World Health Organization

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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Desk Assessment of Quality Control Laboratory (QCL)

Part 1	**General information**		
Laboratory information			
Name and address of QCL	**Intertek (Schweiz) AG** TechCenter Reinach, Kägenstrasse 18, 4153, Reinach BL, Switzerland		
Laboratory units/divisions	Not applicable		
Desk assessment details			
Start and end dates of review	18 March 2019 and 10 May 2019.		
Tests covered by this desk assessment	**Type of Analysis**	**Finished Products**	**Active pharmaceutical ingredients**
	Physical/Chemical analysis	pH, water content (NMR)	pH, water content (NMR)
	Identification tests	HPLC (detectors: UV-VIS, RI, ELSD, FLD, ECD, MS, HR-MS), GC (FID, MS), spectroscopy: FTIR, UV-VIS, NMR, microscopy: Raman imaging, FTIR imaging, SEM-EDX, TEM	HPLC (detectors: UV-VIS, RI, ELSD, FLD, ECD, MS, HR-MS), GC (FID, MS), spectroscopy: FTIR, UV-VIS, NMR, microscopy: Raman imaging, FTIR imaging, SEM-EDX, TEM
	Assay, impurities and related substances	HPLC (detectors: UV-VIS, RI, ELSD, FLD, ECD, MS, HR-MS), GC (FID, MS), spectroscopy: FTIR, UV-VIS, Raman, NMR	HPLC (detectors: UV-VIS, RI, ELSD, FLD, ECD, MS, HR-MS), GC (FID, MS), spectroscopy: FTIR, UV-VIS, Raman, NMR
	Microbiological analysis	Subcontracted	Subcontracted
	Miscellaneous - Counterfeit, substandard and forensic	HPLC (detectors: UV-VIS, RI, ELSD, FLD, ECD, MS, HR-MS), GC (FID, MS),	HPLC (detectors: UV-VIS, RI, ELSD, FLD, ECD, MS, HR-MS), GC (FID, MS),

	investigation	spectroscopy: FTIR, UV-VIS, NMR, microscopy: Raman imaging, FTIR imaging, SEM-EDX, TEM	spectroscopy: FTIR, UV-VIS, NMR, microscopy: Raman imaging, FTIR imaging, SEM-EDX, TEM
	Miscellaneous - Foreign matter investigation	Particle analysis: FTIR, UV-VIS spectroscopy, Raman imaging, FTIR imaging, SEM-EDX, TEM, microscopy, NMR	Particle analysis: FTIR, UV-VIS spectroscopy, Raman imaging, FTIR imaging, SEM-EDX, TEM, microscopy, NMR

List of documents submitted	• Cover-Letter_Laboratory-Information-File-WHO_ed3-2017_signed • LIF L1407-02 WHO_ed3-2017 • Ref-1-Swissmedic-GMP-Certificate_EN-DE • Ref-2-GMP-Swissmedic-Bewilligung-November 2016-Reinach (Provided in German) • Ref-3-Inspection-Correspondence-Swissmedic-RHI-2015 (Provided in German) • Ref-4-ISO-Certificate-Reinach_2015 • Ref-5-IQ-NET-Certificate-Reinach-2015 • Ref-6-Certificate of Registration 2017 (Provided in German) • Ref-7- Site Master File • Ref-8- GLP-Certificate-2017 • Ref-9-List of general SOPs • Ref-10-Organisation chart-Intertek (Schweiz)AG-Jun 2017 • Ref-11-Site-Plans-Reinach-2017 • Ref-12-Equipment_List 2017 • Ref-13-Decision-Tree-OOS Additional documents submitted (18 October 2018) • Copy of ISO 9001:2015 certificate • EIR_FDA inspection report_cover_letter_20180312.pdf • 18-2280_GMP-Certificate_20181114-Intertek(Schweiz)AG.pdf Additional documents submitted (18 March 2019) • Inspektionsbericht_RHI_24.-25.04.2018_GMP-Basis.pdf	
Any documents missing?	None	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last)**	
RHI *Regionales Heilmittel-inspektorat der*	Dates of inspection:	*24 – 25 April 2018*
	Type of inspection:	*Basic inspection*
	Tests covered:	Not available in report

Nordwestschweiz, Switzerland.		
FDA, USA	Dates of inspection:	7-9 November 2016
	Type of inspection:	Re-inspection
	Tests covered:	Not available in report
RHI Regionales Heilmittel-inspektorat der Nordwestschweiz, Switzerland.	Dates of inspection:	12 – 13 January 2016
	Type of inspection:	*Basic inspection*
	Tests covered:	Not available in report
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	WHO have not previously performed an on-site inspection of this facility. A desk review was performed of the Intertek (Schweiz) AG, Zweigniederlassung Basel (Intertek Expert Services) site located at Bio Park Rosental Mattenstrasse 22, CH-4058, Basel on 2 October 2014. This site was found compliant.	
Brief summary of activities	Intertek (Schweiz) AG (Reinach site) has two main functions • analytical laboratory • material technology laboratory. The analytical laboratory conducts the following studies and projects for customers from the pharmaceutical industry: • Quality control analysis of drug substances and drug products • Analytical method development for pharmaceuticals (assay methods, impurity methods) • Analytical method validation for pharmaceuticals • Identification of impurities • Extractables and leachables investigations for container closure systems and process contact material • Analytical support in process validations • Analytical support in change procedures • Analytical support in failure investigations (e.g. for "new" impurities or particle analysis) • Occupational hygiene and cleaning validation • Forensic investigations • Analysis of counterfeit drug products	
General information about the QCL	Intertek (Schweiz) AG is part of the multinational company Intertek Group, with the corporate headquarters in London, UK. The Reinach site has two main functions as an analytical laboratory and as a material technology laboratory. The analytical laboratory is a contract laboratory involved in pharmaceutical analysis and in this context the laboratory is GMP qualified by the national authorities of Switzerland. Intertek is only involved in the field of chemical and physical qualitative and quantitative analysis.	

WHO Prequalified tests covered by the last WHO inspection	**Type of Analysis**	**Finished Products**	**Active pharmaceutical ingredients**
	Physical/Chemical analysis	Not stated	Not stated
	Identification tests	Not stated	Not stated
	Assay, impurities and related substances	Not stated	Not stated
	Microbiological analysis	No capacity for microbial testing (as mentioned under LIF)	No capacity for microbial testing (as mentioned under LIF)
	Stability testing	Performed on customer request	Performed on customer request
Additional tests covered by this desk assessment:	Refer to Desk assessment detail table.		

Abbreviations	**Meaning**
API	Active pharmaceutical ingredient
CAPA	Corrective and preventive action
FPP	Finished pharmaceutical product
FTIR	Fourier transform infrared spectrophotometer
GC	Gas chromatograph or gas chromatography
GLP	Good laboratory practices
GPPQCL	Good practices for pharmaceutical quality control laboratories
HPLC	High performance liquid chromatograph
QA	Quality assurance
QCL	Quality control laboratory
SOP	Standard operating procedure

Part 4	**Summary of the assessment of additional supporting documentation**

a) Authorization granted by the local authority (if any) or ISO 17025 certificate:

The following authorizations have been granted:

- ISO 9001:2008 certificate issued by IQMET – The International Certification Network (Certificate number CH-31087 issued 2015-11-16)
- ISO 9001:2008 certificate issued by SQS (Certificate number 31087 scope number 35 issued November 16, 2015)
- ISO 9001:2015 certificate issued by SQS (Certificate number 31087 scope number 35 issued September 15, 2018)

b) Laboratory information file (LIF):

The Laboratory Information file (LIF) was provided (LIF L1407-02 WHO-ed3-2017). The LIF was arranged in accordance with the WHO guidelines. A summary of processes was available within this document and found to adequately address WHO requirements.

c) List of all regulatory inspections performed in the last 3 years and their outcomes:

- Inspection report provided from 24-25 April 2018 for RHI- Regionales Heilmittelinespektorat der Nordwestschweiz
- Inspection report provided from 12-13 January 2016 for RHI- Regionales Heilmittelinespektorat der Nordwestschweiz
- Inspection conducted by FDA, USA 7-9 November 2016
- Statement of GLP Compliance issues by Swissmedic was provided.

d) Qualification, validation and calibration status of equipment:

The facility had in place a documented procedure for the qualification, validation and calibration of equipment. An equipment list was provided with each item of equipment assigned a unique identifier. The provided list did not list the qualification period for the equipment.

e) Confirmation by the quality manager that a full self-inspection dedicated to the tests submitted for prequalification has been performed and all matters dealt with:

The facility had a documented procedure of internal audits (SOP.GENE.027) that included self-inspection against GLP and ISO 9001 requirements.

f) Additional documents submitted:

Nil

Part 5	**Conclusion – Desk assessment outcome**

Based on the previous WHO desk assessment report and on the GPPQCL evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site ***Intertek (Schweiz) AG*** located at ***TechCenter Reinach, Kägenstrasse 18, 4153, Reinach BL, Switzerland*** is considered to be operating at an acceptable level of compliance with WHO GPPQCL guidelines.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 6	List of guidelines referenced in this inspection report

1. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 1.
   Short name: WHO GPPQCL Guidelines or ***TRS No. 957, Annex 1***
   http://www.who.int/medicines/publications/44threport/en/

2. WHO guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Second Report. Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 9. ***Short name: WHO TRS 1010, Annex 9***
   https://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS1010annex9.pdf?ua=1

3. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Eighth Report. Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. ***Short name: WHO GMP Guidelines*** or ***TRS No. 986, Annex 2***
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

4. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-Sixth Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2.
   Short name: WHO TRS No. 970, Annex 2
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/

5. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-Ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
   Short name: WHO TRS No. 929, Annex 4
   http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

6. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8. **Short name: WHO TRS No. 1010, Annex 8**
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en/

7. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4.
   Short name: WHO TRS No. 937, Annex 4
   http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

8. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. ***Short name: WHO TRS No. 957, Annex 2***
http://www.who.int/medicines/publications/44threport/en/

9. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2.
Short name: WHO TRS No. 957, Annex 2
http://www.who.int/medicines/publications/44threport/en/

10. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6.
Short name: WHO TRS No. 961, Annex 6
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

11. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7.
Short name: WHO TRS No. 961, Annex 7
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

12. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9.
Short name: WHO TRS No. 961, Annex 9
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

13. General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-First Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3. ***Short name: WHO TRS No. 943, Annex 3***
http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

14. WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2.
Short name: WHO TRS No. 961, Annex 2
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

15. WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2.
Short name: WHO TRS No. 981, Annex 2
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

16. WHO guidelines on variation to a prequalified product. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 3. ***Short name: WHO TRS No. 981, Annex 3***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

17. WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14. ***Short name: WHO TRS No. 961, Annex 14***
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

18. WHO Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 3. ***Short name: WHO TRS No. 992, Annex 3***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

19. WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4. ***Short name: WHO TRS No. 992, Annex 4***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

20. WHO Technical supplements to Model Guidance for storage and transport of time – and temperature – sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5. ***Short name: WHO TRS No. 992, Annex 5***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

21. Guidance on good data and record management practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 5. ***Short name: WHO TRS No. 996, Annex 5***
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf

22. WHO general guidance on variations to multisource pharmaceutical products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10.
Short name: WHO TRS No. 996, Annex 10
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

23. WHO Recommendations for quality requirements when plant – derived artemisin is used as a starting material in the prosecution of antimalarial active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 6.
Short name: WHO TRS No. 992, Annex 6
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

24. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 10.
Short name: WHO TRS No. 1010, Annex 10
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf