World Health Organization

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Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT
DESK ASSESSMENT OF CONTRACT RESEARCH ORGANIZATION (CRO)
WHOPIR

Part 1	**General information**	
Company information		
Name of Company	QPS Bioserve India Pvt Limited	
Corporate address of Company	Plot No 47, IDA Balanagar Hyderabad, 500 037 Telangana, India	
Inspected site		
Name & address of CRO if different from that given above	Clinical Facility QPS Bioserve India Pvt Limited 6-56/6/1A, Opp. IDPL Factory Balanagar, Hyderabad, 500 037 Telangana India **The site was closed in February 2020.** Analytical Laboratories & Pharmacokinetic / Statistical analysis QPS Bioserve India Pvt Limited Plot No 47, Second floor IDA Balanagar, Hyderabad, 500037	
Desk assessment details		
Date of review	02 October 2020	
Product and study information covered by this desk assessment	Study number: 607/18 Daclatasvir Tablets 60 mg	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last)**	
NPRA, Malaysia	Dates of inspection:	14 – 18 October 2019
	Type of inspection:	Study specific inspection
	Unit:	Clinical & bioanalytical units
	Type of study covered:	Bioequivalence
US FDA, USA	Dates of inspection:	16 - 20 September 2019
	Type of inspection:	The inspection was conducted in accordance with Compliance

		program 7348.003 In Vivo Bioavailability/Bioequivalence Studies (Clinical)
	Unit:	Clinical Unit
	Type of study covered:	Bioequivalence
MHRA, UK	Dates of inspection:	4 - 8 March 2019
	Type of inspection:	Bioequivalence Good Clinical Practice (GCP) Inspection – System inspection
	Unit:	Bioanalytical & the previous clinical unit
	Type of study covered:	Bioequivalence
US FDA, USA	Dates of inspection:	19 – 23 February 2018
	Type of inspection:	Fiscal Year 2018, CDER pre-approval surveillance inspection of bioequivalence (BE) studies submitted to the FDA
	Unit:	The Clinical site located at 6-56/6/1/A, Opposite IDPL Factory, Balanagar, Bhavani Nagar, Moosapet, Hyderabad, 500 037; India
	Type of study covered:	In-Vivo Bioequivalence
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	The firm was previously inspected on 3-6 October 2017. The studies were considered to be performed in compliance with WHO Good Clinical Practice (GCP) and/or other applicable Guidelines published by the World Health Organization (WHO).	
Brief description of the site's activities	QPS Bioserve was established on 29 Oct 2004 as Bioserve Clinical Research Private Limited to provide clinical research services. In January 2011, the organization was acquired by QPS, LLC and the company was renamed as QPS Bioserve India Private Limited. QPS Holdings, LLC (QPS) was founded in 1995 and is headquartered in Newark, Delaware (USA). QPS consists of a network of subsidiary companies and facilities offering a full range of preclinical and clinical services to pharmaceutical and biotechnology customers worldwide. QPS Bioserve India Private Limited (QPS India) is an independent contract research organization that provides the following to Contract Research Services to Pharmaceutical, Biotechnology and Nutraceutical companies worldwide: - Medical Writing - Early Phase Clinical Studies in Healthy General Population	

	- Late Phase Clinical Studies in Patient Population - Pharmacy - Bioanalysis - Study Monitoring - Clinical Data Management - Pharmacokinetic & Statistics - Report Writing & Publishing - Quality Assurance
Areas inspected during the last WHO inspection	Bioanalytical and clinical facilities
Out of scope and restrictions (last WHO inspection)	Not applicable
WHO product(s) and clinical trial(s) covered by the last WHO inspection	Study no: 661/16 Moxifloxacin Hydrochloride Study no: 776/15 Artemether and Lumefantrine Tablets 80/480 mg Study no: 671/16 Artemether 20 mg and Lumefantrine 120 mg dispersible tablets
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:

A licence to import drugs for the purposes of examination, test or analysis was issued on 22 May 2018. A letter of No Objection was also provided by CDSCO.

b) CRO Master File:
A Quality Manual, with version 02, effective 15 Apr 2020 was provided.

The CRO is recommended to provide a CRO Master File to include all information required by the guidelines for the preparation of a contract research organization master file (WHO Technical Report Series, No. 957, 2010, Annex 7).

According to the abovementioned guideline, the CRO master file should be a document prepared by the CRO containing specific and information about the CRO and the conduct of clinical studies, as well as the analyses of samples and related operations carried out at the named site. It is expected that a CROMF provides information on the policies, approach and general activities of a CRO.

c) List of all regulatory inspections performed in the last 3 years and their outcome:
A list of all regulatory inspections performed in the last 3 years was provided. For more details refer to part 2 of this inspection report.

d) Copy of any warning letter, or equivalent regulatory action, issued by any authority for the site:
The CRO has informed that a warning letter has never been issued by any authority for these sites.

e) Confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the studies conducted for WHO product(s) has been performed and all matters dealt with:
A confirmation that a full audit dedicated to all studies for WHO products was issued by the Senior Manager, Quality Assurance on 23 September 2020.

f) IRB/IEC clinical trial approval (including the approved protocol, the amended protocol and consent form):
The following documents were approved by The QPS Bioserve Ethics Committee on 3 Apr & 14 Aug 2018:

- Study Protocol
- Informed Consent Form, in applicable language
- Proposed methods for subject's accrual including advertisement(s) etc. proposed to be used for the purpose.
- Principal Investigator's Current CV
- Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.
- Investigator's / CRO Agreement with the sponsor
- Investigator's Undertaking

g) A list of any study failures in the last three years:
Lists of study failures, consisting of both pilot and pivotal studies were provided for years 2017 to 2020.

h) Additional documents submitted:
- Notification of EC approved documents of Daclatasvir tablets 60 mg BE studies

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 Pvt Limited*** located at ***the following addresses*** is considered to have performed the study submitted to WHO PQT under an acceptable level of compliance with WHO guidelines.

Clinical Facility
QPS Bioserve India Pvt Limited
6-56/6/1A, Opp. IDPL Factory
Balanagar, Hyderabad, 500 037
Telangana
India
The site was closed in February 2020.

Analytical Laboratories & Pharmacokinetic / Statistical analysis
QPS Bioserve India Pvt Limited
Plot No 47, Second floor
IDA Balanagar, Hyderabad, 500037

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

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***
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex09.pdf

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://www.who.int/tdr/publications/documents/gclp-web.pdf

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***
http://apps.who.int/medicinedocs/en/d/Js5516e/19.11.html

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/ethics/publications/9789241502948/en/

6. 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***
http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf

7. 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***
http://www.who.int/medicines/publications/44threport/en/

8. Glove use information leaflet, Patient Safety, Save lives clean your hands. Geneva, World Health Organization, 2009 (revised). ***Short name: Glove use information leaflet***
http://www.who.int/gpsc/5may/Glove_Use_Information_Leaflet.pdf

9. WHO 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: TRS 996 Annex 5 or ***WHO GDRMP guidance***
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf

10. 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***
http://apps.who.int/medicinedocs/documents/s23245en/s23245en.pdf

11. 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-detail/978-92-4-000182-4

12. 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