

WHO List of Prequalified Quality Control Laboratories

Date: 21 August 2009

- 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.

					volumetric titrations Determination of related substances/impurities and degradation products	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>
TÜV SÜD PSB Pte Ltd Chemical & Materials (Food & Pharmaceutical Testing) 1 Science Park Drive Singapore 118221 Tel: +65 68851303 Fax: +65 67784301 E-mail: xinping.HOU@tuv-sud-psb.sg	13.3.2009/ Estonia	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
				Biological 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
				<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
Vimta Labs Limited Life Sciences Facility Plot No.5, S.P.Biotech Park	14-15.4.2008/ WHO	Compliant with WHO recommen	17.7.2008	Physical/Chemical analysis	pH, loss on drying, water content, friability, disintegration, dissolution, density, tablet	pH, loss on drying, water content, density, melting point, distilling range,

		(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.

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.

Acknowledgement

WHO wishes to gratefully acknowledge the assistance provided in inspection activities by staff from national Drug Regulatory Authorities of Austria, Estonia, France, Poland, Algeria and South Africa.