World Health Organization

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

Part 1	**General information**
Laboratory information	
Name and address of QCL	ALS Testing Services India Private Limited No 65, Bommasandra Jigani Link Road KIADB Industrial Area, Bangalore - 560105 Karnataka, India Tel: +91 080 61116000
Contact person	Mr Arum Janakiraman Email: arun.janakiraman@alsglobal.com
License number or ISO 17025 certificate	• A licence from the Drug Control Department, Government of Karnataka, Bangalore, India License Number KTK/37/56/2019 issued 24/09/2019 valid until 23/09/2024. • ISO 17025 certification issued by the National Accreditation Board for Testing and Calibration Laboratories, India, on 14/08/2022, valid until 13/8/2024
Desk assessment details	
Start and end dates of review	13 – 14 December 2023
Inspection record number	INSP-QCL-2022-0011
Tests covered by this desk assessment	ALS India has the capability for testing chemical and microbiological parameters as per the below matrix:

Type of analysis	**Finished products**	**Active Pharmaceutical Ingredients**
Physical/chemical analysis	pH, refractive index, optical rotation, viscosity, water content, loss on drying, density, residual solvents, limit tests, tablet hardness, friability, disintegration, dissolution, uniformity of dosage unit (mass, content), particulate matter test, Osmolality test	pH, refractive index, optical rotation, viscosity, loss on drying, melting point, heavy metals, sulphated ash, conductivity, water content, residual solvents, limit tests
Characterization	DSC, TGA, Particle size, XRD	DSC, TGA, Particle size, XRD
Identification	HPLC (UV- vis, PDA, RI, DAD, fluorescence detection), GC-MS, UV-Vis spectrophotometry, FTIR, basic test	HPLC (UV- vis, PDA, RI, DAD, fluorescence detection), GC-MS, UV-Vis spectrophotometry, FTIR, basic test
Assay, impurities and related substances	HPLC (UV- vis, PDA, RI, DAD, fluorescence detection), GC-MS, UV-Vis spectrophotometry, FTIR, ICP-MS, polarimetry, volumetric titrations	HPLC (UV- vis, PDA, RI, DAD, fluorescence detection), GC-MS, UV-Vis spectrophotometry, FTIR, ICP-MS, polarimetry, volumetric titrations

	Nitrosamine impurities	LC MSMS, GC MSMS	LC MSMS, GC MSMS
	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
	Bacterial endotoxin testing (BET)	Sterile injections, water, medical devices	Sterile injections, water, medical devices
	Stability testing	All ICH conditions	All ICH conditions
Any documents missing?	N/A		
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments**		
US FDA, USA	Dates of inspection:	24 – 28 February 2020	
	Type of inspection:	Surveillance cGMP inspection	
	Unit/Division:	Pharmaceutical control testing and Microbiology laboratory	
	Tests covered:	Not listed	
	Physical areas inspected:	Facilities and equipment of the pharmaceutical and microbiology laboratory were located on the 3rd floor, together with activities on sample receiving located on the 1st floor of the Site.	
Part 3	**Summary of the last WHO inspection**		
Date and conclusion of most recent WHO inspection	WHO has not previously inspected the site.		
General information about the company and manufacturing site	According to the information from the Laboratory Information File and SMF, together with information from the US FDA inspection report (February 2020), ALS Testing Laboratories was established in 1976 in Brisbane, Australia, as a geochemistry laboratory, i.e., Australian Laboratory Services Private Ltd (ALS) to service mineral exploration companies exploring the eastern part of Australia. In 1981, Campbell Brothers Limited acquired ALS. ALS was expanded into Asia and South America in the 1990s, North America, Africa, and Europe in the early 2000s, and finally the Middle East in 2011. In 2017, ALS Testing Services India Private Ltd was registered in India and continued with the laboratory setup and qualification in 2018. Currently, ALS India functions as a Control Testing Laboratory for Food products and Pharmaceutical products performing chemical and microbiology testing.		
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 site holds the following authorizations:

- A licence from the Drug Control Department, Government of Karnataka, Bangalore, India, license number KTK/37/56/2019, issued 24/09/2019, and valid until 23/09/2024.
- ISO 17025 certification issued by the National Accreditation Board for Testing and Calibration Laboratories, India, on 14/08/2022, valid until 13/8/2024
- EIR was issued by the US FDA on 28 February 2020 with no FDA 483.

b) Laboratory information file (LIF):
A Laboratory Information file and a Site Master File were provided. The documents contained general information on the laboratory, quality management system, document control, personnel, premises, equipment, materials, type of subcontracting and contact details, validation of analytical procedures, internal and external audits, stability, and Microbiological testing.

c) List of all regulatory inspections performed in the last 3 years and their outcomes:
The site has been inspected by the following authority:

- US FDA from 24 to 28 February 2020. No FDA 483 had been issued.

d) Qualification, validation and calibration status of equipment:
Information gathered from the SMF and the US FDA February 2020 inspection indicated that the laboratory had a documented qualification, validation, calibration, and maintenance program.

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:
A signed statement dated 21 July 2023 was provided that a full self–inspection of the laboratory was performed from 7 to 9 Feb 2023 and all the actions were completed.

Part 5	**Conclusion – Desk assessment outcome**

Based on the GPPQCL evidence received and reviewed, and taking into consideration regulatory flexibility following the Covid pandemic, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection for the site ***ALS Testing Services India Private Limited*** located at ***No 65, Bommasandra Jigani Link Road KIADB Industrial Area, Bangalore - 560105 Karnataka, India.***

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

Part 6	List of guidelines referenced in this inspection report

1. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eight Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2.
   Short name: WHO TRS No. 986, Annex 2
   https://www.who.int/publications/m/item/trs986-annex2

2. 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
   https://www.who.int/publications/m/item/annex-2-trs-957

3. 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/publications/m/item/trs1010-annex9

4. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 3.
   Short name: WHO TRS No. 1033, Annex 3
   https://www.who.int/publications/m/item/annex-3-trs-1033

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
   https://www.who.int/publications/m/item/annex-4-trs-929

6. 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 TRS No. 957, Annex 1
   https://www.who.int/publications/m/item/trs957-annex1

7. 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 3.
   Short name: WHO TRS No. 957, Annex 3
   https://www.who.int/publications/m/item/trs957-annex3

8. 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
   https://www.who.int/publications/m/item/Annex-8-trs-1010

9. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditionning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Third Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1019), Annex 2.
Short name: WHO TRS No. 1019, Annex 2
https://www.who.int/publications/m/item/trs1019-annex2

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
Short name: WHO TRS No. 1044, Annex 4
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1044-annex4-technology-transfer-in-pharmaceutical-manufacturing.pdf

11. WHO good manufacturing practices for sterile pharmaceutical products. Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
Short name: WHO TRS No. 1044, Annex 2
https://www.who.int/publications/m/item/trs1044-annex2

12. 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***
https://www.who.int/publications/m/item/trs943-annex3

13. 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
https://www.who.int/publications/m/item/trs961-annex2

14. 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
https://www.who.int/publications/m/item/trs981-annex2

15. 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
https://www.who.int/publications/m/item/annex-3-trs-981

16. 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

https://www.who.int/publications/m/item/tr961-annex14

17. Good Manufacturing Practices: Guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Third Report Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3.
Short name: WHO TRS No. 1019, Annex 3
https://www.who.int/publications/m/item/trs1019-annex3

18. 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
https://www.who.int/publications/m/item/trs992-annex4

19. 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
https://www.who.int/publications/m/item/trs961-annex9-modelguidanceforstoragetransport

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
https://www.who.int/publications/m/item/trs992-annex5

21. WHO Recommendations for quality requirements when plant – derived artemisinin is used as a starting material in the production 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
https://www.who.int/publications/m/item/trs-992-annex-6

22. Guideline on data integrity. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 4.
Short name: WHO TRS No. 1033, Annex 4
https://www.who.int/publications/m/item/annex-4-trs-1033

23. WHO general guidance on variations to multisource pharmaceutical products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10.
Short name: WHO TRS No. 996, Annex 10
https://www.who.int/publications/m/item/trs966-annex10
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***
https://www.who.int/publications/m/item/trs1010-annex10

25. Points to consider when including Health-Based Exposure Limits in cleaning validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 2.
Short name: WHO TRS No. 1033, Annex 2
https://www.who.int/publications/m/item/annex-2-trs-1033

26. Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fourth Report Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 6.
Short name: WHO TRS No. 1025, Annex 6
https://www.who.int/publications/m/item/trs-1025-annex-6

27. Production of water for injection by means other than distillation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 3.
Short name: WHO TRS No. 1025, Annex 3
https://www.who.int/publications/m/item/trs-1025-annex-3-water-for-injection

27. Good chromatography practice. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 4.
Short name: WHO TRS No. 1025, Annex 4
https://www.who.int/publications/m/item/trs1025-annex4