

Annexure A

SIGMA-ALDRICH®

sigma-aldrich.com

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Email USA: techserv@sial.com

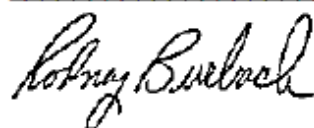
Outside USA: eurtechserv@sial.com

Certificate of Analysis

Product Name:
Quinine sulfate salt, meets USP testing

Product Number: Q0132
Lot Number: 080M1482V
Brand: SIAL
CAS Number: 207671-44-1
MDL Number: MFCD00150792
Formula: C₂₀H₂₄N₂O₂ · 0.5H₂O₄S · H₂O
Formula Weight: 391.47 g/mol
Expiration Date: AUG 2015

Test	Specification	Result
Identity	Pass	Pass
Specific Rotation	-245.000 - -235.000 °	-241.650 °
Water (by Karl Fischer)	4.0 - 5.5 %	4.8 %
Residue on Ignition	≤ 0.1 %	0.0 %
Heavy Metal	≤ 0.001 %	0.000 %
Insoluble Substances	≤ 0.1 %	0.0 %
Chloroform-Alcohol		
Chromatographic Purity	Pass	Pass
Miscellaneous Supplier Data	≤ 10.0	4.5
Assay (Anhydrous Basis)	99.0 - 101.0 %	99.9 %
Residual Solvents USP 467	Meets Requirements	Class 2 Solvents Only, Meets
Option 1		
Expected Solvent	Residual Solvent	Toluene



Rodney Burbach, Manager
Analytical Services
St. Louis, Missouri US

Sigma-Aldrich warrants, that at the time of the quality release or subsequent retest date this product conformed to the information contained in this publication. The current Specification sheet may be available at Sigma-Aldrich.com. For further inquiries, please contact Technical Service. Purchaser must determine the suitability of the product for its particular use. See reverse side of invoice or packing slip for additional terms and conditions of sale.

Annexure B

Certificate of Analysis

SIGMA-ALDRICH

Product Name Quinidine sulfate salt dihydrate
Product Number Q0875
Product Brand SIGMA
CAS Number 6501-63-5
Molecular Formula $C_{40}H_{48}N_4O_4 \cdot H_2O_4S \cdot 2H_2O$
Molecular Weight 782.94

TEST

Appearance (Color)
Appearance (Form)
Solubility (Color)
Solubility (Turbidity)

Infrared spectrum
Purity (HPLC)

% Dihydroquinidine

Recommended Retest Period

Specification Date:

Date of QC Release:

Recommended Retest Date:

Print Date:



Rodney Burbach, Manager
Quality Control
St. Louis, Missouri USA

SPECIFICATION

White to Off-White
Powder
Colorless to Faint Yellow
Clear
50 mg/mL, EtOH
Conforms to Structure
≥80 %
Quinidine
≤20
by HPLC

4 Years

LOT 060M1212V RESULTS

Off-White
Powder
Very Faint Yellow
Clear

Conforms
88 %

14

JUN 2010
JUN 2010
JUN 2014
JUN 30 2010

Annexure C



SIGMA-ALDRICH

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ALDRICH
Certificate of Analysis

Product Brand	Aldrich	
PRODUCT-NO	C80407	
PRODUCT	CINCHONIDINE	
	96 %	
FORMULA	C ₁₉ H ₂₂ N ₂ O	
MOLECULAR MASS	294.39	
CAS NUMBER	485-71-2	
LOT	1412401	
Test	Specification	Result
APPEARANCE (COLOR)	WHITE TO OFF-WHITE	OFF-WHITE
APPEARANCE (FORM)	POWDER	POWDER
TITRATION (NT) HClO ₄ 0.1M	95.5 - 104.5 %	99.7 %
PURITY (HPLC AREA %)	≥ 95.5 %	96.9 %
SPECIFIC ROTATION (20/D)	-109 (± 5) DEGREES	-109.5 DEGREES
CONCENTRATION	C=0.4 % IN ETOH	C=0.4 % IN ETOH
INFRARED SPECTRUM	CONFORMS TO STRUCTURE	CONFORMS
QC RELEASE DATE	16/OCT/08	

Edeltraud Schwärzler, Manager
Quality Control
Buchs, Switzerland

Sigma-Aldrich warrants, that its products conform to the information contained in this and other Sigma-Aldrich publications. Purchaser must determine the suitability of the product for its particular use. See reverse side of invoice for additional terms and conditions of sale. The values given on the 'Certificate of Analysis' are the results determined at the time of analysis.

Annexure D

SIGMA-ALDRICH[®]

Certificate of Analysis

SIGMA-ALDRICH[®]

Product Name	Hydroquinine, 98%
Product Number	337714
Product Brand	ALDRICH
CAS Number	522-66-7
Molecular Formula	C ₂₀ H ₂₀ N ₂ O ₂
Molecular Weight	326.43

TEST	SPECIFICATION	LOT 12113BH RESULTS
APPEARANCE	WHITE TO OFF-WHITE POWDER AND/OR CHUNKS	WHITE POWDER
INFRARED SPECTRUM		CONFORMS TO STRUCTURE.
ELEMENTAL ANALYSIS		CARBON 73.98% NITROGEN 8.76%
OPTICAL ROTATION	-148 DEGREES +/- 5 DEGREES (C=1%, ETHANOL)	-145 DEGREES (C=1%, ETOH)
HIGH PRESSURE LIQUID	97.5% (MINIMUM)	99.9%
CHROMATOGRAPHY		
QUALITY CONTROL		FEBRUARY 2007
ACCEPTANCE DATE		



Barbara Rajzer, Supervisor
Quality Control
Milwaukee, Wisconsin USA

Bibliography

ACHAN, J., TALISUNA, A.O., ERHART, A., YEKA, A., TIBENDERANA, J.K., BALIRAINÉ, F.N., ROSENTHAL, P.J. & D'ALESSANDRO, U. 2011. Quinine, an old anti-malarial in a modern world: role in the treatment of malaria. *Malaria Journal*, 10:144-155, May.

ADEGBITE, A.I., & ADEGBOLAGUN, O.M. 2011. Evaluation of the physicochemical equivalence of three brands of commercially available quinine sulfate tablets from South Western part of Nigeria. *African Health Sciences*, 11(2):197-203, Jun.

AFRICA FIGHTING MALARIA (AFM). 2009. Africa fighting malaria. Bulletin #3: Safe Medicines Project - Phase II: The Zambian Case Study. http://fightingmalaria.org/pdfs/AFMbulletin3_zambia.pdf Date of access: 2 Aug. 2011.

AFM - refer to Africa Fighting Malaria.

AHUJA, S. 2001. Modern Pharmaceutical Analysis: An overview. (In Ahuja, S. & Scypinski, S., eds. Handbook of Modern Pharmaceutical Analysis. San Diego : Academic press. p. 1-22).

ALDERBORN, G. 2007. Tablets and compaction. (In Aulton, M.E., ed. Aulton's Pharmaceutics: The Design and Manufacture of Medicines. Edinburgh : Churchill Livingstone. p. 441-482).

AMIN, A.A. & KOKWARO, G.O. 2009. Anti-malarial drug quality in Africa. *Journal of Clinical Pharmacology and Therapeutics*, 32(5):429-440, Oct.

ANISFELD, M.H. 2012. International GMP's—A detailed background. Global GMP expertise. <http://www.globepharm.org/what-is-gmp/international-gmps.html> Date of access: 29 Jan. 2012.

ANON. 2012. <http://www.flickr.com/photos/crosem/4039863121/> Date of access: 11 Aug. 2012.

ARGUIN, P.M. & MALI, S. 2012. Infectious diseases related to travel. Center for disease Control and Prevention Chapter 3: <http://wwwnc.cdc.gov/travel/yellowbook/2012/chapter-3-infectious-diseases-related-to-travel/malaria.htm> Date of access: 20 Apr. 2012.

ASHLEY, E., MCGREADY, R., PROUX, F. & NOSTEN, F. 2006. Malaria. *Travel Medicine and Infectious disease*, 4:159-173, Jun.

ASHFORD, M. 2007. Bioavailability - physicochemical and dosage form factors (*In Aulton, M.E., ed. Aulton's Pharmaceutics: The Design and Manufacture of Medicines. Edinburgh : Churchill Livingstone. p. 286 - 303.*)

AULTON, M.E. 2007. Dissolution and solubility. (*In Aulton, M.E., ed. Aulton's Pharmaceutics: The Design and Manufacture of Medicines. Edinburgh : Churchill Livingstone. p. 16-32.*)

AULTON, M.E. 2007. Properties of solutions. (*In Aulton, M.E., ed. Aulton's Pharmaceutics: The Design and Manufacture of Medicines. Edinburgh : Churchill Livingstone. p. 33-41.*)

AZARMI, S., ROA, W. & LÖBENBERG, R. 2007. Current perspectives in dissolution testing of conventional and novel dosage forms. *International Journal of Pharmaceutics*, 328:12-21, Oct.

BARNES, K.I. 2012. Anti-malarial Drugs and the Control and Elimination of Malaria. (*In Staines, H.M. & Krishna, S., eds. Milestones in drug therapy. Treatment and prevention of malaria: Anti-malarial drug chemistry, action and use. United Kingdom : Springer. p.1-17.*)

BATE, R., COTICELLI, P., TREN, R. AND ATTARAN, A. 2008. Antimalarial Drug Quality in the Most Severely Malarious Parts of Africa – A Six Country Study. *PLoS ONE*, 3(5):2132-2134, May.

BEEZNEEZ. 2009. Cinchona or quinine tree. <http://blog.mailasail.com/beezeez/177> Date of access: 30 Apr. 2013.

BELL, D & PERKINS, M.D. 2012. Malarial Diagnostics: Lighting the Path. (*In Staines, H.M. & Krishna, S., eds. Milestones in drug therapy. Treatment and prevention of malaria: Anti-malarial drug chemistry, action and use. United Kingdom : Springer. 315p.*)

BIRRER, G.A., MURTHY, S.S. & LIU, J. 2001. Parenteral dosage forms. (*In Ahuja, S. and Scypinski, S., eds. Handbook of Modern Pharmaceutical Analysis. San Diego : Academic press. p. 269-303.*)

BREYTENBACH, JC & VAN DYK, S. 2011. Inleidende medisinale chemie. Potchefstroom: NWU, Potchefstroomkampus. (Studiegids FCHG 221 PAC).

BP – *refer to* British Pharmacopoeia.

BRHLIKOVA, P., HARPER, I. & POLLOCK, A. 2007. Good Manufacturing Practice in the Pharmaceutical Industry. Working paper 3 for Workshop on 'Tracing Pharmaceuticals in South Asia at the University of Edinburgh'. <http://r4d.dfid.gov.uk/Output/179518/Default.aspx> Date of access: 10 Jan. 2012.

BRITISH PHARMACOPOEIA. 2011. The British Pharmacopoeia: Online. <http://www.pharmacopoeia.co.uk/bp2012/ixbin/bp.cgi> Date of access: 2011 - 2013.

BROWN, K.C., CHOKSHI, H.P., NICKERSON, B., REED, R.A., ROHRS, B.R. & SHAH, P.A. 2004. Acceptable analytical practices for dissolution testing of poorly soluble compounds. *Pharmaceutical Technology*, 56-65 p. www.pharmtech.com Date of access: 15 May. 2012.

BURKI, T. 2010. Building medical regulatory authorities in Africa. *The Lancet Infectious Diseases*, 10(4): 222, Apr.

DOLLERY, C. 1999. Therapeutic Drugs. Volume 2 (I-Z). 2nd ed. United Kingdom ; Churchill Livingstone. Q16-Q21.

DUOC, N. 2012. Pharmacognosy: Quinine. <http://www.eppharmacognosy.com> Date of access: 22 Jan. 2013.

EURACHEM. 1998. The Fitness for Purpose of Analytical Methods. A Laboratory Guide to Method Validation and Related Topics. <http://www.eurachem.nl/images/eurachem/Fitnessforpurpose.pdf> Date of access: 10 Jan. 2012.

FDA – *refer to* Food and Drug Administration.

FOOD AND DRUG ADMINISTRATION (FDA) – *refer to* US Food and drug administration.

GAUDIANO, M.C., MAGGIO, A.D., COCCHIERI, E.A., BERTOCCHI, P., ALIMONTI, S. & VALVO, L. 2007. Medicines informal market in Congo, Burundi and Angola: Counterfeit and Substandard anti-malarials. *Malaria Journal*, 6(22):1-9, Febr.

GRAHAM, P. 2011. Quality control in the pharmaceutical industry. (*In* Moffat, A.C., Osselton, M.D., Widdop, B. & Watts, J., eds. *Clarke's analysis of drugs and poisons*). London : Pharmaceutical Press.
<http://www.medicinescomplete.com.nwulib.nwu.ac.za/mc/clarke/current/c21-sec1-0003.htm>
Date of access: 06 Jan. 2012.

GRAHAM, P. 2011. Monographs. (*In* Moffat, A.C., Osselton, M.D., Widdop, B. & Watts, J., eds. *Clarke's analysis of drugs and poisons*). London : Pharmaceutical Press.
http://www.medicinescomplete.com.nwulib.nwu.ac.za/mc/clarke/current/CLK0373.htm?q=cinchonidine&t=search&ss=text&p=1#_hit Date of access: 6 Nov. 2013.

GRAHAM, P. 2011. Monographs. (*In* Moffat, A.C., Osselton, M.D., Widdop, B. & Watts, J., eds. *Clarke's analysis of drugs and poisons*). London : Pharmaceutical Press.
http://www.medicinescomplete.com.nwulib.nwu.ac.za/mc/clarke/current/CLK1440.htm?q=quinidine%20sulfate&t=search&ss=text&p=1#_hit Date of access: 6 Nov. 2013.

GRAHAM, P. 2011. Monographs. (*In* Moffat, A.C., Osselton, M.D., Widdop, B. & Watts, J., eds. *Clarke's analysis of drugs and poisons*). London : Pharmaceutical Press.
http://www.medicinescomplete.com.nwulib.nwu.ac.za/mc/clarke/current/CLK1441.htm?q=quinine%20sulfate&t=search&ss=text&p=1#_hit Date of access: 6 Nov. 2013.

GRAHAM, P. 2011. Monographs. (*In* Moffat, A.C., Osselton, M.D., Widdop, B. & Watts, J., eds. *Clarke's analysis of drugs and poisons*). London : Pharmaceutical Press.
http://www.medicinescomplete.com.nwulib.nwu.ac.za/mc/clarke/current/CLK0853.htm?q=dihydroquinine&t=search&ss=text&p=1#_hit Date of access: 6 Nov. 2013.

GRAHAM, P. 2011. Monographs. (*In* Moffat, A.C., Osselton, M.D., Widdop, B. & Watts, J., eds. *Clarke's analysis of drugs and poisons*). London : Pharmaceutical Press.
http://www.medicinescomplete.com.nwulib.nwu.ac.za/mc/clarke/current/CLK0852.htm?q=dihydroquinidine&t=search&ss=text&p=1#_hit Date of access: 6 Nov. 2013.

HARVEY, R. A., CHAMPE, P.C. & MYCEK, M. J. 2000. *Pharmacology*. Lippincott's Illustrated Reviews. 2nd ed. Philadelphia : Lippincott Williams and Wilkins. 514 p.

HOLLER, F.J., SKOOG, D.A. & CROUCH, S.R. 2007. *Principles of instrumental analysis*. 6th ed. United States of America : Thomson Brooks. 1038 p.

ICH – *refer to* International Conference on Harmonization.

INTERNATIONAL CONFERENCE ON HARMONISATION. 1999. Specifications: test procedures and acceptance criteria for new drug substances and new drug products: chemical substances Q6A. <http://www.ich.org> Date of access: 12 Jun. 2012.

INTERNATIONAL CONFERENCE ON HARMONIZATION. 2005. Validation of Analytical procedures: Text and Methodology Q2(R1). <http://www.ich.org> Date of access: 12 Jun. 2012.

INTERNATIONAL PHARMACOPOEIA. 2011. 4thed. Including First and Second Supplements. <http://apps.who.int/phint/en/p/docf/> Date of access: 2011 - 2013.

KAUFMAN, T. S. & RÚVEDA, E.A. 2005. The quest for Quinine: Those who won the battles and those who won the war. *Angewandte Chemie International Edition*, 44:854-885.

KAR, A. 2005. Pharmaceutical drug analysis. 2nd ed. India : New age international publishers. 533 p.

KOTZ, J.C., TREICHEL, P.M. & HARMAN, P.A. 2003. Chemistry and Chemical Reactivity. 5th ed. South Melbourne : Thomson Learning Incorporated. 997 p.

LEE, D.C. & WEBB, M.L. 2003. Pharmaceutical Analysis. United States of America : Blackwell Publishing. 634 p.

LINDENBERG, M., KOPP, J. & DRESSMAN, J.B. 2004. Classification of orally administered drugs on the World Health Organization Model list of Essential Medicines according to the Biopharmaceutics Classification System. *European Journal of Pharmaceutics and Biopharmaceutic*, 58:265-278, April.

LOBRUTTO, R. & PATEL, T. 2007. Method validation. (*In Kazakevich, Y. & LoBrutto, R., eds. HPLC for pharmaceutical scientists. Hoboken, N.J. : Wiley Interscience. p. 455-502*).

MCMURRY, J. 2003. Fundamentals of Organic Chemistry. 5th ed. United States of America : Thomson Learning. 565 p.

MCC – refer to South African Medicines Control Council.

MOFFAT, A.C., OSSELTON, M.D., WIDDOP, B. & WATTS, J., eds. 2011. Clarke's analysis of drugs and poisons: monographs. London : Pharmaceutical Press.
<http://www.medicinescomplete.com.nwulib.nwu.ac.za/mc/clarke/current/d1e579310.htm> Date of access: 6 Nov. 2013.

OBI-EYISI, O. & WERTHEIMER, A.I. 2012. The Background and History of Counterfeit Medicines. (*In* Wertheimer, A.I. & Wang, P.G., eds. Counterfeit Medicines: Policy, Economics and Counter measures. United Kingdom : International Labmate Publications. p. 1-17).

PABLO, D., AKHLAGHI, F. & ZIA, H. 2009. A comparative pH-dissolution profile study of selected commercial levothyroxine products using indicatively coupled plasma mass spectrometry. *European Journal of Pharmaceutics and Biopharmaceutics*, 72:105 - 110.

PALESHNUIK, L. 2009. Dissolution. Training workshop on regulatory requirements for registration of Artemisinin based combined medicines and assessment of data submitted to regulatory authorities.
http://apps.who.int/prequal/trainingresources/pq_pres/workshop_Uganda_February2009/presentations/3-1_Dissolution.ppt Date of access: 05 Feb. 2013 [PowerPoint presentation].

Ph.Int. – refer to International Pharmacopoeia.

RANG, H.P. DALE, M.M., RITTER, J.M. & MOORE, P.K. 2003. Pharmacology. 5th ed. Edinburg : Churchill Livingstone. 797 p.

RELIABLE CANADIAN PHARMACY.COM. 2013. Quinine sulfate 300mg Tablets. [Web] [<http://www.reliablecanadianpharmacy.com/product-details/quinine-sulfate-300mg-tablets-generic-equivalent/157.html>] [Date of access; 31 May 2013].

REYNOLDS, E.F. 1993. Martindale: The extra pharmacopoeia. 30th ed. London : The Pharmaceutical Press. 2363 p.

RICHARDSON, C.F. 2001. Compendial testing. (*In* Ahuja, S. and Scypinski, S., eds. Handbook of Modern Pharmaceutical Analysis. San Diego : Academic press. p. 325 - 344).

ROSENTHAL, P.J. AND GOLDSMITH, R.S. 2001. Antiprotozoal drugs. (*In* Katzung, B.G., ed. Basic and Clinical Pharmacology. New York : McGraw-Hill p. 882-902).

RXRESOURCE.ORG. 2013. <http://www.rxresource.org/prescription-information/Quinine-Sulfate-Teva-Pharmaceuticals-USA-Inc.html> Date of access: 31 May. 2013.

SARAH. 2010. <http://cornellbiochem.wikispaces.com/Quinine> Date of access: 31 Apr. 2013.

SHARGEL, L., WU-PONG, S. & YU, A.B.C. 2005. Applied Biopharmaceutics and Pharmacokinetics. 5th ed. New York : McGraw-Hill. 892 p.

SKOOG, D.A., WEST, D.M. & HOLLER, F.J. 1997. Fundamentals of Analytical Chemistry. 7th ed. Fort Worth : Harcourt Publishers. 870 p.

SOLOMON, E.P., BERG, L.R. & MARTIN, D.W. 2002. Biology. 6th ed. Australia : Thomson Learning. 1254 p.

SOUTH AFRICA MEDICINES CONTROL COUNCIL. 2011. Registration of medicines: dissolution. <http://www.mccza.com/> Date of access: 25 Oct. 2011.

STEENEKAMP, JH. 2012. Dispensing and compounding of medicines. Potchefstroom: NWU, Potchefstroom Campus. (Study guide FMSG 211 PEC).

STRAUCH, S., DRESSMAN, J.B., SHAH, V.P., KOPP, S., POLLI, J.E. & BARENDS, D.M. 2012. Biowaiver Monographs for Immediate-Release Solid Oral Dosage Forms: Quinine Sulfate. *Journal of Pharmaceutical Sciences*, 101(2):499-508, Febr.

SULLIVAN, D.J. 2012. Cinchona Alkaloids: Quinine and Quinidine. (*In* Staines, H.M. and Krishna, S., eds. Milestones in drug therapy. Treatment and prevention of malaria: Anti-malarial drug chemistry, action and use. United Kingdom : Springer. p.45-68).

UNITED STATES PHARMACOPOEIA. 2013. USP 32 - NF. <http://www.uspnf.com/uspnf/pub/index?usp=35&nf=30&s=2&officialOn=December 1, 2012> Date of access: 2011–2013.

UNITED STATES PHARMACOPOEIA DRUG QUALITY AND INFORMATION PROGRAM AND COLLABORATORS. 2007. Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide. Rockville, Md : United States Pharmacopoeial Convention.

http://www.usp.org/sites/default/files/usp_pdf/EN/dqi/ensuringQualityOperationalGuide.pdf Date of access: 29 Jan. 2012.

US FOOD AND DRUG ADMINISTRATION. 1997. Guidance for Industry. Dissolution testing of immediate release solid oral dosage forms.

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070237.pdf> Date of access: 29 Jan. 2012.

US FOOD AND DRUG ADMINISTRATION. 2007. Office of new drug quality and assessment: Acceptability of Standards from Alternative Compendia (BP/EP/JP).

http://google2.fda.gov/search?q=Acceptability+of+standards+for+alternative+compendia&spell=1&client=FDAGov&site=FDAGov&lr=&proxystylesheet=FDAGov&output=xml_no_dtd&ie=UTF-8&access=p Date of access: 17 Aug. 2012.

US FOOD AND DRUG ADMINISTRATION. 2013.

<http://www.fda.gov/ScienceResearch/FieldScience/ucm171877.htm> Date of access: 26 Jun. 2013.

USP – refer to United States Pharmacopoeia.

VAGHELA, B., KAYASTHA, R., BHATT, N., PATHAK, N. & RATHOD, D. 2011. Development and Validation of dissolution procedures. *Journal of Applied Pharmaceutical Science*, 01(03):50-56, May.

VESTERGAARD, L.S. & RINGWALD, P. 2007. Responding to the Challenge of Antimalarial Drug Resistance by Routine Monitoring to Update National Malaria Treatment Policies. *The American Society of Tropical Medicine and Hygiene*, 77(6): 153-159, Jan.

VINETZ, J.M., CLAIN, J., BOUNKEUA, V., EASTMAN, R.T. & FIDOCK, D. 2011. Goodman & Gilman's the pharmacological basis of therapeutics. 12th ed.

<http://www.accessmedicine.com.nwulib.nwu.ac.za/search/searchAMResult.aspx?searchStr=quinine&rootTerm=quinine&searchtype=1&rootID=32918&gobacklink=1&drug=1> Date of access: 16 Oct. 2013.

WALKER, N.F., NADJM, B. & WHITTY, C.J.M. 2009. Malaria. *Medicine*, 38(1):41-46.

WATSON, D.G. 2005. Pharmaceutical Analysis: A textbook for Pharmacy Students and Pharmaceutical Chemists. 2nd ed. Edinburgh : Churchill Livingstone. 382 p.

WHO – refer to World Health Organisation.

WILLARD, H., MERRIT, L., DEAN, J.A. & SETTLE, F.A. 1981. Instrumental Methods of Analysis. 6thed. New York : D. Van Nostrand Company. 1030 p.

WORLD HEALTH ORGANIZATION. 2003. The International Pharmacopoeia: revised concepts and future perspectives. Annex 2. *WHO technical support series 908, 2003*. http://www.who.int/medicines/areas/quality_safety/quality_assurance/PhIntRevisedConceptsFuturePerspectivesTRS908Annex2.pdf Date of access: 08 Febr. 2011.

WORLD HEALTH ORGANIZATION. 2003. Substandard and Counterfeit Medicines. <http://www.who.int/mediacentre/factsheets/2003/fs275/en/> Date of access: 08 Febr. 2011.

WORLD HEALTH ORGANIZATION. 2010. WHO expert committee on specifications for pharmaceutical preparations. *WHO technical report series 957, 2010*. http://www.who.int/medicines/publications/TRS957_2010.pdf Date of access: 08 Febr. 2011.

WORLD HEALTH ORGANISATION. 2010. WHO guiding principles in transfer of technology. http://www.who.int/medicines/services/expertcommittees/pharmprep/TOT_QAS08259Rev2_27072010.pdf Date of access: 19 Aug. 2012.

WORLD HEALTH ORGANISATION. 2011. Global Malaria Program: World Malaria Report 2011. http://www.who.int/malaria/world_malaria_report_2011/en/ Date of access: 10 Jan. 2012.

WORLD HEALTH ORGANISATION. Medicines. 2012. http://www.who.int/medicines/areas/quality_safety/quality_assurance/production/en/index.html# Date of access: 29 Jan. 2012.

WORLD HEALTH ORGANISATION. 2013. Assessing national medicines regulatory systems http://www.who.int/medicines/areas/quality_safety/regulation_legislation/assessment/en/index.html Date of access: 26 May. 2013.

WU HAN GRAND PHARMACEUTICAL GROUP CO. LTD. 2013. Quinine dihydrochloride injection. <http://www.ecvv.com/product/2967510.html> Date of access: 31 May. 2013.

YORK, N. 2007. Design of dosage forms. (*In* Aulton, M.E., ed. *Aulton's Pharmaceutics: The Design and Manufacture of Medicines*. Edinburgh : Churchill Livingstone. p. 4-14).

©2010 PARTICLE SCIENCES, INC. 2010. In vitro dissolution testing for solid oral dosage forms. (Technical Brief 2010, volume 5)
http://www.particulatesciences.com/docs/technical_briefs/TB_2010_5.pdf Date of access: 31 May. 2013.