World Health Organization

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Prequalification Unit Inspection Services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
CONTRACT RESEARCH ORGANIZATION (CRO)

Part 1	**General information**	
Company information		
Name of Company	QPS Bioserve India Private Limited	
Corporate address of the Company	Plot No 47, IDA Balanagar, Hyderabad, Telangana 500037 Tel: +91-40-23070874 / 6837 5555 GPS coordinat: 17.469537, 78.445939	
Inspected site		
Name & address of CRO if different from that given above	Not applicable	
Clinical trial license number	Not applicable	
Desk assessment details		
Date of review	2-4, 24-30 April and 22 June 2025	
Product and study information covered by this desk assessment	**WHO application no: HA803** Study no. 61120 An open-label, balanced, randomized, two-treatment, two-period, two-sequence, single-dose, crossover, oral bioequivalence study of Abacavir, Dolutegravir and Lamivudine Tablets 600 mg/50 mg/300 mg of Laurus Labs Limited, India, compared with Triumeq® (abacavir, dolutegravir, and lamivudine) 600 mg/50 mg/300 mg Tablets of ViiV Healthcare Research Triangle Park, NC 27709 in healthy, adult, human subjects under fasting conditions.	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last)**	
UK-MHRA	Dates of inspection:	25-29 November 2024
	Type of inspection:	Inspection to assess the level of compliance of the selected studies with the principles of GCP
	Unit:	Plot No 47, Jeedimetla Main Road, IDA, Balanagar, Hyderabad, Telangana, 500037, India
	Type of study covered:	Bioequivalence Studies
US FDA	Dates of inspection:	14-17 August 2023

	Type of inspection:	Remote Regulatory Assessment (RRA)
	Unit:	QPS Bioserve India Pvt., Ltd. Plot No. 47, 2nd Floor, Balanagar IDA, Balanagar Crossroads, Medchal District, Hyderabad, Telangana, India.
	Type of study covered:	The RRA covered the method validation and sample analysis activities conducted by QPS Bioserve India Pvt., Ltd.
US FDA	Dates of inspection:	19-23 September 2022
	Type of inspection:	Foreign, premarket original pre-approval, data validation inspection of a bioequivalence clinical and bioanalytical study facility.
	Unit:	Plot No. 47, IDA Balanagar, Hyderabad, India)
	Type of study covered:	Bioequivalence clinical and bioanalytical study
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	The last WHO on-site inspection was conducted from 3 to 6 October 2017, and the site was deemed compliant with WHO GMP guidelines. A desk assessment was performed in September-October 2020.	
Brief description of the site's activities	QPS India is authorized to conduct clinical and bioanalytical services. The company provides clinical services to new (e.g. re-formulated or fixed dose combinations) and generic drug product manufacturers.	
Areas inspected during the last WHO inspection	Bioanalytical and Clinical activities include organization and management; computer system; quality management; archive facilities; premises; personnel; clinical phase; clinical laboratory; monitoring; investigators; receiving, storage and handling of investigational drug products; case report forms; volunteers and recruitment methods; and Safety, adverse events, adverse event reporting.	
Out of scope and restrictions (last WHO inspection)	Food and Fluids	
WHO product(s) and clinical trial(s) covered by the last WHO inspection	TB341 Study no: 661/16 Moxifloxacin Hydrochloride vs AVELOX® 400 mg Tablets MA138 Study no: 776/15 Artemether and Lumefantrine Tablets 80/480 mg vs COARTEM® Tablets 20/120 mg	

	MA110 Study no: 671/16 Artemether 20 mg and Lumefantrine 120 mg dispersible tablets vs Riamet®) 20 mg/120 mg
Abbreviations	**Meaning**
CCs	Calibration Curve standards
CAPA	Corrective and preventive action
CROMF	CRO master file
GCP	Good clinical practices
GLP	Good laboratory practices
NC	Non-conformity
NRA	National regulatory agency
QA	Quality assurance
QC	Quality control
SOP	Standard operating procedure
SRA	Stringent regulatory authority

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

a) Clinical trial license granted by the local authority:

The company submitted letter No. E-EXPORT/20/000478 dated 8 April 2020 from the Central Drugs Standard Control Organization, which stated the permission for conducting bioavailability or bioequivalence study as per the provisions of New Drugs and Clinical Trial Rules, 2019 under the Drugs and Cosmetics Act,1940. Permission was given to QPS Bioserve India Ltd, Plot No. 47, IDA, Balanagar, Hyderabad, Telangana- 500037 on behalf of the sponsor M/s M/s. Laurus Labs Limited Plot No.21, JNPC, Parawada, Visakhapatnam, Andhra Pradesh, India - 531021.

b) CRO Master File:

The CROMF document No. QAM001 version 03, released by the organization on 6 June 2022, was signed by the responsible individuals and received approval from the Sr. Vice President and Managing Director. The Master File included the necessary sections as per the relevant guidelines.

Based on the CRO Master File, in the year 2017, QPS India leased a new building close to the old facility and built a completely new clinical, bioanalytical, and administrative facility, and the old facility was closed on the 27th of February 2020, and all the activities were moved to new facility Plot No. 47, IDA Balanagar, Hyderabad – 500 037, Telangana, India. The new facility has been operational since August 2019.

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

The list was provided as follows:

No.	Regulatory Agency	Inspection Date
1.	UK-MHRA	25-29 November 2024
2.	DCGI, India	18-20 September 2024
3.	Gulf Cooperation Council (GCC)	28-30 November 2023
4.	US FDA (GLP remote audit)	14-17 August 2023
5.	Anvisa (remote audit)	12-16 June 2023
6.	US FDA	19-23 September 2022

d) Copy of any warning letter, or equivalent regulatory action, issued by any authority for the site:

Not applicable. The company has not received any warning letter or regulatory actions issued by any authority for the site.

e) Confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the studies conducted for the WHO product(s) has been performed and all matters dealt with:

A declaration letter for the Quality Assurance full self-inspection dedicated to all studies performed for the WHO Products, including pharmacy, clinical phase, bioanalytical phase, statistics, and clinical study report.

f) IRB/IEC clinical trial approval (including the approved protocol, the amended protocol and consent form):

Protocol and its associated documentation received approval from QPS Bioserve Ethics Committee.

g) A list of any study failures in the last three years:

A list of failed studies during the period from 2022 to 2024 has been provided.

h) Additional documents submitted:

CAPA plan(s) and proof of the plan's implementation related to the respective stringent authority inspection report observations/deficiencies were also provided.

Part 5	**Conclusion – Desk assessment outcome**

Based on the previous WHO inspection and on the GCP/GLP/BE evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site ***QPS Bioserve India Private Limited,*** located at **Plot No 47, IDA Balanagar, Hyderabad, Telangana 500037, *India,*** is considered to be operating at an acceptable level of compliance with WHO guidelines.

The 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. Guidance for organizations performing in vivo bioequivalence studies. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 9.
   Short name: WHO BE guidance or ***TRS996 Annex 9***
   https://apps.who.int/iris/bitstream/handle/10665/255338/9789241209960-eng.pdf?sequence=1&isAllowed=y

2. Good clinical laboratory practice (GCLP), WHO on behalf of the Special Programme for Research and Training in Tropical Diseases. Geneva, 2009
   Short name: WHO GCLP
   https://apps.who.int/iris/handle/10665/44092

3. Guidelines for good clinical practice for trials on pharmaceutical products. WHO Technical Report Series, No. 850, 1995 (pp. 97–137).
   Short name: WHO GCP
   https://www.who.int/publications/i/item/9241208503

4. Handbook – Good Laboratory Practice (GLP): quality practices for regulated non-clinical research and development – Annex I: The OECD Principles on GLP, 2nd ed., 2009. ***Short name: OECD GLP***
   http://www.who.int/tdr/publications/documents/glp-handbook.pdf

5. Standards and operational guidance for ethics review of health-related research with human participants. Guidance Document. Geneva, World Health Organization, 2011.
   Short name: WHO Ethics Committee Guidance
   https://www.who.int/publications/i/item/9789241502948

6. Guidelines for the preparation of a contract research organization master file, WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 7.
   Short name: WHO CROMF Guidelines or ***TRS No. 957, Annex 7***
   https://www.who.int/publications/i/item/WHO_TRS_957

7. 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 storage and transport guidance or ***TRS 961 Annex 9***
   https://apps.who.int/iris/bitstream/handle/10665/44079/WHO_TRS_961_eng.pdf?sequence=1&isAllowed=y

8. Glove use information leaflet, Patient Safety, Save lives clean your hands. Geneva, World Health Organization, 2009 (revised).
   Short name: Glove use information leaflet
   https://www.who.int/publications/m/item/glove-use-information-leaflet-(revised-august-2009)

9. Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. Republication of multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. WHO Technical Report Series No. 992, Annex 7 with a new appendix 2. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-first Report Geneva, World Health Organization, 2017 (WHO Technical Report Series, No. 1003), Annex 6.
Short name: TRS 1003 Annex 6
chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/regulatory-standards/trs1003-annex6-who-multisource-pharmaceutical-products-interchangeability.pdf

10. 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://apps.who.int/iris/handle/10665/331814

11. 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 1033, Annex 4
https://apps.who.int/iris/handle/10665/340323

12. Declaration of Helsinki, World Medical Association Declaration of Helsinki, Ethical principles for medical research involving human subjects, Bulletin of the World Health Organization, 2001 (79(4)).
Short name: Declaration of Helsinki
https://apps.who.int/iris/handle/10665/268312

13. Bioanalytical Method Validation and Study Sample Analysis M10, ICH Harmonised Guideline, Final version, Adopted on 24 May 2022
Short name: ICH M10
https://database.ich.org/sites/default/files/M10_Guideline_Step4_2022_0524.pdf

14. 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/trs-1019---annex-3-good-manufacturing-practices-guidelines-on-validation

15. Supplementary guidelines on good manufacturing practices: validation, WHO Expert Committee on Specifications for Pharmaceutical Preparations, Fortieth report, World Health Organization, 2006 (Technical Report Series, No. 937), Annex 4.
Short name: WHO No. 937, Annex 4
https://apps.who.int/iris/handle/10665/43443ring-practices-guidelines-on-validation