

WHO List of Prequalified Quality Control Laboratories

Date: 20 October 2011

- This list contains 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 **20th 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 inspection ¹	Final outcome	Date of publication	The area of expertise inspected and considered prequalified		
WHO African Region						
				Type of analysis	Finished products	Active pharmaceutical ingredients
Adcock Ingram Limited - Research and Development 1 Sabax Road, Aeroton Johannesburg, 2013 South-Africa Postal address: Private Bag X69 Bryanston, 2021 South-Africa Tel: + 27 11 494 6215 Fax: + 27 11 494 1069 e-mail: Carla.Kruger@adcock.com	18-20.4.2011	Compliant with WHO recommended standards	15.1.2008	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	
				Type of analysis	Finished products	
Laboratoire National de Contrôle des Produits Pharmaceutiques, LNCPP (Algérie) 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	28-29.4.2010	Compliant with WHO recommended standards	27.10.2005	Physical/Chemical analysis	pH, water content, friability, disintegration time of tablets and suppositories, tablet hardness, dissolution, AA	
				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	

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

				Type of analysis	Finished products	Active pharmaceutical ingredients
Laboratory of the Mission for Essential Drugs and Supplies - (MEDS) PO Box 78040, Viwandani Nairobi, 00507 Kenya Tel. +254 20 3920221, +254 20 3920000, +254 20 551633 E-mail: wnandama@meds.or.ke	3-4.2.2009	Compliant with WHO recommended standards	23.3.2009	Physical/Chemical analysis	pH, loss on drying, water content, conductivity, refractometry, friability, disintegration, dissolution, density, uniformity of dosage unit (mass, content)	pH, loss on drying, water content, conductivity, refractometry, density
				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
				Type of analysis	Finished products	Active pharmaceutical ingredients
National Quality Control laboratory (NQCL) 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: hcchepkwony@nqcl.go.ke	22-24.4.2008	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
				Type of analysis	Finished products	Active pharmaceutical ingredients
Research Institute for Industrial Pharmacy (RIIP) incorporating CENQAM North-West University Potchefstroom Campus Hoffman Street Potchefstroom 2531 South Africa	15-17.4.2008	Compliant with WHO recommended standards	CENQAM: 22.6.2005 RIIP: 5.7.2005 16.5.2008 -	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/	pH, water content (Karl Fischer), loss on drying, X-ray diffractometry, thermal analysis (DSC, TGA)

Postal address: P/Bag X6001 Potchefstroom 2520 South Africa Tel: + 27 18 299 2268 Fax: + 27 18 299 2291 E-mail: Erna.Swanepoel@nwu.ac.za			Change reflecting the merger of RIIP and CENQAM into one organization with a single quality system		reconstitution time, resuspendability and sedimentation rate	
				Identification	IR, TLC, HPLC, spectrophotometry and basic tests	IR, TLC, HPLC, spectrophotometry and basic tests
				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
				Type of analysis	Finished products	Active pharmaceutical ingredients
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	7-8.9.2010	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
WHO Region of the Americas						
				Type of analysis	Finished products	Active pharmaceutical ingredients
Centro Nacional de Control de Calidad (CNCC) - Instituto Nacional de Salud Av. Defensores del Morro No 2268 Chorrillos, Lima 09 PERU Tel: +511 617 6200 Fax: +511 617 6231 e-mail: cncc@ins.gob.pe rtabuchi@ins.gob.pe	25-26.3.2010	Compliant with WHO recommended standards	16.9.2010	Physical/Chemical analysis	pH, water content, loss on drying, melting point, viscosity, density/specific gravity, optical rotation, conductivity, friability, tablet hardness, dimensions, disintegration, dissolution, uniformity of dosage units, particulate matter in injections	pH, water content, loss on drying, melting point, viscosity, density/specific gravity, optical rotation, conductivity
				Identification	HPLC (UV-VIS, DAD, fluorescence detection), TLC, GC, UV-VIS spectrophotometry, IR, AAS, fluorimetry	HPLC (UV-VIS, DAD, fluorescence detection), TLC, GC, UV-VIS spectrophotometry, IR, AAS, fluorimetry

				Assay, impurities and related substances	HPLC (UV-VIS, DAD, fluorescence detection), TLC, GC, UV-VIS spectrophotometry, IR, AAS, fluorimetry, gravimetric analysis, residual solvents, volumetric titrations, potentiometry, total organic carbon Determination of related substances/ impurities, degradations products	HPLC (UV-VIS, DAD, fluorescence detection), TLC, GC, UV-VIS spectrophotometry, IR, AAS, fluorimetry, gravimetric analysis, residual solvents, volumetric titrations, potentiometry, total organic carbon Determination of related substances/ impurities, degradations products
				Microbiological tests	Sterility test, microbial limit tests, disinfectant efficacy of preservatives, test for pyrogens, bacterial endotoxins test (LAL), microbial assay of antibiotics	Sterility test, microbial limit tests, test for pyrogens, bacterial endotoxins test (LAL), microbial assay of antibiotics
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
Comisión para el Control de Calidad de Medicamentos (CCCM) Br. Artigas 3223 Montevideo 11800 Uruguay Tel: +598 2209 4014 Fax: +598 2208 5673 e-mail: bluna@msp.gub.uy mhirschhorn@msp.gub.uy cccm@msp.gub.uy	18-20.3.2010	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

				Type of analysis	Finished products	Active pharmaceutical ingredients
Ezequiel Dias Foundation (FUNED) Institute Octavio Magalhães Medicines Service of Public Health Central Laboratory Conde Pereira Carneiro street 80 Gameleira neighbourhood Belo Horizonte Minas Gerais 30510-010 Brazil fax: +55 31 3314-4653 dpgq@funed.mg.gov.br medicamentos@funed.mg.gov.br	23-25.3.2011	Compliant with WHO recommended standards	20.10.2011	Physical/Chemical analysis	pH, water content, loss on drying, density, disintegration, dissolution, friability, uniformity of dosage units (mass, content)	pH, water content, loss on drying, density
				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, volumetric titrations, potentiometry; Determination of related substances/ impurities, degradations products	HPLC (UV-VIS, DAD, fluorescence detection), TLC, UV-VIS spectrophotometry, FTIR, volumetric titrations, potentiometry; Determination of related substances/ impurities, degradations products
				Microbiological tests	Sterility test, microbial limit tests, bacterial endotoxins test (LAL)	Sterility test, microbial limit tests, bacterial endotoxins test (LAL)

				Type of analysis	Finished products	Active pharmaceutical ingredients
K.A.B.S. Laboratories Inc.² 4500 De Tonnancour St-Hubert, Quebec J3Y 9G2, Canada Tel.: +1 450 656 4404 Fax: +1 450 656 4402 e-mail: kabsafric@kabs.com	6-8.12.2010 US FDA audit 9.12.2010 Health Canada audit	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	HPLC (UV-Vis, RI, conductivity detection), LC/MS, GC (FID,	HPLC (UV-Vis, RI, conductivity detection), LC/MS, GC (FID,

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

				substances	TCD), TLC, UV-Vis spectrophotometry, AAS, fluorimetry, volumetric titrations, potentiometry, coulometry	TCD), TLC, UV-Vis spectrophotometry, AAS, fluorimetry, volumetric titrations, potentiometry, coulometry
				Stability studies	ICH conditions	ICH conditions
				Type of analysis	Finished products	
Laboratorio de Control de Calidad de Medicamentos y Toxicología (CONCAMYT) Calle Rafael Zubieta No. 1889 Zona de Miraflores La Paz Bolivia Tel: +591 2 2226670 e-mail: garnicalopez@yahoo.es	21-23.3.2010	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	
WHO South-East Asia Region						
				Type of analysis	Finished products	Active pharmaceutical ingredients
SGS India Pvt. Ltd. (Life Science Services) 2nd Floor, TICEL Bio Park Ltd. Tharamani Road, Tharamani Chennai - 600113 Tamil Nadu India Tel. +91 44 2254 2601/2602 Fax: +91 44 2254 2600 E-mail: in.lifeqc@sgs.com	19-21.7.2010	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
				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
				Type of analysis	Finished products	Active pharmaceutical ingredients
Vimta Labs Limited Life Sciences Facility Plot No.5, S.P.Biotech Park Genome Valley Hyderabad 500078, India Tel. +91 40 3984 84 84 (Extn: 2101) Fax: +91 40 3984 77 76 E-mail: quality@vimta.com	20.- 22.12.2010	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
WHO European Region						
				Type of analysis	Finished products	Active pharmaceutical ingredients
Central Laboratory for Quality Control of Medicines and Medical Products State Inspection for Quality Control of Medicines 10G Kudryavskaya street Kiev 04053 Ukraine Tel/Fax: +380 44 272 5498, +380 44 272 5798	15-16.12.2009	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
				Assav. impurities	HPLC (UV-Vis, RI detection),	HPLC (UV-Vis, RI detection),

e-mail: CL@statelab.kiev.ua				and related substances	GC (FID), UV-Vis spectrophotometry, AAS, FTIR, volumetric titrations	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
				Type of analysis	Finished products	Active pharmaceutical ingredients
Centrale Humanitaire Médico-Pharmaceutique (CHMP) 4, voie militaire des Gravanches F 63100 Clermont-Ferrand France Tel: +33 4 73 98 24 66 Fax: +33 4 73 98 24 80 e-mail: contact@chmp.org, h.degui@chmp.org	9-10.9.2008	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
				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
				Type of analysis	Finished products	Active pharmaceutical ingredients
INFARMED I.P.³ 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	27-29.2.2008 EDQM audit	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, osmolarity, 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	HPLC (UV-VIS, DAD, fluorescence, RI, ELS, MS, electrochemical detection), GC

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

					(FID, ECD, FPD, NPD, TCD, MS detection), TLC, UV-VIS spectrophotometry, flame photometry, AAS, FTIR, potentiometry, volumetric titrations, gravimetry	(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
				Type of analysis	Finished products	Active pharmaceutical ingredients
Laboratory of Pharmaceutical Analysis State Pharmacological Centre Ministry of Health of Ukraine 14, Ezhenia Pottier St. 03680 Kiev Ukraine Tel: +38 44 536 1338, + 38 50 961 0561 Fax: + 38 44 536 1344 e-mail: zvolinnn@mail.ru	17-18.12.2009	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
				Type of analysis	Finished products	Active pharmaceutical ingredients
PROXY Laboratories B.V. Archimedesweg 25 2333 CM Leiden The Netherlands	24-26.7.2010	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,	pH, refractive index, optical rotation, viscosity, melting point, distilling range, loss on drying, water content, osmolality, conductivity, heavy metals,

Tel: +31 71 5244080 (general) fax: +31 71 5284213 e-mail: info@proxylab.nl					dissolution, uniformity of dosage units (mass, content)	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
				Type of analysis	Finished products	Active pharmaceutical ingredients
SGS Lab Simon S. A. Vieux Chemin du Poète 10 B-1301Wavre Belgium Tel: +32 10 421111; +32 10 42176; +32 10 421186 Fax: +32 10 421100 e-mail: be.lifeqc@sgs.com wim.vanimmerseel@sgs.com	13-15.10.2010	Compliant with WHO recommended standards	31.5.2011	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, refractometry, 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
				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	Sterility test, microbial limit	Sterility test, microbial limit

				tests	tests, bacterial endotoxins test (LAL), microbial assay of antibiotics	tests, bacterial endotoxins test (LAL), microbial assay of antibiotics
WHO Eastern Mediterranean Region						
				Type of analysis	Finished products	Active pharmaceutical ingredients
Laboratoire National de Contrôle des Médicaments - LNCM (Maroc)⁴ Rue Lamfadel Charkaoui - Medinat Al Irfane Rabat 10 000 Maroc Postal address: BP 6202, Rabat - Instituts Rabat Maroc Tel: +212 537681930 Fax: +212 537772520 e-mail: m-a-mahly@wanadoo.net.ma	19-21.2.2007 EDQM audit	Compliant with WHO recommended standards	17.7.2008	Physical/Chemical analysis	pH, density, refractive index, viscosity, loss on drying, water content, conductivity, disintegration, dissolution, uniformity of dosage units (mass, content), friability, tablet hardness	pH, density, refractive index, viscosity, loss on drying, melting point, water content, conductivity, 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
				Microbiological tests	Sterility test, microbial purity, test for pyrogens, bacterial endotoxins test (LAL)	Microbial purity
WHO Western Pacific Region						
				Type of analysis	Finished products	Active pharmaceutical ingredients
Health Sciences Authority - Applied Sciences Group, Pharmaceutical Division - Pharmaceutical Laboratory 11 Outram Road 169078 Singapore	9-10.3.2009	Compliant with WHO recommended standards	25.6.2009	Physical/Chemical analysis	pH, density, loss on drying, water content (Karl Fischer), disintegration, dissolution, uniformity of dosage units (mass, content), tablet hardness, limit tests	pH, refractometry, loss on drying, melting point, water content (Karl Fischer), heavy metals (AA, ICPMS), acid value, acid neutralizing capacity, iodine value, limit tests

⁴ 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.

Tel: +6562130721 Fax:+6562275341 e-mail: cheah_nuan_ping@hsa.gov.sg				Identification	HPLC (UV-Vis, PDA, fluorescence, light scattering detection, RI), GC (FID, MS, TCD), TLC, capillary electrophoresis, UV-VIS spectrophotometry, FTIR, basic tests, optical rotation	HPLC (UV-Vis, PDA, fluorescence, light scattering detection, RI), GC (FID, MS, TCD), TLC, capillary electrophoresis, UV-VIS spectrophotometry, FTIR, basic tests, optical rotation
				Assay, impurities and related substances	HPLC (UV-Vis, PDA, fluorescence, light scattering detection, RI), GC (FID, MS, TCD), UV-VIS spectrophotometry, FTIR, volumetric titrations, Determination of related substances and impurities by comparison with a reference standard	HPLC (UV-Vis, PDA, fluorescence, light scattering detection), GC (FID, MS, TCD, RI), UV-VIS spectrophotometry, FTIR, volumetric titrations, Determination of related substances and impurities by comparison with a reference standard
				Type of analysis	Finished products	Active pharmaceutical ingredients
National Institute of Drug Quality Control of Vietnam (NIDQC) 48 Hai Ba Trung Street Hanoi Vietnam Tel. +844 825 5742 Fax: +844 825 6911 E-mail: khthvkn@hn.vnn.vn vndqc@vnn.vn tvlauvkn@hotmail.com	28-29.7.2008	Compliant with WHO recommended standards	28.11.2008	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
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
TÜV SÜD PSB Pte Ltd Chemical & Materials (Food & Pharmaceutical Testing) 1 Science Park Drive Singapore 118221 Tel: +65 68851303 Fax: +65 67784301 E-mail: Jianhua.lin@tuv-sud-psb.sg	13.3.2009	Compliant with WHO recommended standards	21.8.2009	Physical/Chemical analysis	pH, loss on drying, water content (Karl Fischer), disintegration, dissolution, density, dimensions, uniformity of dosage units (mass, content), limit tests	pH, loss on drying, ash, melting point, water content (Karl Fischer), heavy metals (AA, ICP-MS), acid value, acid neutralizing capacity, iodine value, limit tests
				Identification	HPLC (UV-Vis, PDA, fluorescence, RI detection), GC (FID, MS, TCD, ECD), TLC, FTIR, UV-VIS spectrophotometry, optical rotation, basic tests	HPLC (UV-Vis, PDA, fluorescence, RI detection), GC (FID, MS, TCD), TLC, FTIR, UV-VIS spectrophotometry, optical rotation, basic tests
				Assay, impurities and related substances	HPLC (UV-Vis, PDA, fluorescence, RI detection), GC (FID, MS, TCD, ECD), FTIR, UV-VIS spectrophotometry, volumetric titrations Determination of related substances/impurities by comparison with reference standards	HPLC (UV-Vis, PDA, fluorescence, RI detection), GC (FID, MS, TCD, ECD), FTIR, UV-VIS spectrophotometry, volumetric titrations Determination of related substances and impurities by comparison with reference standards
				Microbiological tests	Sterility test, microbial limit tests, bacterial endotoxins test (LAL), preservative challenge test, antimicrobial effectiveness, microbial assay of antibiotics	Sterility test, microbial limit tests, bacterial endotoxins test (LAL), preservative challenge test, antimicrobial effectiveness, microbial assay of antibiotics

Version history

Edition	Date	Change
20 th 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 th edition	31.8.2011	Date of last inspection of Adcock Ingram Limited - Research and Development, South Africa updated Added Proxy Laboratories B.V. (The Netherlands) and INFARMED I.P. Direcção da Comprovação da Qualidade (Portugal)
18 th edition	31.5.2011	Date of the last inspection of Vimta Labs Limited (India) updated Added SGS Lab Simon S.A. (Belgium)
17 th edition	17.1.2011	Date of the last inspection of Laboratoire National de Contrôle des Produits Pharmaceutiques, LNCPP (Algérie) updated Added SGS India Pvt. Ltd. (Life Science Services), India and Tanzania Food and Drugs Authority (TFDA) Quality Control Laboratory, Tanzania
16 th edition	16.9.2010	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 th edition	16.4.2010	Added Central Laboratory for Quality Control of Medicines and Medical Products, Ukraine and Laboratory of Pharmaceutical Analysis, Ukraine Contact details of Adcock Ingram South Africa, LNCM Morocco and LNCPP Algeria updated
14 th edition	10.02.2010	Added K.A.B.S. Laboratories Inc., Canada
13 th edition	21.08.2009	Added TÜV SÜD PSB Pte Ltd, Chemical & Materials (Food & Pharmaceutical Testing), Singapore
12 th edition	25.06.2009	Added Pharmaceutical Laboratory of the Health Sciences Authority, Applied Sciences Group, Pharmaceutical Division - HSA (Singapore)
11 th edition	23.03.2009	Added Laboratory of Mission for Essential Drugs and Supplies - MEDS (Kenya)
10 th edition	28.11.2008	Added National institute of Drug Quality Control - NIDQC (Vietnam)
9 th edition	28.10.2008	Added Centre Humanitaire Médico-Pharmaceutique - CHMP (France)
8 th edition	17.07.2008	Added Laboratoire National de Contrôle des Médicaments - LNCM (Maroc), National Quality Control laboratory - NQCL (Kenya) and Vimta Labs Limited (India)
7 th edition	16.05.2008	Change reflecting the merger of RIIP and CENQAM into one organization with a single quality system
6 th edition	15.01.2008	Added Adcock Ingram Limited - Research and Development (South Africa)

5 th edition	09.01.2007	Added point 12.; 13. and 14. to General Notes
4 th edition	14.11.2006	Added the background and current status of the Programme and the general notes and the disclaimer
3 rd edition	27.10.2005	Added Laboratoire National de Contrôle des Produits Pharmaceutiques - LNCPP (Algérie)
2 nd edition	05.07.2005	Added Research Institute for Industrial Pharmacy - RIIP (South Africa)
1 st edition	22.06.2005	Added Centre for Quality Assurance of Medicines - CENQAM (South Africa)

General Notes:

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

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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:
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 - 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.
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