

## WHO List of Prequalified Quality Control Laboratories

**Date: 10 December 2019**

- This list contains **fifty-one (51)** 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 **48<sup>th</sup> 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 <sup>1</sup>	Final outcome	Date of pre-qualification	The area of expertise inspected and considered prequalified		
<b>WHO African Region</b>						
<b>Adcock Ingram Limited - Research and Development</b> 1 Sabax Road, Aeroton Johannesburg, 2013 South-Africa  Postal address: Private Bag X69 Bryanston, 2021 South-Africa  Tel: + 27 11 494 8135 e-mail: Palka.Parbhoo@adcock.com	08-09.12.2016	Compliant with WHO recommended standards	15.1.2008	<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
				Physical/Chemical analysis	pH, water content, loss on drying, friability, disintegration time, tablet hardness, dissolution, AA, viscosity, density, dimensions	pH, water content, melting point, loss on drying, refractometry
				Identification	IR, TLC, HPLC, AA, spectrophotometry and basic tests	IR, TLC, HPLC, spectrophotometry and basic tests
				Assay, impurities and related substances	HPLC (UV-VIS, DAD, RI detection), GC, UV, AA and FTIR spectrophotometry and volumetric titrations Determination of related substances and impurities by comparison with a reference standard	HPLC (UV-VIS, DAD, RI detection), GC, UV, AA and FTIR spectrophotometry, polarimetry and volumetric titrations Determination of related substances and impurities by comparison with a reference standard
				Stability studies	ICH conditions	
<b>Laboratoire National de Contrôle des Produits Pharmaceutiques, LNCPP (Algérie)</b> lot Geraud, petit Staoueli, Dely Ibrahim (Site du Nouvel Institut Pasteur) Algiers Algérie  Tel: +213 21 371576; +213 21 372668 Fax: +213 21 37 32 42; +213 21 37 52 53 e-mail: lncpp@sante.dz; lncpp@hotmail.com	23-24.4.2014	Compliant with WHO recommended standards	27.10.2005	<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
				Physical/Chemical analysis	pH, water content, friability, disintegration time of tablets and suppositories, tablet hardness, dissolution, AA	
				Identification	TLC, HPLC and spectrophotometry	
				Assay, impurities and related substances	HPLC (UV- DAD, RI detection), GC, spectrophotometry and volumetric titrations Determination of related substances and impurities by comparison with a reference standard	
<b>Laboratory of the Mission for Essential Drugs and Supplies - (MEDS)</b>	22-23.6.2015	Compliant with WHO	23.3.2009	<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
				Physical/Chemical analysis	pH, loss on drying, water content, conductivity, refractometry, friability, disintegration,	pH, loss on drying, water content, conductivity, refractometry, density

<sup>1</sup> 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		recommended standards			dissolution, density, uniformity of dosage units (mass, content)	
				Identification	HPLC (UV-VIS detection), GC, UV-VIS spectrophotometry, TLC, chemical reaction	HPLC (UV-VIS detection), GC, UV-VIS spectrophotometry, TLC, chemical reaction
				Assay, impurities and related substances	HPLC (UV-VIS detection), GC, UV-VIS spectrophotometry, volumetric titrations, polarimetry Determination of related substances/impurities and degradation products	HPLC (UV-VIS detection), GC, UV-VIS spectrophotometry, volumetric titrations, polarimetry Determination of related substances/impurities and degradation products
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>M&amp;L Laboratory Services (Pty) Ltd</b> 40 Modulus Road, Ormonde, Johannesburg, South Africa, 2091  Tel: +2711 661 7900 Fax: +27 11 496 2239 e-mail: milly.vandayar@za.bureauveritas.com	12-13.12.2016	Compliant with WHO recommended standards	18.7.2017	Physical/Chemical analysis	pH, water content, loss on drying, water content (Karl fisher), friability, disintegration, tablet hardness, dissolutions, viscosity, density.	pH, water content, loss on drying, water content (Karl fisher), melting point, conductivity.
				Identification	IR, TLC, HPLC, UV, spectrophotometry and basic tests.	IR, TLC, HPLC, UV spectrophotometry and basic tests.
				Assay, impurities and related substances	HPLC (UV, fluorescence, RI, conductivity, PDA), UPLC (PDA), GC, UV, potentiometric and volumetric titrations Determination of related substances/impurities and degradation products.	HPLC (UV, fluorescence, RI, conductivity, PDA), UPLC (PDA), GC, UV, potentiometric and volumetric titrations Determination of related substances/impurities and degradation products.
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>Medicines Control Authority of Zimbabwe (MCAZ) Quality Control Laboratory</b> 106 Baines Avenue PO Box 10559 Harare Zimbabwe  Tel. +263 4 736981-5 /708255 /792165 Cell: +263 772145191/3 e-mail: mcaz@mcaz.co.zw; gnmahlangu@mcaz.co.zw	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
				Identification	HPLC (UV-VIS detection), UV-VIS spectrophotometry, basic tests	HPLC (UV-VIS detection), UV-VIS spectrophotometry, basic tests
				Assay, impurities and related substances	HPLC (UV-VIS detection), UV-VIS spectrophotometry, volumetric titrations	HPLC (UV-VIS detection), UV-VIS spectrophotometry, volumetric titrations
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
	4-5.9.2014	Compliant with WHO	16.1.2015	Physical/Chemical analysis	pH, loss on drying, water content, density, friability, dissolution,	pH, loss on drying, water content, density, melting point

<b>National Drug Authority – National Drug Quality Control Laboratory (NDA-NDQCL) – Uganda</b> Mulago Hill P.O. Box 23096 Kampala Uganda  Tel.: +256 414 540067 e-mail: <a href="mailto:laboratory@nda.or.ug">laboratory@nda.or.ug</a>		recommended standards			uniformity of dosage units (mass, content)	
				Identification	IR, HPLC (UV-VIS detection), UV-VIS spectrophotometry	FTIR, HPLC (UV-VIS detection), UV-VIS spectrophotometry
				Assay, impurities and related substances	HPLC (UV-VIS detection), UV-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
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>National Quality Control laboratory (NQCL)</b> Hospital Road - KNH Complex 00202 -KNH, Nairobi Kenya  Postal address: P.O. Box 29726 00202 -KNH, Nairobi Kenya  Tel. +254 20 3544525/30 Fax: +254 20 2718073 e-mail: <a href="mailto:hchepkwony@nqcl.go.ke">hchepkwony@nqcl.go.ke</a>	24-25.6.2015	Compliant with WHO recommended standards	17.7.2008	Physical/Chemical analysis	pH, loss on drying, water content, friability, disintegration, dissolution, density	pH, loss on drying, water content, density, melting point
				Identification	FTIR, HPLC (UV-VIS detection), AAS, UV-VIS spectrophotometry	FTIR, HPLC (UV-VIS detection), AAS, UV-VIS spectrophotometry
				Assay, impurities and related substances	HPLC (UV-VIS detection), UV-VIS spectrophotometry, AAS, volumetric titrations, polarimetry Determination of related substances/impurities and degradation products	HPLC (UV-VIS detection), UV-VIS spectrophotometry, AAS, volumetric titrations, polarimetry Determination of related substances/impurities and degradation products
				Microbiological tests	Sterility test, microbial purity, bacterial endotoxins test (LAL), microbial assay	Microbial purity, microbial assay
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>Research Institute for Industrial Pharmacy (RIIP) incorporating CENQAM</b> North-West University Potchefstroom Campus Hoffman Street Potchefstroom 2531 South Africa  Postal address: P/Bag X6001 Potchefstroom 2520 South Africa	1-2.9.2014	Compliant with WHO recommended standards	CENQAM: 22.6.2005 RIIP: 5.7.2005  16.5.2008 - Change reflecting the merger of RIIP and CENQAM into one organization	Physical/Chemical analysis	pH, water content (Karl Fischer), loss on drying, friability, disintegration, tablet hardness, uniformity of dosage units (mass, content), tablet dimensions, dissolution, AA, viscosity, density/specific gravity, redispersibility/ reconstitution time, resuspendability and sedimentation rate	pH, water content (Karl Fischer), loss on drying, X-ray diffractometry, thermal analysis (DSC, TGA)
				Identification	IR, TLC, HPLC, spectrophotometry and basic tests	IR, TLC, HPLC, spectrophotometry and basic tests

Tel: + 27 18 299 2268 Fax: + 27 18 299 2291 e-mail: Erna.Swanepoel@nwu.ac.za			with a single quality system	Assay, impurities and related substances	HPLC (fluorescence, UV, UV-Vis, DAD, RI detection), GC, spectrophotometry and volumetric titrations Determination of related substances/impurities and degradation products	HPLC (fluorescence, UV, UV-Vis, DAD, RI detection), GC, spectrophotometry and volumetric titrations Determination of related substances/impurities, degradation products and residual solvents
				Stability studies	WHO conditions	WHO conditions
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
Tanzania Food and Drugs Authority (TFDA) Quality Control Laboratory Mandela Road, Mabibo, External P.O. Box 77150 Dar es Salaam Tanzania  Tel: +255 22 2450512 / 2450751 Fax: +255 22 2450793 e-mail: dls@tfda.or.tz info@tfda.or.tz	23-24.1.2014	Compliant with WHO recommended standards	17.1.2011	Physical/Chemical analysis	pH, melting point, optical rotation, conductivity, friability, tablet hardness, disintegration, dissolution, uniformity of dosage units	pH, melting point, optical rotation, conductivity
				Identification	HPLC (UV-VIS, PDA detection), TLC, AAS, UV-VIS spectrophotometry	HPLC (UV-VIS, PDA detection), TLC, AAS, UV-VIS spectrophotometry
				Assay, impurities and related substances	HPLC (UV-VIS, PDA detection), TLC, AAS, UV-VIS spectrophotometry, polarimetry, volumetric titrations	HPLC (UV-VIS, PDA detection), TLC, AAS, UV-VIS spectrophotometry, polarimetry, volumetric titrations
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
United States Pharmacopoeia – Ghana No. 3, Park Avenue, Motorway Extension, North Dzowulu, Accra, Ghana  Tel: +233(0)30 221 6888; +233(0)221 6874 e-mail: cepat@usp.org	11-13.6.2017	Compliant with WHO recommended standards	16.4.2018	Physical/Chemical analysis	pH, Loss on drying, Water content (Karl Fischer), Disintegration, Dissolution, Uniformity of dosage units (by mass or content)	pH, Loss on drying, sulphated ash, Acid insoluble ash, Water content (Karl Fischer), Residual solvents, Limit tests
				Identification	HPLC (UV-Vis, Fluorescence and Refractive index detection), GC with headspace (FID, TCD), UV-Vis spectrophotometry, FT-IR, Basic tests	HPLC (UV-Vis, Fluorescence and Refractive index detection), GC with headspace (FID, TCD), UV-Vis spectrophotometry, FT-IR, Basic tests
				Assay, impurities and related substances	HPLC (UV-Vis, Fluorescence and Refractive index detection), GC with headspace (FID, TCD), UV-Vis spectrophotometry, Volumetric titrations, Potentiometric titrations	HPLC (UV-Vis, Fluorescence and Refractive index detection), GC with headspace (FID, TCD), UV-Vis spectrophotometry, Volumetric titrations, Potentiometric titrations.
<b>WHO Region of the Americas</b>						
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
Comisión de Control Analítico y Ampliación de Cobertura (CCAYAC)	19-22.4.2013	Compliant with WHO	13.11.2013	Physical/Chemical analysis	pH, water content (Karl Fischer), loss on drying, dissolution,	pH, water content, loss on drying

<p>Calzada de Tlalpan No. 4492 Colonia Toriello Guerra Delegación Tlalpan C.P.14050 México, D. F. Mexico</p> <p>Tel: +5255 5080 5200, ext 2000 e-mail: faarguelles@cofepris.gob.mx</p>		recommended standards			uniformity of dosage units (mass, content)	
				Identification	HPLC (UV-VIS, DAD, fluorescence detection), TLC, UV-VIS spectrophotometry, FTIR	HPLC (UV-VIS, DAD, fluorescence, detection), TLC, UV-VIS spectrophotometry, FTIR
				Assay, impurities and related substances	HPLC (UV-VIS, DAD, fluorescence detection), TLC, UV-VIS spectrophotometry, FTIR, AAS/AES, volumetric titrations	HPLC (UV-Vis, DAD fluorescence detection), TLC, UV-VIS spectrophotometry, volumetric titrations
				Microbiological tests	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
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<p><b>Comisión para el Control de Calidad de Medicamentos (CCCM)</b> Br. Artigas 3223 Montevideo 11800 Uruguay</p> <p>Tel: +598 2209 4014 Fax: +598 2208 5673 e-mail: bluna@msp.gub.uy mhirschhorn@msp.gub.uy cccm@msp.gub.uy</p>	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
				Identification	HPLC (UV-VIS, DAD, fluorescence, RI detection), TLC, UV-VIS spectrophotometry, FTIR, AAS/EA, basic tests	HPLC (UV-VIS, DAD, fluorescence, RI detection), TLC, spectroscopy (UV-VIS, FTIR, AA/EA), basic tests
				Assay, impurities and related substances	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	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
				Microbiological tests	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
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<p><b>Ezequiel Dias Foundation (FUNED) Institute Octavio Magalhães Medicines Service of Public Health Central Laboratory</b> Conde Pereira Carneiro street 80 Gameleira neighbourhood Belo Horizonte Minas Gerais 30510-010 Brazil</p>	9-11.4.2018	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
				Identification	HPLC (UV-VIS, DAD, fluorescence detection), TLC, UV-VIS spectrophotometry, FTIR, basic tests	HPLC (UV-VIS, DAD, fluorescence detection), GC/MS, TLC, UV-VIS spectrophotometry, FTIR, basic tests
				Assay, impurities and related substances	HPLC (UV-VIS, DAD, fluorescence detection), TLC, UV-VIS spectrophotometry, FTIR,	HPLC (UV-VIS, DAD, fluorescence detection), TLC, UV-VIS spectrophotometry, FTIR,

Fax: +55 31 3314-4653 e-mail: dpgq@funed.mg.gov.br medicamentos@funed.mg.gov.br					volumetric titrations, potentiometry; Determination of related substances/ impurities, degradations products	volumetric titrations, potentiometry, Determination of related substances/ impurities, degradations products
				Microbiological tests	Sterility test, microbial limit tests, bacterial endotoxins test (LAL)	Sterility test, microbial limit tests, bacterial endotoxins test (LAL)
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>Instituto Nacional de Controle de Qualidade em Saúde (INCQS)</b> Av. Brasil no 4362 Manguinhos, CEP 21040-900 Rio de Janeiro Brazil  Tel.: +55 21 3865 5151; +55 21 3865 5104 Fax: +55 21 2290 0915 e-mail: incqs@incqs.fiocruz.br; vdquali@incqs.fiocruz.br vera.machado@incqs.fiocruz.br	19-24.4.2018	Compliant with WHO recommended standards	11.3.2014	Physical/Chemical analysis	pH, density, optical rotation, disintegration, dissolution, uniformity of dosage units (mass, content)	
				Identification	HPLC (UV-Vis, PDA detection), TLC, UV-VIS spectrophotometry, IR, basic tests	
				Assay, impurities and related substances	HPLC (UV-Vis, PDA detection)	
				Microbiological tests	Sterility test, microbial limit tests, bacterial endotoxins test (LAL), microbial assay of antibiotics	
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>K.A.B.S. Laboratories Inc.<sup>2</sup></b> 4500 De Tonnancour St-Hubert, Quebec J3Y 9G2, Canada  Tel.: +1 450 656 4404 Fax.: +1 450 656 4402 e-mail: kabsafric@kabs.com	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 test	pH, density, refractometry, specific optical rotation, viscosity, osmolarity, loss on drying, melting point, water content, heavy metals, acid value, iodine value, limit tests
				Identification	HPLC (UV-Vis, RI, conductivity detection), LC/MS, GC (FID, TCD), TLC, capillary electrophoresis, UV-Vis spectrophotometry, FTIR, AAS	HPLC (UV-Vis, RI, conductivity detection), LC/MS, GC (FID, TCD), TLC, capillary electrophoresis, UV-VIS spectrophotometry, FTIR, AAS, chemical reaction
				Assay, impurities and related substances	HPLC (UV-Vis, RI, conductivity 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

<sup>2</sup> 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.



<b>Laboratorio de Control de Calidad de Medicamentos y Toxicología (CONCAMYT)</b> Calle Rafael Zubieta No. 1889 Zona de Miraflores La Paz Bolivia  Tel: +591 2 2226670 e-mail: garnicalopez@yahoo.es	13-15.8.2013	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)	
				Identification	HPLC (UV-VIS, PDA, fluorescence detection), TLC, UV-VIS spectrophotometry, IR, basic tests	
				Assay, impurities and related substances	HPLC (UV-VIS, PDA, fluorescence detection), UV-VIS spectrophotometry, IR, volumetric titrations, polarimetry	
				Microbiological tests	Sterility test, microbial limit tests, microbial assay of antibiotics	
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>The Drug Service of the Public Laboratory Dr Giovanni Cysneiros (LACEN-GO)</b>  Av Contorno No 3556, Jardim Bela Vista, Goiania, Goias, 74853-120, Brazil Tel: +55 62 32013885 +55 62 32013890 +55 62 32019633  e-mail: rosa.msantos@saude.go.gov.br lacen.dirgeral@saude.go.gov.br	13 to 17 April 2018	Compliant with WHO recommended standards	26.7.2018	Physical/Chemical analysis	pH, water content, loss on drying, dissolution, friability, uniformity of dosage units (mass, content).	n/a
				Identification	FTIR, TLC, HPLC (UV-Vis, DAD, fluorescence detection), UV-Vis spectrophotometry, basic tests.	n/a
				Assay, impurities and related substances	HPLC (UV-Vis, DAD, fluorescence detection), TLC, UV-Vis spectrophotometry, FTIR, Volumetric and potentiometry. Titrations.	n/a
				Microbiological tests	Microbial limit tests	n/a
<b>WHO South-East Asia Region</b>						
<b>Bureau of Drug and Narcotic (BDN) Department of Medical Sciences Ministry of Public Health</b> 88/7 Tiwanond Road Muang Nonthaburi 11000 Thailand	3.11-4.11.2014	Compliant with WHO recommended standards	02.11.2012	<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
				Physical/Chemical analysis	pH, viscosity, loss on drying, 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
				Identification	HPLC (UV-Vis detection), LC/MS, GC (FID), TLC, UV-Vis	HPLC (UV-Vis detection), LC/MS, GC (FID), TLC, UV-Vis



Tel: + 66 2580 4074 or +66 2951 0000 ext. 99122 or 99179 Fax: +66 2580 5733 e-mail: suratchanee.s@dmsc.mail.go.th boontarika.b@dmsc.mail.go.th					spectrophotometry, FTIR, basic tests  Assay, impurities and related substances HPLC (UV-Vis), GC (FID), TLC, UV-Vis spectrophotometry, AAS, fluorimetry, polarimetry, potentiometry	spectrophotometry, FTIR, basic tests  HPLC (UV-Vis), GC (FID), TLC, UV-Vis spectrophotometry, AAS, fluorimetry, polarimetry, potentiometry
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>SGS India Pvt. Ltd. (Life Science Services)</b> 2nd Floor, TICEL Bio Park Ltd. Tharamani Road, Tharamani Chennai - 600113 Tamil Nadu India  Tel. +91 44 2254 2601/2602 Fax: +91 44 2254 2600 e-mail: in.lifeqc@sgs.com	28-31.10.2016	Compliant with WHO recommended standards	17.1.2011	Physical/Chemical analysis pH, refractive index, optical rotation, viscosity, water content, conductivity, density, residual solvents, limit tests, tablet hardness, friability, disintegration, dissolution, uniformity of dosage units (mass, content)	pH, refractive index, optical rotation, viscosity, melting point, loss on drying, heavy metals, sulphated ash, water content, conductivity, residual solvents, limit tests	pH, refractive index, optical rotation, viscosity, melting point, loss on drying, heavy metals, sulphated ash, water content, conductivity, residual solvents, limit tests
				Identification	HPLC (UV-Vis, PDA, RI, 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
				Assay, impurities and related substances	HPLC (UV-Vis, PDA, RI, 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
				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
				Stability studies	ICH conditions	ICH conditions
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>Stabicon Life Sciences Pvt Ltd</b> Plot No. 28, Bommasandra Industrial Area (Sub-layout), 4th Phase Jigani Hobli, Anekal Taluk Bangalore 560 100, India  Tel. +9180 27839259/60 e-mail: vijay.ranka@stabicon.com	10-12.9.2013	Compliant with WHO recommended standards	9.12.2013	Physical/Chemical analysis pH, loss on drying, water content (Karl Fischer), friability, disintegration, dissolution, density, tablet hardness, uniformity of dosage units (mass, content)	pH, loss on drying, water content (Karl Fischer), heavy metals, limit tests	pH, loss on drying, water content (Karl Fischer), heavy metals, limit tests
				Identification	TLC, HPLC (UV-VIS, DAD, RI), GC (FID), UV-VIS spectrophotometry, basic tests	TLC, HPLC (UV-VIS, DAD, RI), GC (FID), UV-VIS spectrophotometry, basic tests
				Assay, impurities and related substances	HPLC (UV-VIS, DAD, RI detection), GC (FID), TLC, UV-VIS spectrophotometry, volumetric titrations	HPLC (UV-VIS, DAD, RI detection), GC (FID), TLC, UV-VIS spectrophotometry, volumetric titrations

					Determination of related substances/impurities, degradation products and residual solvents	Determination of related substances/impurities, degradation products
				Microbiological tests	Microbial limit tests, preservative efficacy test, microbial assay of antibiotics	Microbial limit tests, preservative efficacy test, microbial assay of antibiotics
				Stability studies	ICH conditions	ICH conditions
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>Vimta Labs Limited</b> Life Sciences Facility Plot No.5, S.P.Biotech Park Genome Valley Hyderabad 500078, India  Tel. +91 40 3984 84 84 (Extn: 2101) Fax: +91 40 3984 77 76 e-mail: anu@vimta.com	21-23.8.2013	Compliant with WHO recommended standards	17.7.2008	Physical/Chemical analysis	pH, loss on drying, water content, 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
				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
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>Indian Pharmacopoeia Commission - Indian Pharmacopoeial Laboratory,</b> Ministry of Health & Family Welfare, Sector 23, Raj Nagar, Ghaziabad, Uttar Pradesh, 201002, India  Tel.: +91 120 2783392 e-mail: ipclab@vsnl.net	9-11.10.2014	Compliant with WHO recommended standards		Physical/Chemical analysis	pH, loss on drying, water content, density, friability, dissolution, uniformity of dosage units (mass, content)	pH, loss on drying, water content, density, melting point, thermal analysis (DSC) and optical rotation
				Identification	IR, HPLC (UV-VIS detection), UV-VIS spectrophotometry, LC-MS, NMR, AAS, CHNSO analysis	FTIR, HPLC (UV-VIS detection), UV-VIS spectrophotometry, NMR, AAS, CHNSO analysis
				Assay, impurities and related substances	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
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>Health Concepts International Ltd</b> 113 Thailand Science Park, Paholyothin Rd., Klong 1, Klong Luang, Pathumthani Thailand 12120  <b>Email:</b> lester.chinery@conceptfoundation.org  <b>Tel.:</b> +66 2564 8009/11 <b>Fax:</b> +66 2564 8012	7-8.3.2016	Compliant with WHO recommended standards	14.7.2016	Physical/Chemical analysis	pH, dissolution, uniformity of dosage units.	pH
				Identification	HPLC, UV-VIS Spectrophotometer.	HPLC, UV-VIS Spectrophotometer.
				Assay, impurities and related substances	HPLC (UV-VIS, DAD detection), UV-VIS spectrophotometer, determination of related substances and impurities by comparison with reference standards.	HPLC (UV-VIS, DAD detection), UV-VIS Spectrophotometer, Determination of related substances and impurities by comparison with reference standards.
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>National Quality Control Laboratory for Drugs and Foods (NQCLDF)</b> Building 1, Third Floor of PPPOMN, Jalan Percetakan Negara 23, Jakarta Pusat, 10560 Indonesia  Tel: +62 21 4245075 ext. 1303 Fax: +62 21 4201427 e-mail: produkterapetik@yahoo.co.id	18-20.2.2019	Compliant with WHO recommended standards	10.12.2019	Physical/Chemical analysis	pH, water content (Karl Fischer), loss on drying, density, dissolution, uniformity of dosage units (mass, content).	n/a
				Identification	HPLC (UV-VIS, PDA, fluorescence detector), UV-VIS spectrophotometry, FTIR, and basic tests.	n/a
				Assay, impurities and related substances	HPLC (UV-VIS, Fluorescence detector), GC-FID, volumetric and potentiometric titrations.	n/a
<b>WHO European Region</b>						
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>Agency for Medicinal Products and Medical Devices (HALMED),</b> Official Medicines Control Laboratory (OMCL),	20-22 July 2015	Compliant with WHO recommended standards	16.06.2016	Physical/Chemical analysis	Appearance, clarity and degree of opalescence of liquids, degree of coloration of liquids, test for extractable volume of parenteral solution, potentiometric determination of pH, conductivity,	Appearance, clarity and degree of opalescence of liquids, degree of coloration of liquids, test for extractable volume of parenteral solution, potentiometric determination of pH, conductivity,

<p>Ksaverska cesta 4, 10000 Zagreb, Croatia</p> <p><b>Email:</b> rajka.truban@halmed.hr</p> <p><b>Tel.:</b> +3851 4884 202</p>					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.	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.
				Identification	TLC, GC, UV-Vis, FTIR, NIR	TLC, GC, UV-Vis, FTIR, NIR
				Assay, impurities and related substances	HPLC, TLC (semiquantitative), GC, UV-Vis, Optical rotation.	HPLC, TLC (semiquantitative), GC, UV-Vis, Optical rotation.
				Microbiological tests	Sterility, microbial purity, bacterial endotoxins test (LAL), pyrogens.	Sterility, microbial purity, bacterial endotoxins test (LAL), pyrogens.
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<p><b>Central Laboratory for Quality Control of Medicines and Medical Products, SE</b> <b>State Drug Administration of Ukraine</b></p> <p>10G Kudryavskaya street Kiev 04053 Ukraine</p> <p>Tel/Fax: +380 44 272 5498, +380 44 272 5798 e-mail: CL@statelab.kiev.ua</p>	10- 11.5.2016	Compliant with WHO recommended standards	16.4.2010	Physical/Chemical analysis	pH, density, refractometry, viscosity, water content, limit tests, disintegration, dissolution, uniformity of dosage units (mass, content), friability, dimensions	pH, refractometry, viscosity, loss on drying, water content, heavy metals, acid value, iodine value, limit tests, acid neutralizing capacity, distilling range, nitrogen determination
				Identification	HPLC (UV-Vis, RI detection), GC (FID), TLC, UV-VIS spectrophotometry, FTIR, basic tests	HPLC (UV-Vis, RI detection), GC (FID), TLC, UV-VIS spectrophotometry, FTIR, basic tests
				Assay, impurities and related substances	HPLC (UV-Vis, RI detection), GC (FID), UV-Vis spectrophotometry, AAS, FTIR, volumetric titrations	HPLC (UV-Vis, RI detection), GC (FID), UV-Vis spectrophotometry, AAS, FTIR, volumetric titrations
				Microbiological tests	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
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<p><b>Centre Humanitaire des Métiers de la Pharmacie (CHMP)</b> 4, voie militaire des Gravanches F 63100 Clermont-Ferrand</p>	26-27.9.2013	Compliant with WHO recommended standards	28.10.2008	Physical/Chemical analysis	pH, density, disintegration, dissolution, uniformity of dosage units (mass, content), friability, dimensions, limit tests	pH, density, acid value, iodine value, limit tests, neutralizing capacity, heavy metals

France Tel: +33 4 73 98 24 70 Fax: +33 4 73 98 24 81 e-mail: contact@chmp.org, a.ba@chmp.org				Identification	FTIR, TLC, HPLC, spectrophotometry, basic tests	FTIR, TLC, HPLC, spectrophotometry, basic tests
				Assay, impurities and related substances	HPLC (UV-Vis, PDA detection), UV spectrophotometry, FTIR, volumetric titrations	HPLC (UV-Vis, PDA detection), UV spectrophotometry, FTIR, volumetric titrations
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>INFARMED I.P.<sup>3</sup></b> Direcção da Comprovação da Qualidade (DCQ) Av. Brasil No 53 Edifício Tomé Pires 1749-004 Lisboa Portugal  Tel: +35 1217987350 Fax: +35 1217987369 e-mail: mjoao.portela@infarmed.pt	March 2019 (Desk Review)	Compliant with WHO recommended standards	31.8.2011	Physical/Chemical analysis	pH, density, optical rotation, viscosity, water content, conductivity, residual solvents, limit tests, tablet hardness, friability, disintegration, dissolution, uniformity of dosage units (mass, content)	pH, optical rotation, viscosity, melting point, loss on drying, water content, osmolality, conductivity, residual solvents, sulphated ash, limit tests
				Identification	HPLC (UV-VIS, DAD, fluorescence, RI, ELS, MS, electrochemical detection), GC (FID, ECD, FPD, NPD, TCD, MS detection), capillary electrophoresis, TLC, UV-VIS spectrophotometry, FTIR, basic tests	HPLC (UV-VIS, DAD, fluorescence, RI, ELS, MS, electrochemical detection), GC (FID, ECD, FPD, NPD, TCD, MS detection), capillary electrophoresis, TLC, UV-VIS spectrophotometry, FTIR, basic tests
				Assay, impurities and related substances	HPLC (UV-VIS, DAD, 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	HPLC (UV-VIS, DAD, 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
				Microbiological tests	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
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>InphA GmbH - Institute for Pharmaceutical and Applied Analytics<sup>4</sup></b> Emil-Sommer-Strasse 7 D-28329 Bremen	4-6.6.2013 EDQM audit	Compliant with WHO recommended standards	1.4.2014	Physical/Chemical analysis	pH, density, refractive index, optical rotation, osmolality, water content, residual solvents, limit tests, tablet hardness, friability, disintegration, dissolution,	pH, density, refractive index, optical rotation, melting point, loss on drying, water content, residual solvents, sulphated ash, limit tests

<sup>3</sup> 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.

<sup>4</sup> 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.

Germany  Tel: +49 421 4361-111 Fax: +49 421 4361-189 e-mail: konrad.horn@inpha.de					uniformity of dosage units (mass, content)	
				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
				Assay, impurities and 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)
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>Intertek (Schweiz) AG<sup>5</sup></b> Mattenstrasse 22 Biopark Rosenthal, Building 1047 CH-4058 Basel Switzerland  Tel: +41 61 686 48 00 Fax: +41 61 686 48 99 e-mail: mara.guzzetti@intertek.com	2-3.5.2013 US FDA inspection; 9.4.2013 Swissmedic, Switzerland inspection	Compliant with WHO recommended standards	27.10.2014	Physical/Chemical analysis	pH, solubility, particulate matter in injections, uniformity of dosage units (mass, content)	pH, solubility
				Identification	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

<sup>5</sup> 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.

				Assay, impurities and 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
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>Laboratorios Basi - Industria Farmaceutica, S.A., Quality Control Unit<sup>6</sup></b> Parque Industrial de Mortágua Lote 15 3450-232 Mortágua Portugal  Tel: +351 231 920 250 e-mail: basi@basi.pt	23-25.7.2012 INFARMED, Portugal inspection	Compliant with WHO recommended standards	12.6.2013	Physical/Chemical analysis	pH, density, refractive index, optical rotation, viscosity, loss on 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
				Identification	HPLC (UV-Vis, RI, DAD), GC (FID, $\mu$ ECD), TLC, UV-Vis spectrophotometry, FTIR/NIR	HPLC (UV-Vis, RI, DAD), GC (FID, $\mu$ ECD), TLC, UV-Vis spectrophotometry, FTIR/NIR
				Assay, impurities and related substances	HPLC (UV-Vis, RI, DAD), GC (FID, $\mu$ ECD), UV-Vis spectrophotometry, FTIR/NIR, potentiometry, volumetric titrations, gravimetry	HPLC (UV-Vis, RI, DAD), GC (FID, $\mu$ ECD), UV-Vis spectrophotometry, FTIR/NIR, potentiometry, volumetric titrations, gravimetry
				Microbiological tests	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, preservative efficacy test
				Stability studies	ICH conditions	ICH conditions
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>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</b>  Laboratories for Control and Coordination; Biotechnological Products; Nano-medicines, Cell and	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
				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
				Assay, impurities and 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

<sup>6</sup> The laboratory has been included on the list based on the WHO assessment, which utilized the results of inspection performed by the INFARMED, Portugal.



Gene Therapy Products; Vitamins, Hormones and Synthetic Analogues and Microbiology Laboratory  Schukinskaya street, 6-1 Moscow 123182 Russian Federation  Tel: +7 495 6254342 Fax: +7 4956254350 e-mail: gladkaja@expmed.ru						spectrophotometry, FTIR, volumetric titrations
				Microbiological tests	Laboratory of antibiotics - Sterility testing and Microbial assay and limit tests.  Microbiology Laboratory - Microbial limit tests	Laboratory of antibiotics - Sterility testing and microbial limit tests.  Microbiology Laboratory - Microbial limit tests
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
Laboratory of Pharmaceutical Analysis State Expert Centre Ministry of Health of Ukraine 14, Ezhena Pottier St. 03680 Kiev Ukraine  Tel: +38 44 536 1338, +38 50 959 7924 Fax: + 38 44 536 1344 e-mail: sashavbfc@yandex.ru	12-13.5.2016	Compliant with WHO recommended standards	16.4.2010	Physical/Chemical analysis	pH, density, 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	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
				Identification	HPLC (UV-Vis, DAD, fluorescence, RI detection), GC, TLC, UV-Vis and NIR spectrophotometry, AAS, basic tests	HPLC (UV-Vis, DAD, fluorescence, RI detection), GC, TLC, UV-Vis and NIR spectrophotometry, AAS, basic tests
				Assay, impurities and related substances	HPLC (UV-Vis, DAD, fluorescence, RI detection), GC, UV-Vis spectrophotometry, AAS, volumetric titrations	HPLC (UV-Vis, DAD, fluorescence, RI detection), GC, UV-Vis spectrophotometry, AAS, volumetric titrations
				Microbiological tests	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
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
Medicines Control Laboratory (SCM-DGO) Stevinstraat 137 1000 Brussels, Belgium  Tel.: +32 228 54250 e-mail: dgo_scm@apb.be	8 May 2015 (Desk Review)	Compliant with WHO recommended standards	30.10.2015	Physical/Chemical analysis	pH, water content, loss on drying, friability, tablet hardness melting point, optical rotation, refractive index, disintegration time, dissolution, density, viscosity, osmolality, conductivity, uniformity of	pH, water content, loss on drying, , refractive index, optical rotation, viscosity, melting point, residue on ignition, conductivity, heavy metals, residual solvents, limit tests,

					dosage units (mass, content), uniformity of delivered dose of (non)pressurized MDI, residual solvents, limit tests.	acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value
				Identification	(U)HPLC (UV-Vis, DAD, RI, Fluorescence, ELSD, MS), GC(FID), (HP)TLC, UV-Vis, FTIR, AAS/AES, basic tests	(U)HPLC (UV-Vis, DAD, RI, Fluorescence, ELSD, MS), GC (FID), (HP)TLC, UV-Vis, FTIR, AAS/AES, basic tests
				Assay, impurities and related substances	(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, 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
				Microbiological tests	Sterility test, microbiological, examination of non-sterile products, bacterial endotoxins test (LAL), microbial assay of antibiotics, ELISA, preservative challenge test	Sterility test, microbiological examination of non-sterile products, bacterial endotoxins test (LAL), microbial assay of antibiotics, ELISA, preservative challenge test
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>PROXY Laboratories B.V.</b> Archimedesweg 25 2333 CM Leiden The Netherlands  Tel: +31 71 5244080 (general) Fax: +31 71 5284213 e-mail: info@proxylab.nl	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 solvents, limit tests, tablet hardness, friability, disintegration, dissolution, uniformity of dosage units (mass, content)	pH, refractive index, optical rotation, viscosity, melting point, distilling range, 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, sulphated ash, residue on ignition, total organic carbon, solubility
				Identification	HPLC (UV-VIS, PDA, RI, conductivity detection), LC/MS, GC (FID, MS), TLC, UV-VIS spectrophotometry, IR, basic tests	HPLC (UV-VIS, PDA, RI, conductivity detection), LC/MS, GC (FID, MS), TLC, UV-VIS spectrophotometry, IR, basic tests
				Assay, impurities and related substances	HPLC (UV-VIS, PDA, RI, conductivity detection), LC/MS, GC (FID, MS), TLC, UV-VIS spectrophotometry, AAS, FTIR, volumetric titrations	HPLC (UV-VIS, PDA, RI, conductivity detection), LC/MS, GC (FID, MS), TLC, UV-VIS spectrophotometry, AAS, FTIR, volumetric titrations

				Microbiological tests	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
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>Republican Control and Analytical Laboratory of the Centre for Expertise and Testing in Health Care Ministry of Health Care of the Republic of Belarus</b> Building 15 Dzerzhinsky Avenue 83 220140 Minsk Belarus  Tel: +375 17 254-95-63 Tel/Fax: +375 17 254-95-74 e-mail: rkal@rceth.by maisak@rceth.by	5-7.12.2018	Compliant with WHO recommended standards	21.6.2012	Physical/Chemical 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
				Identification	HPLC (UV-Vis, DAD, RI, detection), GC, TLC, UV-VIS spectrophotometry, IR, basic tests	HPLC (UV-Vis, DAD, RI, detection), GC, TLC, UV-VIS spectrophotometry, IR, basic tests
				Assay, impurities and related substances	HPLC (UV-Vis, DAD, RI detection), GC, UV-Vis spectrophotometry, volumetric titrations	HPLC (UV-Vis, DAD, RI, detection), GC, UV-Vis spectrophotometry, volumetric titrations
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>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</b> Chentsova street 71/63B Rostov-on-Don Rostov region 344037 Russian Federation  Tel: +7 863 2806914; +7 863 2806911 e-mail: annagranf@yandex.ru	19-21.11.2013	Compliant with WHO recommended standards	11.3.2014	Physical/Chemical analysis	pH, density, refractive index, optical rotation, water content, loss on drying, residual solvents, 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
				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
				Assay, impurities and related substances	HPLC (UV-Vis, RI, DAD detection), GC (FID, TCD), UV-Vis spectrophotometry, volumetric titrations	HPLC (UV-Vis, RI, DAD detection), GC (FID, TCD), UV-Vis spectrophotometry, volumetric titrations
				Microbiological tests	Sterility test, microbial limit tests, bacterial endotoxins test (LAL), microbial assay of antibiotics	Sterility test, microbial limit tests, bacterial endotoxins test (LAL)
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>SGS Lab Simon S. A.</b> Vieux Chemin du Poète 10	20.01.15	Compliant with WHO	31.5.2011	Physical/Chemical analysis	pH, density, refractive index, optical rotation, viscosity, water	pH, refractometry, refractive index, optical rotation, viscosity,

<p>B-1301 Wavre Belgium</p> <p>Tel: +32 10 421111; +32 10 42176; +32 10 421186 Fax: +32 10 421100 e-mail: be.lifeqc@sgs.com wim.vanimmerseel@sgs.com</p>		recommended standards			content, conductivity, residual solvents, limit tests, tablet hardness, friability, disintegration, dissolution, uniformity of dosage units (mass, content)	melting point, distilling range, 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
				Identification	HPLC (UV-Vis, PDA, RI, conductivity detection), LC/MS, GC (FID, MS), TLC, UV-VIS spectrophotometry, IR, basic tests	HPLC (UV-Vis, PDA, RI, conductivity, fluorescence detection), LC/MS, GC (FID, MS), TLC, UV-VIS spectrophotometry, IR, basic tests
				Assay, impurities and related substances	HPLC (UV-Vis, PDA, RI, conductivity detection), LC/MS, GC (FID, MS), UV-Vis spectrophotometry, AAS, FTIR, volumetric titrations	HPLC (UV-Vis, PDA, RI, conductivity detection), LC/MS, GC (FID, MS), UV-Vis spectrophotometry, AAS, FTIR, volumetric titrations
				Microbiological tests	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
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<p><b>Synergy Health Utrecht B.V., a STERIS Company</b> Reactorweg 47A 3542 AD Utrecht The Netherlands</p> <p>Tel: +31 30 2843010 Fax: +31 30 2843011 e-mail: Utrecht@steris.com</p>	18.12.2012 and 4.9.2013 Dutch Healthcare Inspectorate inspections	Compliant with WHO recommended standards	23.9.2014	Physical/Chemical analysis	pH, density, refractive index, optical rotation, viscosity, water content, loss on drying, conductivity, neutralizing capacity, tablet hardness, dimensions, friability, disintegration, dissolution, uniformity of dosage units (mass, content), particulate matter test (visible and sub-visible)	pH, density, refractive index, optical rotation, viscosity, water content, loss on drying, conductivity, particle size, melting point, freezing point, drop point, boiling point, distilling range
				Identification	FTIR, (HP)TLC, (U)HPLC (UV-VIS, PDA, RI detection), GC (FID detection), UV-VIS spectrophotometry, fluorimetry, AAS/AES, basic tests	FTIR, (HP)TLC, (U)HPLC (UV-VIS, PDA, RI detection), GC (FID detection), UV-VIS spectrophotometry, fluorimetry, AAS/AES, basic tests
				Assay, impurities and related substances	(U)HPLC (UV-VIS, PDA, RI detection), GC (FID detection), (HP)TLC, UV-VIS spectrophotometry, fluorimetry, polarimetry, AAS/AES, gravimetric analysis, volumetric	(U)HPLC (UV-VIS, PDA, RI detection), GC (FID detection), (HP)TLC, UV-VIS spectrophotometry, fluorimetry, polarimetry, AAS/AES, gravimetric analysis, volumetric

					titrations, potentiometry, nitrogen determination, residual solvents, ethylene oxide residual analysis	titrations, potentiometry, nitrogen determination, residual solvents, ethylene oxide residual analysis, oxygen flask combustion, composition of fatty acids
				Microbiological tests	Sterility test, microbial limit tests, identification of microorganisms, preservative efficacy test, bacterial endotoxins test (LAL), microbial assay of antibiotics	Sterility test, microbial limit tests, identification of microorganisms, bacterial endotoxins test (LAL), microbial assay of antibiotics
				Stability studies	ICH conditions	ICH conditions
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<p><b>State Scientific Research Laboratory on Quality Control of Medicines (SSRL)</b>, OM Marzeyev Institute for Hygiene and Medical Ecology, National Academy of Medical Sciences of Ukraine, 50 Popudrenka str, Kiev, 02660, Ukraine</p> <p>Tel: + 38(044)559-57-11 Fax: + 38(044)559-57-00 e-mail: 3526309@ukr.net</p>	28-30.09.2015	Compliant with WHO recommended standards	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
				Identification	HPLC (DAD, RID, UV-Vis, FLD), GC (FID, ECD), TLC, UV-Vis Spectrophotometry, FTIR	HPLC (DAD, RID, UV-Vis, FLD), GC (FID, ECD), TLC, UV-Vis Spectrophotometry, FTIR
				Assay, impurities and related substances	HPLC (DAD, RID, UV-Vis, FLD), GC (Au/HS(FID, ECD)), UV-Vis Spectrophotometry, FTIR spectroscopy, Water determination	HPLC (DAD, RID, UV-Vis, FLD), GC (Au/HS(FID, ECD)), UV-Vis Spectrophotometry, FTIR spectroscopy, Water determination
				Microbiological tests	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
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>

<p><b>University of Liege, Faculty of Medicine, Department of Pharmacy,</b> B36 Building, Tower Pharmacy, Level 2 Hospital district Hippocrate Avenue 15 4000 Liège Belgium</p> <p>Tel: + 32 4 366 3979 Fax: + 32 4 366 4317 e-mail: rmarini@ulg.ac.be</p>	<p>June 2015 - Belgium Federal Agency for Medicines and Health Products (FAMHP) + 03.11.2016 (WHO PQT Desk Review)</p>	<p>Compliant with WHO recommended standards</p>	<p>22.12.2016</p>	<p>Physical/Chemical analysis</p>	<p>pH, density, optical rotation, 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.</p>	<p>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.</p>
				<p>Identification</p>	<p>UV-Vis, PDA, refractive index, LCUV-ELSD-, UHPLC-UV-MS, MS, GC-FID, TLC, UV-VIS spectrophotometry, FT- IR spectroscopy, spectroscopy NIR, NMR, Raman spectroscopy, CEDAD, basic tests.</p>	<p>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.</p>
				<p>Assay, impurities and related substances</p>	<p>HPLC (UV-Vis, PDA), LC/MS, GC (FID, ), UHPLC-UV-MS, LC-UV-ELSD, Spectrophotometry UV-Vis, AAS, FTIR, NIR, LC-RMN, CE-DAD.</p>	<p>HPLC (UV-Vis, PDA), LC/MS, GC (FID, ), UHPLC-UV-MS, LC-UV-ELSD, Spectrophotometry UV-Vis, AAS, FTIR, NIR, LC-RMN, CE-DAD volumetric titrations.</p>
				<p>Stability Testing</p>	<p>Under ICH conditions.</p>	<p>Under ICH conditions.</p>
				<p><i>Type of analysis</i></p>	<p><i>Finished products</i></p>	<p><i>Active pharmaceutical ingredients</i></p>
<p><b>APTYS Pharmaservices</b> Biopôle Clermont-Limagne F-63360 Saint Beauzire France</p> <p>Tel: +33 473 670 670</p>	<p>23 January 2018 (Desk Review)</p>	<p>Compliant with WHO recommended standards</p>	<p>26.7.2018</p>	<p>Physical/Chemical analysis</p>	<p>pH, density, water content (Karl Fisher), friability, disintegration, tablet hardness, dissolution, viscosity, dimensions, uniformity of dosage (mass, content), extractable volume, average volume.</p>	<p>pH, density, water content (Karl Fisher), loss on drying, viscosity, limit tests, solubility, conductivity.</p>
				<p>Identification</p>	<p>HPLC (UV-VIS detection, amperometric detection, RI), - DAD, FTIR, UV-VIS spectrophotometry, TLC, chemical reaction (basic tests).</p>	<p>HPLC (UV-VIS detection, amperometric detection, RI) - DAD, FTIR, UV-VIS spectrophotometry, TLC, chemical reaction (basic tests).</p>

Fax : +33 473 670 687  e-mail: contact@aptys-pharmaceuticals.com				Assay, impurities and related substances	HPLC (UV-VIS detection, amperometric detection, RI), , UV-VIS spectrophotometry, volumetric titrations, Potentiometry.	HPLC (UV-VIS detection, amperometric detection, RI), DAD, UV-VIS spectrophotometry, volumetric titrations, Potentiometry.
				Stability testing	Under ICH conditions	Under ICH conditions
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>Gimopharm</b> 1, Chemin de Saulxier 91160 Longjumeau France  Tel: +33 1 69 35 54 90 Fax: +33 1 69 85 31 18  e-mail: aurelie.bertheault@gimopharm.com contacts@gimopharm.com	23 January 2018 (Desk Review)	Compliant with WHO recommended standards	26.7.2018	Physical/Chemical analysis	pH, density, refractive index, optical rotation, osmolality, water content, residual solvents, limit tests, tablet hardness, friability, disintegration, dissolution, viscosity, uniformity of dosage units (mass, content), particle size (laser,) Differential scanning calorimetry, X-ray Diffraction.	pH, density, refractive index, optical rotation, osmolality, water content, residual solvents, limit tests, particle size, Total Organic Carbon, conductivity, viscosity, heavy metals, Ash, sulfated ash, Differential scanning calorimetry, X-ray Diffraction.
				Identification	HPLC (UV-VIS, DAD, RI fluorescence detection), TLC, GC, UV-VIS spectrophotometry, IR, AAS, fluorimetry, MS, MS-MS.	HPLC (UV-VIS, DAD, RI, fluorescence detection), TLC, GC, UV-VIS spectrophotometry, IR, AAS, fluorimetry.
				Assay, impurities and related substances	GC-FID/ MS-MS HPLC-UV/ PDA/ MS-MS/ MS/Fluo/ RI / ELSD, UPLC-MS, Ionic, ICP/MS, AAS	GC- FID/ MS-MS HPLC-UV/ PDA/ MS-MS/ MS/ Fluo/ RI / ELSD, UPLC-MS, Ionic, ICP/MS, AAS Post column derivatization.
				Stability testing	ICH conditions	ICH Conditions
				Microbiological tests	Microbial limit tests, Bacterial endotoxins test (LAL); Challenge Test	Microbial limit tests, Bacterial endotoxins test (LAL)
<b>WHO Eastern Mediterranean Region</b>						
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>Laboratoire National de Contrôle des Médicaments - LNCM (Maroc)<sup>7</sup></b>	26.3-28.3.2018	Compliant with WHO	17.7.2008	Physical/Chemical analysis	pH, density, refractive index, viscosity, loss on drying, water content, conductivity,	pH, density, refractive index, viscosity, loss on drying, melting point, water content, conductivity,

<sup>7</sup> 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.



<p>Rue Lamfadel Charkaoui - Medinat Al Irfane Rabat 10 000 Maroc</p> <p>Postal address: BP 6202, Rabat - Instituts Rabat Maroc</p> <p>Tel: +212 537681930 Fax: +212 537772520 e-mail: d.lncm.dmp@sante.gov.ma</p>		recommended standards			disintegration, dissolution, uniformity of dosage units (mass, content), friability, tablet hardness	thermal analysis (DSC), X-ray diffractometry, osmolarity, heavy metals, sulphated ash
				Identification	HPLC (fluorescence, UV, UV-Vis, DAD, RI detection), GC (FID, MS), TLC, IR, UV-VIS spectrophotometry	HPLC (fluorescence, UV, UV-Vis, DAD, RI detection) GC (FID, MS), TLC, IR, UV-VIS spectrophotometry, chemical reaction
				Assay, impurities and related substances	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	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
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<p><b>Food and Drugs Control Reference Laboratories (FDCRL), Food &amp; Drugs Administration</b>, Ministry of Health and Medical Education. No 31 Imam Khomeini Avenue, Tehran, 11136-15911, Islamic Republic of Iran</p> <p>Tel: +98 21 66496153 Fax: +982166404330</p> <p>e-mail: FDCRL@fda.gov.ir or h.rastegar@fda.gov.ir</p>	21-23.09.2015	Compliant with WHO recommended standards	11.03.2016	Physical/Chemical analysis	pH, water content, loss on drying, 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).
				Identification	HPLC (UV-VIS detection, RI, 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	HPLC (UV-VIS detection, RI, fluorescence detection), UV-VIS spectrophotometry, GC (FID, TCD), AAS, ICP, Fluorimetry, gravimetric analysis, volumetric titrations, Potentiometry	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)
				<i>Type of</i>	<i>Type of analysis</i>	<i>Type of analysis</i>
	23-24.7.2018	Compliant with WHO	0304.2019	Physical/Chemical analysis	pH	pH

<b>Pakistan Drugs Testing and Research Center (PDTRC)</b>  Sundar Raiwind Road, Commercial Area (North) Sundar Industrial Estates, Raiwind  Lahore  Pakistan  Tel: +92 42 35297281-4  e-mail: info@pdtrc.org.pk		recommended standards		Identification	HPLC (UV-VIS, UV-VIS spectrophotometry.	HPLC (UV-VIS, UV-VIS spectrophotometry
				Assay, impurities and related substances	HPLC (UV-VIS), UV-VIS spectrophotometry.	HPLC (UV-VIS), UV-VIS spectrophotometry.
<b>WHO Western Pacific Region</b>						
<b>National Institutes for Food and Drug Control (NIFDC) - Divisions of Chemical Drugs, Antibiotics, Narcotic Drugs and Pharmacology of the Institute for Chemical Drug Control</b>  2 Tiantan Xili (Temple of Heaven) 100050 Beijing P.R. CHINA  Tel: +86 10 67095866 Fax: +86 10 65113805 e-mail: yanghx@nifdc.org.cn zhanghz@nicpbp.org.cn	27-30.8.2018	Compliant with WHO recommended standards	20.11.2012	<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
				Physical/Chemical analysis	pH, density, refractometry, water content, limit tests, disintegration, dissolution, uniformity of dosage units (mass, content), friability, dimensions	pH, refractometry, optical rotation, loss on drying, water content, heavy metals, acid value, iodine value, limit tests, nitrogen determination
				Identification	HPLC (UV-Vis, RI detection), GC (FID), TLC, UV-VIS spectrophotometry, FTIR, basic tests	HPLC (UV-Vis, RI detection), GC (FID), TLC, UV-VIS spectrophotometry, FTIR, basic tests
				Assay, impurities and related substances	HPLC (UV-Vis, RI detection), GC (FID), UV-VIS spectrophotometry, AAS, FTIR, volumetric titrations	HPLC (UV-Vis, RI detection), GC (FID), UV-VIS spectrophotometry, AAS, FTIR, volumetric titrations
				Microbiological tests	Bacterial endotoxins test (LAL), microbial assay of antibiotics	Bacterial endotoxins test (LAL), microbial assay of antibiotics
<b>National Institute of Drug Quality Control of Vietnam (NIDQC)</b>  48 Hai Ba Trung Street Hoan Kiem District Hanoi Vietnam  Tel. +844 824 5009 Fax: +844 825 6911 e-mail: npthaodz@yahoo.com.vn nhlienvkn@gmail.com tranthuyhanh1974@yahoo.com	20-21.10.2016	Compliant with WHO recommended standards	28.11.2008	<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
				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 test	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
				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, FTIR, AAS, chemical reaction

				Assay, impurities and related substances	HPLC (UV-Vis, DAD, 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	HPLC (UV-Vis, DAD, 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 (DSC)
				Microbiological tests	Sterility test, microbial purity, test for pyrogens, bacterial endotoxins test (LAL), microbial assay	Microbial assay
				Stability studies	WHO conditions	WHO conditions
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>TÜV SÜD PSB Pte Ltd Chemical &amp; Materials (Food &amp; Pharmaceutical Testing)</b> 1 Science Park Drive Singapore 118221  Tel: +65 68851313 Fax: +65 67784301 e-mail: Jianhua.lin@tuv-sud-psb.sg	24-26.10.2016	Compliant with WHO recommended standards	21.8.2009	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 test	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
				Identification	HPLC (UV-Vis), GC (FID), GC/MS, TLC, HPTLC, UV-VIS spectrophotometry, IR, AAS.	HPLC (UV-Vis), GC (FID), GC/MS, TLC, HPTLC, UV-VIS spectrophotometry, IR, FTIR, AAS, chemical reaction, UHPLC.
				Assay, impurities and related substances	HPLC (UV-Vis, DAD, fluorescence, light scattering detection), GC (FID), TLC, HPTLC, UV-VIS spectrophotometry, AAS, volumetric titrations, potentiometry, nitrogen assay, UHPLC.	HPLC (UV-Vis, DAD, fluorescence, light scattering detection), GC (FID), TLC, HPTLC, UV-VIS spectrophotometry, AAS, volumetric titrations, potentiometry, nitrogen assay, UHPLC.
				Microbiological tests	Sterility test, microbial purity, test for pyrogens, bacterial endotoxins test (LAL), microbial assay.	Microbial assay, Sterility test, bacterial endotoxins test (LAL), Microbial Limit Test
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>Institute of Drug Quality Control (IDQC)</b>  200 Co Bac Street District 1 Ho Chi Minh City Viet Nam	17-19.10.2016	Compliant with WHO recommended standards	18.7.2017	Physical/Chemical analysis	pH, loss on drying, water content, , optical rotation, disintegration, dissolution, density, uniformity of dosage unit (mass, content)	pH, loss on drying, water content, melting point, sulphated ash, acid insoluble ash, residual solvents, limit test.
				Identification	HPLC (UV-VIS, Fluorescence, RI, DAD, MS detection), GC (FID, MS detection), FTIR, UV-VIS	HPLC (UV-VIS detection), GC (FID, MS detection), FTIR, UV-

Tel: +848 38368518 ; +848 9325271 Fax: +848 38367900 e-mail: info@idqc-hcm.gov.vn					spectrophotometry, TLC, chemical reaction.	VIS spectrophotometry, TLC, chemical reaction.
				Assay, impurities and related substances	HPLC (UV-VIS, Fluorescence, RI, DAD, MS detection), GC, UV-VIS spectrophotometry, volumetric and potentiometric titrations.	HPLC (UV-VIS, Fluorescence, RI, DAD, MS detection), GC, UV-VIS spectrophotometry, volumetric and potentiometric titrations.
				Microbiological tests	Sterility, microbial limit test, LAL test, microbial assay of antibiotics.	Sterility, microbial limit test, LAL test, microbial assay of antibiotics.
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
<b>Shenzhen Institute for Drug Control (SZIDC)</b> No. 28, Gaoxin Central 2 <sup>nd</sup> Avenue Nanshan District Shenzhen Guangdong P R China Tel: +86 755-26031123 Fax: +86 755-26031719 e-mail: szidc@szidc.org.cn wangxiaowei@szidc.org.cn	14-16.12.2017	Compliant with WHO recommended standards	1.5.2018	Physical/Chemical analysis	pH, Density, Refractometry, Water content, Limit tests, Disintegration time, Dissolution, Uniformity of dosage units (by mass or content), Friability.	pH, Refractometry, Optical rotation, Loss on drying, Water content, Heavy metals, Acid Value, Iodine value, Limit tests, Nitrogen determination.
				Identification	HPLC (UV-Vis, Refractive index detection, Fluorescence), GC with headspace (FID), TLC, IR, basic tests.	HPLC (UV-Vis, Refractive index detection, Fluorescence), GC with headspace (FID), TLC, IR, basic tests.
				Assay, impurities and related substances	HPLC (UV-Vis, Fluorescence and Refractive index detection), GC with headspace (FID), TLC, UV-Vis spectrophotometry, AAS, IR, Volumetric titrations.	HPLC (UV-Vis, Fluorescence and Refractive index detection), GC with headspace (FID), TLC, UV-Vis spectrophotometry, AAS, IR, Volumetric titrations.

## Version history

<b><i>Edition</i></b>	<b><i>Date</i></b>	<b><i>Change</i></b>
48 <sup>th</sup> Edition	10.12.2019	Corrected WHO region for Pakistan Drugs Testing and Research Centre, Lahore, Pakistan to EMRO Added National Quality Control Laboratory for Drugs and Foods (NQCLDF), Jakarta Pusat, Indonesia
47 <sup>th</sup> Edition	03.07.2019	Added Pakistan Drugs Testing and Research Centre, Lahore, Pakistan Change of name from For APTYS Pharmaceuticals to APTYS Pharmaservices Updated contact details for Synergy Health Utrecht B.V Updated inspection date (desk review) for INFARMED, Portugal; Laboratoire National de Contrôle des Médicaments – LNCM, Morocco; National Institutes for Food and Drug Control (NIFDC), China; Republican Control and Analytical Laboratory of the Centre for Expertise and Testing in Health Care (RCAL), Belarus Updated contact email for Vimta Labs Limited
46 <sup>th</sup> Edition	26.07.2018	Added APTYS Pharmaceuticals, Saint Beuzire, France Added Gimopharm, Longjumeau, France Added The Drug Service of the Public Laboratory Dr Giovanni Cysneiros (LACEN-GO), Brazil Updated dates of last inspection for Instituto Nacional de Controle de Qualidade em Saude / National Institute of Health Quality Control (INCQS), Brazil; Ezequiel Dias Foundation (FUNED), Central Laboratory of Public Health of Minas Gerais (Lacen-MG), Brazil;
45 <sup>th</sup> Edition	01.05.2018	Added Shenzhen Institute for Drug Control (SZIDC), Shenzhen, China
44 <sup>th</sup> Edition	16.4.2018	Updated contact details for Health Concepts International Ltd, Klong Luang, Pathumthani, Thailand and Laboratoire National de Contrôle des Médicaments – LNCM, Morocco. Added The United States Pharmacopoeia – Ghana (USP-Ghana), Accra, Ghana
43 <sup>rd</sup> Edition	18.07.2017	Updated Laboratoire National de Contrôle des Médicaments - LNCM (Maroc), area of expertise inspected and considered prequalified. Voluntary withdrawal of microbiology testing. Added Institute of Drug Quality Control (IDQC), Ho Chi Minh City, Viet Nam

		<p>Updated scope of expertise that is prequalified and date of last inspection for TUV SUD PSB Pve Ltd</p> <p>Added M&amp;L Laboratory Services (Pty) Ltd, Johannesburg, South Africa</p> <p>Updated date of last inspection for LNCM, Morocco; Adcock Ingram Limited Research and Development, Aeroton, Gauteng, South Africa; National Institute of Drug Quality Control of Vietnam (NIDQC), Hanoi, Vietnam; and SGS India Pvt. Ltd. (Life Science Services), Chennai, India.</p>
42 <sup>nd</sup> Edition	22.12.2016	<p>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.</p> <p>Removal of Getz Pharma Pvt Ltd from list following voluntary withdrawal.</p> <p>Removal of Centro Nacional de Control de Calidad (CNCC) - Instituto Nacional de Salud, Peru from list following voluntary withdrawal.</p> <p>Added University of Liege, Faculty of Medicine, Department of Pharmacy, Liege, Belgium</p>
41 <sup>st</sup> Edition	14.07.2016	<p>Added Health Concepts International Ltd, Pathumthani, Thailand</p> <p>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).</p> <p>Updated date of last inspection for Central Laboratory for Quality Control of Medicines and Medical Products (CLQCM), Ukraine.</p> <p>Updated date of last inspection for Laboratory of Pharmaceutical Analysis (LPA), Ukraine.</p>
40 <sup>th</sup> edition	16.06.2016	<p>Added Agency for Medicinal Products and Medical Devices (HALMED), Official Medicines Control Laboratory (OMCL), Zagreb, Croatia</p>
39 <sup>th</sup> edition	11.03.2016	<p>Added Food and Drugs Control Reference Laboratories (FDCRL), Food &amp; Drugs Administration, Ministry of Health and Medical Education, Tehran, Islamic Republic of Iran.</p> <p>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 &amp; Materials (Food &amp; Pharmaceutical Testing), Singapore; National Institute of Drug Quality Control of Vietnam (NIDQC), Hanoi, Vietnam</p>

38 <sup>th</sup> 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 <sup>th</sup> 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 <sup>th</sup> edition	15.05.2015	Added Indian Pharmacopoeia 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 <sup>th</sup> 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
34 <sup>th</sup> edition	27.10. 2014	Added Intertek (Schweiz) AG, Switzerland 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 <sup>rd</sup> edition	23.9.2014	Added Synergy Health Utrecht B.V., Pharmaceutical Laboratories (SHPL), The Netherlands
32 <sup>nd</sup> edition	19.9.2014	Added Medicines Control Authority of Zimbabwe (MCAZ) Quality Control Laboratory (Zimbabwe) 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
31 <sup>st</sup> edition	01.04.2014	Added InphA GmbH - Institute for Pharmaceutical and Applied Analytics, Germany Updated dates of last inspections of SGS India Pvt. Ltd. (Life Science Services)
30 <sup>th</sup> edition	11.03.2014	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 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 <sup>th</sup> edition	17.02.2014	Added Getz Pharma Pvt Ltd – Quality Control Laboratory, Pakistan Updated dates of the last inspection of Vimta Labs India
28 <sup>th</sup> edition	09.12.2013	Added Stabicon Life Sciences Pvt Ltd, India 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
27 <sup>th</sup> edition	13.11.2013	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 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 Drug and Narcotic (BDN) Thailand
26 <sup>th</sup> edition	12.06.2013	Added Laboratorios Basi - Industria Farmaceutica, S.A., Quality Control Unit (Portugal) 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 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 <sup>th</sup> 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 <sup>th</sup> 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 <sup>rd</sup> edition	21.06.2012	Added Republican Control and Analytical Laboratory of the Centre for Expertise and Testing in Health Care (Belarus)
22 <sup>nd</sup> 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
21 <sup>st</sup> edition	26.04.2012	Pharmaceutical Laboratory of the Health Sciences Authority - Applied Sciences Group - Pharmaceutical Division withdrawn from the list on its request 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 <sup>th</sup> edition	20.10.2011	Date of last inspection of K.A.B.S. Laboratories Inc., Canada updated Added Ezequiel Dias Foundation, Institute Octavio Magalhães, Medicines Service of Public Health Central Laboratory (Brazil)
19 <sup>th</sup> 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 <sup>th</sup> edition	31.05.2011	Date of the last inspection of Vimta Labs Limited (India) updated Added SGS Lab Simon S.A. (Belgium)
17 <sup>th</sup> 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 <sup>th</sup> 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 Toxicología (CONCAMYT) Bolivia Contact details of Adcock Ingram South Africa and TÜV SÜD PSB Pte Ltd Singapore updated
15 <sup>th</sup> 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 <sup>th</sup> edition	10.02.2010	Added K.A.B.S. Laboratories Inc., Canada
13 <sup>th</sup> edition	21.08.2009	Added TÜV SÜD PSB Pte Ltd, Chemical & Materials (Food & Pharmaceutical Testing), Singapore
12 <sup>th</sup> edition	25.06.2009	Added Pharmaceutical Laboratory of the Health Sciences Authority, Applied Sciences Group, Pharmaceutical Division - HSA (Singapore)
11 <sup>th</sup> edition	23.03.2009	Added Laboratory of Mission for Essential Drugs and Supplies - MEDS (Kenya)
10 <sup>th</sup> edition	28.11.2008	Added National institute of Drug Quality Control - NIDQC (Vietnam)
9 <sup>th</sup> edition	28.10.2008	Added Centre Humanitaire Médico-Pharmaceutique - CHMP (France)
8 <sup>th</sup> 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 <sup>th</sup> edition	16.05.2008	Change reflecting the merger of RIIP and CENQAM into one organization with a single quality system
6 <sup>th</sup> edition	15.01.2008	Added Adcock Ingram Limited - Research and Development (South Africa)
5 <sup>th</sup> edition	09.01.2007	Added point 12.; 13. and 14. to General Notes
4 <sup>th</sup> edition	14.11.2006	Added the background and current status of the Programme and the general notes and the disclaimer

3 <sup>rd</sup> edition	27.10.2005	Added Laboratoire National de Contrôle des Produits Pharmaceutiques - LNCPP (Algérie)
2 <sup>nd</sup> edition	05.07.2005	Added Research Institute for Industrial Pharmacy - RIIP (South Africa)
1 <sup>st</sup> 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.
- The fact that certain laboratories are not included in the list does not necessarily mean that, if assessed, they could not be found to comply with the above-mentioned standards.
- The list may not be used by laboratories for commercial or promotional purposes.

#### Suggestions to organizations using services of listed laboratories

- This list indicates the laboratories found to be acceptable, in principle, for use by United Nations agencies and other procurement organizations.
- The list does not constitute any guarantee for the use of the laboratories mentioned. The pre-qualification focuses on laboratory information evaluation as well as site inspections as described in the prequalification procedure (Procedure for assessing the acceptability, in principle, of quality control laboratories for use by United Nations agencies). Organizations using this list should perform due diligence prior to using the laboratory, including but not limited to the financial situation and standing of the laboratory, ability to test the required samples and other related aspects. It is recommended that prior to using the laboratories, organizations familiarize themselves with aspects such as infrastructure, capacity, and patents of the products in question as well as other related matters.
- 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.

### **Disclaimer to the WHO List of Prequalified Quality Control Laboratories**

1. Inclusion in the list does not constitute an endorsement, or warranty of the fitness, of any laboratory for a particular purpose.
2. WHO does not furthermore warrant or represent that:
  - a) the list is complete or error free; and/or that
  - b) the laboratories which have been found to meet the standards recommended by WHO, will continue to do so; and/or that
  - c) the laboratories listed have obtained regulatory approval for use for testing drugs, or that their activities are in accordance with the national laws and regulations of any country, including but not limited to patent laws.
3. In addition, WHO wishes to alert United Nations agencies and other procurement organizations that the improper storage, handling and transportation of pharmaceutical products may affect their quality, efficacy and safety and the outcome of analysis. WHO disclaims any and all liability and responsibility for any injury, death, loss, damage or other prejudice of any kind whatsoever that may arise as a result of, or in connection with the use of any laboratory included in the list.

By using this list, you confirm that you have read, understand and to the extent applicable, accept and agree with the information provided under the above-mentioned bullet points.