WHO List of Prequalified Quality Control Laboratories

Date: 22 December 2016

- This list contains **forty-one (41)** quality control laboratories, which expressed their interest to participate in the World Health Organization (WHO) prequalification procedure, have been assessed as part of the WHO Prequalification Programme and found to comply with standards recommended by WHO. Only laboratories meeting these standards are included in the list.
- WHO ensures compliance with Good Practices for National Pharmaceutical Control Laboratories (GPCL) and relevant parts of WHO Good Manufacturing Practices (GMP) at the quality control laboratories prior to listing them as being prequalified.
- WHO inspections are done by a team of inspectors including:
 - 1. An inspector/expert from one of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) countries
 - 2. A WHO representative (inspector / expert)
 - 3. An inspector (or inspectors) as an observer from the National Drug Regulatory Authority of the country, in which the laboratory is located, subject to their availability at the time and as relevant.
- Observations listed in the inspection reports should be addressed to a satisfactory level of compliance by the laboratories prior to listing in the list of prequalified laboratories. The corrective actions taken by the laboratories are assessed through documentation review and follow-up inspections when these are required.
- WHO Public Inspection Reports (WHOPIRs) are published on this web page for laboratories found to be meeting WHO norms and standards. A WHOPIR provides a summary of the initial inspection report.

This list is the **42nd Edition**. Laboratories are listed according to WHO regions and within the region in the alphabetical order. Kindly ensure that the most current list is used. For changes to the list, see Version history (below the list).

The Quality Control Laboratory and contact details	Date of last inspection ¹		Date of pre- qualification	The area	a of expertise inspected and cons	sidered prequalified
	Inspection	outcome	quanneation			
WHO African Region				Truch a formation		
	40.00.40044		45 4 0000	Type of analysis	Finished products	Active pharmaceutical ingredients
Adcock Ingram Limited - Research and Development 1 Sabax Road, Aeroton Johannesburg, 2013	18-20.4.2011	Compliant with WHO recommended standards	15.1.2008	Physical/Chemical analysis	friability, disintegration time, tablet hardness, dissolution, AA, viscosity, density, dimensions	
South-Africa Postal address:				Identification	spectrophotometry and basic	IR, TLC, HPLC, spectrophotometry and basic tests
Private Bag X69 Bryanston, 2021 South-Africa				related substances	spectrophotometry and volumetric titrations	and volumetric titrations
Tel: + 27 11 494 8135 e-mail: Palka.Parbhoo@adcock.com					substances and impurities by comparison with a reference standard	Determination of related substances and impurities by comparison with a reference standard
				Stability studies	ICH conditions	
	I	1	I	Type of analysis	Finished products	Active pharmaceutical ingredients
Laboratoire National de Contrôle des Produits Pharmaceutiques, LNCPP (Algérie) lot Geraud, petit Staoueli, Dely Ibrahim	23-24.4.2014	Compliant with WHO recommended standards	27.10.2005	Physical/Chemical analysis	pH, water content, friability, disintegration time of tablets and suppositories, tablet hardness, dissolution, AA	
(Site du Nouvel Institut Pasteur) Algiers				Identification	TLC, HPLC and spectrophotometry	
Algérie Tel: +213 21 371576; +213 21 372668 Fax: +213 21 37 32 42; +213 21 37 52 53 e-mail: Incpp@sante.dz; Incpp@hotmail.com				related substances	HPLC (UV- DAD, RI detection), GC, spectrophotometry and volumetric titrations Determination of related substances and impurities by comparison with a reference standard	
		-		Type of analysis	Finished products	Active pharmaceutical ingredients
Laboratory of the Mission for Essential Drugs and Supplies - (MEDS)	22-23.6.2015	Compliant with WHO recommended	23.3.2009	Physical/Chemical analysis	pH, loss on drying, water content, conductivity, refractometry, friability, disintegration,	pH, loss on drying, water content, conductivity, refractometry, density

¹ Date of last inspection performed by WHO unless otherwise indicated.

PO Box 78040, Viwandani Nairobi, 00507 Kenya Tel. +254 20 3920202, +254 20 3920000 e-mail: lab@meds.or.ke		standards		Identification Assay, impurities and related substances	UV-VIS spectrophotometry, TLC, chemical reaction HPLC (UV-VIS detection), GC, UV-VIS spectrophotometry, volumetric titrations, polarimetry Determination of related	HPLC (UV-VIS detection), GC, UV-VIS spectrophotometry, TLC, chemical reaction HPLC (UV-VIS detection), GC, UV-VIS spectrophotometry, volumetric titrations, polarimetry Determination of related substances/impurities and degradation products
	1			Type of analysis	Finished products	Active pharmaceutical ingredients
Medicines Control Authority of Zimbabwe (MCAZ) Quality Control Laboratory 106 Baines Avenue	20-21.1.2014	Compliant with WHO recommended standards	19.9.2014	Physical/Chemical analysis	pH, loss on drying, water content, limit tests, dissolution, uniformity of dosage units (mass, content)	pH, loss on drying, water content, limit tests
PO Box 10559 Harare Zimbabwe				Identification	VIS spectrophotometry, basic tests	HPLC (UV-VIS detection), UV- VIS spectrophotometry, basic tests
Tel. +263 4 736981-5 /708255 /792165 Cell: +263 772145191/3 e-mail: mcaz@mcaz.co.zw; gnmahlangu@mcaz.co.zw				Assay, impurities and related substances	HPLC (UV-VIS detection), UV- VIS spectrophotometry, volumetric titrations	HPLC (UV-VIS detection), UV- VIS spectrophotometry, volumetric titrations
				Type of analysis	Finished products	Active pharmaceutical ingredients
National Drug Authority – National Drug Quality Control Laboratory (NDA-NDQCL) – Uganda Mulago Hill	4-5.9.2014	Compliant with WHO recommended standards	16.1.2015	Physical/Chemical analysis	density, friability, dissolution, uniformity of dosage units (mass, content)	pH, loss on drying, water content, density, melting point
P.O. Box 23096 Kampala Uganda				Identification		UV-VIS spectrophotometry
Tel.: +256 414 540067 e-mail: <u>laboratory@nda.or.ug</u>				related substances	VIS spectrophotometry, volumetric titrations, polarimetry Determination of related substances/impurities and degradation products	HPLC (UV-VIS detection), UV- VIS spectrophotometry, volumetric titrations, polarimetry Determination of related substances/impurities and degradation products
	1		1	Type of analysis	Finished products	Active pharmaceutical ingredients
National Quality Control laboratory (NQCL) Hospital Road - KNH Complex	24-25.6.2015	Compliant with WHO recommended	17.7.2008	Physical/Chemical analysis		pH, loss on drying, water content, density, melting point

00202 -KNH, Nairobi		standards				
Kenya		3101100103		Identification	FTIR, HPLC (UV-VIS detection),	FTIR, HPLC (UV-VIS detection),
Kenya				Identification		
Destal address:					AAS, UV-VIS spectrophotometry	AAS, UV-VIS spectrophotometry
Postal address:						
P.O. Box 29726					HPLC (UV-VIS detection), UV-	HPLC (UV-VIS detection), UV-
00202 -KNH, Nairobi				related substances	VIS spectrophotometry, AAS,	VIS spectrophotometry, AAS,
Kenya					volumetric titrations, polarimetry	volumetric titrations, polarimetry
					Determination of related	Determination of related
Tel. +254 20 3544525/30					substances/impurities and	substances/impurities and
Fax: +254 20 2718073					degradation products	degradation products
e-mail: hchepkwony@nqcl.go.ke					degradation products	degradation products
e mail: nonopriverty enquigelike						
				Microbiological tests	Sterility test, microbial purity,	Microbial purity, microbial assay
					bacterial endotoxins test (LAL),	
					microbial assay	
				Type of analysis	Finished products	Active pharmaceutical ingredients
Research Institute for Industrial	1-2.9.2014	Compliant with	CENQAM:	Physical/Chemical	pH, water content (Karl Fischer),	pH, water content (Karl Fischer),
Pharmacy (RIIP) incorporating		WHO	22.6.2005	analysis	loss on drying, friability,	loss on drying,
CENQAM		recommended			disintegration, tablet hardness,	X-ray diffractometry, thermal
North-West University		standards	5.7.2005			analysis (DSC, TGA)
Potchefstroom Campus		otaridardo	0.1.2000		content), tablet dimensions,	
Hoffman Street					dissolution, AA, viscosity,	
			40 5 0000			
Potchefstroom 2531			16.5.2008 -		density/specific gravity,	
South Africa			Change		redispersibility/ reconstitution	
			reflecting the		time, resuspendability and	
Postal address:			merger of RIIP		sedimentation rate	
P/Bag X6001			and CENQAM			
Potchefstroom 2520			into one	Identification	IR, TLC, HPLC,	IR, TLC, HPLC,
South Africa			organization		spectrophotometry and basic	spectrophotometry and basic
			with a single		tests	tests
Tel: + 27 18 299 2268			quality system		10010	10010
Fax: + 27 18 299 2291			quality system			
					HPLC (fluorescence, UV, UV-Vis,	
e-mail: Erna.Swanepoel@nwu.ac.za				related substances	DAD, RI detection), GC,	DAD, RI detection), GC,
						spectrophotometry and volumetric
					titrations	titrations
					Determination of related	Determination of related
					substances/impurities and	substances/impurities,
					degradation products	degradation products and residual
						solvents
				Stability studies	WHO conditions	WHO conditions
				Stability studies		
				Type of analysis	Finished products	Active pharmaceutical ingredients
Tanzania Food and Drugs Authority	23-24.1.2014	Compliant with	17.1.2011	Physical/Chemical		pH, melting point, optical rotation,
(TFDA) Quality Control Laboratory		WHO		analysis	conductivity, friability, tablet	conductivity
Mandela Road, Mabibo, External		recommended			hardness, disintegration,	
	•	•	•			

P.O. Box 77150		standards			dissolution, uniformity of dosage	
Dar es Salaam					units	
Tanzania				Identification		HPLC (UV-VIS, PDA detection), TLC, AAS, UV-VIS
Tel: +255 22 2450512 / 2450751					spectrophotometry	spectrophotometry
Fax: +255 22 2450793				Assay, impurities and	HPLC (UV-VIS, PDA detection),	HPLC (UV-VIS, PDA detection),
e-mail: dls@tfda.or.tz				related substances	TLC, AAS, UV-VIS	TLC, AAS, UV-VIS
info@tfda.or.tz					spectrophotometry, polarimetry, volumetric titrations	spectrophotometry, polarimetry, volumetric titrations
WHO Region of the Ame	ricas					
				Type of analysis	Finished products	Active pharmaceutical ingredients
Comisión de Control Analítico y Ampliación de Cobertura (CCAYAC) Calzada de Tlalpan No. 4492 Colonia Toriello Guerra		Compliant with WHO recommended standards	13.11.2013	analysis	pH, water content (Karl Fischer), loss on drying, dissolution, uniformity of dosage units (mass, content)	pH, water content, loss on drying
Delegación Tlalpan C.P.14050 México, D. F. Mexico		otandarao			fluorescence detection), TLC, UV- VIS spectrophotometry, FTIR	UV-VIS spectrophotometry, FTIR
Tel: +5255 5080 5200, ext 2000 e-mail: faarguelles@cofepris.gob.mx				related substances	AAS/AES, volumetric titrations	spectrophotometry, volumetric titrations
						Sterility test, microbial limit tests, bacterial endotoxins test (LAL), microbial assay of antibiotics
				Type of analysis	Finished products	Active pharmaceutical ingredients
Comisión para el Control de Calidad de Medicamentos (CCCM) Br. Artigas 3223 Montevideo 11800	19-21.8.2013	Compliant with WHO recommended standards	16.9.2010	Physical/Chemical analysis	pH, water content, loss on drying, density, neutralizing capacity, dimensions, disintegration, dissolution, uniformity of dosage units (mass, content)	pH, water content, loss on drying, melting point, density, neutralizing capacity
Tel: +598 2209 4014 Fax: +598 2208 5673 e-mail: bluna@msp.gub.uy						HPLC (UV-VIS, DAD, fluorescence, RI detection), TLC, spectroscopy (UV-VIS, FTIR, AA/EA), basic tests
mhirschhorn@msp.gub.uy cccm@msp.gub.uy					fluorescence, RI detection), TLC, UV-VIS spectrophotometry, FTIR, AAS/AES, volumetric titrations, potentiometry, polarimetry Determination of related substances/ impurities, degradations products	HPLC (UV-VIS, DAD, fluorescence, RI detection), TLC, UV-VIS spectrophotometry, FTIR, AAS/AES, volumetric titrations, potentiometry, polarimetry Determination of related substances/ impurities, degradations products
						Sterility test, microbial limit tests, bacterial endotoxins test (LAL),

]			microbial assay of antibiotics	microbial assay of antibiotics
				Type of analysis	Finished products	Active pharmaceutical ingredients
Ezequiel Dias Foundation (FUNED) Institute Octavio Magalhães Medicines Service of Public Health Central Laboratory	23-25.3.2011	Compliant with WHO recommended standards	20.10.2011	Physical/Chemical analysis	pH, water content, loss on drying, density, disintegration, dissolution, friability, uniformity of dosage units (mass, content)	pH, water content, loss on drying, density
Conde Pereira Carneiro street 80 Gameleira neighbourhood Belo Horizonte Minas Gerais				Identification	HPLC (UV-VIS, DAD, fluorescence detection), TLC, UV- VIS spectrophotometry, FTIR, basic tests	TLC, UV-VIS spectrophotometry, FTIR, basic tests
30510-010 Brazil Fax: +55 31 3314-4653 e-mail: dpgq@funed.mg.gov.br medicamentos@funed.mg.gov.br					fluorescence detection), TLC, UV- VIS spectrophotometry, FTIR, volumetric titrations, potentiometry; Determination of related substances/ impurities, degradations products	HPLC (UV-VIS, DAD, fluorescence detection), TLC, UV- VIS spectrophotometry, FTIR, volumetric titrations, potentiometry, Determination of related substances/ impurities, degradations products
				, , , , , , , , , , , , , , , , , , ,	bacterial endotoxins test (LAL)	Sterility test, microbial limit tests, bacterial endotoxins test (LAL)
		-		Type of analysis	Finished products	Active pharmaceutical ingredients
Instituto Nacional de Controle de Qualidade em Saúde (INCQS) Av. Brasil no 4362 Manguinhos, CEP 21040-900	9-11.4.2013	Compliant with WHO recommended standards	11.3.2014	Physical/Chemical analysis	pH, density, optical rotation, disintegration, dissolution, uniformity of dosage units (mass, content)	
Rio de Janeiro Brazil				Identification	HPLC (UV-Vis, PDA detection), TLC, UV-VIS spectrophotometry, IR, basic tests	
Tel.: +55 21 3865 5151; +55 21 3865 5104				Assay, impurities and related substances	HPLC (UV-Vis, PDA detection)	
Fax: +55 21 2290 0915 e-mail: incqs@incqs.fiocruz.br; vdquali@incqs.fiocruz.br vera.machado@incqs.fiocruz.br				Microbiological tests	Sterility test, microbial limit tests, bacterial endotoxins test (LAL), microbial assay of antibiotics	
				Type of analysis	Finished products	Active pharmaceutical ingredients
K.A.B.S. Laboratories Inc.² 4500 De Tonnancour St-Hubert, Quebec J3Y 9G2, Canada	9-11.12.2013 US FDA inspection	Compliant with WHO recommended standards	10.2.2010	Physical/Chemical analysis	pH, density, refractometry, viscosity, loss on drying, water content, disintegration, dissolution, uniformity of dosage units (mass, content), friability, tablet hardness, particulate matter	pH, density, refractometry, specific optical rotation, viscosity, osmolarity, loss on drying, melting point, water content, heavy metals, acid value, iodine value, limit tests
Tel.: +1 450 656 4404 Fax:: +1 450 656 4402				Identification	test	HPLC (UV-Vis, RI, conductivity

² The laboratory has been included on the list based on the WHO assessment, which utilized the results of inspections performed by the US Food and Drug Administration and Department of Health, Canada. Therefore no WHO Public Inspection Report is published in this case.

e-mail: kabsafric@kabs.com	1				detection), LC/MS, GC (FID,	detection), LC/MS, GC (FID,
r-mail. Kausamu w Kaus.cum					TCD), TLC, capillary electrophoresis, UV-Vis spectrophotometry, FTIR, AAS	TCD), TLC, capillary electrophoresis, UV-VIS spectrophotometry, FTIR, AAS, chemical reaction
				related substances	detection), LC/MS, GC (FID, TCD), TLC, UV-Vis spectrophotometry, AAS, fluorimetry, volumetric titrations, potentiometry, coulometry	HPLC (UV-Vis, RI, conductivity detection), LC/MS, GC (FID, TCD), TLC, UV-Vis spectrophotometry, AAS, fluorimetry, volumetric titrations, potentiometry, coulometry
				Stability studies	ICH conditions	ICH conditions
			-	Type of analysis	Finished products	
Laboratorio de Control de Calidad de Medicamentos y Toxicologia (CONCAMYT) Calle Rafael Zubieta No. 1889 Zona de Miraflores La Paz		Compliant with WHO recommended standards	16.9.2010	Physical/Chemical analysis	pH, water content, loss on drying, density, conductivity, refractometry, dimensions, disintegration, dissolution, uniformity of dosage units (mass, content)	
Bolivia Tel: +591 2 2226670 e-mail: garnicalopez@yahoo.es					HPLC (UV-VIS, PDA, fluorescence detection), TLC, UV- VIS spectrophotometry, IR, basic tests	
				Assay, impurities and related substances	fluorescence detection), UV-VIS spectrophotometry, IR, volumetric titrations, polarimetry	
				Microbiological tests	Sterility test, microbial limit tests, microbial assay of antibiotics	
WHO South-East Asia R	egion					L
			1	Type of analysis	Finished products	Active pharmaceutical ingredients
Bureau of Drug and Narcotic (BDN) Department of Medical Sciences Ministry of Public Health 88/7 Tiwanond Road Muang Nonthaburi 11000		Compliant with WHO recommended standards	02.11.2012		particle size, water content, disintegration, dissolution, uniformity of dosage units (mass, content)	pH, refractive index, optical rotation, viscosity, melting point, loss on drying, sulphated ash, acid insoluble ash, water content, differential scanning calorimetry
Thailand Tel: + 66 2580 4074 or +66 2951 0000 ext. 99122 or 99179				Identification	GC (FID), TLC, UV-Vis spectrophotometry, FTIR, basic tests	HPLC (UV-Vis detection), LC/MS, GC (FID), TLC, UV-Vis spectrophotometry, FTIR, basic tests
Fax: +66 2580 5733 e-mail: suratchanee.s@dmsc.mail.go.th boontarika.b@dmsc.mail.go.th				related substances	UV-Vis spectrophotometry, AAS,	HPLC (UV-Vis), GC (FID), TLC, UV-Vis spectrophotometry, AAS, fluorimetry, polarimetry, potentiometry
				Type of analysis	Finished products	Active pharmaceutical ingredients

SGS India Pvt. Ltd. (Life Science Services) 2nd Floor, TICEL Bio Park Ltd. Tharamani Road, Tharamani Chennai - 600113 Tamil Nadu India	26-28.8.2013	Compliant with WHO recommended standards	17.1.2011	Physical/Chemical analysis	rotation, viscosity, water content, conductivity, density, residual solvents, limit tests, tablet hardness, friability, disintegration,	pH, refractive index, optical rotation, viscosity, melting point, loss on drying, heavy metals, sulphated ash, water content, conductivity, residual solvents, limit tests
Tel. +91 44 2254 2601/2602 Fax: +91 44 2254 2600 e-mail: in.lifeqc@sgs.com				Identification	fluorescence detection), GC (FID), TLC, UV-Vis spectrophotometry, FTIR, basic tests	HPLC (UV-Vis, PDA, RI, fluorescence detection), GC (FID), TLC, UV-Vis spectrophotometry, FTIR, basic tests
				related substances	fluorescence detection), GC (FID), UV-Vis spectrophotometry, AAS, FTIR, ICP-MS, flame photometry, polarimetry, potentiometry, volumetric titrations	HPLC (UV-Vis, PDA, RI, fluorescence detection), GC (FID), UV-Vis spectrophotometry, AAS, FTIR, ICP-MS, flame photometry, polarimetry, potentiometry, volumetric titrations
					bacterial endotoxins test (LAL), preservative efficacy test, microbial assay of antibiotics	Sterility test, microbial limit tests, bacterial endotoxins test (LAL), preservative efficacy test, microbial assay of antibiotics
				Stability studies		ICH conditions
				Type of analysis	Finished products	Active pharmaceutical ingredients
Stabicon Life Sciences Pvt Ltd Plot No. 28, Bommasandra Industrial Area (Sub-layout), 4th Phase Jigani Hobli, Anekal Taluk Bangalore 560 100, India	10-12.9.2013	Compliant with WHO recommended standards	9.12.2013	Physical/Chemical analysis	(Karl Fischer), friability,	pH, loss on drying, water content (Karl Fischer), heavy metals, limit tests
Tel. +9180 27839259/60 e-mail: vijay.ranka@stabicon.com				Identification	spectrophotometry, basic tests	TLC, HPLC (UV-VIS, DAD, RI), GC (FID), UV-VIS spectrophotometry, basic tests
				related substances	detection), GC (FID), TLC, UV- VIS spectrophotometry, volumetric titrations Determination of related substances/impurities, degradation products and residual solvents	
				Microbiological tests	efficacy test, microbial assay of	Microbial limit tests, preservative efficacy test, microbial assay of antibiotics

				Stability studies	ICH conditions	ICH conditions
				Type of analysis	Finished products	Active pharmaceutical ingredients
Vimta Labs Limited Life Sciences Facility Plot No.5, S.P.Biotech Park Genome Valley Hyderabad 500078, India	WH	Compliant with WHO recommended standards		Physical/Chemical analysis	friability, disintegration, dissolution, density, tablet hardness, viscosity, dimensions, uniformity of dosage units (mass, content), limit tests	pH, loss on drying, water content, density, melting point, distilling range, refractometry, acid insoluble ash, acid value, iodine value, nitrogen, limit tests, neutralizing capacity
Tel. +91 40 3984 84 84 (Extn: 2101) Fax: +91 40 3984 77 76 e-mail: quality@vimta.com				Identification	FTIR, TLC, HPLC (UV-VIS, PDA, RI, fluorescence detection), UV- VIS spectrophotometry, basic tests	FTIR, TLC, HPLC (UV-VIS, PDA, RI, fluorescence detection), UV- VIS spectrophotometry, basic tests
				Assay, impurities and related substances	HPLC (UV-VIS, PDA, RI, fluorescence detection), GC (HRGC-MS, GC-MS), UV-VIS spectrophotometry, FTIR, polarimetry, AAS, ICP-MS, flame photometry, volumetric titrations	HPLC (UV-VIS, DAD, RI, fluorescence detection), GC (HRGC-MS, GC-MS), UV-VIS spectrophotometry, FTIR, polarimetry, AAS, ICP-MS, flame photometry, volumetric titrations
				Microbiological tests	Sterility test, microbial purity, bacterial endotoxins test (LAL), antimicrobial effectiveness	Sterility test, microbial purity, bacterial endotoxins test (LAL), antimicrobial effectiveness
				Stability studies	WHO conditions	WHO conditions
				Type of analysis	Finished products	Active pharmaceutical ingredients
Indian Pharmacopoiea Commission - Indian Pharmacopoeial Laboratory, Ministry of Health & Family Welfare, Sector 23,	9-11.10.2014	Compliant with WHO recommended standards		Physical/Chemical analysis	content)	pH, loss on drying, water content, density, melting point, thermal analysis (DSC) and optical rotation
Raj Nagar, Ghaziabad, Uttar Pradesh, 201002,				Identification	VIS spectrophotometry, LC-MS, NMR, AAS, CHNSO analysis	FTIR, HPLC (UV-VIS detection), UV-VIS spectrophotometry, NMR, AAS, CHNSO analysis
India Tel.: +91 120 2783392 e-mail: ipclab@vsnl.net					HPLC (UV-VIS detection), GC, GC-MS, AA, UV-VIS spectrophotometry, volumetric titrations, polarimetry Determination of related substances/impurities and degradation products	HPLC (UV-VIS detection), GC. GC-MS, AA, UV-VIS spectrophotometry, volumetric titrations, polarimetry Determination of related substances/impurities and degradation products
				Microbiological tests	Sterility test, microbial limit tests, bacterial endotoxins test (LAL), preservative efficacy test, microbial assay of antibiotics	Sterility test, microbial limit tests, bacterial endotoxins test (LAL), preservative efficacy test, microbial assay of antibiotics
				Type of analysis	Finished products	Active pharmaceutical ingredients
Health Concepts International Ltd	7-8.3.2016	Compliant with	14.7.2016	Physical/Chemical	pH, dissolution, uniformity of	рН

113 Thailand Science Park, Paholyothin		who		analysis	dosage units.	
Rd., Klong 1,		recommended		Identification	HPLC, UV-VIS	HPLC, UV-VIS
Klong Luang,		standards			Spectrophotometer.	Spectrophotometer.
Pathumthani Thailand 12120				Assay, impurities and related substances	HPLC (UV-VIS, DAD detection), UV-VIS spectrophotometer, determination of related	HPLC (UV-VIS, DAD detection), UV-VIS Spectrophotometer, Determination of related
Email: navaporn@hc-intl.com					substances and impurities by comparison with reference standards.	substances and impurities by comparison with reference standards.
Tel.: +66 2564 8009/11 Fax: +66 2564 8012					Standards.	Standards.
WHO European Region					I	I
				Type of analysis	Finished products	Active pharmaceutical ingredients
Agency for Medicinal Products and Medical Devices (HALMED), Official Medicines Control Laboratory (OMCL), Ksaverska cesta 4, 10000 Zagreb, Croatia Email: rajka.truban@halmed.hr Tel.: +3851 4884 202	20-22 July 2015	Compliant with WHO recommended standards	16.06.2016	Physical/Chemical analysis	coloration of liquids, test for extractable volume of parenteral solution, potentiometric determination of pH, conductivity, refractive index, relative density, loss on drying, loss on drying (vacuum), determination of nitrogen by sulphuric acid, optical rotation, viscosity, water content: semi-micro determination, water content: micro determination, particulate contamination: visible particles, optical rotation, osmolality, Disintegration (tablets, capsules, suppositories, pessaries), Dissolution, Hardness (resistance to crushing), Uniformity of Dosage Units.	opalescence of liquids, degree o coloration of liquids, test fo extractable volume of parentera solution, potentiometric determination of pH, conductivity refractive index, relative density loss on drying, loss on drying (vacuum), determination o nitrogen by sulphuric acid, optica rotation, viscosity, water conten (semi-micro determination), wate content (micro determination) particulate contamination (visible particles), optical rotation osmolality.
					TLC, GC, UV-Vis, FTIR, NIR HPLC, TLC (semiquantitative),	TLC, GC, UV-Vis, FTIR, NIR HPLC, TLC (semiquantitative),
				related substances	GC, UV-Vis, Optical rotation.	GC, UV-Vis, Optical rotation.
				Microbiological tests	Sterility, microbial purity, bacterial endotoxins test (LAL), pyrogens.	Sterility, microbial purity, bacteria endotoxins test (LAL), pyrogens.
			_1	Type of analysis	Finished products	Active pharmaceutical ingredients
Central Laboratory for Quality Control of Medicines and Medical	10- 11.5.2016	Compliant with WHO	16.4.2010		pH, density, refractometry, viscosity, water content, limit	pH, refractometry, viscosity, loss on drying, water content, heavy

Products, SE	1	recommended			tests, disintegration, dissolution,	metals, acid value, iodine value,
State Drug Administration of Ukraine		recommended				
State Drug Administration of Okraine		standards				limit tests, acid neutralizing
					content), friability, dimensions	capacity, distilling range, nitrogen
10G Kudryavskaya street						determination
Kiev					HPLC (UV-Vis, RI detection), GC	
04053 Ukraine					(FID), TLC, UV-VIS	(FID), TLC, UV-VIS
					spectrophotometry, FTIR, basic	spectrophotometry, FTIR, basic
Tel/Fax: +380 44 272 5498,					tests	tests
+380 44 272 5798						
e-mail: CL@statelab.kiev.ua					HPLC (UV-Vis, RI detection), GC	
				related substances	(FID), UV-Vis spectrophotometry,	(FID), UV-Vis spectrophotometry,
					AAS, FTIR, volumetric titrations	AAS, FTIR, volumetric titrations
				Microbiological tests	Sterility test, microbial limit tests,	Sterility test, microbial limit tests,
					bacterial endotoxins test (LAL),	bacterial endotoxins test (LAL),
					microbial assay of antibiotics	microbial assay of antibiotics
	1	I I		Type of analysis	Finished products	Active pharmaceutical ingredients
Centre Humanitaire des Métiers de la	26-27 9 2013	Compliant with 2	28 10 2008		pH, density, disintegration,	pH, density, acid value, iodine
Pharmacie (CHMP)		WHO			dissolution, uniformity of dosage	value, limit tests, neutralizing
4, voie militaire des Gravanches		recommended			units (mass, content), friability,	capacity, heavy metals
F 63100 Clermont-Ferrand		standards			dimensions, limit tests	oupdoity, nouvy motalo
France		Standards		Identification	FTIR, TLC, HPLC,	FTIR, TLC, HPLC,
i idiloo					spectrophotometry, basic tests	spectrophotometry, basic tests
Tel: +33 4 73 98 24 70					HPLC (UV-Vis, PDA detection),	HPLC (UV-Vis, PDA detection),
Fax: +33 4 73 98 24 81					UV spectrophotometry, FTIR,	UV spectrophotometry, FTIR,
e-mail: contact@chmp.org,				related substances	volumetric titrations	volumetric titrations
a.ba@chmp.org						
a.ba@onnp.org	1			Type of analysis	Finished products	Active pharmaceutical ingredients
INFARMED I.P. ³	16-17.7.2015	Compliant with 3	21 9 2011		pH, density, optical rotation,	pH, optical rotation, viscosity,
Direcção da Comprovação da		WHO	51.0.2011		viscosity, water content,	melting point, loss on drying,
Qualidade (DCQ)		recommended			conductivity, residual solvents,	water content, osmolarity,
Av. Brasil No 53		standards			limit tests, tablet hardness,	conductivity, residual solvents,
Edifício Tomé Pires		stanuarus			friability, disintegration,	sulphated ash, limit tests
1749-004 Lisboa					dissolution, uniformity of dosage	sulphated ash, inflit tests
Portugal				1.1	units (mass, content)	
T 1 05 1017007050					HPLC (UV-VIS, DAD,	HPLC (UV-VIS, DAD,
Tel: +35 1217987350	1					fluorescence, RI, ELS, MS,
Fax: +35 1217987369					electrochemical detection), GC	electrochemical detection), GC
e-mail: mjoao.portela@infarmed.pt						(FID, ECD, FPD, NPD, TCD, MS
					detection), capillary	detection), capillary
	1				electrophoresis, TLC, UV-VIS	electrophoresis, TLC, UV-VIS
						spectrophotometry, FTIR, basic
					tests	tests
	1			Assay, impurities and	HPLC (UV-VIS, DAD,	HPLC (UV-VIS, DAD,

³ The laboratory has been included on the list based on the WHO assessment, which utilized the results of audit performed by the European Directorate for the Quality of Medicines & HealthCare (EDQM). Therefore no WHO Public Inspection Report is published in this case.

		Microbiological tests	fluorescence, RI, ELS, MS, electrochemical detection), GC (FID, ECD, FPD, NPD, TCD, MS detection), TLC, UV-VIS spectrophotometry, flame photometry, AAS, FTIR, potentiometry, volumetric titrations, gravimetry Sterility test, microbial limit tests, bacterial endotoxins test (LAL), microbial assay of antibiotics	fluorescence, RI, ELS, MS, electrochemical detection), GC (FID, ECD, FPD, NPD, TCD, MS detection), TLC, UV-VIS spectrophotometry, flame photometry, AAS, FTIR, potentiometry, volumetric titrations, gravimetry Sterility test, microbial limit tests, bacterial endotoxins test (LAL), microbial assay of antibiotics
	 	 Type of analysis	Finished products	Active pharmaceutical ingredients
InphA GmbH - Institute for Pharmaceutical and Applied Analytics ⁴ Emil-Sommer-Strasse 7 D-28329 Bremen Germany	Compliant with WHO recommended standards	Physical/Chemical analysis	pH, density, refractive index, optical rotation, osmolality, water content, residual solvents, limit tests, tablet hardness, friability, disintegration, dissolution, uniformity of dosage units (mass, content)	pH, density, refractive index, optical rotation, melting point, loss on drying, water content, residual solvents, sulphated ash, limit tests
Tel: +49 421 4361-111 Fax: +49 421 4361-189 e-mail: konrad.horn@inpha.de		Identification	HPLC (DAD; UV-Vis, RI, conductivity, fluorescence, ELS, MS, charged aerosol, chemiluminescence, pulsed amperometric detection), GC (FID,MS), capillary electrophoresis, TLC, UV-Vis spectrophotometry, FTIR, AAS, AES, ICP/OES, electrophoresis, isoelectric focussing, basic tests	HPLC (DAD; UV-Vis, RI, conductivity, fluorescence, ELS, MS, charged aerosol, chemiluminescence, pulsed amperometric detection), GC (FID,MS), capillary electrophoresis, TLC, UV-Vis spectrophotometry, FTIR, AAS, AES, ICP/OES, electrophoresis, isoelectric focussing, basic tests
		related substances	HPLC (DAD; UV-Vis, RI, conductivity, fluorescence, ELS, MS, charged aerosol, chemiluminescence, pulsed amperometric detection), GC (FID,MS), capillary electrophoresis, TLC, UV-Vis spectrophotometry, FTIR, AAS, AES, ICP/OES, electrophoresis, isoelectric focussing, volumetric titration (visual, potentiometric), gravimetry	HPLC (DAD; UV-Vis, RI, conductivity, fluorescence, ELS, MS, charged aerosol, chemiluminescence, pulsed amperometric detection), GC (FID,MS), capillary electrophoresis, TLC, UV-Vis spectrophotometry, FTIR, AAS, AES, ICP/OES, electrophoresis, isoelectric focussing, volumetric titration (visual, potentiometric), gravimetry
		Microbiological tests	Sterility test, microbial limit tests, bacterial endotoxins (LAL)	Sterility test, microbial limit tests, bacterial endotoxins (LAL)

⁴ The laboratory has been included on the list based on the WHO assessment, which utilized the results of audit performed by the European Directorate for the Quality of Medicines & HealthCare (EDQM). Therefore no WHO Public Inspection Report is published in this case.

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				Type of analysis	Finished products	Active pharmaceutical ingredients
Intertek (Schweiz) AG ⁵ Mattenstrasse 22 Biopark Rosenthal, Building 1047	2-3.5.2013 US FDA inspection;	Compliant with WHO recommended	27.10.2014	Physical/Chemical analysis	pH, solubility, particulate matter in injections, uniformity of dosage units (mass, content)	
CH-4058 Basel Switzerland Tel: +41 61 686 48 00 Fax: +41 61 686 48 99 e-mail: mara.guzzetti@intertek.com	9.4.2013 Swissmedic, Switzerland inspection	standards			HPLC (UV-Vis, DAD, fluorescence, MS, electrochemical detection), GC (FID, ECD, MS detection), mass spectrometry, NMR, FTIR, residual solvents, determination of degradation products, forensic investigations, IR- and Raman- imaging	HPLC (UV-Vis, DAD, fluorescence, MS, electrochemical detection), GC (FID, ECD, MS detection), mass spectrometry, NMR, FTIR, residual solvents, determination of degradation products, forensic investigations, IR- and Raman- imaging
				related substances	HPLC (UV-Vis, DAD, fluorescence, MS, electrochemical detection), GC (FID, ECD, MS detection), mass spectrometry, NMR, FTIR	HPLC (UV-Vis, DAD, fluorescence, MS, electrochemical detection), GC (FID, ECD, MS detection), mass spectrometry, NMR, FTIR
				Type of analysis	Finished products	Active pharmaceutical ingredients
Laboratorios Basi - Industria Farmaceutica, S.A., Quality Control Unit ⁶ Parque Industrial de Mortágua Lote 15 3450-232 Mortágua Portugal		Compliant with WHO recommended standards	12.6.2013		drying, water content, conductivity, total organic carbon, tablet hardness, dimensions, friability, disintegration, dissolution, uniformity of dosage units (mass, content), particulate matter test	pH, density, refractive index, optical rotation, viscosity, melting point, loss on drying, water content, conductivity, sulphated ash, acid value, ester value, hydroxyl value iodine value, peroxide value, saponification value, total organic carbon, particulate matter test
Tel: +351 231 920 250 e-mail: basi@basi.pt				related substances	HPLC (UV-Vis, RI, DAD), GC (FID, μECD), TLC, UV-Vis spectrophotometry, FTIR/NIR HPLC (UV-Vis, RI, DAD), GC (FID, μECD), UV-Vis spectrophotometry, FTIR/NIR, potentiometry, volumetric titrations, gravimetry	HPLC (UV-Vis, RI, DAD), GC (FID, μECD), TLC, UV-Vis spectrophotometry, FTIR/NIR HPLC (UV-Vis, RI, DAD), GC (FID, μECD), UV-Vis spectrophotometry, FTIR/NIR, potentiometry, volumetric titrations, gravimetry
					Sterility test, microbial limit tests, bacterial endotoxins test (LAL), microbial assay of antibiotics,	Sterility test, microbial limit tests, bacterial endotoxins test (LAL), microbial assay of antibiotics,

The laboratory has been included on the list based on the WHO assessment, which utilized the results of inspections performed by the US FDA and Swissmedic, Switzerland. Therefore no WHO Public Inspection Report is published in this case. The laboratory has been included on the list based on the WHO assessment, which utilized the results of inspection performed by the INFARMED, Portugal. 5

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					preservative efficacy test	preservative efficacy test
				Stability studies	ICH conditions	ICH conditions
				Type of analysis	Finished products	Active pharmaceutical ingredients
Laboratory of chemical- pharmaceutical preparations No. 2 and Laboratory of antibiotics of the Federal State Budgetary Institution «Scientific Centre for Expert	16-20.5.2016	Compliant with WHO recommended standards	21.5.2012	Physical/Chemical analysis	pH, density, refractive index, optical rotation, water content, residual solvents, limit tests, disintegration, dissolution, uniformity of dosage units (mass, content)	pH, refractometry, refractive index, optical rotation, viscosity, melting point, loss on drying, water content, heavy metals, residual solvents and limit tests
Evaluation of Medicinal Products», Ministry of Health of the Russian Federation				Identification	HPLC (UV-Vis, PDA, RI, detection), GC (FID, ECD, TCD), TLC, UV-VIS spectrophotometry, IR, basic tests	HPLC (UV-Vis, PDA, RI, detection), GC (FID, ECD, TCD), TLC, UV-VIS spectrophotometry, IR, basic tests
Laboratories for Control and Coordination; Biotechnological Products; Nano-medicines, Cell and Gene Therapy Products; Vitamins, Hormones and Synthetic Analogues				related substances	HPLC (UV-Vis, PDA, RI detection), GC (FID, ECD, TCD), UV-Vis spectrophotometry,FTIR, volumetric titrations	HPLC (UV-Vis, PDA, RI, detection), LC/MS, GC (FID, ECD, TCD), UV-Vis spectrophotometry, FTIR, volumetric titrations
and Microbiology Laboratory				Microbiological tests	Laboratory of antibiotics - Sterility testing and Microbial assay and limit tests.	Laboratory of antibiotics - Sterility testing and microbial limit tests.
Schukinskaya street, 6-1 Moscow 123182 Russian Federation					Microbiology Laboratory - Microbial limit tests	Microbiology Laboratory - Microbial limit tests
Tel: +7 495 6254342 Fax: +7 4956254350 e-mail: gladkaja@expmed.ru						
	1	1	1	Type of analysis	Finished products	Active pharmaceutical ingredients
Laboratory of Pharmaceutical Analysis State Expert Centre Ministry of Health of Ukraine 14, Ezhena Pottier St. 03680 Kiev Ukraine Tel: +38 44 536 1338,	12-13.5.2016	Compliant with WHO recommended standards	16.4.2010	Physical/Chemical analysis	rotation, viscosity, conductivity, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, nitrogen determination, heavy metals, loss on drying, limit tests, disintegration, dissolution,	pH, density, refractometry, optical rotation, viscosity, conductivity, melting point, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, acid neutralizing capacity, nitrogen determination, heavy metals, loss on drying, limit tests
+38 50 959 7924 Fax: + 38 44 536 1344 e-mail: sashavbfc@yandex.ru					uniformity of dosage units (mass, content), friability, tablet hardness, dimensions	
				Identification	HPLC (UV-Vis, DAD, fluorescense, RI detection), GC, TLC, UV-Vis and NIR spectrophotometry, AAS, basic	HPLC (UV-Vis, DAD, fluorescense, RI detection), GC, TLC, UV-Vis and NIR spectrophotometry, AAS, basic

					tests	tests
				Assay, impurities and related substances	HPLC (UV-Vis, DAD, fluorescense, RI detection), GC, UV-Vis spectrophotometry, AAS,	HPLC (UV-Vis, DAD, fluorescense, RI detection), GC, UV-Vis spectrophotometry, AAS, volumetric titrations
					bacterial endotoxins test (LAL), microbial assay of antibiotics	Sterility test, microbial limit tests, bacterial endotoxins test (LAL), microbial assay of antibiotics
				Type of analysis	Finished products	Active pharmaceutical ingredients
Medicines Control Laboratory (SCM- DGO) Stevinstraat 137 1000 Brussels, Belgium Tel.: +32 228 54250 e-mail: dgo_scm@apb.be	4-7.02.2014 FAMHP Belgium, Inspection	Compliant with WHO recommended standards	30.10.2015	analysis	friability, tablet hardness melting point, optical rotation, refractive index, disintegration time, dissolution, density, viscosity, osmolality, conductivity, uniformity of dosage units (mass, content), uniformity of delivered dose of (non)pressurized MDI, residual solvents, limit tests.	pH, water content, loss on drying, , refractive index, optical rotation, viscosity, melting point, residue on ignition, conductivity, heavy metals, residual solvents, limit tests, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value
				Identification	Fluorescence, ELSD, MS), GC(FID), (HP)TLC, UV-Vis, FTIR,	(U)HPLC (UV-Vis, DAD, RI, Fluorescence, ELSD, MS), GC (FID), (HP)TLC, UV-Vis, FTIR, AAS/AES, basic tests
				related substances	Fluorescence, ELSD, MS), GC (FID), (HP)TLC, UV-Vis, FTIR, AAS/AES, titrations, determination of related substances/impurities, degradation products and residual solvents, nitrogen determination	(U)HPLC (UV-Vis, DAD, RI, Fluorescence, ELSD, MS), GC (FID), (HP)TLC, UV-Vis, FTIR, AAS/AES, titrations, determination of related substances/impurities, degradation products and residual solvents, oxygen flask combustion, nitrogen determination
				, , , , , , , , , , , , , , , , , , ,	Sterility test, microbiological, examination of non-sterile products, bacterial endotoxins test (LAL), microbial assay of antibiotics, ELISA, preservative	Sterility test, microbiological examination of non-sterile products, bacterial endotoxins test (LAL), microbial assay of antibiotics, ELISA, preservative challenge test
				Type of analysis	Finished products	Active pharmaceutical ingredients
PROXY Laboratories B.V. Archimedesweg 25 2333 CM Leiden The Netherlands	7-9.1.2014	Compliant with WHO recommended standards	31.8.2011	Physical/Chemical analysis	pH, density, refractive index, optical rotation, viscosity, water content, conductivity, residual	pH, refractive index, optical rotation, viscosity, melting point, distilling range, loss on drying, water content, osmolarity,

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Tel: +31 71 5244080 (general) Fax: +31 71 5284213 e-mail: info@proxylab.nl				dissolution, uniformity of dosage units (mass, content)	conductivity, heavy metals, residual solvents, limit tests, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, sulphated ash, residue on ignition, total organic carbon, solubility
				HPLC (UV-VIS, PDA, RI, conductivity detection), LC/MS, GC (FID, MS), TLC, UV-VIS	HPLC (UV-VIS, PDA, RI, conductivity detection), LC/MS, GC (FID, MS), TLC, UV-VIS spectrophotometry, IR, basic tests
			related substances	HPLC (UV-VIS, PDA, RI, conductivity detection), LC/MS, GC (FID, MS), TLC, UV-VIS	HPLC (UV-VIS, PDA, RI, conductivity detection), LC/MS, GC (FID, MS), TLC, UV-VIS spectrophotometry, AAS, FTIR, volumetric titrations
				Sterility test, microbial limit tests, bacterial endotoxins test (LAL), microbial assay of antibiotics, preservative efficacy test	Sterility test, microbial limit tests, bacterial endotoxins test (LAL), microbial assay of antibiotics
			Type of analysis	Finished products	Active pharmaceutical ingredients
Laboratory of the Centre for Expertise and Testing in Health Care Ministry of Health Care of the Republic of Belarus	Compliant with WHO recommended standards	21.6.2012	analysis	pH, density, refractive index, optical rotation, water content, conductivity, residual solvents, limit tests, friability, disintegration, dissolution, uniformity of dosage units (mass, content)	pH, refractometry, refractive index, optical rotation, viscosity, melting point, loss on drying, water content, heavy metals, residual solvents and limit tests
78 Pritytskiy St. 220140 Minsk Belarus				HPLC (UV-Vis, DAD, RI, detection), GC, TLC, UV-VIS	HPLC (UV-Vis, DAD, RI, detection), GC, TLC, UV-VIS spectrophotometry, IR, basic tests
Tel: +375 17 254-95-63 Tel/Fax: +375 17 254-95-74 e-mail: rkal@rceth.by maisak@rceth.by			Assay, impurities and related substances	HPLC (UV-Vis, DAD, RI detection), GC, UV-Vis	HPLC (UV-Vis, DAD, RI, detection), GC , UV-Vis spectrophotometry, volumetric titrations
			Type of analysis	Finished products	Active pharmaceutical ingredients
State Budgetary Institution "Information and Methodological Center for Expertise, Stocktaking and Analysis of Circulation of Medical products" of the Federal	Compliant with WHO recommended standards	11.3.2014	analysis	limit tests, disintegration, dissolution, uniformity of dosage units (mass, content)	pH, density, refractive index, optical rotation, water content, loss on drying, residual solvents, limit tests
Service on Surveillance in Healthcare Chentsova street 71/63B Rostov-on-Don Rostov region			Identification	HPLC (UV-Vis, RI, DAD detection), GC (FID, TCD), TLC, UV-VIS spectrophotometry, IR, basic tests	HPLC (UV-Vis, RI, DAD detection), GC (FID, TCD), TLC, UV-VIS spectrophotometry, IR, basic tests

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344037						HPLC (UV-Vis, RI, DAD
Russian Federation						detection), GC (FID, TCD), UV-
T 1 7 000 0000044						Vis spectrophotometry, volumetric
Tel: +7 863 2806914;					titrations	titrations
+7 863 2806911					Sterility test, microbial limit tests,	Sterility test, microbial limit tests,
e-mail:annagranf@yandex.ru					bacterial endotoxins test (LAL),	bacterial endotoxins test (LAL)
					microbial assay of antibiotics	
				Type of analysis	Finished products	Active pharmaceutical ingredients
SGS Lab Simon S. A.	20.01.15	Compliant with	31.5.2011	Physical/Chemical	pH, density, refractive index,	pH, refractometry, refractive
Vieux Chemin du Poète 10		WHO		analysis	optical rotation, viscosity, water	index, optical rotation, viscosity,
B-1301 Wavre		recommended			content, conductivity, residual	melting point, distilling range, loss
Belgium		standards				on drying, water content,
						osmolarity, conductivity, heavy
Tel: +32 10 421111;					dissolution, uniformity of dosage	metals, residual solvents, limit
+32 10 42176;					units (mass, content)	tests, acid value, iodine value,
+32 10 421186						peroxide value, ester value,
Fax: +32 10 421100						hydroxyl value, saponification
e-mail: be.lifeqc@sgs.com						value
wim.vanimmerseel@sgs.com				Identification	HPLC (UV-Vis, PDA, RI,	HPLC (UV-Vis, PDA, RI,
wini.vaniininorooor@ogo.com				lacitimeation		conductivity, fluorescence
					GC (FID, MS), TLC, UV-VIS	detection), LC/MS, GC (FID, MS),
					spectrophotometry, IR, basic tests	
					spectrophotometry, IK, basic tests	
						IR, basic tests
						HPLC (UV-Vis, PDA, RI,
					conductivity detection), LC/MS,	conductivity detection), LC/MS,
					GC (FID, MS), UV-Vis	GC (FID, MS), UV-Vis
						spectrophotometry, AAS, FTIR,
					volumetric titrations	volumetric titrations
					Sterility test, microbial limit tests,	Sterility test, microbial limit tests,
					bacterial endotoxins test (LAL),	bacterial endotoxins test (LAL),
					microbial assay of antibiotics	microbial assay of antibiotics
				Type of analysis	Finished products	Active pharmaceutical ingredients
Synergy Health Utrecht B.V.,	18.12.2012	Compliant with	23.9.2014		pH, density, refractive index,	pH, density, refractive index,
Pharmaceutical Laboratories (SHPL) ⁷	and 4.9.2013	WHO		analysis	optical rotation, viscosity, water	optical rotation, viscosity, water
Reactorweg 47A	Dutch	recommended			content, loss on drying,	content, loss on drying,
3542 AD Utrecht	Healthcare	standards				conductivity, particle size, melting
The Netherlands	Inspectorate				tablet hardness, dimensions,	point, freezing point, drop point,
	inspections					boiling point, distilling range
Tel: +31 30 2843010					dissolution, uniformity of dosage	
Fax: +31 30 2843011					units (mass, content), particulate	
e-mail: utrecht@synergyhealthplc.com					matter test (visible and sub-	
					visible)	
	1	1	1			

⁷ The laboratory has been included on the list based on the WHO assessment, which utilized the results of inspections performed by the Healthcare Inspectorate, Ministry of Public Health, Welfare and Sport of The Netherlands. Therefore no WHO Public Inspection Report is published in this case.

	I	I	I	Identification	FTIR, (HP)TLC, (U)HPLC (UV-	FTIR, (HP)TLC, (U)HPLC (UV-
				Identification		VIS, PDA, RI detection), GC (FID
					detection), UV-VIS	detection), UV-VIS
						spectrophotometry, fluorimetry,
					AAS/AES, basic tests	AAS/AES, basic tests
				Assay, impurities and	(U)HPLC (UV-VIS, PDA, RI	(U)HPLC (UV-VIS, PDA, RI
				related substances	detection), GC (FID detection), (HP)TLC, UV-VIS	detection), GC (FID detection), (HP)TLC, UV-VIS
					spectrophotometry, fluorimetry, polarimetry, AAS/AES,	spectrophotometry, fluorimetry, polarimetry, AAS/AES,
					gravimetric analysis, volumetric	gravimetric analysis, volumetric
						titrations, potentiometry, nitrogen
					determination, residual solvents,	determination, residual solvents,
					ethylene oxide residual analysis	ethylene oxide residual analysis, oxygen flask combustion,
						composition of fatty acids
				Microbiological tests	Sterility test, microbial limit tests,	Sterility test, microbial limit tests,
					identification of microorganisms,	identification of microorganisms,
					preservative efficacy test,	bacterial endotoxins test (LAL),
					bacterial endotoxins test (LAL),	microbial assay of antibiotics
					microbial assay of antibiotics	
				Stability studies	ICH conditions	ICH conditions
				Type of analysis	Finished products	Active pharmaceutical ingredients
State Scientific Research Laboratory			22.01.2016	Physical/Chemical	Clarity and degree of	pH, density, refractometry, optical
on Quality Control of Medicines		WHO	22.01.2016	Physical/Chemical analysis	Clarity and degree of opalescence of liquids, degree of	pH, density, refractometry, optical rotation, viscosity, osmolality,
on Quality Control of Medicines (SSRL), OM Marzeyev Institute for		WHO recommended	22.01.2016	Physical/Chemical analysis	Clarity and degree of opalescence of liquids, degree of coloration of liquids, pH, density,	pH, density, refractometry, optical rotation, viscosity, osmolality, conductivity, melting point, water
on Quality Control of Medicines (SSRL), OM Marzeyev Institute for Hygiene and Medical Ecology, National		WHO	22.01.2016	Physical/Chemical analysis	Clarity and degree of opalescence of liquids, degree of coloration of liquids, pH, density, osmolality, refractometry, optical	pH, density, refractometry, optical rotation, viscosity, osmolality, conductivity, melting point, water content, acid value, iodine value,
on Quality Control of Medicines (SSRL), OM Marzeyev Institute for Hygiene and Medical Ecology, National Academy of Medical Sciences of		WHO recommended	22.01.2016	Physical/Chemical analysis	Clarity and degree of opalescence of liquids, degree of coloration of liquids, pH, density, osmolality, refractometry, optical rotation, viscosity, conductivity,	pH, density, refractometry, optical rotation, viscosity, osmolality, conductivity, melting point, water content, acid value, iodine value, peroxide value, ester value,
on Quality Control of Medicines (SSRL), OM Marzeyev Institute for Hygiene and Medical Ecology, National Academy of Medical Sciences of Ukraine, 50 Popudrenka str, Kiev,		WHO recommended	22.01.2016	Physical/Chemical analysis	Clarity and degree of opalescence of liquids, degree of coloration of liquids, pH, density, osmolality, refractometry, optical rotation, viscosity, conductivity, water content, acid value, iodine	pH, density, refractometry, optical rotation, viscosity, osmolality, conductivity, melting point, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification
on Quality Control of Medicines (SSRL), OM Marzeyev Institute for Hygiene and Medical Ecology, National Academy of Medical Sciences of		WHO recommended	22.01.2016	Physical/Chemical analysis	Clarity and degree of opalescence of liquids, degree of coloration of liquids, pH, density, osmolality, refractometry, optical rotation, viscosity, conductivity,	pH, density, refractometry, optical rotation, viscosity, osmolality, conductivity, melting point, water content, acid value, iodine value, peroxide value, ester value,
on Quality Control of Medicines (SSRL), OM Marzeyev Institute for Hygiene and Medical Ecology, National Academy of Medical Sciences of Ukraine, 50 Popudrenka str, Kiev, 02660, Ukraine Tel: + 38(044)559-57-11		WHO recommended	22.01.2016	Physical/Chemical analysis	Clarity and degree of opalescence of liquids, degree of coloration of liquids, pH, density, osmolality, refractometry, optical rotation, viscosity, conductivity, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, nitrogen	pH, density, refractometry, optical rotation, viscosity, osmolality, conductivity, melting point, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, unsaponifiable matter,
on Quality Control of Medicines (SSRL), OM Marzeyev Institute for Hygiene and Medical Ecology, National Academy of Medical Sciences of Ukraine, 50 Popudrenka str, Kiev, 02660, Ukraine Tel: + 38(044)559-57-11 Fax: + 38(044)559-57-00		WHO recommended	22.01.2016	Physical/Chemical analysis	Clarity and degree of opalescence of liquids, degree of coloration of liquids, pH, density, osmolality, refractometry, optical rotation, viscosity, conductivity, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, nitrogen determination, heavy metals, loss	pH, density, refractometry, optical rotation, viscosity, osmolality, conductivity, melting point, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, unsaponifiable matter, nitrogen determination, heavy
on Quality Control of Medicines (SSRL), OM Marzeyev Institute for Hygiene and Medical Ecology, National Academy of Medical Sciences of Ukraine, 50 Popudrenka str, Kiev, 02660, Ukraine Tel: + 38(044)559-57-11		WHO recommended	22.01.2016	Physical/Chemical analysis	Clarity and degree of opalescence of liquids, degree of coloration of liquids, pH, density, osmolality, refractometry, optical rotation, viscosity, conductivity, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, nitrogen determination, heavy metals, loss on drying, limit tests,	pH, density, refractometry, optical rotation, viscosity, osmolality, conductivity, melting point, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, unsaponifiable matter, nitrogen determination, heavy
on Quality Control of Medicines (SSRL), OM Marzeyev Institute for Hygiene and Medical Ecology, National Academy of Medical Sciences of Ukraine, 50 Popudrenka str, Kiev, 02660, Ukraine Tel: + 38(044)559-57-11 Fax: + 38(044)559-57-00		WHO recommended	22.01.2016	Physical/Chemical analysis	Clarity and degree of opalescence of liquids, degree of coloration of liquids, pH, density, osmolality, refractometry, optical rotation, viscosity, conductivity, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, nitrogen determination, heavy metals, loss on drying, limit tests, disintegration, dissolution,	pH, density, refractometry, optical rotation, viscosity, osmolality, conductivity, melting point, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, unsaponifiable matter, nitrogen determination, heavy
on Quality Control of Medicines (SSRL), OM Marzeyev Institute for Hygiene and Medical Ecology, National Academy of Medical Sciences of Ukraine, 50 Popudrenka str, Kiev, 02660, Ukraine Tel: + 38(044)559-57-11 Fax: + 38(044)559-57-00		WHO recommended	22.01.2016	Physical/Chemical analysis	Clarity and degree of opalescence of liquids, degree of coloration of liquids, pH, density, osmolality, refractometry, optical rotation, viscosity, conductivity, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, nitrogen determination, heavy metals, loss on drying, limit tests, disintegration, dissolution, uniformity of dosage units (mass,	pH, density, refractometry, optical rotation, viscosity, osmolality, conductivity, melting point, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, unsaponifiable matter, nitrogen determination, heavy
on Quality Control of Medicines (SSRL), OM Marzeyev Institute for Hygiene and Medical Ecology, National Academy of Medical Sciences of Ukraine, 50 Popudrenka str, Kiev, 02660, Ukraine Tel: + 38(044)559-57-11 Fax: + 38(044)559-57-00		WHO recommended	22.01.2016	Physical/Chemical analysis	Clarity and degree of opalescence of liquids, degree of coloration of liquids, pH, density, osmolality, refractometry, optical rotation, viscosity, conductivity, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, nitrogen determination, heavy metals, loss on drying, limit tests, disintegration, dissolution, uniformity of dosage units (mass, content), friability, tablet	pH, density, refractometry, optical rotation, viscosity, osmolality, conductivity, melting point, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, unsaponifiable matter, nitrogen determination, heavy
on Quality Control of Medicines (SSRL), OM Marzeyev Institute for Hygiene and Medical Ecology, National Academy of Medical Sciences of Ukraine, 50 Popudrenka str, Kiev, 02660, Ukraine Tel: + 38(044)559-57-11 Fax: + 38(044)559-57-00		WHO recommended	22.01.2016	Physical/Chemical analysis	Clarity and degree of opalescence of liquids, degree of coloration of liquids, pH, density, osmolality, refractometry, optical rotation, viscosity, conductivity, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, nitrogen determination, heavy metals, loss on drying, limit tests, disintegration, dissolution, uniformity of dosage units (mass,	pH, density, refractometry, optical rotation, viscosity, osmolality, conductivity, melting point, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, unsaponifiable matter, nitrogen determination, heavy
on Quality Control of Medicines (SSRL), OM Marzeyev Institute for Hygiene and Medical Ecology, National Academy of Medical Sciences of Ukraine, 50 Popudrenka str, Kiev, 02660, Ukraine Tel: + 38(044)559-57-11 Fax: + 38(044)559-57-00		WHO recommended	22.01.2016	Physical/Chemical analysis	Clarity and degree of opalescence of liquids, degree of coloration of liquids, pH, density, osmolality, refractometry, optical rotation, viscosity, conductivity, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, nitrogen determination, heavy metals, loss on drying, limit tests, disintegration, dissolution, uniformity of dosage units (mass, content), friability, tablet hardness, dimensions, particulate contamination (sub-visible/visible particles)	pH, density, refractometry, optical rotation, viscosity, osmolality, conductivity, melting point, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, unsaponifiable matter, nitrogen determination, heavy metals, loss on drying, limit tests
on Quality Control of Medicines (SSRL), OM Marzeyev Institute for Hygiene and Medical Ecology, National Academy of Medical Sciences of Ukraine, 50 Popudrenka str, Kiev, 02660, Ukraine Tel: + 38(044)559-57-11 Fax: + 38(044)559-57-00		WHO recommended	22.01.2016	Physical/Chemical analysis	Clarity and degree of opalescence of liquids, degree of coloration of liquids, pH, density, osmolality, refractometry, optical rotation, viscosity, conductivity, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, nitrogen determination, heavy metals, loss on drying, limit tests, disintegration, dissolution, uniformity of dosage units (mass, content), friability, tablet hardness, dimensions, particulate contamination (sub-visible/visible particles) HPLC (DAD, RID,UV-Vis, FLD),	pH, density, refractometry, optical rotation, viscosity, osmolality, conductivity, melting point, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, unsaponifiable matter, nitrogen determination, heavy metals, loss on drying, limit tests
on Quality Control of Medicines (SSRL), OM Marzeyev Institute for Hygiene and Medical Ecology, National Academy of Medical Sciences of Ukraine, 50 Popudrenka str, Kiev, 02660, Ukraine Tel: + 38(044)559-57-11 Fax: + 38(044)559-57-00		WHO recommended	22.01.2016	Physical/Chemical analysis Identification	Clarity and degree of opalescence of liquids, degree of coloration of liquids, pH, density, osmolality, refractometry, optical rotation, viscosity, conductivity, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, nitrogen determination, heavy metals, loss on drying, limit tests, disintegration, dissolution, uniformity of dosage units (mass, content), friability, tablet hardness, dimensions, particulate contamination (sub-visible/visible particles) HPLC (DAD, RID,UV-Vis, FLD), GC (FID, ECD), TLC, UV-Vis	pH, density, refractometry, optical rotation, viscosity, osmolality, conductivity, melting point, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, unsaponifiable matter, nitrogen determination, heavy metals, loss on drying, limit tests HPLC (DAD, RID,UV-Vis, FLD), GC (FID, ECD), TLC, UV-Vis
on Quality Control of Medicines (SSRL), OM Marzeyev Institute for Hygiene and Medical Ecology, National Academy of Medical Sciences of Ukraine, 50 Popudrenka str, Kiev, 02660, Ukraine Tel: + 38(044)559-57-11 Fax: + 38(044)559-57-00		WHO recommended	22.01.2016	Physical/Chemical analysis Identification	Clarity and degree of opalescence of liquids, degree of coloration of liquids, pH, density, osmolality, refractometry, optical rotation, viscosity, conductivity, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, nitrogen determination, heavy metals, loss on drying, limit tests, disintegration, dissolution, uniformity of dosage units (mass, content), friability, tablet hardness, dimensions, particulate contamination (sub-visible/visible particles) HPLC (DAD, RID,UV-Vis, FLD), GC (FID, ECD), TLC, UV-Vis Spectrophotometry, FTIR	pH, density, refractometry, optical rotation, viscosity, osmolality, conductivity, melting point, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, unsaponifiable matter, nitrogen determination, heavy metals, loss on drying, limit tests

				related substances Microbiological tests Type of analysis	Spectrophotometry, FTIR spectroscopy, Water determination Sterility test, microbial limit tests, bacterial endotoxins test (LAL),	FLD),GC (Au/HS(FID, ECD)), UV-Vis Spectrophotometry, FTIR spectroscopy, Water determination Sterility test, microbial limit tests, bacterial endotoxins test (LAL), microbial assay of antibiotics Active pharmaceutical ingredients
University of Liege, Faculty of Medicine, Department of Pharmacy, B36 Building, Tower Pharmacy, Level 2 Hospital district Hippocrate Avenue 15 4000 Liège Belgium Tel: + 32 4 366 3979 Fax: + 32 4 366 4317 e-mail: rmarini@ulg.ac.be	June 2015 - Belgium Federal Agency for Medicines and Health Products (FAMHP) + 03.11.2016 (WHO PQT Desk Review)	Compliant with WHO recommended standards	22.12.2016	Physical/Chemical analysis	refractive index, viscosity, water content, conductivity, residual solvents, limit tests, tablet hardness, friability, disintegration, dissolution, uniformity of dosage units (mass, content), tapped density, particles size, molarity.	pH, optical rotation, refractive index, viscosity, melting point, loss on drying, water content, osmolarity, conductivity, heavy metals, residual solvents, limit tests, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, tapped density, particle size, molarity.
				Identification	LCUV- ELSD-, UHPLC-UV-MS, MS, GC-FID, TLC, UV-VIS spectrophotometry, FT- IR spectroscopy, spectroscopy NIR, NMR, Raman spectroscopy,	UV-Vis, PDA, refractive index , LC-UV-ELSD-, UHPLC-UV-MS, MS, GC-FID, TLC, UV-VIS spectrophotometry, FT- IR spectroscopy, spectroscopy NIR, NMR , Raman spectroscopy, CEDAD, basic tests.
				related substances	HPLC (UV-Vis, PDA), LC/MS, GC (FID,), UHPLC-UV-MS, LC- UVELSD, Spectrophotometry UV-Vis, AAS, FTIR, NIR, LC-RMN, CE-DAD.	HPLC (UV-Vis, PDA), LC/MS, GC (FID,), UHPLC-UV-MS, LC- UVELSD, Spectrophotometry UV-Vis, AAS, FTIR, NIR, LC-RMN, CE-DAD volumetric titrations.
				Stability Testing	Under ICH conditions.	Under ICH conditions.
WHO Eastern Mediterranean Region						
Laborataira National da Contrâla das		Compliant	47 7 0000	Type of analysis	Finished products	Active pharmaceutical ingredients
Laboratoire National de Contrôle des Médicaments - LNCM (Maroc) ⁸		Compliant with WHO	17.7.2008	Physical/Chemical analysis		pH, density, refractive index, viscosity, loss on drying, melting

⁸ The laboratory has been included on the list based on the WHO assessment, which utilized the results of audits performed by the European Directorate for the Quality of Medicines & HealthCare (EDQM). Therefore no WHO Public Inspection Report is published in this case.

Rue Lamfadel Charkaoui - Medinat Al Irfane Rabat 10 000 Maroc Postal address: BP 6202, Rabat - Instituts Rabat		recommended standards		Identification	disintegration, dissolution, uniformity of dosage units (mass, content), friability, tablet hardness HPLC (fluorescence, UV, UV-Vis,	HPLC (fluorescence, UV, UV-Vis, DAD, RI detection) GC (FID, MS), TLC, IR, UV-VIS spectrophotometry, chemical
Maroc Tel: +212 537681930 Fax: +212 537772520 e-mail: m-a-mahly@wanadoo.net.ma				related substances	DAD, RI detection), GC (FID, MS), UV-VIS spectrophotometry, fluorimetry, volumetric titrations, polarimetry Determination of related substances/impurities,	reaction HPLC(fluorescence, UV, UV-Vis, DAD, RI detection), GC (FID, MS), UV-VIS spectrophotometry, fluorimetry, volumetric titrations, polarimetry Determination of related substances/impurities, degradation products and residual solvents
				Microbiological tests	Microbial purity, test for pyrogens, bacterial endotoxins test (LAL)	Microbial assay
				Type of analysis	Finished products	Active pharmaceutical ingredients
Food and Drugs Control Reference Laboratories (FDCRL), Food & Drugs Administration, Ministry of Health and Medical Education. No 31 Imam Khomeini Avenue, Tehran, 11136-15911, Islamic Republic of Iran	21-23.09.2015	Compliant with WHO recommended standards	11.03.2016	Physical/Chemical analysis	friability, disintegration, tablet hardness, dissolution, viscosity, density, dimensions, uniformity of dosage unit (mass, content).	pH, Water content, loss on drying, refractive index, optical rotation, viscosity, melting point, heavy metals, sulphated ash, residual solvents, limit tests, solubility, Conductivity, Organic Volatile Impurities (OVI).
Tel: +98 21 66496153 Fax:+982166404330 e-mail: FDCRL@fda.gov.ir or h.rastegar@fda.gov.ir					fluorescence detection), GC-MS, IR, FTIR, UV-VIS spectrophotometry, TLC, chemical reaction (basic tests)	HPLC (UV-VIS detection, RI, fluorescence detection), GC-MS, IR, FTIR, UV-VIS spectrophotometry, TLC, chemical reaction (basic tests)
				Assay, impurities and related substances	fluorescence detection), UV-VIS spectrophotometry, GC (FID, TCD), AAS, ICP, Fluorimetry, gravimetric analysis, volumetric	HPLC (UV-VIS detection, RI, fluorescence detection), UV-VIS spectrophotometry, GC (FID, TCD), AAS, ICP-MS, Fluorimetry, gravimetric analysis, volumetric titrations, Potentiometry
				Microbiological tests	Sterility test, microbial limit tests, microbial assay of antibiotics, Bacterial Endotoxins Tests (LAL test)	Bacterial Endotoxins Tests (LAL test)

National institutes for Food and Drug Control (NFPC) - Divisions of Chemical Drugs, Antibiotics, Narcotic Drugs and Pharmacology of the Institute for Chemical Drug Control 2 Tiantan XIII (Temple of Heaven) 100505 Beijing P.R. CHINA Physical/Chemical analysis PH, density, refractometry, date dissolution, uniformity of dosagu bits (mass, content), finability, dimensions PH - cluX-Vis, RI detection, GC (FID), TLC, UV-VIS, RI detection, GC (FID), UV-VIS, Spectrophotometry, FTIR, basic tests Tel: +861 10 67095866 Frax: +661 10 65113005 e-mail: yanghx@nide.org.cn e-mail: yanghx@nide.org.cn e-mail: yanghx@nide.org.cn e-mail: yanghx@nide.org.cn e-mail: phanghz@nicobp.org.cn 04-06.12.2014 Compliant with 28.11.2008 28.11.2008 Type of analysis analysis Raterial endotoxins test (LAL) microbial assay of antibiotics ficional status of analysis analysis Adver phrameteutica transformatics Adver phrameteutica transformatics Adver phrameteutica transformatics National Institute of Drug Quality Control of Vienam (MDQC) teenam 04-06.12.2014 Compliant with 28.11.2008 28.11.2008 Physical/Chemical tests Adver phrameteutica tests Adver phrameteutica tests Adver phrameteutica tests Tel. +844 825 5019 Frax: +844 825 6911 04-06.12.2014 Compliant with 28.4164 advards File andvards Hell C(UV-Vis, DAD, fluorescence, light scattering detection), LC/MS/MS, GC (FID, ECD), GC/MS, TLC, HTUC, UV-Vis, DAD,				Type of analysis	Finished products	Active pharmaceutical ingredient
2 Tiantan Xili (Temple of Heaven) 100505 Beijing P.R. CHINA Tel: +86 10 67095866 Fax: +86 10 65113805 e-mail: yanghx@nifd.corg.cn zhanghz@nicpbp.org.cn National Institute of Drug Quality Control of Vietnam (NIDDC) 48 Hai Ba Trung Street Hanoi Vietnam Tel. +844 824 5009 Tel. +844 825 6911 e-mail: org.com.yn nhlienvkn@gmail.com tranthuyhanh1974@yahoo.com/ tranthuyhanh1974@yahoo.com/ hilenvkn@gmail.com tranthuyhanh1974@yahoo.com/ tranthuyhanh1974@yahoo.com/ hilenvkn@gmail.com tranthuyhanh1974@yahoo.com/ hilenvkn@gmail.com tranthuyhanh1974@yahoo.com/ tranthuyhanh1974@yahoo.com/ hilenvkn@gmail.com tranthuyhanh1974@yahoo.com/ tranthuyhanh1974@yahoo.com/ hilenvkn@gmail.com tranthuyhanh1974@yahoo.com/ hilenvkn@gmail.com tranthuyhanh1974@yahoo.com/ tranthuyhanh1974@yahoo.com/ hilenvkn@gmail.com tranthuyhanh1974@yahoo.com/ tranthuyhanh1974@yahoo.com/ hilenvkn@gmail.com	ontrol (NIFDC) - visions of Chemical Drugs, atibiotics, Narcotic Drugs and armacology of the Institute for	22-24.10.2013	WHO recommended	Physical/Chemical	pH, density, refractometry, water content, limit tests, disintegration, dissolution, uniformity of dosage units (mass, content), friability, dimensions	pH, refractometry, optical rotatior loss on drying, water content, heavy metals, acid value, iodine value, limit tests, nitrogen determination
Tel: +861 10 67095866 [FID], UV-VIS spectrophotometry, zhanghz@nicpbp.org.cn [FID], UV-VIS spectrophotometry, AAS, FTIR, volumetric ittrations, AAS, FTIR, volumetric ittrations, AAS, FTIR, volumetric ittrations, analysis National institute of Drug Quality Control of Vietnam (NIDQC) 04-06.12.2014 Compliant with Vietnam 28.11.2008 PH, density, refractometry, viscosity, loss on drying, water content, disintegration, dissolution, uniformity of dosage value, acetyl value, per value, acetyl value,	Fiantan Xili (Temple of Heaven) 0050 Beijing				(FID), TLC, UV-VIS spectrophotometry, FTIR, basic tests	spectrophotometry, FTIR, basic tests
zhanghz@nicpbp.org.cn microbiological tock <t< td=""><td>x: +86 10 65113805</td><td></td><td></td><td>related substances</td><td>(FID), UV-VIS spectrophotometry, AAS, FTIR, volumetric titrations</td><td>AAS, FTIR, volumetric titrations</td></t<>	x: +86 10 65113805			related substances	(FID), UV-VIS spectrophotometry, AAS, FTIR, volumetric titrations	AAS, FTIR, volumetric titrations
National Institute of Drug Quality Control of Vietnam (NIDQC) 48 Hai Ba Trung Street Hanoi Vietnam Tel. +844 825 6091 e-mail: npthaodz@yahoo.com.vn nhienvkn@gmail.com tranthuyhanh1974@yahoo.com04-06.12.2014 Compliant with 28.11.2008Physical/Chemical analysispH, density, refractometry, viscosity, loss on drying, water content, disintegration, dissolution, uniformity of dosage units (mass, content), friability, tablet hardness, particulate matter acid value, iodine valu est value, acetyl value, po- value, acetyl value, po- value, saponification HPLC (UV-Vis, DAD, fluorescence, light scattering detection), LC/MS/MS, GC (FID, HPLC (UV-Vis, DAD, fluorescence, light scattering detection), LC/MS/MS, GC (FID, HPLC (UV-Vis, DAD, fluorescence, light scattering fluorescence, light scattering detection), LC/MS/MS, GC (FID, detection), LC/MS/MS, GC (FID, detect				Microbiological tests		Bacterial endotoxins test (LAL), microbial assay of antibiotics
Control of Vietnam (NIDQC) 48 Hai Ba Trung Street Hoan Kiem District Hanoi VietnamWHO recommended standardsanalysisviscosity, loss on drying, water content, disintegration, dissolution, uniformity of dosage units (mass, content), friability, tablet hardness, particulate mater estspecific optical rotation loss on drying, melting water content, heavy i subphated ash, acid in value, acety value, particulate value, acety value, particulate value, acety value, particulate value, acety value, particulate meter content, friability, tablet hardness, particulate mater acid value, iodine valu testHPLC (UV-Vis, DAD, HPLC (UV-Vis, DAD, ECD), GC/MS, TLC, HPTLC, UV- VIS spectrophotometry, IR, AAS VIS spectrophotometry, IR, AAS vis spectrophotometry, N, amperometry, volumetric titrations, amperometry, volumetric titrations, amperometry, volumetric titrations, amperometry, volumetric titrations, amperometry, potentiometry, nitrogen assayHPLC (UV-Vis, DAD, HPLC (UV-Vis, DAD, fluorescence, light scattering detection), LC/MS/MS, GC (FID, ECD), GC/MS, TLC, HPTLC, UV- VIS spectrophotometry AS, chemical reactioMicrobiological testsSterility test, microbial purity, test for pyrogens, bacterial endotoxins test (LAL), microbial assayHicrobial assay					Finished products	Active pharmaceutical ingredient
Fax: +844 825 6911 Identification HPLC (UV-Vis, DAD, fluorescence, light scattering detection), LC/MS/MS, GC (FID, ECD), GC/MS, TLC, HPTLC, UV-VIS, Spectrophotometry, IR, AAS HPLC (UV-Vis, DAD, fluorescence, light scattering detection), LC/MS/MS, GC (FID, ECD), GC/MS, TLC, HPTLC, UV-VIS spectrophotometry, IR, AAS HPLC (UV-Vis, DAD, fluorescence, light scattering detection), LC/MS/MS, GC (FID, ECD), GC/MS, TLC, HPTLC, UV-VIS, DAD, fluorescence, light scattering detection), LC/MS/MS, GC (FID, ECD), GC/MS, TLC, HPTLC, UV-VIS, DAD, fluorescence, light scattering detection), LC/MS/MS, GC (FID, ECD), GC/MS, TLC, HPTLC, UV-VIS, Spectrophotometry, AAS, fluorescence, light scattering detection), LC/MS/MS, GC (FID, ECD), GC/MS, TLC, HPTLC, UV-VIS, Spectrophotometry, AAS, fluorescence, light scattering detection), LC/MS/MS, GC (FID, ECD), GC/MS, TLC, HPTLC, UV-VIS spectrophotometry, AAS, fluorescence, light scattering detection), LC/MS/MS, GC (FID, ECD), GC/MS, TLC, HPTLC, UV-VIS spectrophotometry, AAS, fluorescence, light scattering detection), LC/MS/MS, GC (FID, ECD), GC/MS, TLC, HPTLC, UV-VIS spectrophotometry, volumetric titrations, amperometry, volumetric titrations, amperometry, potentiometry, nitrogen assay HPLC (UV-Vis, DAD, fluorescence, light scattering detection), LC/MS/MS Microbiological tests Sterility test, microbial purity, test for pyrogens, bacterial endotoxins Microbial assay	ontrol of Vietnam (NIDQC) Hai Ba Trung Street ban Kiem District noi etnam	04-06.12.2014	WHO recommended		viscosity, loss on drying, water content, disintegration, dissolution, uniformity of dosage units (mass, content), friability, tablet hardness, particulate matter	pH, density, refractometry, specific optical rotation, viscosity, loss on drying, melting point, water content, heavy metals, sulphated ash, acid insoluble ash acid value, iodine value, ester value, acetyl value, peroxide value, saponification value
related substancesfluorescence, light scattering detection), LC/MS/MS, GC (FID, ECD), GC/MS, TLC, HPTLC, UV- VIS spectrophotometry, AAS, fluorimetry, volumetric titrations, amperometry, potentiometry, nitrogen assayfluorescence, light scattering detection), LC/MS/MS ECD), GC/MS, TLC, H VIS spectrophotometry, amperometry, potentiometry, nitrogen assayfluorescence, light scattering detection), LC/MS/MS ECD), GC/MS, TLC, H VIS spectrophotometry fluorimetry, volumetric initrogen assay, therm (DSC)Microbiological testsSterility test, microbial purity, test for pyrogens, bacterial endotoxins test (LAL), microbial assayMicrobial assay	nail: npthaodz@yahoo.com.vn nhlienvkn@gmail.com				fluorescence, light scattering detection), LC/MS/MS, GC (FID, ECD), GC/MS, TLC, HPTLC, UV- VIS spectrophotometry, IR, AAS	HPLC (UV-Vis, DAD, fluorescence, light scattering detection), LC/MS/MS, GC (FID, ECD), GC/MS, TLC, HPTLC, UV- VIS spectrophotometry, IR, FTIR AAS, chemical reaction
for pyrogens, bacterial endotoxins test (LAL), microbial assay					fluorescence, light scattering detection), LC/MS/MS, GC (FID, ECD), GC/MS, TLC, HPTLC, UV- VIS spectrophotometry, AAS, fluorimetry, volumetric titrations, amperometry, potentiometry,	fluorescence, light scattering detection), LC/MS/MS, GC (FID, ECD), GC/MS, TLC, HPTLC, UV VIS spectrophotometry, AAS, fluorimetry, volumetric titrations, amperometry, potentiometry, nitrogen assay, thermal analysis
				Microbiological tests	for pyrogens, bacterial endotoxins	
Stability studies WHO conditions WHO conditions				Stability studies	WHO conditions	WHO conditions
						Active pharmaceutical ingredient

Chemical & Materials (Food & Pharmaceutical Testing) 1 Science Park Drive Singapore 118221 Tel: +65 68851313 Fax: +65 67784301 e-mail: Jianhua.lin@tuv-sud-psb.sg	WHO recommended standards	Identification Assay, impurities and related substances	(FID, MS, TCD, ECD), TLC, FTIR, UV-VIS spectrophotometry, optical rotation, basic tests HPLC (UV-Vis, PDA, fluorescence, RI detection), GC (FID, MS, TCD, ECD), FTIR, UV- VIS spectrophotometry, volumetric titrations Determination of related substances/impurities by comparison with reference standards	capacity, iodine value, limit tests HPLC (UV-Vis, PDA, fluorescence, RI detection), GC (FID, MS, TCD), TLC, FTIR, UV- VIS spectrophotometry, optical rotation, basic tests HPLC (UV-Vis, PDA, fluorescence, RI detection), GC (FID, MS, TCD, ECD), FTIR, UV- VIS spectrophotometry, volumetric titrations Determination of related substances and impurities by comparison with reference standards
		Microbiological tests	standards Sterility test, microbial limit tests, bacterial endotoxins test (LAL), preservative challenge test, antimicrobial effectiveness, microbial assay of antibiotics	standards Sterility test, microbial limit tests, bacterial endotoxins test (LAL), preservative challenge test, antimicrobial effectiveness, microbial assay of antibiotics

Version history

Edition	Date	Change
		Updated date of last inspection and address for Laboratory of chemical-pharmaceutical preparations No. 2 and Laboratory of antibiotics of the Federal State Budgetary Institution «Scientific Centre for Expert Evaluation of Medicinal Products», SCEEMP, Russian Federation.
42 nd Edition	22.12.2016	Removal of Getz Pharma Pvt Ltd from list following voluntary withdrawal.
42 Edition	22.12.2010	Removal of Centro Nacional de Control de Calidad (CNCC) - Instituto Nacional de Salud, Peru from list following voluntary withdrawal.
		Added University of Liege, Faculty of Medicine, Department of Pharmacy, Liege, Belgium
		Added Health Concepts International Ltd, Pathumthani, Thailand
		Change of the name of Centre Humanitaire Médico-Pharmaceutique to Pharmacie et Aide Humanitaire - Centre Humanitaire Médico-Pharmaceutique (PAH-CHMP) to Centre Humanitaire des Métiers de la Pharmacie (CHMP).
41 st Edition	41 st Edition 14.07.2016	Updated date of last inspection for Central Laboratory for Quality Control of Medicines and Medical Products (CLQCM), Ukraine.
		Updated date of last inspection for Laboratory of Pharmaceutical Analysis (LPA), Ukraine.
40 th edition	16.06.2016	Added Agency for Medicinal Products and Medical Devices (HALMED), Official Medicines Control Laboratory (OMCL), Zagreb, Croatia
		Added Food and Drugs Control Reference Laboratories (FDCRL), Food & Drugs Administration, Ministry of Health and Medical Education, Tehran, Islamic Republic of Iran.
39 th edition	11.03.2016	Updated dates of last inspection for Laboratory of chemical-pharmaceutical preparations No. 2 and Laboratory of antibiotics of the Federal State Budgetary Institution «Scientific Centre for Expert Evaluation of Medicinal Products», Ministry of Health of the Russian Federation; TÜV SÜD PSB Pte Ltd, Chemical & Materials (Food & Pharmaceutical Testing), Singapore; National Institute of Drug Quality Control of Vietnam (NIDQC), Hanoi, Vietnam
38 th edition	03.02.2016	Added State Scientific Research Laboratory on Quality Control of Medicines, Kiev, Ukraine Updated dates of last inspections for Laboratory of the Mission for Essential Drugs and Supplies - (MEDS), Kenya and National Quality Control laboratory (NQCL), Kenya

37 th edition	19.11.2015	Added Medicines Control Laboratory (SCM-DGO)m Stevinstraat 137, 1000 Brussels, Belgium Date of last inspection Bureau of Drug and Narcotic (BDN), Department of Medical Sciences, Ministry of Public Health (Thailand) and INFARMED I.P. Direcção da Comprovação da Qualidade (DCQ), Lisboa, Portugal.
36 th edition	15.05.2015	Added Indian Pharmacopoiea Commission - Indian Pharmacopoeial Laboratory – Ghaziabad, India Updated dates of last inspections of Research Institute for Industrial Pharmacy (RIIP) incorporating CENQAM, South Africa; SGS Lab Simon S. A., Wavre, Belgium;
35 th edition	22.01.2015	Added National Drug Authority – National Drug Quality Control Laboratory (NDA-NDQCL) – Uganda Updated dates of last inspections of Laboratoire National de Contrôle des Médicaments (LNCM), Morocco. Change in the scope of areas of expertise for Laboratoire National de Contrôle des Médicaments (LNCM), Morocco
		Added Intertek (Schweiz) AG, Switzerland
34 th edition	27.10. 2014	Microbiological testing added to the area of expertise of Laboratorio de Control de Calidad de Medicamentos y Toxicologia (CONCAMYT) Bolivia
		Updated dates of last inspections of Laboratorio de Control de Calidad de Medicamentos y Toxicologia (CONCAMYT) Bolivia and Laboratoire National de Contrôle des Produits Pharmaceutiques (LNCPP) Algeria
33 rd edition	23.9.2014	Added Synergy Health Utrecht B.V., Pharmaceutical Laboratories (SHPL), The Netherlands
		Added Medicines Control Authority of Zimbabwe (MCAZ) Quality Control Laboratory (Zimbabwe)
32 nd edition	19.9.2014	Updated dates of last inspections of Tanzania Food and Drugs Authority (TFDA) Quality Control Laboratory (Tanzania), K.A.B.S. Laboratories Inc. (Canada) and Republican Control and Analytical Laboratory of the Centre for Expertise and Testing in Health Care (Belarus)
		Updated contact details of National Institutes for Food and Drug Control (NIFDC) - Divisions of Chemical Drugs, Antibiotics, Narcotic Drugs and Pharmacology of the Institute for Chemical Drug Control, China and Centro Nacional de Control de Calidad (CNCC) - Instituto Nacional de Salud, Peru
ot		Added InphA GmbH - Institute for Pharmaceutical and Applied Analytics, Germany
31 st edition	01.04.2014	Updated dates of last inspections of SGS India Pvt. Ltd. (Life Science Services)
		Added Rostov-on-Don Branch of Federal State Budgetary Institution "Information and Methodological Center for Expertise, Stocktaking and Analysis of Circulation of Medical products" of the Federal Service on Surveillance in Healthcare, Russian Federation and Instituto Nacional de Controle de Qualidade em Saúde (INCQS), Brazil
30 th edition 11.03.2014	11.03.2014	Updated dates of last inspections of National Institutes for Food and Drug Control (NIFDC) - Divisions of Chemical Drugs, Antibiotics, Narcotic Drugs and Pharmacology of the Institute for Chemical Drug Control (China) and Proxy Laboratories B.V. (The Netherlands)
		Change of the name of Centre Humanitaire Médico-Pharmaceutique to Pharmacie et Aide Humanitaire - Centre Humanitaire Médico-Pharmaceutique (PAH-CHMP) and updated date of its last inspection
29 th edition	17.02.2014	Added Getz Pharma Pvt Ltd – Quality Control Laboratory, Pakistan Updated dates of the last inspection of Vimta Labs India

		Added Stabicon Life Sciences Pvt Ltd, India
28 th edition	09.12.2013	Updated dates of last inspections of Comisión para el Control de Calidad de Medicamentos (CCCM), Uruguay; Centro Nacional de Control de Calidad (CNCC) - Instituto Nacional de Salud, Peru
		Added Comisión de Control Analítico y Ampliación de Cobertura (CCAYAC), Mexico
		Updated date of last inspection of K.A.B.S. Laboratories Inc., Canada
		Stability studies added to the area of expertise of National Institute of Drug Quality Control of Vietnam
27 th edition	13.11.2013	Change of the name of Federal State Budgetary Institution «Scientific Centre for Expert Evaluation of Medicinal Products», Ministry of Health and Social Development of the Russian Federation and update of contact details
		Updated contact details of Centro Nacional de Control de Calidad (CNCC) Peru; National Quality Control Laboratory (NQCL) Kenya, Adcock Ingram South Africa, Bureau of Drud and Narcotic (BDN) Thailand
		Added Laboratorios Basi - Industria Farmaceutica, S.A., Quality Control Unit (Portugal)
26 th edition	10.00.0040	Change of the name of Laboratory of Pharmaceutical Analysis, State Pharmacological Centre, Ukraine Change of the name of Central Laboratory for Quality Control of Medicines and Medical Products, State Inspection for Quality Control of Medicines
26 eation	edition 12.06.2013	Updated dates of last inspections of INFARMED I.P. Direcção da Comprovação da Qualidade, Portugal; Laboratory of Pharmaceutical Analysis, State Expert Centre, Ukraine; Central Laboratory for Quality Control of Medicines and Medical Products SE, State Drug Administration of Ukraine; National Institute of Drug Quality Control of Vietnam, Vietnam and Laboratory of the Mission for Essential Drugs and Supplies - MEDS
25 th edition	20.11.2012	Added National Institutes for Food and Drug Control (NIFDC) - Divisions of Chemical Drugs, Antibiotics, Narcotic Drugs and Pharmacology of the Institute for Chemical Drug Control (China) Contact details of TÜV SÜD PSB Pte Ltd, Singapore updated
24 th edition	02.11.2012	Added Bureau of Drug and Narcotic (BDN), Department of Medical Sciences, Ministry of Public Health (Thailand) Date of last inspection of TÜV SÜD PSB Pte Ltd updated and stability studies added to the area of expertise
23 rd edition	21.06.2012	Added Republican Control and Analytical Laboratory of the Centre for Expertise and Testing in Health Care (Belarus)
22 nd edition	21.05.2012	Added Laboratory of chemical-pharmaceutical preparations No. 2 and Laboratory of antibiotics of the Federal State Budgetary Institution «Scientific Centre for Expert Evaluation of Medicinal Products», Ministry of Health and Social Development of the Russian Federation
		Date of last inspection of RIIP incorporating CENQAM, South Africa updated
		Pharmaceutical Laboratory of the Health Sciences Authority - Applied Sciences Group - Pharmaceutical Division withdrawn from the list on its request
21 st edition	st edition 26.04.2012	Date of last inspection of NQCL Kenya and LNCM Morocco updated
		Contact details of MEDS Kenya, NQCL Kenya, CHMP France, Laboratory of Pharmaceutical Analysis Ukraine and NIDQC Vietnam updated
20 th edition	20.10.2011	Date of last inspection of K.A.B.S. Laboratories Inc., Canada updated
	20.10.2011	Added Ezequiel Dias Foundation, Institute Octavio Magalhães, Medicines Service of Public Health Central Laboratory

		(Brazil)
19 th edition	31.08.2011	Date of last inspection of Adcock Ingram Limited - Research and Development, South Africa updated Added Proxy Laboratories B.V. (The Netherlands) and INFARMED I.P. Direcção da Comprovação da Qualidade (Portugal)
18 th edition	31.05.2011	Date of the last inspection of Vimta Labs Limited (India) updated Added SGS Lab Simon S.A. (Belgium)
17 th edition	17.01.2011	Date of the last inspection of Laboratoire National de Contrôle des Produits Pharmaceutiques, LNCPP (Algérie) updated Added SGS India Pvt. Ltd. (Life Science Services), India and Tanzania Food and Drugs Authority (TFDA) Quality Control Laboratory, Tanzania
16 th edition	16.09.2010	Added Centro Nacional de Control de Calidad (CNCC) Peru, Comisión para el Control de Calidad de Medicamentos (CCCM) Uruguay and Laboratorio de Control de Calidad de Medicamentos y Toxicologia (CONCAMYT) Bolivia Contact details of Adcock Ingram South Africa and TÜV SÜD PSB Pte Ltd Singapore updated
15 th edition	16.04.2010	Added Central Laboratory for Quality Control of Medicines and Medical Products, Ukraine and Laboratory of Pharmaceutical Analysis, Ukraine Contact details of Adcock Ingram South Africa, LNCM Morocco and LNCPP Algeria updated
14 th edition	10.02.2010	Added K.A.B.S. Laboratories Inc., Canada
13 th edition	21.08.2009	Added TÜV SÜD PSB Pte Ltd, Chemical & Materials (Food & Pharmaceutical Testing), Singapore
12 th edition	25.06.2009	Added Pharmaceutical Laboratory of the Health Sciences Authority, Applied Sciences Group, Pharmaceutical Division - HSA (Singapore)
11 th edition	23.03.2009	Added Laboratory of Mission for Essential Drugs and Supplies - MEDS (Kenya)
10 th edition	28.11.2008	Added National institute of Drug Quality Control - NIDQC (Vietnam)
9 th edition	28.10.2008	Added Centre Humanitaire Médico-Pharmaceutique - CHMP (France)
8 th edition	17.07.2008	Added Laboratoire National de Contrôle des Médicaments - LNCM (Maroc), National Quality Control laboratory - NQCL (Kenya) and Vimta Labs Limited (India)
7 th edition	16.05.2008	Change reflecting the merger of RIIP and CENQAM into one organization with a single quality system
6 th edition	15.01.2008	Added Adcock Ingram Limited - Research and Development (South Africa)
5 th edition	09.01.2007	Added point 12.; 13. and 14. to General Notes
4 th edition	14.11.2006	Added the background and current status of the Programme and the general notes and the disclaimer
3 rd edition	27.10.2005	Added Laboratoire National de Contrôle des Produits Pharmaceutiques - LNCPP (Algérie)
2 nd edition	05.07.2005	Added Research Institute for Industrial Pharmacy - RIIP (South Africa)
1 st edition	22.06.2005	Added Centre for Quality Assurance of Medicines - CENQAM (South Africa)

General Notes:

- This list is updated regularly. Quality control laboratories are added to the list when found to meet the norms and standards recommended by WHO. Inclusion in the list does not, however, imply any approval by WHO of the laboratories (which is the sole prerogative of national authorities).
- WHO cannot represent that the listed laboratories will continue to meet the above-mentioned standards. WHO may suspend or remove a laboratory from the list if it is found that it no longer meets the standards recommended by WHO.
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- The list may not be used by laboratories for commercial or promotional purposes.

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- There should be an agreement between the organization (contract giver) and the prequalified laboratory (contract acceptor) indicating the responsibilities of both parties.
- Laboratories should ensure that the testing of products would not be in breach of their national legislation including patent restrictions.
- Laboratories should declare any possible conflict of interest in testing product samples prior to agreeing to perform work on behalf of the contract giver.

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