® to the propylene glycol, use water to rinse all the Nipastat® into container and add rest of the water. Add the xanthangum to the water mixture while stirring with overhead stirrer at 1200 rpm for 10 minutes or until fully hydrated. Heat the water mixture to 70 °C on hotplate.

Temp: 68 °C

2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,
   Butylated Hydroxyanisole ☑, Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat to 60 °C. Temp: 58 °C
3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Continue stirring with overhead stirrer at 1000 rpm until room temperature is reached.

		Sign	Date
Prepared:	CHARLENE		2008/09/22
Checked:	CARLIE	CMBritz	2008/09/22

Packaging:

Describe containers: 1x 50ml Clear glass for visible detection
1x 100ml Amber glass for viscosity, pH, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign	✓	✓	✓

Quantity filled: Two by

Volume of each 50ml and 100ml

Example of label:

Product Name : Xanthan gum 2.00% Method A (PG)
Batch Number : XG 2.00% A (PG)
Packaging Date : 22/09/2008
Expiry Date : 22/09/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	29/09/2008	Batch No:	XG2.00B
Requested by:	Charlene		

Product description: 2.00% Xanthangum emulgel formulation without co-solvent according to method B

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	150 g			
Vit F ethyl ester	308E009	2.8	4.2g	4.21g	CE	CMB
Cremophor EL®	04517856PO	1.0	1.5g	1.50g	CE	CMB
dl-α- Tocopherol	U707090036	0.2	0.3g	0.32g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.06g	0.0604g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.3g	0.3002g	CE	CMB
TBHQ	1254992	0.2	0.3g	0.3005g	CE	CMB
Nipastat®	GBG0001069	0.175	0.263g	0.2631g	CE	CMB
Xanthangum	2509089	2.0	3.0g	3.0015g	CE	CMB
N_2O . H_2O	NO8020	93.385	140.078g	140.08g	CE	CMB
Total		100	150g	150.04g	CE	CMB

Method:

1. Weigh off and heat together: Vit F ethyl ester ☑ Cremophor EL ☑,
   Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑
   Mix well together with spatula.
2. Weigh off the xanthangum and add it slowly to the oil phase while stirring with spatula.
   Heat to 60 °C. Temp: 62 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Weigh off Nipastat®, $N_2O.H_2O$ and mix well together. Heat on hotplate until 70 °C.
   Temp: 68 °C
5. Immediately add 3 to 4 while homogenizing @ 13500 rpm for 5 minutes.
6. Continue stirring with overhead stirrer at 1100 rpm until room temperature is reached.

		Sign	Date
Prepared:	CHARLENE		2008/09/29
Checked:	CARLIE		2008/09/29

Packaging:

Describe containers: 1 X 50ml Clear glass for visible detection
1X 100ml Amber glass for viscosity, pH, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign			

Quantity filled: Two by
Volume of each 50ml and 100ml

Example of label:

Product Name : Xanthangum 2.00% Method B
Batch Number : XG 2.00% B
Packaging Date : 29/09/2008
Expiry Date : 29/09/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	29/09/2008	Batch No:	XG2.00B (PG)
Requested by:	Charlene		

Product description: 2.00% Xanthangum emulgel formulation with co-solvent according to method B

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	150 g			
Vit F ethyl ester	308E009	2.8	4.2g	4.19g	CE	CMB
Cremophor EL®	04517856PO	1.0	1.5g	1.50g	CE	CMB
dl-α- Tocopherol	U707090036	0.2	0.3g	0.35g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.06g	0.0609g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.3g	0.3006g	CE	CMB
TBHQ	1254992	0.2	0.3g	0.3008g	CE	CMB
Nipastat®	GBG0001069	0.175	0.263g	0.2636g	CE	CMB
Propylene glycol	52560	10.0	15.0g	15.01g	CE	CMB
Xanthangum	2509089	2.0	3.0 g	3.0011g	CE	CMB
N_2O . H_2O	NO8020	83.385	125.077g	125.08g	CE	CMB
Total		100	150.0g	150.065g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$, propylene glycol and Nipastat®. Add the Nipastat® to the propylene glycol, use water to rinse all the Nipastat® into container and add rest of the water. Heat the water mixture to 70 °C on hotplate. Temp: 72 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,

Butylated Hydroxyanisole ☑, Butylated Hydroxytoluene ☑ and TBHQ ☑

Mix well together with spatula.

3. Weigh off the xanthangum and add it slowly to the oil phase while stirring with spatula. Heat the oil mixture on hotplate to 60 °C. Temp: 62 °C
4. Weigh off dl-α-Tocopherol and add to 3. Mix well together.
5. Immediately add 4 to 1 while homogenizing @ 13500 rpm for 5 minutes.
6. Continue stirring with overhead stirrer at 1200 rpm until room temperature is reached.

		Sign	Date
Prepared:	CHARLENE		29/09/2008
Checked:	CARLIE		29/09/2008

Packaging:

Describe containers: 1x 50ml Clear glass for visible detection
1x 100ml Amber glass for viscosity, ptl, confocal

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Two by

Volume of each 50ml and 100ml

Example of label:

Product Name : Xanthangum 2.00% Method B (PG)
Batch Number : XG 2.00% B (PG)
Packaging Date : 29/09/2008
Expiry Date : 29/09/2008

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ANNEXURE C

Table C1: Viscosity values obtained for Carbopol® 934P emulgel preparations at stability points 24 hours, 72 hours, seven days and 28 days.

Thickening agent	*Concentration*	*Stability point*	*Plastic viscosity (CP)*	*Yield stress (Pa)*
Carbopol® 934P	0.10%	24 Hours	34.7	0.61
		72 Hours	37.2	0.31
		7 Days	45.8	0.77
		28 Days	9.37	0.5
Carbopol® 934P	0.10%(PG)	24 Hours	35.6	0.54
		72 Hours	38.2	0.32
		7 Days	43.3	0.53
		28 Days	55.7	0.97
Carbopol® 934P	0.20%	24 Hours	1336	26.8
		72 Hours	1286	28.8
		7 Days	566.5	25.4
		28 Days	179.8	7.91
Carbopol® 934P	0.20%(PG)	24 Hours	1235	26
		72 Hours	692.2	28.7
		7 Days	658.6	28.3
		28 Days	655.8	31.2
Carbopol® 934P	0.30%	24 Hours	Out of range	Out of range
		72 Hours	Out of range	Out of range
		7 Days	Out of range	Out of range
		28 Days	2840	58.1
Carbopol® 934P	0.30%(PG)	24 Hours	Out of range	Out of range
		72 Hours	Out of range	Out of range
		7 Days	Out of range	Out of range

Table C2: Viscosity values obtained for XG emulgel preparations at stability points 24 hours, 72 hours, seven days and 28 days.

Thickening agent	*Concentration*	*Stability point*	*Plastic viscosity*	*Yield stress*
Xanthan gum	1.00%A	24 Hours	197.2	39.2
		72 Hours	190.6	39.4
		7 Days	190.8	38.7
		28 Days	176.7	36.8
Xanthan gum	1.00%A(PG)	24 Hours	226.7	51.6
		72 Hours	228.6	52.6
		7 Days	235.2	53.3
		28 Days	239.2	54.2
Xanthan gum	1.50%A	24 Hours	337.6	51.5
		72 Hours	510.2	49.3
		7 Days	340.3	50
		28 Days	342.8	39
Xanthan gum	1.50%A(PG)	24 Hours	1151	64.5
		72 Hours	1172	64.6
		7 Days	1172	65.5
		28 Days	1127	62.1
Xanthan gum	2.00%A	24 Hours	2009	62.5
		72 Hours	2037	64.9
		7 Days	2172	57.1
		28 Days	1289	56.2
Xanthan gum	2.00%A(PG)	24 Hours	24651	49.2
		72 Hours	Out of range	Out of range
		7 Days	17199	75.6
		28 Days	Out of range	Out of range
Xanthan gum	1.00%B	24 Hours	180.4	44.8
		72 Hours	194.2	40.1
		7 Days	193.6	43.4
		28 Days	183.1	41.2
Xanthan gum	1.00%B(PG)	24 Hours	222	54.9
		72 Hours	222.9	53.5
		7 Days	214.7	52.6
		28 Days	222.7	55.9
Xanthan gum	1.50%B	24 Hours	312	52.5
		72 Hours	222.9	53.5
		7 Days	525.2	59.9
		28 Days	285.7	48.2
Xanthan gum	1.50%B(PG)	24 Hours	501.3	57.9
		72 Hours	222.9	53.5
		7 Days	319.6	52.6
		28 Days	493.1	57.8
Xanthan gum	2.00%B	24 Hours	1248	68.6
		72 Hours	1286	67
		7 Days	1939	62.7
		28 Days	1175	58.3
Xanthan gum	2.00%B(PG)	24 Hours	10779	97.1
		72 Hours	Out of range	Out of range
		7 Days	Out of range	Out of range
		28 Days	8764	95.7

Table C3: Viscosity values obtained for HPMC emulgel preparations at stability points 24 hours, 72 hours, seven days and 28 days.

Thickening agent	*Concentration*	*Stablity point*	*Plastic viscosity*	*Yield stress*
HPMC	2.00%A	24 Hours	784.7	2.09
		72 Hours	684.8	1.83
		7 Days	430.4	1.28
		28 Days	Out of range	Out of range
HPMC	2.00%A(PG)	24 Hours	1265	1.99
		72 Hours	1299	2.1
		7 Days	1142	1.99
		28 Days	Out of range	Out of range
HPMC	3.00%A	24 Hours	4210	4.04
		72 Hours	3666	3.21
		7 Days	2638	2.15
		28 Days	Out of range	Out of range
HPMC	3.00%A(PG)	24 Hours	8731	8
		72 Hours	8790	7.45
		7 Days	7928	6.53
		28 Days	Out of range	Out of range
HPMC	2.00%B	24 Hours	1174	1.54
		72 Hours	1010	1.29
		7 Days	586.7	0.61
		28 Days	Out of range	Out of range
HPMC	2.00%B(PG)	24 Hours	1665	2.8
		72 Hours	1627	2.44
		7 Days	1508	1.43
		28 Days	Out of range	Out of range
HPMC	3.00%B	24 Hours	5689	2.83
		72 Hours	4515	4.29
		7 Days	3319	2.43
		28 Days	Out of range	Out of range
HPMC	3.00%B(PG)	24 Hours	9632	5.2
		72 Hours	9396	11.9
		7 Days	8176	5.93
		28 Days	Out of range	Out of range

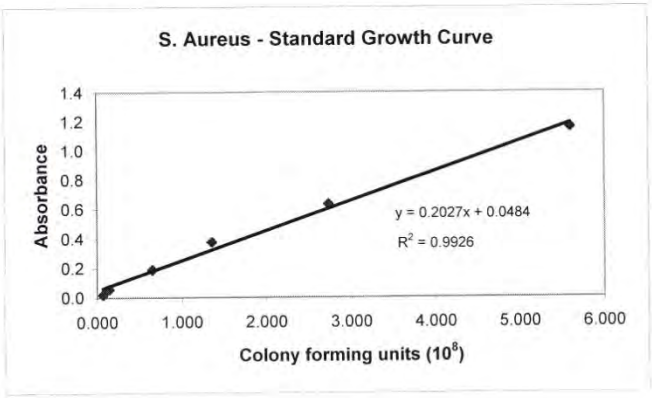
Efficacy of Antimicrobial Preservation Test
Preparation of the Inoculum

Test organism: *Staphylococcus aureus*
Incubated at 30-35 °C for 18-24h on Tryptone Soy Agar (TSA) plates
Sterile Suspending fluid containing 0.9% sodium chloride and 0.1% peptone is made up to volume with distilled water and incubated before use
The *S.aureus* cultures is harvested with the suspending fluid into a sterilised container
The absorbancies of these dilutions were read with a spectrophotometer at 600nm (the suspending fluid is used as a blank)
Dilutions are made of the culture and a triplicate standard plate count is conducted in the order of 10^{-1} to 10^{-8}
Readings is taken with the spectrophotometer for each dilution made.
*CFU - Colony Forming Units

Spectrophotometric analysis of *S.aureus* Concentration (2008/03/04)

Dilution	Amount of Colonies ($CFUx10^8$)	Absorbance
1:1	13.900	1.608
1:2	5.600	1.156
1:4	2.730	0.633
1:8	1.350	0.375
1:16	0.650	0.188
1:32	0.140	0.056
1:64	0.068	0.019

m =	0.2027
c =	0.0484
y =	0.25
x =	1



Absorbance: 0.25
Ilse: 0.09

Efficacy of Antimicrobial Preservation Test
Preparation of the Inoculum

Test organism: *Escherichia coli*
Incubated at 30-35 ^{o}C for 18-24h on Tryptone Soy Agar (TSA) plates
Sterile Suspending fluid containing 0.9% sodium chloride and 0.1% peptone is made up to volume with distilled water and incubated before use
The *E.coli* cultures is harvested with the suspending fluid into a sterilised container
The absorbancies of these dilutions were read with a spectrophotometer at 600nm (the suspending fluid is used as a blank)
Dilutions are made of the culture and a triplicate standard plate count is conducted in the order of 10^{-1} to 10^{-8}
Readings is taken with the spectrophotometer for each dilution made.
*CFU - Colony Forming Units

Spectrophotometric analysis of *E.Coli* Concentration (2008/02/04)

Dilution	Amount of Colonies (CFUx10^{8})	Absorbance
1:1	25.3	2.002
1:2	7.4	1.556
1:4	4.6	1.062
1:8	2.9	0.631
1:32	3.1	0.188
1:64	3.6	0.095

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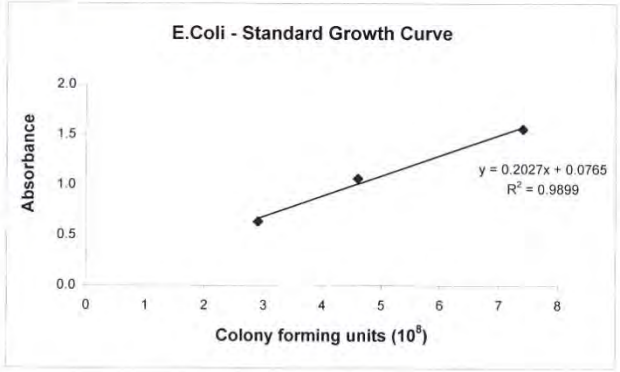
c = 0.0765
y = 0.0765
x = 0.00000001



Efficacy of Antimicrobial Preservation Test
Preparation of the Inoculum

Test organism: *Candida Albicans*
Incubated at 20-25 °C for 48h on Sabaroyd Dextrose Agar (SDA) plates
Sterile Suspending fluid containing 0.9% sodium chloride and 0.1% Peptone is made up to volume with distilled water and incubated before use
The *C. Albicans* cultures is harvested with the suspending fluid into a sterilised container
The absorbancies of these dilutions were read with a spectrophotometer at 600nm (the suspending fluid is used as a blank)
Dilutions are made of the culture and a triplicate standard plate count is conducted in the order of 10^{-1} to 10^{-8}
Readings is taken with the spectrophotometer for each dilution made.
*CFU - Colony Forming Units

Spectrophotometric analysis of *C. Albicans* Concentration (2008/09/02)

Dilution	Amount of Colonies ($CFUx10^7$)	Absorbance
1:1	11.800	2.415
1:2	6.400	2.011
1:4	3.200	1.556
1:8	1.700	1.112
1:16	0.850	0.680
1:32	0.160	0.149

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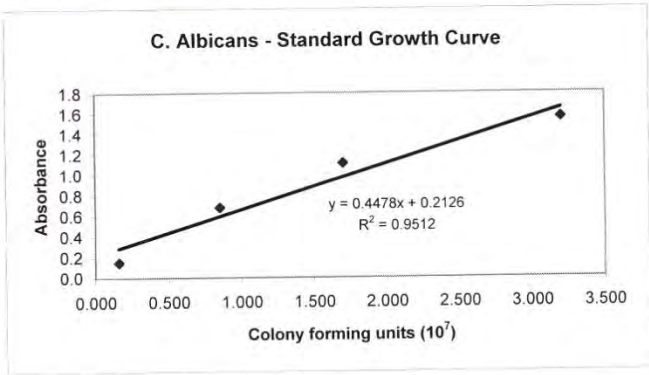
c =	0.2126
y =	0.6604
x =	1.0000



Absorbance: 0.6604
Ilse: 0.429

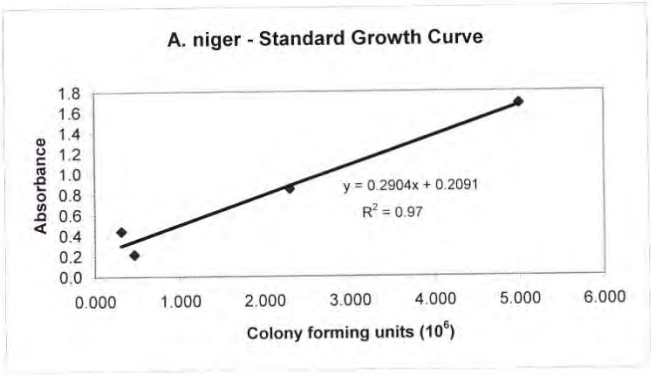
Efficacy of Antimicrobial Preservation Test
Preparation of the Inoculum

Test organism: *Aspergillus niger*
Incubated at 20-25 °C for 7days on Sabaroyd Dextrose Agar (SDA) plates
Sterile Suspending fluid containing 0.9% sodium chloride and 0.05% Tween 80 is made up to volume with distilled water and incubated before use
The *A.niger* cultures is harvested with the suspending fluid into a sterilised container
The absorbancies of these dilutions were read with a spectrophotometer at 600nm (the suspending fluid is used as a blank)
Dilutions are made of the culture and a triplicate standard plate count is conducted in the order of 10^{-1} to 10^{-8}
Readings is taken with the spectrophotometer for each dilution made.
*CFU - Colony Forming Units

Spectrophotometric analysis of *A.niger* Concentration (2008/09/02)

Dilution	Amount of Colonies (CFUx10^6)	Absorbance
1:1	5.000	1.678
1:2	2.300	0.847
1:4	0.310	0.440
1:8	0.460	0.215
1:16	0.170	0.105
1:32	0.200	0.021

m =	0.2904
c =	0.2091
y =	0.4995
x =	1



Absorbance: 0.4995
Ilse: 0.174-0.2

ANNEXURE E

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	29/07/2008	Batch No:	Pheroid 0%a
Requested by:	Charlene		

Product description: Preservative action of Pheroid™ without added preservative for bacteria.

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	600 g			
Vit F ethyl ester	308E009	2.8	16.8g	16.81g	CE	CMB
Cremophor® EL	04517856PO	1.0	6.0g	6.01g	CE	CMB
dl-α- Tocopherol	707090036	0.2	1.2g	1.22g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.24g	0.241g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	1.2g	1.202g	CE	CMB
TBHQ	1254992	0.2	1.2g	1.202g	CE	CMB
N_2O . H_2O	NO8022	95.56	573.36g	573.38g	CE	CMB
Total		100	600g	600.065g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$. Heat the water mixture to 70 °C on hotplate. Temp: 72 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑, Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat to 60 °C. Temp: 58 °C
3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.

Page 1 of 2

5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		09/09/2008
Prepared:	CHARLENE		09/09/2008
Checked:	CARLIE	CMBritz	09/09/2008

Packaging:

Describe containers: 3 x 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Three by

Volume of each 100 ml

Example of label:

Product Name : Pherold o% a
Batch Number : Ph o% a
Packaging Date : 29/07/2008
Expiry Date : 29/07/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	09/09/2008	Batch No:	Pheroid 0 %b

Requested by:	Charlene		

Product description: Preservative action of Pheroid™ formulation without any preservatives for *Aspergilus* and *Candida*.

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	300 g			
Vit F ethyl ester	308E009	2.8	8.4g	8.41g	CE	CMB
Cremophor® EL	04517856PO	1.0	3.0g	3.03g	CE	CMB
dl-α- Tocopherol	707090036	0.2	0.6g	0.61g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.12g	0.1208g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.6g	0.6004g	CE	CMB
TBHQ	1254992	0.2	0.6g	0.6008g	CE	CMB
N_2O . H_2O	NO8022	95.56	286.68g	286.69g	CE	CMB
Total		100	300g	300.062g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$. Add the propylene glycol to the N_2O water. Heat the water mixture to 70 °C on hotplate. Temp: 82 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑, Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑ Heat to 60 °C. Temp: 62 °C
3. Weigh off dl-α-Tocopherol and add to 2.

5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		29/07/2008
Prepared:	CHARLENE		29/07/2008
Checked:	CARLIE		29/07/2008

Packaging:

Describe containers: 6 x 100ml Amber glass

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Six by

Volume of each 100ml

Example of label:

Product Name : Pheroid 0% b
Batch Number : Ph 0% b
Packaging Date : 29/07/2008
Expiry Date : 29/01/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	29/07/2008	Batch No:	PG 10.0%a
Requested by:	Charlene		

Product description: Preservative action of Propylene glycol alone for bacteria.

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	600 g			
Vit F ethyl ester	308E009	2.8	16.8g	16.80g	CE	CMB
Cremophor® EL	04517856PO	1.0	6.0g	6.01g	CE	CMB
dl-α- Tocopherol	707090036	0.2	1.2g	1.22g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.24g	0.24g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	1.2g	1.201g	CE	CMB
TBHQ	1254992	0.2	1.2g	1.200g	CE	CMB
Propylene glycol	52560	10.0	60.0g	60.00g	CE	CMB
N_2O . H_2O	NO8022	85.56	513.36g	513.37g	CE	CMB
Total		100	600g	600.041g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and propylene glycol. Add the propylene glycol to the N_2O water. Heat the water mixture to 70 °C on hotplate. Temp: 70 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑, Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat to 60 °C. Temp: 63 °C
3. Weigh off dl-α-Tocopherol and add to 2.

4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.

5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		29/07/2008
Prepared:	CHARLENE		29/07/2008
Checked:	CARLIE	CMBritz	29/07/2008

Packaging:

Describe containers: 6 x 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: 6 x

Volume of each 100ml

Example of label:

Product Name : Propylene glycol 10% a
Batch Number : PG 10% a
Packaging Date : 29/07/2008
Expiry Date : 29/08/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	09/09/2008	Batch No:	PG 10.0%b
Requested by:	Charlene		

Product description: Preservative action of Propylene glycol alone used for *Aspergillus* and *Candida*

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	300 g			
Vit F ethyl ester	308E009	2.8	8.4g	8.41g	CE	CMB
Cremophor® EL	04517856PO	1.0	3.0g	3.09g	CE	CMB
dl-α- Tocopherol	707090036	0.2	0.6g	0.60g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	0.12g	0.1205g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.6g	0.6003g	CE	CMB
TBHQ	1254992	0.2	0.6g	0.5999g	CE	CMB
Propylene glycol	52560	10.0	30.0g	30.01g	CE	CMB
N_2O . H_2O	NO8022	85.56	256.68g	256.69g	CE	CMB
Total		100	300g	300.1207g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and propylene glycol. Add the propylene glycol to the N_2O water. Heat the water mixture to 70 °C on hotplate. Temp: 87 °C
2. Weigh off and heat together: Vit F ethyl ester [✓], Cremophor EL [✓], Butylated Hydroxyanisole [✓] Butylated Hydroxytoluene [✓] and TBHQ [✓]
   Heat to 60 °C. Temp: 62 °C
3. Weigh off dl-α-Tocopherol and add to 2.

4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.

5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		09/09/2008
Prepared:	CHARLENE		09/09/2008
Checked:	CARLIE	CMBritz	09/09/2008

Packaging:

Describe containers: 3 x 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Three by

Volume of each 100ml

Example of label:

Product Name : Propylene glycol 10% b
Batch Number : PG 10% b
Packaging Date : 09/09/2008
Expiry Date : 09/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	05/08/2008	Batch No:	MHB 0.1%a
Requested by:	Charlene		

Product description: Preservative action of Methylparaben 0.1% without Propylene glycol for bacteria

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	600 g			
Vit F ethyl ester	3086009	2.8	16.8g	16.81g	CE	CMB
Cremophor® EL	04517856PO	1.0	6.0g	6.0g	CE	CMB
dl-α- Tocopherol	UT07090036	0.2	1.2g	1.2g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.24g	0.24g	CE	CMB
Butylated Hydroxytoluene	04416KO-076	0.2	1.2g	1.2g	CE	CMB
TBHQ	1254992	0.2	1.2g	1.2g	CE	CMB
Methylparaben	506780321	0.1	0.6g	0.6g	CE	CMB
N_2O . H_2O	NO8023	95.46	572.76g	572.76g	CE	CMB
Total		100	600g	600.01g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Methylparaben. Add the Methylparaben to the N_2O water. Rinse all of the Methylparaben into the container. Heat the water mixture to 70 °C on hotplate.
   Temp: 74 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,
   Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat to 60 °C. Temp: 60 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		05/08/2008
Prepared:	CHARLENE		05/08/2008
Checked:	CARLIE	CMBritz	05/08/2008

Packaging:

Describe containers: 6 X 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Six by

Volume of each 100ml

Example of label:

Product Name : Methyl hydroxy benzoate 0.1% a
Batch Number : MHB 0.1% a
Packaging Date : 05/08/2008
Expiry Date : 05/09/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	29/07/2008	Batch No:	MHB0.1%PG10%a
Requested by:	Charlene		

Product description: Preservative action of Methylparaben 0.1% with Propylene glycol 10.0% for bacteria

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	600 g			
Vit F ethyl ester	3086009	2.8	16.8g	16.80g	CE	CMB
Cremophor® EL	04517856PO	1.0	6.0g	6.01g	CE	CMB
dl-α- Tocopherol	UT07090036	0.2	1.2g	1.22g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.24g	0.240g	CE	CMB
Butylated Hydroxytoluene	04416KO-076	0.2	1.2g	1.200g	CE	CMB
TBHQ	1254992	0.2	1.2g	1.201g	CE	CMB
Methylparaben	506780321	0.1	0.6g	0.602g	CE	CMB
Propylene glycol	52560	10.0	60.0g	60.00g	CE	CMB
N_2O . H_2O	NO8023	85.46	512.76g	512.76g	CE	CMB
Total		100	600g	600.033g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Methylparaben and Propylene glycol. Add the Methylparaben to the propylene glycol and add the mixture to the N_2O water. Rinse all of the Methylparaben into the container. Heat the water mixture to 70 °C on hotplate. Temp: 70 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑, Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑

4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.

5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		29/07/2008
Prepared:	CHARLENE		29/07/2008
Checked:	CARLIE		29/07/2008

Packaging:

Describe containers: 6x 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Six by

Volume of each 100ml

Example of label:

Product Name : Methylhydroxybenzoate 0.1% + PG 10% a
Batch Number : MHB 0.1% PG 10% a
Packaging Date : 29/07/2008
Expiry Date : 29/09/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	09/09/2008	Batch No:	MHB 0.1%b
Requested by:	Charlene		

Product description: Preservative action of Methylparaben 0.1% without Propylene glycol for *Aspergillus* and *Candida*

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign					

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	300 g			
Vit F ethyl ester	3086009	2.8	8.4g	8.41g	CE	CMB
Cremophor® EL	04517856PO	1.0	3.0g	3.03g	CE	CMB
dl-α- Tocopherol	UT07090036	0.2	0.6g	0.61g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.12g	0.1196g	CE	CMB
Butylated Hydroxytoluene	04416KO-076	0.2	0.6g	0.6005g	CE	CMB
TBHQ	1254992	0.2	0.6g	0.6009g	CE	CMB
Methylparaben	506780321	0.1	0.3g	0.3002g	CE	CMB
N_2O . H_2O	NO8023	95.46	286.38g	286.39g	CE	CMB
Total		100	300g	300.0612g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Methylparaben. Add the Methylparaben to the N_2O water. Rinse all of the Methylparaben into the container. Heat the water mixture to 70 °C on hotplate.
   Temp: 73 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑, Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑

Heat to 60 °C. Temp: 64 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		09/09/2008
Prepared:	CHARLENE		09/09/2008
Checked:	CARLIE		09/09/2008

Packaging:

Describe containers: 3 x 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Three by

Volume of each 100ml

Example of label:

Product Name : Methylhydroxybenzoate 0.1% b
Batch Number : MHB 0.1% b
Packaging Date : 09/09/2008
Expiry Date : 09/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	09/09/2008	Batch No:	MHB0.1%PG10%b

Requested by:	Charlene		

Product description: Preservative action of Methylparaben 0.1% with Propylene glycol 10.0% for *Aspergillus* and *Candida*

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	300 g			
Vit F ethyl ester	3086009	2.8	8.4g	8.40g	CE	CMB
Cremophor® EL	04517856PO	1.0	3.0g	3.03g	CE	CMB
dl-α- Tocopherol	UT07090036	0.2	0.6g	0.62g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.12g	0.1204g	CE	CMB
Butylated Hydroxytoluene	04416KO-076	0.2	0.6g	0.6006g	CE	CMB
TBHQ	1254992	0.2	0.6g	0.6009g	CE	CMB
Methylparaben	506780321	0.1	0.3g	0.3004g	CE	CMB
Propylene glycol	52560	10.0	30.0g	30.02g	CE	CMB
N_2O . H_2O	NO8023	85.46	256.38g	256.38g	CE	CMB
Total		100	300g	300.072g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Methylparaben and propylene glycol. Add the Methylparaben to the propylene glycol and add the mixture to the N_2O water. Rinse all of the Methylparaben into the container. Heat the water mixture to 70 °C on hotplate. Temp: 76 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,

Butylated Hydroxyanisole [✓] Butylated Hydroxytoluene [✓] and TBHQ [✓]

Heat to 60 °C. Temp: 61 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		09/09/2008
Prepared:	CHARLENE		09/09/2008
Checked:	CARLIE	CJBritz	09/09/2008

Packaging:

Describe containers: 3 x 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Three by

Volume of each 100ml

Example of label:

Product Name : Methylhydroxybenzoate 0.1% PG 10% b
Batch Number : MHB 0.1% PG 10% b
Packaging Date : 09/09/2008
Expiry Date : 09/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	05/08/2008	Batch No:	EHB0.15%a
Requested by:	Charlene		

Product description: Preservative action of Ethylparaben 0.15% without Propylene glycol for bacteria

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	600 g			
Vit F ethyl ester	3086009	2.8	16.8g	16.81g	CE	CMB
Cremophor® EL	04517856PO	1.0	6.0g	6.02g	CE	CMB
dl-α- Tocopherol	UT07090036	0.2	1.2g	1.22g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.24g	0.241g	CE	CMB
Butylated Hydroxytoluene	04416KO-076	0.2	1.2g	1.202g	CE	CMB
TBHQ	1254992	0.2	1.2g	1.200g	CE	CMB
Ethylparaben	528990-356	0.15	0.9g	0.901g	CE	CMB
N_2O . H_2O	NO8023	95.41	572.46g	572.46g	CE	CMB
Total		100	600g	600.054g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Ethylparaben. Add the Ethylparaben to the N_2O water. Rinse all of the Ethylparaben into the container. Heat the water mixture to 75 °C on hotplate.
   Temp: 84 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,
   Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat to 60 °C. Temp: 58 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		05/08/2008
Prepared:	CHARLENE		05/08/2008
Checked:	CARLIE		05/08/2008

Packaging:

Describe containers: 6 x 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Six by

Volume of each 100ml

Example of label:

Product Name : Ethylhydroxybenzoate 0.15% a
Batch Number : EHB 0.15% a
Packaging Date : 05 08 2008
Expiry Date : 05/09/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	05/08/2008	Batch No:	EHB0.15%PG10%a
Requested by:	Charlene		

Product description: Preservative action of Ethylparaben 0.15% with Propylene glycol 10.0% for bacteria

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	600 g			
Vit F ethyl ester	3086009	2.8	16.8g	16.8g	CE	CMB
Cremophor® EL	04517856PO	1.0	6.0g	6.01g	CE	CMB
dl-α- Tocopherol	UT07090036	0.2	1.2g	1.21g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.24g	0.241g	CE	CMB
Butylated Hydroxytoluene	04416KO-076	0.2	1.2g	1.200g	CE	CMB
TBHQ	1254992	0.2	1.2g	1.201g	CE	CMB
Ethylparaben	528990-356	0.15	0.9g	0.900g	CE	CMB
Propylene glycol	52560	10.0	60.0g	60.00g	CE	CMB
N_2O . H_2O	NO8023	85.41	512.46g	512.47g	CE	CMB
Total		100	600g	600.032g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Ethylparaben and propylene glycol. Add the Ethylparaben to the propylene glycol and add the mixture to the N_2O water. Rinse all of the Ethylparaben into the container. Heat the water mixture to 70 °C on hotplate. Temp: 79 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑, Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑

Heat to 60 °C. Temp: 62 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		05/08/2008
Prepared:	CHARLENE		05/08/2008
Checked:	CARLIE		05/08/2008

Packaging:

Describe containers: 6 X 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Six by

Volume of each 100ml

Example of label:

Product Name : Ethylhydroxybenzoate 0.15% PG 10% a
Batch Number : EHB 0.15% PG 10% a
Packaging Date : 05/08/2008
Expiry Date : 05/09/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	09/09/2008	Batch No:	EHB0.15%b
Requested by:	Charlene		

Product description: Preservative action of Ethylparaben 0.15% without Propylene glycol for *Aspergillus* and *Candida*

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	300 g			
Vit F ethyl ester	3086009	2.8	8.4g	8.40g	CE	CMB
Cremophor® EL	04517856PO	1.0	3.0g	3.01g	CE	CMB
dl-α- Tocopherol	UT07090036	0.2	0.6g	0.62g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.12g	0.1204g	CE	CMB
Butylated Hydroxytoluene	04416KO-076	0.2	0.6g	0.6002g	CE	CMB
TBHQ	1254992	0.2	0.6g	0.6001g	CE	CMB
Ethylparaben	528990-356	0.15	0.45g	0.4507g	CE	CMB
N_2O . H_2O	NO8023	95.41	286.23g	286.23g	CE	CMB
Total		100	300g	300.0314g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Ethylparaben. Add the Ethylparaben to the N_2O water. Rinse all of the Ethylparaben into the container. Heat the water mixture to 75 °C on hotplate.
   Temp: 86 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑, Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑

Heat to 60 °C. Temp: 61 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		09/09/2008
Prepared:	CHARLENE		09/09/2008
Checked:	CARLIE		09/09/2008

Packaging:

Describe containers: 3 x 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Six by

Volume of each 100ml

Example of label:

Product Name : Ethylhydroxybenzoate 0.15% b
Batch Number : EHB 0.15% b
Packaging Date : 09/09/2008
Expiry Date : 09/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	15/09/2008	Batch No:	EHB0.15%PG10%b
Requested by:	Charlene		

Product description: Preservative action of Ethylparaben 0.15% with Propylene glycol 10.0% for *Aspergillus* and *Candida*

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	300 g			
Vit F ethyl ester	3086009	2.8	8.4g	8.41g	CE	CMB
Cremophor® EL	04517856PO	1.0	3.0g	3.00g	CE	CMB
dl-α- Tocopherol	UT07090036	0.2	0.6g	0.62g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.12g	0.1202g	CE	CMB
Butylated Hydroxytoluene	04416KO-076	0.2	0.6g	0.6011g	CE	CMB
TBHQ	1254992	0.2	0.6g	0.6003g	CE	CMB
Ethylparaben	528990-356	0.15	0.45g	0.4500g	CE	CMB
Propylene glycol	52560	10.0	30.0g	30.03g	CE	CMB
N_2O . H_2O	NO8023	85.41	256.23g	256.25g	CE	CMB
Total		100	300g	300.0816g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Ethylparaben and propylene glycol. Add the Ethylparaben to the propylene glycol and add the mixture to the N_2O water. Rinse all of the Ethylparaben into the container. Heat the water mixture to 70 °C on hotplate. Temp: 85 ° C
2. Weigh off and heat together: Vit F ethyl ester ☒, Cremophor EL ☑,

Butylated Hydroxyanisole [✓] Butylated Hydroxytoluene [ ] and TBHQ [ ]

Heat to 60 °C. Temp: 60 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		15/09/2008
Prepared:	CHARLENE		15/09/2008
Checked:	CARLIE		15/09/2008

Packaging:

Describe containers: 3 x 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Three by

Volume of each 100ml

Example of label:

Product Name : Ethylhydroxy benzoate 0.15% PG 10% b
Batch Number : EHB 0.15% PG 10% b
Packaging Date : 15/09/2008
Expiry Date : 15/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	20/08/2008	Batch No:	PHB0.015%a
Requested by:	Charlene		

Product description: Preservative action of Propylparaben 0.015% without Propylene glycol for bacteria

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	600 g			
Vit F ethyl ester	3086009	2.8	16.8g	16.8g	CE	CMB
Cremophor® EL	04517856PO	1.0	6.0g	6.01g	CE	CMB
dl-α- Tocopherol	UTO7090036	0.2	1.2g	1.27g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.24g	0.241g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	1.2g	1.206g	CE	CMB
TBHQ	1254992	0.2	1.2g	1.209g	CE	CMB
Propylparaben	GBG0001484	0.015	0.09g	0.090g	CE	CMB
N_2O . H_2O	NO8012	95.55	573.27g	573.28g	CE	CMB
Total		100	600g	600.106g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Propylparaben. Add the Propylparaben to the N_2O water. Rinse all of the Propylparaben into the container. Heat the water mixture to 80 °C on hotplate.
   Temp: 75 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,
   Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat to 60 °C. Temp: 63 °C

3. Weigh off dl-α-Tocopherol and add to 2.

4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.

5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		20/08/2008
Prepared:	CHARLENE		20/08/2008
Checked:	CARLIE	CNBritz	20/08/2008

Packaging:

Describe containers: 6 x 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: 6 X

Volume of each 100ml

Example of label:

Product Name : Propylhydroxybenzoate 0.015%a
Batch Number : PHB 0.015% a
Packaging Date : 20/08/2008
Expiry Date : 20/09/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	20/08/2008	Batch No:	PHB0.015%PG10%a
Requested by:	Charlene		

Product description: Preservative action of Propylparaben 0.015% with Propylene glycol 10.0% for bacteria

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	600 g			
Vit F ethyl ester	3086009	2.8	16.8g	16.82g	CE	CMB
Cremophor® EL	04517856PO	1.0	6.0g	6.03g	CE	CMB
dl-α- Tocopherol	UTO7090036	0.2	1.2g	1.20g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.24g	0.241g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	1.2g	1.204g	CE	CMB
TBHQ	1254992	0.2	1.2g	1.203g	CE	CMB
Propylparaben	GBG0001484	0.015	0.09g	0.092g	CE	CMB
Propylene glycol	52560	10.0	60.0g	60.01g	CE	CMB
N_2O . H_2O	NO8012	85.55	513.27g	513.28g	CE	CMB
Total		100	600g	600.08g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Propylparaben and propylene glycol. Add the Propylparaben to the propylene glycol and add the mixture to the N_2O water. Rinse all of the Propylparaben into the container. Heat the water mixture to 70 °C on hotplate. Temp: 75 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,

Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑

Heat to 60 °C. Temp: 59°C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		20/08/2008
Prepared:	CHARLENE		20/08/2008
Checked:	CARLIE		20/08/2008

Packaging:

Describe containers: 6 x 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Six by

Volume of each 100ml

Example of label:

Product Name : Propylhydroxybenzoate 0.015% PG 10% a
Batch Number : PHB 0.015% PG 10% a
Packaging Date : 20/08/2008
Expiry Date : 20/09/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	09/09/2008	Batch No:	PHB0.015%b

Requested by:	Charlene	

Product description: Preservative action of Propylparaben 0.015% without Propylene glycol for *Aspergillus* and *Candida*

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	300 g			
Vit F ethyl ester	3086009	2.8	8.4g	8.40g	CE	CMB
Cremophor® EL	04517856PO	1.0	3.0g	3.02g	CE	CMB
dl-α- Tocopherol	UTO7090036	0.2	0.6g	0.63g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.12g	0.1205g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.6g	0.6007g	CE	CMB
TBHQ	1254992	0.2	0.6g	0.6004g	CE	CMB
Propylparaben	GBG0001484	0.015	0.045g	0.452g	CE	CMB
N_2O . H_2O	NO8012	95.55	286.65g	286.67g	CE	CMB
Total		100	300g	300.086g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Propylparaben. Add the Propylparaben to the N_2O water. Rinse all of the Propylparaben into the container. Heat the water mixture to 80 °C on hotplate.
   Temp: 78 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,
   Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑

Heat to 60 °C. Temp: 60 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		09/09/2008
Prepared:	CHARLENE		09/09/2008
Checked:	CARLIE		09/09/2008

Packaging:

Describe containers: 3 x 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Three by

Volume of each 100ml

Example of label:

Product Name : Propylhydroxybenzoate 0.015% b
Batch Number : PHB 0.015% b
Packaging Date : 09/09/2008
Expiry Date : 09/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	09/09/2008	Batch No:	PHB0.015%PG10%b
Requested by:	Charlene		

Product description: Preservative action of Propylparaben 0.015% with Propylene glycol 10.0% for *Aspergillus* and *Candida*

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	300 g			
Vit F ethyl ester	3086009	2.8	8.4g	8.40g	CE	CMB
Cremophor® EL	04517856PO	1.0	3.0g	3.01g	CE	CMB
dl-α- Tocopherol	UTO7090036	0.2	0.6g	0.61g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.12g	0.2104g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	0.6g	0.6002g	CE	CMB
TBHQ	1254992	0.2	0.6g	0.6003g	CE	CMB
Propylparaben	GBG0001484	0.015	0.045g	0.0455g	CE	CMB
Propylene glycol	52560	10.0	30.0g	30.00g	CE	CMB
N_2O . H_2O	NO8012	85.55	256.65g	256.65g	CE	CMB
Total		100	300g	300.0364g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Propylparaben and rpopylene glycol. Add the Propylparaben to the propylene glycol and add the mixture to the N_2O water. Rinse all of the Propylparaben into the container. Heat the water mixture to 70 °C on hotplate. Temp:78 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑ ,

Butylated Hydroxyanisole [✓] Butylated Hydroxytoluene [✓] and TBHQ [✓]

Heat to 60 °C. Temp: 60 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		09/09/2008
Prepared:	CHARLENE		09/09/2008
Checked:	CARLIE		09/09/2008

Packaging:

Describe containers: 3 x 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Three by

Volume of each 100ml

Example of label:

Product Name : Propylhydroxy benzoate 0.015% PG 10% b
Batch Number : PHB 0.015% PG 10% b
Packaging Date : 09/09/2008
Expiry Date 09/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	20/08/2008	Batch No:	BHB0.03%a
Requested by:	Charlene		

Product description: Preservative action of Butylparaben 0.03% without Propylene glycol for bacteria

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	600 g			
Vit F ethyl ester	3086009	2.8	16.8g	16.80g	CE	CMB
Cremophor® EL	04517856PO	1.0	6.0g	6.02g	CE	CMB
dl-α- Tocopherol	UT07090036	0.2	1.2g	1.22g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.24g	0.242g	CE	CMB
Butylated Hydroxytoluene	04416KO-076	0.2	1.2g	1.202g	CE	CMB
TBHQ	1254992	0.2	1.2g	1.202g	CE	CMB
Butylparaben	908970554	0.03	0.18g	0.18g	CE	CMB
N_2O . H_2O	NO8023	95.53	573.18g	573.18g	CE	CMB
Total		100	600g	600.046g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Butylparaben. Add the Butylparaben to the N_2O water. Rinse all of the Butylparaben into the container. Heat the water mixture to 80 °C on hotplate.
   Temp: 80 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,
   Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat to 60 °C. Temp: 60 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		20/08/2008
Prepared:	CHARLENE		20/08/2008
Checked:	CARLIE		20/08/2008

Packaging:

Describe containers: 6 X 10ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Six by

Volume of each 10ml

Example of label:

Product Name : Butylhydroxybenzoate 0.03%-a
Batch Number : BHB 0.03% a
Packaging Date : 20/08/2008
Expiry Date : 20/08/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	20/08/2008	Batch No:	BHB0.03%PG10%a
Requested by:	Charlene		

Product description: Preservative action of Butylparaben 0.03% with Propylene glycol 10.0% for bacteria

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	600 g			
Vit F ethyl ester	3086009	2.8	16.8g	16.81g	CE	CMB
Cremophor® EL	04517856PO	1.0	6.0g	6.00g	CE	CMB
dl-α- Tocopherol	UT07090036	0.2	1.2g	1.21g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.24g	0.240g	CE	CMB
Butylated Hydroxytoluene	04416KO-076	0.2	1.2g	1.200g	CE	CMB
TBHQ	1254992	0.2	1.2g	1.200g	CE	CMB
Butylparaben	908970554	0.03	0.18g	0.181g	CE	CMB
Propylene glycol	52560	10.0	60.0g	60.00g	CE	CMB
N_2O . H_2O	NO8023	85.53	513.18g	513.19g	CE	CMB
Total		100	600g	600.031g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Butylparaben and propylene glycol. Add the Butylparaben to the propylene glycol and add the mixture to the N_2O water. Rinse all of the Butylparaben into the container. Heat the water mixture to 70 °C on hotplate. Temp: 77 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑, Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑

Heat to 60 °C. Temp: 59 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		20/08/2008
Prepared:	CHARLENE		20/08/2008
Checked:	CARLIE		20/08/2008

Packaging:

Describe containers: 6 x 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Six by

Volume of each 100ml

Example of label:

Product Name : Butylhydroxybenzoate 0.03% PG 10% a
Batch Number : BtlB 0.03% PG 10% a
Packaging Date : 20/08/2008
Expiry Date : 20/09/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	15/09/2008	Batch No:	BHB0.03%b
Requested by:	Charlene		

Product description: Preservative action of Butylparaben 0.03% without Propylene glycol for *Apergillus* and *Candida*

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	300 g			
Vit F ethyl ester	3086009	2.8	8.4g	8.41g	CE	CMB
Cremophor® EL	04517856PO	1.0	3.0g	3.00g	CE	CMB
dl-α- Tocopherol	UT07090036	0.2	0.6g	0.61g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.12g	0.1201g	CE	CMB
Butylated Hydroxytoluene	04416KO-076	0.2	0.6g	0.6001g	CE	CMB
TBHQ	1254992	0.2	0.6g	0.6000g	CE	CMB
Butylparaben	908970554	0.03	0.09g	0.0904g	CE	CMB
N_2O . H_2O	NO8023	95.53	286.59g	286.61g	CE	CMB
Total		100	300.0g	300.0406g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Butylparaben. Add the Butylparaben to the N_2O water. Rinse all of the Butylparaben into the container. Heat the water mixture to 80 °C on hotplate.
   Temp: 80 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑, Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑

Heat to 60 °C. Temp: 60 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		15/09/2008
Prepared:	CHARLENE		15/09/2008
Checked:	CARLIE		15/09/2008

Packaging:

Describe containers: 3 X 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Three by

Volume of each 100ml

Example of label:

Product Name : Butylhydroxybenzoate 0.03% b
Batch Number : BHB of 03% b
Packaging Date : 15/09/2008
Expiry Date : 15/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	15/09/2008	Batch No:	BHB0.03%PG10%b
Requested by:	Charlene		

Product description: Preservative action of Butylparaben 0.03% with Propylene glycol 10.0% for *Aspergillus* and *Candida*

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	300 g			
Vit F ethyl ester	3086009	2.8	8.4g	8.40g	CE	CMB
Cremophor® EL	04517856PO	1.0	3.0g	3.01g	CE	CMB
dl-α- Tocopherol	UT07090036	0.2	0.6g	0.60g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.12g	0.1202g	CE	CMB
Butylated Hydroxytoluene	04416KO-076	0.2	0.6g	0.6004g	CE	CMB
TBHQ	1254992	0.2	0.6g	0.6003g	CE	CMB
Butylparaben	908970554	0.03	0.09g	0.0900g	CE	CMB
Propylene glycol	52560	10.0	30.0g	30.01g	CE	CMB
N_2O . H_2O	NO8023	85.53	256.59g	256.61g	CE	CMB
Total		100	300g	299.4409g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Butylparaben and propylene glycol. Add the Butylparaben to the propylene glycol and add the mixture to the N_2O water. Rinse all of the Butylparaben into the container. Heat the water mixture to 70 °C on hotplate. Temp: 82 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑ ,

Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑

Heat to 60 °C. Temp: 60 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		15/09/2008
Prepared:	CHARLENE		15/09/2008
Checked:	CARLIE	CMBritz	15/09/2008

Packaging:

Describe containers: 3 x 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: three by

Volume of each 100ml

Example of label:

Product Name : Butylhydroxybenzoate 0.03% PG 10% b
Batch Number : BtHB 0.03% PG 10% b
Packaging Date : 15/09/2008
Expiry Date : 15/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	26/08/2008	Batch No:	Nipasept 0.175%a
Requested by:	Charlene		

Product description: Preservative action of Nipasept® 0.175% without Propylene glycol for bacteria

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	400 g			
Vit F ethyl ester	3086009	2.8	11.2g	11.21g	CE	CMB
Cremophor® EL	04517856PO	1.0	4.0g	4.01g	CE	CMB
dl-α- Tocopherol	UT07090036	0.2	0.8g	0.80g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.16g	0.160g	CE	CMB
Butylated Hydroxytoluene	04416KO-076	0.2	0.8g	0.800g	CE	CMB
TBHQ	1254992	0.2	0.8g	0.801g	CE	CMB
Nipasept®	3380965234	0.175	0.7g	0.700g	CE	CMB
N_2O . H_2O	NO8023	95.38	381.54g	381.54g	CE	CMB
Total		100	400g	400.021g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Nipasept®. Add the Nipasept® to the N_2O water. Rinse all of the Nipasept® into the container. Heat the water mixture to 70 °C on hotplate.
   Temp: 75
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,
   Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat to 60 °C. Temp: 60 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		26/08/2008
Prepared:	CHARLENE		26/08/2008
Checked:	CARLIE		26/08/2008

Packaging:

Describe containers: 4 x 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: four by

Volume of each 100ml

Example of label:

Product Name : Nipasept 0.175% a
Batch Number : Nipasept 0.175% a
Packaging Date : 26/08/2008
Expiry Date : 26/09/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	26/08/2008	Batch No:	Nipasept 0.175% PG10%a
Requested by:	Charlene		

Product description: Preservative action of Nipasept 0.175% with Propylene glycol 10.0% for bacteria

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	400 g			
Vit F ethyl ester	3086009	2.8	11.2g	11.20g	CE	CMB
Cremophor® EL	04517856PO	1.0	4.0g	4.00g	CE	CMB
dl-α- Tocopherol	UT07090036	0.2	0.8g	0.80g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.16g	0.160g	CE	CMB
Butylated Hydroxytoluene	04416KO-076	0.2	0.8g	0.800g	CE	CMB
TBHQ	1254992	0.2	0.8g	0.803g	CE	CMB
Nipasept®	3380965234	0.175	0.7g	0.700g	CE	CMB
Propylene glycol	52560	10.0	40.0g	40.00g	CE	CMB
N_2O . H_2O	NO8023	85.38	341.54g	341.56g	CE	CMB
Total		100	400g	400.023g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Nipasept® and propylene glycol. Add the Nipasept® to the propylene glycol and add the mixture to the N_2O water. Rinse all of the Nipasept® into the container. Heat the water mixture to 70 °C on hotplate. Temp: 73 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑, Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑

Heat to 60 °C. Temp: 65 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		26/08/2008
Prepared:	CHARLENE		26/08/2008
Checked:	CARLIE		26/08/2008

Packaging:

Describe containers: 4 x 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Four by

Volume of each 100ml

Example of label:

Product Name : Nipasept 0.175% PG107 a
Batch Number : Nipasept 0.175% PG107 a
Packaging Date : 26/08/2008
Expiry Date : 26/09/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	15/09/2008	Batch No:	Nipasept 0.175%b
Requested by:	Charlene		

Product description: Preservative action of Nipasept® 0.175% without Propylene glycol for *Aspergillus* and *Candida*

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	300 g			
Vit F ethyl ester	3086009	2.8	8.4g	8.40g	CE	CMB
Cremophor® EL	04517856PO	1.0	3.0g	3.01g	CE	CMB
dl-α- Tocopherol	UT07090036	0.2	0.6g	0.60g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.12g	0.1209g	CE	CMB
Butylated Hydroxytoluene	04416KO-076	0.2	0.6g	0.6010g	CE	CMB
TBHQ	1254992	0.2	0.6g	0.6009g	CE	CMB
Nipasept®	3380965234	0.175	0.525g	0.5253g	CE	CMB
N_2O . H_2O	NO8023	95.38	286.14g	286.16g	CE	CMB
Total		100	300g	300.0181g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Nipasept®. Add the Nipasept® to the N_2O water. Rinse all of the Nipasept® into the container. Heat the water mixture to 70 °C on hotplate. Temp: 78 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑, Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat to 60 °C. Temp: 60 °C
3. Weigh off dl-α-Tocopherol and add to 2.

4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.

5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		15/09/2008
Prepared:	CHARLENE		15/09/2008
Checked:	CARLIE	CMBritz	15/09/2008

Packaging:

Describe containers: 3 x 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Three by

Volume of each 100ml

Example of label:

Product Name : Nipasept 0.175% b
Batch Number : Nipasept 0.175% b
Packaging Date : 15/09/2008
Expiry Date : 15/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	15/09/2008	Batch No:	Nipasept 0.175%b PG10%b
Requested by:	Charlene		

Product description: Preservative action of Nipasept 0.175% with Propylene glycol 10.0% for *Aspergillus* and *Candida*

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	300 g			
Vit F ethyl ester	3086009	2.8	8.4g	8.40g	CE	CMB
Cremophor® EL	04517856PO	1.0	3.0g	3.01g	CE	CMB
dl-α- Tocopherol	UT07090036	0.2	0.6g	0.61g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.12g	0.1204g	CE	CMB
Butylated Hydroxytoluene	04416KO-076	0.2	0.6g	0.6009g	CE	CMB
TBHQ	1254992	0.2	0.6g	0.6006g	CE	CMB
Nipasept®	3380965234	0.175	0.525g	0.5259g	CE	CMB
Propylene glycol	52560	10.0	30.0g	30.03g	CE	CMB
N_2O . H_2O	NO8023	85.38	256.14g	256.15g	CE	CMB
Total		100	300g	300.0478g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Nipasept® and propylene glycol. Add the Nipasept® to the propylene glycol and add the mixture to the N_2O water. Rinse all of the Nipasept® into the container. Heat the water mixture to 70 °C on hotplate. Temp: 70 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑, Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑

Heat to 60 °C. Temp: 60 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		25/09/2008
Prepared:	CHARLENE		15/09/2008
Checked:	CARLIE		15/09/2008

Packaging:

Describe containers: 3 x 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Three by

Volume of each 100ml

Example of label:

Product Name : Nipasept 0.175% b
Batch Number : Nipasept 0.175% b
Packaging Date : 15/09/2008
Expiry Date : 15/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	26/08/2008	Batch No:	Nipastat 0.175%a
Requested by:	Charlene		

Product description: Preservative action of Nipastat® 0.175% without Propylene glycol for bacteria

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	400 g			
Vit F ethyl ester	3086009	2.8	11.2g	11.20g	CE	CMB
Cremophor® EL	04517856PO	1.0	4.0g	4.00g	CE	CMB
dl-α- Tocopherol	UT07090036	0.2	0.8g	0.80g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.16g	0.160g	CE	CMB
Butylated Hydroxytoluene	04416KO-076	0.2	0.8g	0.801g	CE	CMB
TBHQ	1254992	0.2	0.8g	0.800g	CE	CMB
Nipastat®	3380965234	0.175	0.7g	0.700g	CE	CMB
N_2O . H_2O	NO8023	95.38	381.54g	381.54g	CE	CMB
Total		100	400g	400.001g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Nipastat®. Add the Nipastat® to the N_2O water. Rinse all of the Nipastat® into the container. Heat the water mixture to 70 °C on hotplate. Temp: 75 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑, Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat to 60 °C. Temp: 60 °C
3. Weigh off dl-α-Tocopherol and add to 2.

4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.

5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		26/08/2008
Prepared:	CHARLENE		26/08/2008
Checked:	CHARLIE		26/08/2008

Packaging:

Describe containers: 4 X 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Four by

Volume of each 100ml

Example of label:

Product Name : Nipastat 0.175% a
Batch Number : Nipastat 0.175% a
Packaging Date : 26/08/2008
Expiry Date : 26/09/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	26/08/2008	Batch No:	Nipastat 0.175% PG10%a
Requested by:	Charlene		

Product description: Preservative action of Nipastat® 0.175% with Propylene glycol 10.0% for bacteria

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	400 g			
Vit F ethyl ester	3086009	2.8	11.2g	11.20g	CE	CMB
Cremophor® EL	04517856PO	1.0	4.0g	4.00g	CE	CMB
dl-α- Tocopherol	UT07090036	0.2	0.8g	0.81g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.16g	0.161g	CE	CMB
Butylated Hydroxytoluene	04416KO-076	0.2	0.8g	0.800g	CE	CMB
TBHQ	1254992	0.2	0.8g	0.800g	CE	CMB
Nipastat®	3380965234	0.175	0.7g	0.700g	CE	CMB
Propylene glycol	52560	10.0	40.0g	40.00g	CE	CMB
N_2O . H_2O	NO8023	85.38	341.54g	341.55g	CE	CMB
Total		100	400g	400.021g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Nipastat® and propylene glycol. Add the Nipastat® to the propylene glycol and add the mixture to the N_2O water. Rinse all of the Nipastat into the container. Heat the water mixture to 70 °C on hotplate. Temp: 72 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑, Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑

Page 1 of 2

Heat to 60 °C. Temp: 60°C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		26/08/2008
Prepared:	CHARLENE		26/08/2008
Checked:	CARLIE		26/08/2008

Packaging:

Describe containers: 4 x 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Four by

Volume of each 100ml

Example of label:

Product Name : Nipastat 0.175% PG10% a
Batch Number : Nipastat 0.175% PG10% a
Packaging Date : 26/08/2008
Expiry Date : 26/04/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	15/09/2008	Batch No:	Nipastat 0.175%b
Requested by:	Charlene		

Product description: Preservative action of Nipastat® 0.175% without Propylene glycol for *Aspergillus* and *Candida*

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	300 g			
Vit F ethyl ester	3086009	2.8	8.4g	8.40g	CE	CMB
Cremophor® EL	04517856PO	1.0	3.0g	3.02g	CE	CMB
dl-α- Tocopherol	UT07090036	0.2	0.6g	0.60g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.12g	0.1204g	CE	CMB
Butylated Hydroxytoluene	04416KO-076	0.2	0.6g	0.6010g	CE	CMB
TBHQ	1254992	0.2	0.6g	0.6004g	CE	CMB
Nipastat®	3380965234	0.175	0.525g	0.5254g	CE	CMB
N_2O . H_2O	NO8023	95.38	286.14g	286.16g	CE	CMB
Total		100	300g	300.0272g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Nipastat®. Add the Nipastat® to the N_2O water. Rinse all of the Nipastat® into the container. Heat the water mixture to 70 °C on hotplate. Temp: 82 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑ , Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑ Heat to 60 °C. Temp: 60 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		15/09/2008
Prepared:	CHARLENE		15/09/2008
Checked:	CARLIE		15/09/2008

Packaging:

Describe containers: 3 x 100ml Amber bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Three by

Volume of each 100ml

Example of label:

Product Name : Nipastat 0.175% b
Batch Number : Nipastat 0.1757.b
Packaging Date : 15/09/2008
Expiry Date : 15/10/2008

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	15/09/2008	Batch No:	Nipastat 0.175% PG10%b
Requested by:	Charlene		

Product description: Preservative action of Nipastat® 0.175% with Propylene glycol 10.0% for *Aspergillus* and *Candida*

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	300 g			
Vit F ethyl ester	3086009	2.8	8.4g	8.4g	CE	CMB
Cremophor® EL	04517856PO	1.0	3.0g	3.01g	CE	CMB
dl-α- Tocopherol	UT07090036	0.2	0.6g	0.61g	CE	CMB
Butylated Hydroxyanisole	07115PC-475	0.04	0.12g	0.1204g	CE	CMB
Butylated Hydroxytoluene	04416KO-076	0.2	0.6g	0.6009g	CE	CMB
TBHQ	1254992	0.2	0.6g	0.6006g	CE	CMB
Nipastat®	3380965234	0.175	0.525g	0.5259g	CE	CMB
Propylene glycol	52560	10.0	30.0g	30.03g	CE	CMB
N_2O . H_2O	NO8023	85.38	256.14g	256.15g	CE	CMB
Total		100	300g	300.0478g	CE	CMB

Method:

1. Weigh off $N_2O.H_2O$ and Nipastat ®and propylene glycol. Add the Nipastat® to the propylene glycol and add the mixture to the N_2O water. Rinse all of the Nipastat® into the container. Heat the water mixture to 70 °C on hotplate. Temp: 70 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑ ,

Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑

Heat to 60 °C. Temp: 60 °C

3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

		Sign	Date
Approved:	CHARLENE		15/09/2008
Prepared:	CHARLENE		15/09/2008
Checked:	CARLIE		15/09/2008

Packaging:

Describe containers: 3 X 100ml Amber Bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign	CE	CE	CE

Quantity filled: Three by

Volume of each 100ml

Example of label:

Product Name : Nipastat 0.175% PG 10% b
Batch Number : Nipastat 0.175% PG 10% b
Packaging Date : 15/09/ 2008
Expiry Date : 15/10/2008

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ANNEXURE F

Table F1A: Particle size values measured during the preservative efficacy test. Duplicate readings at t = 48 hours (without added organisms) and repeated after 28 days (for Pheroid® formulas with added *Pseudomonas auruginosa*, *Escherichia coli* and *Staphylococcus aureus)*. D (0.9) represents 90% of the particle size range.

Formulation excipient tested	Particle size D (0.9)			
	L1	L2	AVE	STDEV
Pheroid 0% - 48 H	0.262	0.281	0.272	0.013
28 Days – P. aeruginosa	0.267	0.267	0.267	0.000
28 Days - E.coli	0.267	0.267	0.267	0.000
28 Days – S.aureus	0.267	0.267	0.267	0.000
Pheroid + PG 10% -48 H	0.796	0.794	0.795	0.001
28 Days – P. aeruginosa	2.847	2.866	2.857	0.013
28 Days - E.coli	2.208	2.223	2.216	0.011
28 Days – S.aureus	2.640	4.742	3.691	1.486
MBH 0.1% - 48 H	0.259	0.259	0.259	0.000
28 Days – P. aeruginosa	0.260	0.265	0.263	0.004
28 Days - E.coli	0.260	0.260	0.260	0.000
28 Days – S.aureus	0.276	0.263	0.270	0.009
MBH 0.1% + PG10% - 48 H	0.261	0.262	0.262	0.001
28 Days – P. aeruginosa	0.259	0.259	0.259	0.000
28 Days - E.coli	0.260	0.260	0.260	0.000
28 Days – S.aureus	0.260	0.260	0.260	0.000
EHB 0.15% - 48 H	0.259	0.262	0.261	0.002
28 Days – P. aeruginosa	0.260	0.261	0.261	0.001
28 Days - E.coli	0.260	0.260	0.260	0.000
28 Days – S.aureus	0.260	0.260	0.260	0.000
EHB 0.15% + PG 10% - 48 H	0.259	0.259	0.259	0.000
28 Days – P. aeruginosa	0.260	0.260	0.260	0.000
28 Days - E.coli	0.260	0.261	0.261	0.000
28 Days – S.aureus	0.260	0.260	0.260	0.001
PHB 0.015% - 48 H	0.262	0.262	0.262	0.000
28 Days – P. aeruginosa	0.260	0.260	0.260	0.000
28 Days - E.coli	0.260	0.260	0.260	0.000
28 Days – S.aureus	0.261	0.261	0.261	0.000

Table F1B: Particle size values measured during the preservative efficacy test. Duplicate readings at t = 48 hours (without added organisms) and repeated after 28 days (for Pheroid® formulas with added *Pseudomonas auruginosa*, *Escherichia coli* and *Staphylococcus aureus)*. D (0.9) represents 90% of the particle size range

Formulation excipient tested	Particle size D (0.9)			
	L1	L2	AVE	STDEV
PHB 0.015% + 10% - 48 H	0.267	0.267	0.267	0.000
28 Days – P. aeruginosa	0.343	0.340	0.342	0.002
28 Days - E.coli	0.266	0.268	0.267	0.001
28 Days – S.aureus	0.331	0.330	0.331	0.001
BHB 0.03% - 48 H	0.260	0.295	0.278	0.025
28 Days – P. aeruginosa	0.259	0.259	0.259	0.000
28 Days - E.coli	0.259	0.259	0.259	0.000
28 Days – S.aureus	0.259	0.259	0.259	0.000
BHB 0.03% + PG 10% - 48 H	0.268	0.267	0.268	0.001
28 Days – P. aeruginosa	0.917	0.884	0.901	0.023
28 Days - E.coli	0.268	0.267	0.268	0.001
28 Days – S.aureus	0.927	1.036	0.982	0.077
NIPASEPT 0.175% - 48 H	0.259	0.260	0.260	0.001
28 Days – P. aeruginosa	0.259	0.259	0.259	0.000
28 Days - E.coli	0.272	0.268	0.270	0.003
28 Days – S.aureus	0.277	0.269	0.273	0.006
NIPASEPT + PG 10% - 48 H	0.259	0.259	0.259	0.000
28 Days – P. aeruginosa	0.260	0.260	0.260	0.000
28 Days - E.coli	0.259	0.259	0.259	0.000
28 Days – S.aureus	0.260	0.260	0.260	0.000
NIPASTAT 0.175% - 48 H	0.258	0.258	0.258	0.000
28 Days – P. aeruginosa	0.260	0.260	0.260	0.000
28 Days - E.coli	0.261	0.288	0.275	0.019
28 Days – S.aureus	0.262	0.265	0.264	0.002
NIPAST 0.175% + PG 10% - 48 H	0.259	0.259	0.259	0.000
28 Days – P. aeruginosa	0.260	0.260	0.260	0.000
28 Days - E.coli	0.260	0.260	0.260	0.000
28 Days – S.aureus	0.260	0.260	0.260	0.000

Table F2: pH values measured during the preservative efficacy test. Readings at t = 48 hours (without added organisms) and repeated after 28 days (for Pheroid® formulas with added *Pseudomonas auruginosa*, *Escherichia coli* and *Staphylococcus aureus)*.

Formulation excipient tested	*pH*	*Formulation excipient tested*	*pH*
Pheroid 0% - 48 H	6.608	**PHB 0.015% + 10%- 48 H**	6.278
28 Days – P. aeruginosa	5.116	28 Days – P. aeruginosa	4.826
28 Days - E.coli	5.308	28 Days - E.coli	5.044
28 Days – S.aureus	5.250	28 Days – S.aureus	5.014
Pheroid + PG 10%- 48 H	6.759	**BHB 0.03%- 48 H**	6.323
28 Days – P. aeruginosa	4.908	28 Days – P. aeruginosa	4.932
28 Days - E.coli	5.008	28 Days - E.coli	5.081
28 Days – S.aureus	4.893	28 Days – S.aureus	5.013
MBH 0.1%- 48 H	5.957	**BHB 0.03% + PG 10%- 48 H**	6.358
28 Days – P. aeruginosa	4.924	28 Days – P. aeruginosa	4.986
28 Days - E.coli	4.923	28 Days - E.coli	4.986
28 Days – S.aureus	5.124	28 Days – S.aureus	4.948
MBH 0.1% + PG10%- 48 H	6.594	**NIPASEPT 0.175%- 48 H**	6.185
28 Days – P. aeruginosa	4.858	28 Days – P. aeruginosa	5.278
28 Days - E.coli	4.928	28 Days - E.coli	5.427
28 Days – S.aureus	5.050	28 Days – S.aureus	5.265
EHB 0.15%- 48 H	6.215	**NIPASEPT + PG 10%- 48 H**	6.185
28 Days – P. aeruginosa	5.317	28 Days – P. aeruginosa	5.361
28 Days - E.coli	5.367	28 Days - E.coli	5.446
28 Days – S.aureus	5.284	28 Days – S.aureus	5.471
EHB 0.15% + PG 10%- 48 H	6.041	**NIPASTAT 0.175%- 48 H**	6.144
28 Days – P. aeruginosa	4.700	28 Days – P. aeruginosa	5.547
28 Days - E.coli	4.853	28 Days - E.coli	5.605
28 Days – S.aureus	4.919	28 Days – S.aureus	5.444
PHB 0.015% - 48 H	6.187	**NIPAST 0.175% + PG 10% - 48 H**	6.281
28 Days – P. aeruginosa	5.062	28 Days – P. aeruginosa	5.423
28 Days - E.coli	5.024	28 Days - E.coli	5.400
28 Days – S.aureus	5.157	28 Days – S.aureus	5.434

Table F3A: Particle size values measured during the preservative efficacy test. Duplicate readings at t = 48 hours without added organisms and repeated after 28 days for Pheroid® formulas with added *Candida albicans* and *Aspergillus brasilliensis*. D (0.9) represents 90% of the particle size range.

Formulation excipient tested	*Particle size D (0.9)*			
	L1	*L2*	*AVE*	*SD*
Pheroid 0% - 48 H	0.270	0.270	0.270	0.000
28 Days – C. albicans	0.262	0.263	0.263	0.001
28 Days – A. brasilliensis	0.261	0.262	0.262	0.001
Pheroid + PG 10%- 48 H	1.026	1.024	1.025	0.001
28 Days – C. albicans	2.092	1.756	1.924	0.238
28 Days – A. brasilliensis	0.364	0.351	0.358	0.009
MBH 0.1%- 48 H	0.260	0.263	0.262	0.002
28 Days – C. albicans	0.260	0.291	0.276	0.022
28 Days – A. brasilliensis	0.264	0.308	0.286	0.031
MBH 0.1% + PG10%- 48 H	0.258	0.258	0.258	0.000
28 Days – C. albicans	0.260	0.261	0.261	0.001
28 Days – A. brasilliensis	0.259	0.259	0.259	0.000
EHB 0.15%- 48 H	0.258	0.258	0.258	0.000
28 Days – C. albicans	0.259	0.259	0.259	0.000
28 Days – A. brasilliensis	0.259	0.259	0.259	0.000
EHB 0.15% + PG 10%- 48 H	0.257	0.257	0.257	0.000
28 Days – C. albicans	0.259	0.258	0.259	0.001
28 Days – A. brasilliensis	0.259	0.259	0.259	0.000
PHB 0.015% - 48 H- 48 H	0.261	0.261	0.261	0.000
28 Days – C. albicans	0.267	0.275	0.271	0.006
28 Days – A. brasilliensis	0.262	0.269	0.266	0.005

Table F3B: Particle size values measured during the preservative efficacy test. Duplicate readings at t = 48 hours without added organisms and repeated after 28 days for Pheroid® formulas with added *Candida albicans* and *Aspergillus brasilliensis*. D (0.9) represents 90% of the particle size range

Formulation excipient tested	*Particle size D (0.9)*			
	L1	*L2*	*AVE*	*SD*
PHB 0.015% + 10%- 48 H	0.273	0.272	0.273	0.001
28 Days – C. albicans	0.279	0.283	0.281	0.003
28 Days – A. brasilliensis	0.277	0.276	0.277	0.001
BHB 0.03%- 48 H	0.261	0.261	0.261	0.000
28 Days – C. albicans	0.273	0.302	0.288	0.021
28 Days – A. brasilliensis	0.262	0.262	0.262	0.000
BHB 0.03% + PG 10%- 48 H	0.266	0.266	0.266	0.000
28 Days – C. albicans	0.270	0.270	0.270	0.000
28 Days – A. brasilliensis	0.270	0.269	0.270	0.001
NIPASEPT 0.175%- 48 H	0.256	0.255	0.256	0.001
28 Days – C. albicans	0.259	0.259	0.259	0.000
28 Days – A. brasilliensis	0.258	0.259	0.259	0.001
NIPASEPT + PG 10%- 48 H	0.257	0.257	0.257	0.000
28 Days – C. albicans	0.259	0.259	0.259	0.000
28 Days – A. brasilliensis	0.259	0.259	0.259	0.000
NIPASTAT 0.175%- 48 H	0.257	0.258	0.258	0.001
28 Days – C. albicans	0.259	0.258	0.259	0.001
28 Days – A. brasilliensis	0.258	0.258	0.258	0.000
NIPAST 0.175% + PG 10% - 48 H	0.256	0.256	0.256	0.000
28 Days – C. albicans	0.258	0.257	0.258	0.001
28 Days – A. brasilliensis	0.261	0.258	0.260	0.002

Table F4: pH values measured during the preservative efficacy test. Duplicate readings at t = 48 hours (without added organisms) and repeated after 28 days (for Pheroid® formulas with added *Candida albicans* and *Aspergillus brasilliensis)*.

Formulation excipient tested	*pH*	*Formulation excipient tested*	*pH*
Pheroid 0% - 48 H	6.857	**PHB 0.015% + 10%- 48 H**	6.278
28 Days – C. albicans	5.178	28 Days – C. albicans	5.271
28 Days – A. brasilliensis	5.231	28 Days – A. brasilliensis	5.128
Pheroid + PG 10%- 48 H	6.709	**BHB 0.03%- 48 H**	6.770
28 Days – C. albicans	5.123	28 Days – C. albicans	4.878
28 Days – A. brasilliensis	5.243	28 Days – A. brasilliensis	5.411
MBH 0.1%- 48 H	6.431	**BHB 0.03% + PG 10%- 48 H**	6.641
28 Days – C. albicans	5.614	28 Days – C. albicans	4.444
28 Days – A. brasilliensis	5.504	28 Days – A. brasilliensis	5.078
MBH 0.1% + PG10%- 48 H	6.342	**NIPASEPT 0.175%- 48 H**	6.362
28 Days – C. albicans	5.213	28 Days – C. albicans	4.959
28 Days – A. brasilliensis	5.279	28 Days – A. brasilliensis	5.269
EHB 0.15%- 48 H	6.077	**NIPASEPT + PG 10%- 48 H**	6.185
28 Days – C. albicans	5.130	28 Days – C. albicans	4.922
28 Days – A. brasilliensis	5.134	28 Days – A. brasilliensis	5.031
EHB 0.15% + PG 10%- 48 H	6.564	**NIPASTAT 0.175%- 48 H**	6.517
28 Days – C. albicans	4.840	28 Days – C. albicans	5.089
28 Days – A. brasilliensis	4.913	28 Days – A. brasilliensis	5.347
PHB 0.015% - 48 H- 48 H	6.187	**NIPAST 0.175% + PG 10% - 48 H**	6.543
28 Days – C. albicans	5.469	28 Days – C. albicans	5.109
28 Days – A. brasilliensis	5.297	28 Days – A. brasilliensis	4.843

ANNEXURE G

Test Results:	*Pheroid 0%, Pack 30/07/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	**14 days**	**28 days**
	(30/07/08)	(13/08/08)	(20/08/08)
Staphylococcus aureus	6.5×10^5	ND	ND
Pseudomonas aeruginosa	2.0×10^5	ND	ND
Escherichia coli	9.5×10^5	ND	ND
Candida albicans	1.9×10^4	ND	ND
Aspergillus niger	0.25×10^4	ND	ND

**ND - None detected*
**Cfu - Colony forming units*
**NI - No Increase*

Test Results:	*Controle, Pack 30/07/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	#	#
	(30/07/08)	#	#
Staphylococcus aureus	5.5×10^5	#	#
Pseudomonas aeruginosa	4.6×10^5	#	#
Escherichia coli	1.29×10^6	#	#
Candida albicans	3.3×10^4	#	#
Aspergillus niger	5.3×10^4	#	#

** Controle is peptone water for the bacterial cultures and candida and tween water for aspergillus*

Test organism	**Log Reduction**	
	0h - 14days	**0h - 28days**
Staphylococcus aureus	>3	NI
Pseudomonas aeruginosa	>3	NI
Escherichia coli	>3	NI
Candida albicans	>1	NI
Aspergillus niger	>1	NI

pH values:	**48H**	**28 Days + E.Coli**
	6.608	5.308
		28 Days + Pseud
		5.116
		28 Days + Staph
		5.25
	Candida	
	48H - 6.857	**28 Days** - 5.178
	Aspergillus	
	48H - 6.857	**28 Days** - 5.231

Test Results:	*Pheroid + 10%PG, Pack 30/07/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	**14 days**	**28 days**
	(30/07/08)	(13/08/08)	(20/08/08)
Staphylococcus aureus	6.3×10^5	ND	ND
Pseudomonas aeruginosa	6.0×10^4	ND	ND
Escherichia coli	4.2×10^5	ND	ND
Candida albicans	10.3×10^3	1.0×10^2	ND
Aspergillus niger	6.1×10^4	ND	ND

**ND - None detected*
**Cfu - Colony forming units*

Test Results:	*Controle, Pack 30/07/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	#	#
	(30/07/08)	#	#
Staphylococcus aureus	5.5×10^5	#	#
Pseudomonas aeruginosa	4.6×10^5	#	#
Escherichia coli	1.29×10^6	#	#
Candida albicans	3.3×10^4	#	#
Aspergillus niger	5.3×10^4	#	#

** Controle is peptone water for the bacterial cultures and candida and tween water for aspergillus*

Test organism	**Log Reduction**	
	0h - 14days	**0h - 28days**
Staphylococcus aureus	>3	NI
Pseudomonas aeruginosa	>3	NI
Escherichia coli	>3	NI
Candida albicans	>1	NI
Aspergillus niger	>1	NI

pH values:	**48H**	**28 Days + E.Coli**
	6.759	5.008
		28 Days + Pseud
		4.908
		28 Days + Staph
		4.893
	Candida	
	48H - 6.709	**28 Days -** 5.123
	Aspergillus	
	48H - 6.709	**28 Days -** 5.243

Test Results:	*Pheroid + MHB 0.1%, Pack 06/08/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	**14 days**	**28 days**
	(06/08/08)	(20/08/08)	(03/09/08)
Staphylococcus aureus	3.19×10^5	ND	ND
Pseudomonas aeruginosa	ND	ND	ND
Escherichia coli	5.0×10^5	ND	ND
Candida albicans	1.52×10^4	ND	ND
Aspergillus niger	0.74×10^4	0.3×10^3	ND

**ND - None detected*
**Cfu - Colony forming units*

Test Results:	*Controle, Pack 06/08/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	#	#
	(06/08/08)	#	#
Staphylococcus aureus	4.55×10^5	#	#
Pseudomonas aeruginosa	9.32×10^5	#	#
Escherichia coli	11.3×10^5	#	#
Candida albicans	3.3×10^4	#	#
Aspergillus niger	5.3×10^4	#	#

** Controle is peptone water for the bacterial cultures and candida and tween water for aspergillus*

Test organism	**Log Reduction**	
	0h - 14days	**0h - 28days**
Staphylococcus aureus	>3	NI
Pseudomonas aeruginosa	>3	NI
Escherichia coli	>3	NI
Candida albicans	>1	NI
Aspergillus niger	>1	NI

pH values:	**48H**	**28 Days + E.Coli**
	5.957	4.923
		28 Days + Pseud
		4.924
		28 Days + Staph
		5.124
	Candida	
	48H - 6.431	**28 Days** - 5.614
	Aspergillus	
	48H - 6.431	**28 Days** - 5.504

Test Results:	*Pheroid + 0.1%MHB + 10%PG, Pack 30/07/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	**14 days**	**28 days**
	(30/07/08)	(13/08/08)	(20/08/08)
Staphylococcus aureus	5.5×10^5	1.13×10^5	ND
Pseudomonas aeruginosa	ND	ND	ND
Escherichia coli	1.1×10^5	ND	ND
Candida albicans	0.72×10^4	ND	ND
Aspergillus niger	0.34×10^4	ND	ND

*ND - None detected
*Cfu - Colony forming units

Test Results:	*Controle, Pack 30/07/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	#	#
	(30/07/08)	#	#
Staphylococcus aureus	5.5×10^5	#	#
Pseudomonas aeruginosa	4.6×10^5	#	#
Escherichia coli	1.29×10^5	#	#
Candida albicans	3.3×10^4	#	#
Aspergillus niger	5.3×10^4	#	#

* *Controle is peptone water for the bacterial cultures and candida and tween water for aspergillus*

Test organism	**Log Reduction**	
	0h - 14days	**0h - 28days**
Staphylococcus aureus	<3	NI
Pseudomonas aeruginosa	>3	NI
Escherichia coli	>3	NI
Candida albicans	>1	NI
Aspergillus niger	>1	NI

pH values:	**48H**	**28 Days + E.Coli**
	6.594	4.928
		28 Days + Pseud
		4.858
		28 Days + Staph
		5.05
	Candida	
	48H - 6.342	**28 Days -** 5.213
	Aspergillus	
	48H - 6.342	**28 Days -** 5.279

Test Results:	*Pheroid + EHB 0.15%, Pack 06/08/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	**14 days**	**28 days**
	(06/08/08)	(20/08/08)	(03/09/08)
Staphylococcus aureus	2.54×10^5	ND	3.3×10^1
Pseudomonas aeruginosa	ND	ND	ND
Escherichia coli	5.05×10^5	ND	ND
Candida albicans	1×10^3	ND	0.3×10^3
Aspergillus niger	22.9×10^4	ND	ND

*ND - None detected
*Cfu - Colony forming units

Test Results:	*Controle, Pack 06/08/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	#	#
	(06/08/08)	#	#
Staphylococcus aureus	4.55×10^5	#	#
Pseudomonas aeruginosa	9.32×10^5	#	#
Escherichia coli	11.3×10^5	#	#
Candida albicans	3.3×10^4		
Aspergillus niger	5.3×10^4		

* *Controle is peptone water for the bacterial cultures and candida and tween water for aspergillus*

Test organism	**Log Reduction**	
	0h - 14days	**0h - 28days**
Staphylococcus aureus	>3	INCREASED
Pseudomonas aeruginosa	>3	NI
Escherichia coli	>3	NI
Candida albicans	>1	INCREASED
Aspergillus niger	>1	NI

pH values:	**48H**	**28 Days + E.Coli**
	6.215	5.367
		28 Days + Pseud
		5.317
		28 Days + Staph
		5.284
	Candida	
	48H - 6.077	**28 Days** -5.130
	Aspergillus	
	48H - 6.077	**28 Days** - 5.134

Test Results:	*Pheroid + EHB 0.15% + 10%PG, Pack 06/08/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	**14 days**	**28 days**
	(06/08/08)	(20/08/08)	(03/09/08)
Staphylococcus aureus	3.87×10^5	ND	ND
Pseudomonas aeruginosa	ND	ND	ND
Escherichia coli	6.1×10^5	ND	ND
Candida albicans	3.92×10^3	ND	ND
Aspergillus niger	3.04×10^3	ND	ND

**ND - None detected*
**Cfu - Colony forming units*

Test Results:	*Controle, Pack 06/08/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	#	#
	(06/08/08)	#	#
Staphylococcus aureus	4.55×10^5	#	#
Pseudomonas aeruginosa	9.32×10^5	#	#
Escherichia coli	11.3×10^5	#	#
Candida albicans	14.88×10^3	#	#
Aspergillus niger	3.77×10^3	#	#

** Controle is peptone water for the bacterial cultures and candida and tween water for aspergillus*

Test organism	**Log reduction**	
	0h - 14days	**0h - 28days**
Staphylococcus aureus	>3	NI
Pseudomonas aeruginosa	>3	NI
Escherichia coli	>3	NI
Candida albicans	>1	NI
Aspergillus niger	>1	NI

pH values:	**48H**	**28 Days + E.Coli**
	6.041	4.853
		28 Days + Pseud
		4.7
		28 Days + Staph
		4.919
	Candida	
	48H - 6.564	**28 Days** - 4.840
	Aspergillus	
	48H - 6.564	**28 Days** - 4.913

Test Results:	*Pheroid + PHB 0.015%, Pack 20/08/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	**14 days**	**28 days**
	(20/08/08)	(03/09/08)	(17/09/08)
Staphylococcus aureus	1.61×10^5	ND	ND
Pseudomonas aeruginosa	ND	ND	ND
Escherichia coli	5.12×10^5	ND	ND
Candida albicans	0.65×10^4	ND	0.3×10^1
Aspergillus niger	3.64×10^4	ND	ND

*ND - None detected
*Cfu - Colony forming units

Test Results:	*Controle, Pack 20/08/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	#	#
	(20/08/08)	#	#
Staphylococcus aureus	15.4×10^5	#	#
Pseudomonas aeruginosa	4.24×10^5	#	#
Escherichia coli	8.89×10^5	#	#
Candida albicans	3.3×10^4	#	#
Aspergillus niger	5.3×10^4	#	#

* *Controle is peptone water for the bacterial cultures and candida and tween water for aspergillus*

Test organism	**Log Reduction**	
	0h - 14days	**0h - 28days**
Staphylococcus aureus	>3	NI
Pseudomonas aeruginosa	>3	NI
Escherichia coli	>3	NI
Candida albicans	>1	INCREASED
Aspergillus niger	>1	NI

pH values:	**48H**	**28 Days + E.Coli**
	6.187	5.024
		28 Days + Pseud
		5.062
		28 Days + Staph
		5.157
	Candida	
	48H - 6.187	**28 Days** - 5.469
	Aspergillus	
	48H - 6.187	**28 Days** - 5.297

Test Results:	*Pheroid + 0.015%PHB + 10%PG, Pack 20/08/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	**14 days**	**28 days**
	(20/08/08)	(03/09/08)	(17/09/08)
Staphylococcus aureus	1.98×10^5	ND	ND
Pseudomonas aeruginosa	ND	ND	ND
Escherichia coli	4.95×10^5	ND	ND
Candida albicans	1.69×10^4	ND	1×10^2
Aspergillus niger	0.82×10^4	ND	ND

*ND - None detected
*Cfu - Colony forming units

Test Results:	*Controle, Pack 30/07/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	#	#
	(20/08/08)	#	#
Staphylococcus aureus	15.4×10^5	#	#
Pseudomonas aeruginosa	4.24×10^5	#	#
Escherichia coli	8.89×10^5	#	#
Candida albicans	$3.3\ 10^4$	#	#
Aspergillus niger	5.3×10^4	#	#

* *Controle is peptone water for the bacterial cultures and candida and tween water for aspergillus*

Test organism	**Log Reduction**	
	0h - 14days	**0h - 28days**
Staphylococcus aureus	>3	NI
Pseudomonas aeruginosa	>3	NI
Escherichia coli	>3	NI
Candida albicans	>1	INCREASED
Aspergillus niger	>1	NI

pH values:	**48H**	**28 Days + E.Coli**
	6.278	5.044
		28 Days + Pseud
		4.826
		28 Days + Staph
		5.014
	Candida	
	48H - 6.278	**28 Days** - 5.271
	Aspergillus	
	48H - 6.278	**28 Days** - 5.128

Test Results:	*Pheroid + BHB 0.03%, Pack 20/08/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours (20/08/08)	**14 days** (03/09/08)	**28 days** (17/09/08)
Staphylococcus aureus	3.2×10^5	3.3×10^2	ND
Pseudomonas aeruginosa	ND	ND	ND
Escherichia coli	4.74×10^5	ND	ND
Candida albicans	3.7×10^3	1.65×10^2	ND
Aspergillus niger	2.25×10^3	1.84×10^2	ND

*ND - None detected
*Cfu - Colony forming units

Test Results:	*Controle, Pack 20/08/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours (20/08/08)	# #	# #
Staphylococcus aureus	15.4×10^5	#	#
Pseudomonas aeruginosa	4.24×10^5	#	#
Escherichia coli	8.89×10^5	#	#
Candida albicans	14.88×10^3	#	#
Aspergillus niger	3.77×10^3	#	#

* *Controle is peptone water for the bacterial cultures and candida and tween water for aspergillus*

Test organism	**Log Reduction**	
	0h - 14days	**0h - 28days**
Staphylococcus aureus	>3	NI
Pseudomonas aeruginosa	>3	NI
Escherichia coli	>3	NI
Candida albicans	>1	NI
Aspergillus niger	>1	NI

pH values:	**48H**	**28 Days + E.Coli**
	6.323	5.081
		28 Days + Pseud
		4.932
		28 Days + Staph
		5.013
	Candida	
	48H - 6.770	**28 Days** - 4.878
	Aspergillus	
	48H - 6.770	**28 Days** - 5.411

Test Results:	*Pheroid + 0.03%BHB + 10%PG, Pack 20/08/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	**14 days**	**28 days**
	(20/08/08)	(03/09/08)	(17/09/08)
Staphylococcus aureus	2.62×10^5	ND	ND
Pseudomonas aeruginosa	ND	ND	ND
Escherichia coli	3.84×10^5	ND	ND
Candida albicans	11.21×10^3	ND	ND
Aspergillus niger	24.4×10^3	ND	ND

*ND - None detected
*Cfu - Colony forming units

Test Results:	*Controle, Pack 30/07/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	#	#
	(20/08/08)	#	#
Staphylococcus aureus	15.4×10^5	#	#
Pseudomonas aeruginosa	4.24×10^5	#	#
Escherichia coli	8.89×10^5	#	#
Candida albicans	14.88×10^3	#	#
Aspergillus niger	3.77×10^3	#	#

* *Controle is peptone water for the bacterial cultures and candida and tween water for aspergillus*

Test organism	**Log Reduction**	
	0h - 14days	**0h - 28days**
Staphylococcus aureus	>3	NI
Pseudomonas aeruginosa	>3	NI
Escherichia coli	>3	NI
Candida albicans	>1	NI
Aspergillus niger	>1	NI

pH values:	**48H**	**28 Days + E.Coli**
	6.358	4.969
		28 Days + Pseud
		4.986
		28 Days + Staph
		4.948
	Candida	
	48H - 6.641	**28 Days** - 4.444
	Aspergillus	
	48H - 6.641	**28 Days** - 5.078

Test Results:	*Pheroid + Nipasept 0.175%, Pack 27/08/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	**14 days**	**28 days**
	(27/08/08)	(10/09/08)	17/09/08)
Staphylococcus aureus	3.6×10^5	ND	ND
Pseudomonas aeruginosa	ND	3.03×10^2	ND
Escherichia coli	5.6×10^6	ND	ND
Candida albicans	0.75×10^3	ND	0.67×10^1
Aspergillus niger	1.84×10^3	ND	ND

*ND - None detected
*Cfu - Colony forming units

Test Results:	*Controle, Pack 27/08/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	#	#
	(27/08/08)	#	#
Staphylococcus aureus	5.7×10^5	#	#
Pseudomonas aeruginosa	7.6×10^5	#	#
Escherichia coli	6.35×10^5	#	#
Candida albicans	14.88×10^3	#	#
Aspergillus niger	3.77×10^3	#	#

* *Controle is peptone water for the bacterial cultures and candida and tween water for aspergillus*

Test organism	**Log reduction**	
	0h - 14days	**0h - 28days**
Staphylococcus aureus	>3	NI
Pseudomonas aeruginosa	>3	NI
Escherichia coli	>3	NI
Candida albicans	>1	INCREASED
Aspergillus niger	>1	NI

pH values:	**48H**	**28 Days + E.Coli**
	6.185	5.427
		28 Days + Pseud
		5.278
		28 Days + Staph
		5.265
	Candida	
	48H - 6.362	**28 Days** - 4.959
	Aspergillus	
	48H - 6.362	**28 Days** - 5.269

Test Results:	*Pheroid + Nipasept 0.175% + 10%PG, Pack 27/08/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	**14 days**	**28 days**
	(27/08/08)	(10/09/08)	17/09/08)
Staphylococcus aureus	4.7×10^5	ND	ND
Pseudomonas aeruginosa	ND	ND	ND
Escherichia coli	5.9×10^5	0.33×10^1	ND
Candida albicans	10.64×10^3	ND	ND
Aspergillus niger	12.6×10^3	ND	ND

**ND - None detected*
**Cfu - Colony forming units*

Test Results:	*Controle, Pack 27/08/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	#	#
	(27/08/08)	#	#
Staphylococcus aureus	5.7×10^5	#	#
Pseudomonas aeruginosa	7.6×10^5	#	#
Escherichia coli	6.35×10^5	#	#
Candida albicans	14.88×10^3	#	#
Aspergillus niger	3.77×10^3	#	#

** Controle is peptone water for the bacterial cultures and candida and tween water for aspergillus*

Test organism	**Log reduction**	
	0h - 14days	**0h - 28days**
Staphylococcus aureus	>3	NI
Pseudomonas aeruginosa	>3	NI
Escherichia coli	>3	NI
Candida albicans	>1	NI
Aspergillus niger	>1	NI

pH values:	**48H**	**28 Days + E.Coli**
	6.185	5.446
		28 Days + Pseud
		5.361
		28 Days + Staph
		5.471
	Candida	
	48H - 6.277	**28 Days** - 4.922
	Aspergillus	
	48H - 6.277	**28 Days** - 5.031

Test Results:	*Pheroid + Nipastat 0.175%, Pack 27/08/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	**14 days**	**28 days**
	(27/08/08)	(10/09/08)	17/09/08)
Staphylococcus aureus	4.9×10^5	ND	ND
Pseudomonas aeruginosa	1×10^2	ND	ND
Escherichia coli	15.1 x 105	ND	ND
Candida albicans	10.47×10^3	ND	ND
Aspergillus niger	3.34×10^3	ND	ND

*ND - None detected
*Cfu - Colony forming units

Test Results:	*Controle, Pack 27/08/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	#	#
	(27/08/08)	#	#
Staphylococcus aureus	5.7×10^5	#	#
Pseudomonas aeruginosa	7.6×10^5	#	#
Escherichia coli	6.35×10^5	#	#
Candida albicans	14.88×10^3	#	#
Aspergillus niger	3.77×10^3	#	#

* *Controle is peptone water for the bacterial cultures and candida and tween water for aspergillus*

Test organism	**Log reduction**	
	0h - 14days	**0h - 28days**
Staphylococcus aureus	>3	NI
Pseudomonas aeruginosa	>3	NI
Escherichia coli	>3	NI
Candida albicans	>1	NI
Aspergillus niger	>1	NI

pH values:	**48H**	**28 Days + E.Coli**
	6.144	5.605
	28D	**28 Days + Pseud**
	*	5.547
		28 Days + Staph
		5.444
	Candida	
	48H - 6.517	**28 Days** - 5.089
	Aspergillus	
	48H - 6.517	**28 Days** - 5.347

Test Results:	*Pheroid + Nipastat 0.175% + PG 10%, Pack 27/08/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	**14 days**	**28 days**
	(27/08/08)	(10/09/08)	17/09/08)
Staphylococcus aureus	4.2×10^5	ND	ND
Pseudomonas aeruginosa	3.3×10^1	ND	ND
Escherichia coli	39.7×10^4	ND	ND
Candida albicans	0.49×10^3	ND	ND
Aspergillus niger	11.9×10^3	ND	ND

**ND - None detected*
**Cfu - Colony forming units*

Test Results:	*Controle, Pack 27/08/2008*		
Test organism	**Total viable cell count (Cfu/ml)**		
	0 hours	#	#
	(27/08/08)	#	#
Staphylococcus aureus	5.7×10^5	#	#
Pseudomonas aeruginosa	7.6×10^5	#	#
Escherichia coli	6.35×10^5	#	#
Candida albicans	14.88×10^3	#	#
Aspergillus niger	3.77×10^3	#	#

** Controle is peptone water for the bacterial cultures and candida and tween water for aspergillus*

Test organism	**Log reduction**	
	0h - 14days	**0h - 28days**
Staphylococcus aureus	>3	NI
Pseudomonas aeruginosa	>3	NI
Escherichia coli	>3	NI
Candida albicans	>1	NI
Aspergillus niger	>1	NI

pH values:	**48H**	**28 Days + E.Coli**
	6.281	5.4
	28D	**28 Days + Pseud**
	*	5.423
		28 Days + Staph
		5.434
	Candida	
	48H - 6.543	**28 Days** - 5.109
	Aspergillus	
	48H - 6.543	**28 Days** - 4.843

ANNEXURE H

Table H1: Particle size and pH values measured for the individual Pheroid® formula (without preservatives added) at t = 48 hours (without added organisms) and repeated after 28 days (for Pheroid® formulas with added *Pseudomonas aeruginosa, Staphylococcus aureus, Eschiricia coli*, *Candida albicans* and *Aspergillus brasilliensis)*. D(0.9) represents 90% of the particle range.

Formulation excipient tested	*Particle size D (0.9)*	*Formulation excipient tested*	*pH*
Pheroid® (48 H)	0.266	**Pheroid® (48 H)**	6.281
Pheroid® (28 Days)		**Pheroid® (28 Days)**	
P.aeruginosa	291.917	P.aeruginosa	5.423
S.aureus	0.265	S.aureus	5.400
E.coli	0.290	E.coli	5.434
C.albicans	348.133	C.albicans	5.109
A.brasilliensis	266.658	A.brasilliensis	4.843

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[illegible]

TEST REPORT

To: Innovation fund
Address: Private Bag X6001
Potchefstroom
2520
Att: Sharlene

Analysis date 12/09/2011
Date received 12/09/2011
Sample type Pheroid
Sample quality Good
Ref: Pheroid.12.09.11

Preservative efficacy: Method used: Tec 34

Test organism	*7 days (cfu)*	*14 days (cfu)*	*28 days (cfu)*
S. aureus	ND	ND	ND
E. coli	ND	ND	ND
P. aeruginosa	ND	ND	ND
C. albicans	ND	ND	ND
A. brasiliensis	ND	ND	ND

Log reduction:

Test organism	Log Reduction		
	0 h – 7 days	*0 h – 14 days*	*0 h -28 days*
S. aureus	*>1*	*NI*	*NI*
E. coli	*>1*	*NI*	*NI*
P. aeruginosa	*>1*	*NI*	*NI*
C. albicans	*NI*	*NI*	*NI*
A. Brasiliensis	*NI*	*NI*	*NI*

NI – No Increase
ND - None detected

Cfu – Colony forming units
ISO 7954:1987 rounding off policy was applied

Ilse Simpson
Technical signatory

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	12/09/2011	Batch No:	Pheroid 0%
Requested by:	Charlene		

Product description: Vesicles for Preservative efficacy test

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign					

Raw material	Batch nr	Quantity		Weight	Action Sign	Check sign
		%	600 g			
Vit F ethyl ester	3102976	2.8	16.8g	16.79g		
Cremophor® EL	04517856PO	1.0	6.0g	6.04g		
dl-α- Tocopherol	UT10020016	0.2	1.2g	1.25g		
Butylated Hydroxyanisole	CD-63	0.04	0.24g	0.239g		
Butylated Hydroxytoluene	01165106	0.2	1.2g	1.200g		
TBHQ	04109BE-148	0.2	1.2g	1.200g		
N_2O . H_2O	N11015	95.56	573.36g	573.40g		
Total		100	600g	600.119g		

Method:

1. Weigh off $N_2O.H_2O$. Heat the water mixture to 70 °C on hotplate. Temp: 77 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑, Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat to 60 °C. Temp: 68 °C
3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.

5. Shake until room temperature is reached.

	Sign	Date
Approved: Charlene		2011 09 12
Prepared: Carolene		2011 09 12
Checked: Mel-Ann		2011 09 12

Packaging:

Describe containers: 6 X 100 ml Amber Bottles

Action	Containers clean	Filling area clean	Correct dress code
Sign			

Quantity filled: Six

Volume of each 100ml

Example of label:

Product Name : Pheroid 0%
Batch Number : Th 0%
Packaging Date : 12/09/2011
Expiry Date : 12/10/2011

ANNEXURE I

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	25/03/2013	Batch No:	V13015
Requested by:	Charlene		

Product description: Preservative efficacy test – a standard basic Pheroid ™ formula

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign					

Raw material	Batch nr	Quantity %	Quantity 600 g	Weight (g)	Action Sign	Check sign
Vit F ethyl ester	3113440	2.8	16.8g	16.80		
Cremophor® EL	04517856PO	1.0	6.0g	6.01		
dl-α- Tocopherol	UT12050032	0.2	1.2g	1.21		
Butylated Hydroxyanisole	L12030396	0.04	0.24g	0.24		
Butylated Hydroxytoluene	01165106	0.2	1.2g	1.20		
TBHQ	MKBK3867v	0.2	1.2g	1.20		
N_2O . H_2O	N13007	95.56	573.36g	573.36		
Total		100	600g	600.03		

Method:

1. Weigh off $N_2O.H_2O$. Heat the water mixture to 70 °C on hotplate. Temp: 72 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑, Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑

   Heat to 60 °C. Temp: 60 °C
3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.

Page 1 of 2

5. Shake until room temperature is reached.

	Sign	Date
Approved:		
Prepared: Charlene		2013/03/25
Checked:		

Packaging:

Describe containers: 6 x 100ml AMBER BOTTLES

Action	Containers clean	Filling area clean	Correct dress code
Sign			

Quantity filled: 6 x 100ml

Volume of each 100ml

Example of label:

Product Name : Phenpid™ Basic Formula
Batch Number : V13015
Packaging Date : 25/3/2013
Expiry Date : 25/04/2013

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	25/03/2013	Batch No:	V13020

Requested by:	Charlene		

Product description: Preservative efficacy test – a Pheroid™ formula with distilled water

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	LE	LE	LE	LE	LE

Raw material	Batch nr	Quantity		Weight (g)	Action Sign	Check sign
		%	600 g			
Vit F ethyl ester	3113440	2.8	16.8g	16.81	LE	
Cremophor® EL	04517656PO	1.0	6.0g	6.03	LE	
dl-α- Tocopherol	UT12050032	0.2	1.2g	1.30	LE	
Butylated Hydroxyanisole	L12030396	0.04	0.24g	0.25	LE	
Butylated Hydroxytoluene	01165106	0.2	1.2g	1.20	LE	
TBHQ	MKBK3867v	0.2	1.2g	1.20	LE	
H_2O	M43456	95.56	573.36g	573.35	LE	
Total		100	600g	600.14	LE	

Method:

1. Weigh off H_2O. Heat the water mixture to 70 °C on hotplate. Temp: 70 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑, Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat to 60 °C. Temp: 60 °C
3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.

5. Shake until room temperature is reached.

	Sign	Date
Approved:		
Prepared: Charlene		2013/03/25
Checked:		

Packaging:

Describe containers: 6 x 100 ml AMBER BOTTLES

Action	Containers clean	Filling area clean	Correct dress code
Sign			

Quantity filled: 6 x 100ml

Volume of each 100ml

Example of label:

Product Name : Phenoid™ with distilled H2O
Batch Number : V13020
Packaging Date : 25/03/ 2013
Expiry Date 25/04/ 2013

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	25/03/2013	Batch No:	V13018
Requested by:	Charlene		

Product description: Preservative efficacy test – a Pheroid™ formula without Cremophor EL

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign					

Raw material	Batch nr	Quantity %	Quantity 600 g	Weight (g)	Action Sign	Check sign
Vit F ethyl ester	31113440	2.8	16.8g	16.80		
dl-α- Tocopherol	04517856PO	0.2	1.2g	1.24		
Butylated Hydroxyanisole	L12030396	0.04	0.24g	0.25		
Butylated Hydroxytoluene	01165106	0.2	1.2g	1.20		
TBHQ	MKBK3867V	0.2	1.2g	1.20		
N_2O . H_2O	N13007	95.56	573.36g	579.37		
Total		100	600g	600.06		

Method:

1. Weigh off $N_2O.H_2O$. Heat the water mixture to 70 °C on hotplate. Temp: 70 °C
2. Weigh off and heat together: Vit F ethyl ester ☑,
   Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat to 60 °C. Temp: 60 °C
3. Weigh off dl-α-Tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

	Sign	Date
Approved:		
Prepared: Charlene	Charlene	25/03/2013
Checked:		

Packaging:

Describe containers: 6 x 100ml AMBER BOTTLES

Action	Containers clean	Filling area clean	Correct dress code
Sign	lt	lt	lt

Quantity filled: 6x 100ml

Volume of each 100ml

Example of label:

Product Name : Pheroid™ without Cremophor RL
Batch Number : V13018
Packaging Date 25/03/2013
Expiry Date 25/04/2013

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document

Date:	25/03/2013	Batch No:	V13016
Requested by:	Charlene		

Product description: Preservative efficacy test – a Pheroid™ formula without dl-α-tocopherol

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign					

Raw material	Batch nr	Quantity %	Quantity 600 g	Weight (g)	Action Sign	Check sign
Vit F ethyl ester	3113440	2.8	16.8g	16.81		
Cremophor® EL	04517856PO	1.0	6.0g	6.04		
Butylated Hydroxyanisole	L12030396	0.04	0.24g	0.26		
Butylated Hydroxytoluene	01165106	0.2	1.2g	1.20		
TBHQ	MKBK3867v	0.2	1.2g	1.21		
N_2O . H_2O	N13007	95.56	573.36g	574.59		
Total		100	600g	600.11		

Method:

1. Weigh off $N_2O.H_2O$. Heat the water mixture to 70 °C on hotplate. Temp: 70 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑,
   Butylated Hydroxyanisole ☑ Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat to 60 °C. Temp: 62 °C
4. Immediately add 2 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

	Sign	Date
Approved:		
Prepared: Charlene		2013/03/25
Checked:		

Packaging:

Describe containers: 6 X 100ml AMBER BOTTLES

Action	Containers clean	Filling area clean	Correct dress code
Sign			

Quantity filled: 6 X 100ml

Volume of each 100ml

Example of label:

Product Name : Pherokil™ without di-α-tocopherol
Batch Number : V13016
Packaging Date : 25/03/2013
Expiry Date 25/04/2013

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	25/03/2013	Batch No:	V13017
Requested by:	Charlene		

Product description: Preservative efficacy test – a Pheroid™ formula without BHA and BHT

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign					

Raw material	Batch nr	Quantity %	Quantity 600 g	Weight (g)	Action Sign	Check sign
Vit F ethyl ester	3113440	2.8	16.8g	16.81		
Cremophor® EL	04517856PO	1.0	6.0g	6.01		
dl-α-tocopherol	UT12050032	0.2	1.2g	1.25		
TBHQ	MKBK3867v	0.2	1.2g	1.20		
N_2O . H_2O	N13007	95.56	573.8g	574.80		
Total		100	600g	600.07		

Method:

1. Weigh off $N_2O.H_2O$. Heat the water mixture to 70 °C on hotplate. Temp: 72 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑, and TBHQ ☑ Heat to 60 °C. Temp: 60 °C.
3. Weigh off dl-α-tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.
5. Shake until room temperature is reached.

	Sign	Date
Approved:		
Prepared: Charlene		25/03/2013
Checked:		

Packaging:

Describe containers: 6X 100ml AMBER BOTTLES

Action	Containers clean	Filling area clean	Correct dress code
Sign			

Quantity filled: 6X 100ml

Volume of each 100ml.

Example of label:

Product Name : Pheroid™ without BHT+BHT
Batch Number : V 13017
Packaging Date : 25/03/ 2013
Expiry Date 25/04/ 2013

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Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	25/03/2013	Batch No:	V13019
Requested by:	Charlene		

Product description: Preservative efficacy test – a Pheroid™ formula without TBHQ

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign					

Raw material	Batch nr	Quantity %	Quantity 600 g	Weight (g)	Action Sign	Check sign
Vit F ethyl ester	3113440	2.8	16.8g	16.82		
Cremophor® EL	04517856PO	1.0	6.0g	6.03		
dl-α-tocopherol	UT12050032	0.2	1.2g	1.22		
Butylated Hydroxlanisole	L12030396	0.04	0.24g	0.24		
Butylated Hydroxitoluene	01165106	0.2	1.2g	1.21		
N_2O . H_2O	N13007	95.56	574.56g	574.58		
Total		100	600g	600.1		

Method:

1. Weigh off $N_2O.H_2O$. Heat the water mixture to 70 °C on hotplate. Temp: 70 °C
2. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor EL ☑, Butylated Hydroxyanisole : ☑ Butylated Hydroxytoluene ☑.
   Heat to 60 °C. Temp: 62 °C.
3. Weigh off dl-α-tocopherol and add to 2.
4. Immediately add 3 to 1 while homogenizing @ 13500 rpm for 5 minutes.

5. Shake until room temperature is reached.

	Sign	Date
Approved.		
Prepared: Charlene		2013/03/25
Checked:		

Packaging:

Describe containers: 6 x 100ml AMBER BOTTLES

Action	Containers clean	Filling area clean	Correct dress code
Sign			

Quantity filled: 6 x 100ml

Volume of each 100ml

Example of label:

Product Name : Phefaid™ without TBHQ
Batch Number : V13019
Packaging Date : 25/03/2013
Expiry Date 25/04/2013

Table I1: Particle size values for each individual component of the Pheroid® formula (sample A – F). Average readings at t = 48 hours (without added organisms) and repeated after 28 days (for Pheroid® formulas kept at 4°C and with added organisms) and tested for preservative efficacy. D (0.9) represents 90% of the particle size range.

Formulation excipient tested	*Particle size D (0.9)*	*Formulation excipient tested*	*Particle size D (0.9)*
	AVE		*AVE*
Sample A (48 H)	0.279	**Sample D (48 H)**	0.269
Sample A (28 Days)		**Sample D (28 Days)**	
4 °C	0.276	4 °C	0.270
P.aeruginosa	0.275	P.aeruginosa	0.270
S.aureus	0.275	S.aureus	0.270
E.coli	0.274	E.coli	0.271
C.albicans	0.277	C.albicans	0.271
A.brasilliensis	0.275	A.brasilliensis	0.271
Sample B (48 H)	0.275	**Sample E (48 H)**	0.277
Sample B (28 Days)		**Sample E (28 Days)**	
4 °C	0.272	4 °C	0.275
P.aeruginosa	0.272	P.aeruginosa	0.275
S.aureus	0.272	S.aureus	0.274
E.coli	0.275	E.coli	0.275
C.albicans	0.272	C.albicans	0.275
A.brasilliensis	0.272	A.brasilliensis	0.276
Sample C (48 H)	91.886	**Sample F(48 H)**	2.739
Sample C (28 Days)		**Sample F (28 Days)**	
4 °C	122.917	4 °C	2.697
P.aeruginosa	177.156	P.aeruginosa	3.409
S.aureus	157.524	S.aureus	2.609
E.coli	162.157	E.coli	2.505
C.albicans	134.457	C.albicans	2.620
A.brasilliensis	120.739	A.brasilliensis	2.590

Table I2: pH values for each individual component of the Pheroid® formula (sample A – F). Readings at t = 48 hours (without added organisms) and repeated after 28 days (for Pheroid® formulas kept at 4°C and with added organisms) and tested for preservative efficacy.

Formulation excipient tested	pH	Formulation excipient tested	pH
Sample A (48 H)	6.876	**Sample D (48 H)**	6.535
Sample A (28 Days)		**Sample D (28 Days)**	
4 °C	7.161	4 °C	6.572
P.aeruginosa	5.307	P.aeruginosa	5.788
S.aureus	6.212	S.aureus	5.503
E.coli	5.909	E.coli	5.118
C.albicans	5.855	C.albicans	5.550
A.brasilliensis	5.525	A.brasilliensis	4.957
Sample B (48 H)	6.904	**Sample E (48 H)**	6.674
Sample B (28 Days)		**Sample E (28 Days)**	
4 °C	6.641	4 °C	6.476
P.aeruginosa	5.764	P.aeruginosa	5.307
S.aureus	6.290	S.aureus	6.490
E.coli	6.043	E.coli	5.513
C.albicans	5.471	C.albicans	5.299
A.brasilliensis	5.457	A.brasilliensis	5.130
Sample C (48 H)	7.203	**Sample F(48 H)**	6.592
Sample C (28 Days)		**Sample F (28 Days)**	
4 °C	6.883	4 °C	6.506
P.aeruginosa	5.601	P.aeruginosa	5.648
S.aureus	5.941	S.aureus	5.920
E.coli	5.914	E.coli	5.708
C.albicans	5.421	C.albicans	5.766
A.brasilliensis	4.779	A.brasilliensis	5.393

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084 7806971
[illegible]

[illegible]
Corner of [illegible]
[illegible]
Potchefstroom
[illegible]

PO Box 1553
Potchefstroom
[illegible]

Test Results:

Sample name: ***Pherold basic formula***
B/N: ***V13015***
Received: ***26.03.2013***

Sample code: ***A***
Packaging date ***26.03.2013***
Expiry date: ***25.04.2013***

Test organism	0 Hour	7 days (cfu)	14 days (cfu)	28 days (cfu)
S. aureus	12×10^3	ND	ND	ND
E. coli	61×10^5	ND	ND	ND
P. auruginosa	3×10^5	ND	ND	ND
C. albicans	3 x 10^[illegible]	ND	ND	ND
A. brasiliensis	10×10^3	ND	ND	ND

Log reduction:

Test organism	Log Reduction		
	0 h – 7 days	*0 h – 14 days*	*0 h -28 days*
S. aureus	*NI*	*NI*	*NI*
E. coli	*NI*	*NI*	*NI*
P. auruginosa	*NI*	*NI*	*NI*
C. albicans	*NI*	*NI*	*NI*
A. Brasiliensis	*NI*	*NI*	*NI*

NI – No increase
Cfu – Colony forming units
ND - None detected
ISO 7954:1987 rounding off policy was applied

CC Chisik trading 57_Registration nr: [illegible]_VAT nr: [illegible]

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[illegible]sat[illegible].co.za

Test Results:

Sample name: *Pherold with distilled H20*
B/N: *V13020*
Received: *26.03.2013*

Sample code: *B*
Packaging date: *26.03.2013*
Expiry date: *25.04.2013*

Test organism	0 Hour	7 days *(cfu)*	14 days *(cfu)*	28 days *(cfu)*
S. aureus	36×10^{5}	ND	ND	ND
E. coli	51×10^{5}	ND	ND	ND
P. auruginosa	17×10^{5}	ND	ND	ND
C. albicans	12×10^{1}	ND	ND	ND
A. brasiliensis	2×10^{3}	ND	ND	ND

Log reduction:

Test organism	Log Reduction		
	0 h – 7 days	*0 h – 14 days*	*0 h -28 days*
S. aureus	*NI*	*NI*	*NI*
E. coli	*NI*	*NI*	*NI*
P. auruginosa	*NI*	*NI*	*NI*
C. albicans	*NI*	*NI*	*NI*
A. Brasiliensis	*NI*	*NI*	*NI*

NI – No Increase
Cfu – Colony forming units
ND – None detected
ISO 7954:1987 rounding off policy was applied

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Test Results:

Sample name: ***Pherold without Cremophorel***
B/N: ***V13018***
Received: ***26.03.2013***

Sample code: ***C***
Packaging date: ***25.03.2013***
Expiry date: ***25.04.2013***

Test organism	0 Hour	7 days *(cfu)*	14 days *(cfu)*	28 days *(cfu)*
S. aureus	62×10^3	ND	ND	ND
E. coli	42×10^3	ND	ND	ND
P. auruginosa	7×10^3	ND	ND	ND
C. albicans	ND	ND	ND	ND
A. brasiliensis	1×10^3	ND	ND	ND

Log reduction:

Test organism	Log Reduction		
	0 h – 7 days	*0 h – 14 days*	*0 h -28 days*
S. aureus	*NI*	*NI*	*NI*
E. coli	*NI*	*NI*	*NI*
P. auruginosa	*NI*	*NI*	*NI*
C. albicans	*NI*	*NI*	*NI*
A. Brasiliensis	*NI*	*NI*	*NI*

NI – No Increase
Cfu – Colony forming units
ND - None detected
ISO 7954:1987 rounding off policy was applied

CC Chalk trading 57 Registration no: 2007/112970/23 VAT no: 4120238524

sanas

envirocare
laboratory

Dawes Village Park
Corner of Pel... &
Govan Mbeki Str
Potchefstroom
2531

PO Box 1553
Potchefstroom
2520

Test Results:

Sample name:	*Pheroid without dl-x-tocophert*	Sample code:	*D*
B/N:	*V13016*	Packaging date:	*26.03.2013*
Received:	*26.03.2013*	Expiry date:	*25.04.2013*

Test organism	0 Hour	7 days *(cfu)*	14 days *(cfu)*	28 days *(cfu)*
S. aureus	64 x 10^3	ND	ND	ND
E. coli	153 x 10^5	ND	ND	ND
P. auruginosa	8 x 105	ND	ND	ND
C. albicans	1 x 10^1	ND	ND	ND
A. brasiliensis	6 x 10^3	ND	ND	ND

Log reduction:

Test organism	Log Reduction		
	0 h – 7 days	*0 h – 14 days*	*0 h -28 days*
S. aureus	*NI*	*NI*	*NI*
E. coli	*NI*	*NI*	*NI*
P. auruginosa	*NI*	*NI*	*NI*
C. albicans	*NI*	*NI*	*NI*
A. Brasiliensis	*NI*	*NI*	*NI*

NI – No Increase
Cfu – Colony forming units
ND – None detected
ISO 7954:1987 rounding off policy was applied

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Test Results:

Sample name: *Pherold without BHA+BHT* **Sample code:** *E*
B/N: *V13017* **Packaging data:** *26.03.2013*
Received: *26.03.2013* **Expiry date:** *25.04.2013*

Test organism	0 Hour	7 days *(cfu)*	14 days *(cfu)*	28 days *(cfu)*
S. aureus	54×10^3	ND	ND	ND
E. coli	36×10^5	ND	ND	ND
P. auruginosa	6×10^3	ND	ND	ND
C. albicans	4×10[illegible]	ND	ND	ND
A. brasiliensis	2×10^3	ND	ND	ND

Log reduction:

Test organism	Log Reduction		
	0 h – 7 days	*0 h – 14 days*	*0 h -28 days*
S. aureus	*NI*	*NI*	*NI*
E. coli	*NI*	*NI*	*NI*
P. auruginosa	*NI*	*NI*	*NI*
C. albicans	*NI*	*NI*	*NI*
A. Brasiliensis	*NI*	*NI*	*NI*

NI – No increase
Cfu – Colony forming units
ND – None detected
ISO 7954:1987 rounding off policy was applied

CC Check trading 57 Registration no 2007/112570/23 VAT no 4120229524

sanas

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Test Results:

Sample name: *Pheroid without TBHQ*
B/N: *V13026*
Received: *23.05.2013*
Client:

Sample code: *F*
Packaging date: *13.05.2013*
Expiry date:

Test organism	**0 Hour**	**7 days** *(cfu)*	**14 days** *(cfu)*	**28 days** *(cfu)*
S. aurous	65×10^4	ND	ND	ND
E. coli	202×10^4	ND	ND	ND
P. auruginosa	97×10^4	ND	ND	ND
C. albicans	16×10^3	ND	ND	ND
A. brasiliensis	170×10^2	124×10^2	165×10^2	28×10^2

Log reduction:

Test organism	**Log Reduction**		
	0 h – 7 days	*0 h – 14 days*	*0 h -28 days*
S. aureus	*NI*	*NI*	*NI*
E. coli	*NI*	*NI*	*NI*
P. auruginosa	*NI*	*NI*	*NI*
C. albicans	*NI*	*NI*	*NI*
A. Brasiliensis	*NI*	*NI*	*NI*

NI – No Increase
Cfu – Colony forming units
ND - None detected
ISO 7954:1987 rounding off policy was applied

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Criteria for Antimicrobial effectiveness (Reference: USO 30, Section 51)
The requirements for antimicrobial effectiveness are met if the criteria specified in the table below are met.

Product Category	Measure	Criteria
Category 1: Injections, other parenterals including emulsions, otic products, sterile nasal products, and ophthalmic products made with aqueous bases or vehicles	Bacteria	Not less than 1.0 log reduction from the initial calculated count at 7 days, not less than 3.0 log reduction from the initial count at 14 days, and no increase from the 14 days count at 28 days
	Yeast & Molds	No increase from the initial calculated count at 7, 14 and 28 days
Category 2: Topically used products made with aqueous bases or vehicles, non-sterile nasal products, and emulsion, including those applied to mucous membranes	Bacteria	Not less than 2.0 log reduction from the initial count at 14 days, and no increase from the 14 days count at 28 days
	Yeast & Molds	No increase from the initial calculated count at 7, 14 and 28 days
Category 3: Oral products other than antacids, made with aqueous bases or vehicles	Bacteria	Not less than 1.0 log reduction from the initial count at 14 days, and no increase from the 14 days count at 28 days
	Yeast & Molds	No increase from the initial calculated count at 7, 14 and 28 days
Category 4: Antacids made with a aqueous base	Bacteria, Yeast & Molds	No increase from the initia calculated count at 7, 14 and 28 days

**Note: No increase is defined as not more than 0.5 Log_{10} unit higher than the previous value measured.*

Ilse Simpson
Lab Manager

End of Report

CC Chair trading as Registration no: 2007/112570/23 VAT no: 4120237524

SANAS

ANNEXURE J

NORTH-WEST UNIVERSITY
YUNIBESITI YA BOKONE-BOPHIRIMA
NOORDWES-UNIVERSITEIT

Drug R&D

Pheroid™ Experimental Batch Manufacturing Document.

Date:	16/11/2008	Batch No:	Carbopol® 934 P 0.2% (PG)
Requested by:	Charlene		

Product description: 0.2% Carbopol® emulgel formulation with co-solvent

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign					

Raw material	Batch nr	Quantity %	Quantity 4000g	Weight	Action Sign	Check sign
Vit F ethyl ester	308E009	2.8	112.0g	112.01g		
Cremophor® EL	04517856PO	1.0	40.0g	40.00g		
dl-α- Tocopherol	707090036	0.2	8.0g	8.02g		
Butylated Hydroxyanisole	07115PG-475	0.04	1.60g	1.6003g		
Butylated Hydroxytoluene	04416KD-076	0.2	8.0g	8.0001g		
TBHQ	1254992	0.2	8.0g	8.000g		
Nipastat®	GBG0001069	0.175	7.0g	7.0005g		
Propylene glycol	CC67JBB139	10.0	400.0g	400.01g		
Carbopol® 934 P	52560	0.2	8.0g	8.00g		
NaOH (18%)	1028176	0.46g	18.4g	18.40g		
N_2O . H_2O	NO6032	84.725	3389.0	3389.01g		
Total		100	4000	4000.05		

Method:

1. In a 5000 mL glass beaker weigh off $N_2O.H_2O$.
2. Weigh the propylene glycol and Nipastat®. Add the Nipastat® to the propylene glycol. Rinse all of the Nipastat® into the container. Stir well. Add the propylene glycol mixture

Page 1 of 2

to the $N_2O.H_2O$ mixture. Heat mixture until 60 °C on hotplate. Temp: 75 °C

3. Weigh off the Carbopol® and add it slowly to the vortex of the heated water mixture at 900 rpm.
4. Add the Sodium hydroxide buffer slowly to the mixture at 300 rpm while stirring continuously for 20 minutes or until fully hydrated.
5. Weigh off and heat together: Vit F ethyl ester ☑ Cremophor® EL ☑, Butylated Hydroxyanisole ☑, Butylated Hydroxytoluene ☑ and TBHQ ☑ Heat to 60 °C. Temp: 60 °C
6. Weigh off dl-α-Tocopherol and add to 5.
7. Immediately add 6 to 4 while homogenizing @ 13500 rpm for 10 minutes. Homogenizing temperature of water phase is 51 °C and oil phase is 60 °C.
8. Continue stirring with overhead stirrer at 500rpm until room temperature is reached.

	Sign	Date
Approved: CHARLENE UYS		16/11/2008
Prepared: CHARLENE UYS		16/11/2008
Checked: CARLIE BRITZ		16/11/2008

Packaging:

Describe containers: 5ml Amber bottles, 5ml Clear bottles, Foil sachets

Action	Containers clean	Filling area clean	Correct dress code
Sign	CL	CL	CL

Quantity filled: 1 x 5ml Clear bottle / 4 x 5ml Amber bottle / 4 x Foil Sachets } Volume of each 5ml } At 4 Stability points namely 5°C, 25°C, 30°C, 40°C

Example of label:

Sample name: Carbopol 934P (CAR 0.2 (PGT))
Student : Charlene Uys
Temp : 5°C
Age : 1 Month
Sample on : 17.11.2008
Sample off : 17.12.2008

NORTH-WEST UNIVERSITY
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Drug R&D

Pherold™ Experimental Batch Manufacturing Document.

Date:	16/11/2008	Batch No:	XG1.50A (PG)
Requested by:	Charlene		

Product description: 1.50% Xanthangum emulgel formulation with co-solvent according to method A

Action	Weighing equipment clean	Weighing area clean	Balances calibrated	Containers clean	Correct dress code
Sign	CE	CE	CE	CE	CE

Raw material	Batch nr	Quantity %	Quantity 4000g	Weight	Action Sign	Check sign
Vit F ethyl ester	308E009	2.8	112.0g	112.00g	CE	CMB
Cremophor® EL	04517856PO	1.0	40.0g	40.01g	CE	CMB
dl-α- Tocopherol	U707090036	0.2	8.0g	8.04g	CE	CMB
Butylated Hydroxyanisole	07115PG-475	0.04	1.60g	1.6000g	CE	CMB
Butylated Hydroxytoluene	04416KD-076	0.2	8.0g	8.0001g	CE	CMB
TBHQ	1254892	0.2	8.0g	8.0002g	CE	CMB
Nipastat®	GBG0001069	0.175	7.0g	7.0001g	CE	CMB
Propylene glycol	52560	10.0	400.0g	400.01g	CE	CMB
Xanthangum	2509089	1.5	60.0g	60.00g	CE	CMB
N_2O . H_2O	NO8020	83.885	3355.4	3355.42g	CE	CMB
Total		100	4000	4000.08	CE	CMB

Method:

1. In a 5000 mL glass beaker weigh off the $N_2O.H_2O$.
2. Weigh off propylene glycol and Nipastat®. Add the Nipastat® to the propylene glycol, rinse all the Nipastat® into container. Add the mixture to the $N_2O.H_2O$.

3. Heat the $N_2O.H_2O$ mixture on the hotplate until ± 75 °C. Temp: 76 °C
4. Weigh off xanthangum. Add the xanthangum slowly in the vortex of the water mixture while stirring with the overhead stirrer at 1200 rpm for 30 minutes or until fully hydrated.
5. Weigh off and heat together: Vit F ethyl ester ☑, Cremophor® EL ☑, Butylated Hydroxyanisole ☑, Butylated Hydroxytoluene ☑ and TBHQ ☑
   Heat to 60 °C. Temp: 61 °C
6. Weigh off dl-α-Tocopherol and add to 5.
7. Immediately add 6 to 4 while homogenizing @ 13500 rpm for 10 minutes. Homogenizing temperature of water phase is 57 °C and oil phase is 63 °C.
8. Continue stirring with overhead stirrer at 300 rpm until room temperature is reached.

		Sign	Date
Approved:	CHARLENE Uys		16/11/2008
Prepared:	CHARLENE Uys		16/11/2008
Checked:	CARVIE BRITZ	CMBritz	16/11/2008

Packaging:

Describe containers: 50ml Amber bottles; 50ml Clear bottle; Foil Sachets

Action	Containers clean	Filling area clean	Correct dress code
Sign	CU	CU	CU

Quantity filled: 1x 50ml Clear bottle / 4 x 50ml Amber bottle / 4 x Foil Sachets Volume of each 50ml } At 4 stability points namely 5°C; 25°C; ~~30°C~~ 40°C

Example of label:

Sample name: Xanthan Gum (XG 1.50A (PG))
Student : Charlene Uys
Temp : 5°C
Age : 1 month
Date on : 17.11.2008
Date off : 17.12.2008
Date end : 17.02.2009

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