World Health Organization

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Prequalification Unit 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	Instituto Nacional de Controle de Qualidade em Saude-INCQS Rio de Janeiro (RJ-Brasil), Av. Brasil nº 4365, Manguinhos, CEP 21040-900.
Contact person(s)	Dr Tatiana Forti Fundação Oswaldo Cruz-FIOCRUZ Instituto Nacional de Controle de Qualidade em Saude-INCQS Vice-Diretoria de Gestão da Qualidade Tel: (21) 3865-5195 e-mail: incqs.vdquali@fiocruz.br
License number or ISO 17025 certificate	Accreditation Certificate issued by the National Institute of Metrology *The General Coordination for Accreditation of Inmetro (Cgcre) grants accreditation to the Conformity Assessment Body above identified, at the mentioned address, according to the requirements of ABNT NBR ISO/IEC 17025:2017. This accreditation is the formal expression of the recognition of its competence to carry out testing activities, as described in the Accreditation Scope.*
Desk assessment details	
Start and end dates of review	20-21 February 2025
Inspection record number	I-01173 (INSP-QCL-2018-0094)
Tests covered by this desk assessment	Instituto Nacional de Controle de Qualidade em Saude-INCQS has the capacity for testing chemical and microbiological parameters as per the below table.

Type of Analysis	**Finished Products**
Physical/Chemical analysis	pH, Disintegration time, Density, Dissolution, Uniformity of content, Uniformity of weight, Specific Rotation (polarimetry)
Identification tests	FTIR, Identification reactions, TLC, HPLC, UV-vis Spectrophotometry, Basic tests
Assay, impurities, and related substances	HPLC (UV-VIS, PDA, refractometer), UV-vis Spectrophotometry, FTIR

	Microbiological analysis	Microbial limit tests, Bacterial Endotoxins
	Sterility testing has been removed from the scope.	
Part 2	**Summary of SRA/NRA inspection evidence considered**	
ANVISA Public Health laboratory Office	Dates of inspection:	20-22 June 2023
	Type of inspection:	Surveillance Audit
	Unit/Division:	Pharmaceutical control testing and Microbiology laboratory
	Tests covered:	Not listed
	Physical areas inspected:	Facilities and equipment of the Physiochemistry laboratory and microbiology laboratory were inspected.
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	An initial WHO onsite inspection was conducted between 19-24 April 2018. The site was found compliant on 11 July 2018. The laboratory submitted a corrective action plan with supporting evidence that was found acceptable.	
Summary of activities	The activities listed in the previous WHO inspection report were the same as those listed above. The laboratory has not declared any major changes to the facility, testing processes or personnel since the last WHO inspection.	
General information about the company and manufacturing site	INCQS is a National Reference Laboratory that is responsible for the quality control of foods, drugs, biological products, health related and dialysis items, hygiene and disinfectant reagents, diagnostic kits, cosmetics, blood and blood derivatives, as well as environmental services. As delegated by the Brazilian National Regulatory Agency (ANVISA), INCQS is responsible for the analysis and approval for release and distribution of blood products and its derivatives that are to be consumed in Brazil or exported. INCQS is responsible for the analysis and approval for release and distribution of all batches of vaccines and sera produced and consumed in Brazil.	
Focus of the last WHO inspection	The scope of the inspection was to verify that the laboratory was operating in accordance with international and WHO requirements.	
Areas inspected	Chemical, physicochemical, and microbiological laboratories were inspected.	
Out of scope and restrictions (last WHO inspection)	None listed	

WHO Prequalified tests covered by the last WHO inspection	**Type of Analysis**	**Finished Products**
	Physical/Chemical analysis	pH, Disintegration time, Density, Dissolution, Uniformity of content, Uniformity of weight, Specific Rotation (polarimetry)
	Identification tests	FTIR, Identification reactions, TLC, HPLC, UV-vis Spectrophotometry, Basic tests
	Assay, impurities, and related substances	HPLC (UV-VIS, PDA, refractometer), UV-vis Spectrophotometry, FTIR
	Microbiological analysis	Microbial limit tests, Bacterial Endotoxins, Sterility test (temporarily interrupted)

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 or ISO 17025 certificate:
The laboratory submitted the ANVISA declaration stating that the laboratory was declared as part of the National Network of Health Surveillance Laboratories (RNLVISA) as a result of the audit conducted between 20 and 22 June 2023.

b) Laboratory information file (LIF):
A Laboratory Information file was provided (dated February 2024). This document was set out in accordance with WHO requirements. It contained general information on the quality management system, a copy of the organizational chart, with appropriate reporting lines, document control, personnel, premises, equipment, materials, OOS investigations, internal and external audits, stability, and Microbiological and chemical testing. Photographs of the storage areas and pictorials of the laboratory layout were available.

The LIF stated that INCQS did not subcontract sample analysis services.

c) List of all regulatory inspections performed in the last 3 years and their outcomes:
The laboratory was last audited by ANVISA Public Health Laboratory Office between 20 and 22 June 2023. The audit report provided was comprehensive and detailed. All major areas of the laboratory were reported upon.

d) Qualification, validation, and calibration status of equipment:
The laboratory provided a copy of the list of analytical equipment containing the last date of calibration, the last date of qualification and the unique identifier.

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 statement was provided and signed on 23 September 2024 that a full self – inspection of the laboratory was performed for the year 2024. The laboratory also stated that they had performed a gap analysis of TRS 1052 – Annex 4: WHO good practices for pharmaceutical quality control laboratories (26 April 2024) and were in the process of adapting their documentation to meet the new Annex 4 requirements.

f) Additional documents submitted:
The laboratory provided a copy of the tests performed from 2021 to early 2024. Including failed tests. The information contained sample number, product description, test, and method information.

Part 5	**Conclusion – Desk assessment outcome**

Based on the previous WHO inspection and on the GPPQCL evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. ***Instituto Nacional de Controle de Qualidade em Saude-INCQS*** *located at* ***Rio de Janeiro (RJ-Brasil), Av. Brasil nº 4365, Manguinhos, CEP 21040-900****, is considered to be operating at an acceptable level of compliance with WHO GPPQCL guidelines.*

This compliance status shall be valid until 22 June 2026, unless an earlier inspection conducted by WHO or a WHO-recognized authority results in a different outcome.

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. Fifty-seventh Report, Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1052), Annex 4.
   Short name: WHO GPPQCL Guidelines, TRS No 1052, Annex 4
   https://www.who.int/publications/i/item/9789240091030

2. 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

3. 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

4. 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-

5. 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***
   https://www.who.int/publications/m/item/trs986-

6. 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

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. 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
   https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/production/trs961-annex6-gmp-sterile-pharmaceutical-products.pdf

9. 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
   https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/production/trs961-annex7-transfer-technology-pharmaceutical-manufacturing.pdf?sfvrsn=2e302838_0

10. 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. 96, Annex 9)
    Short name: WHO TRS No. 961, Annex 9
    https://www.who.int/publications/m/item/trs961-annex9-modelguidanceforstoragetransport

11. 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

12. 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
    Short name: WHO TRS No. 1010, Annex 8
    https://www.who.int/publications/m/item/Annex-8-trs-1010

13. 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

14. 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

15. WHO guidelines for preparing a laboratory information file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report, Geneva. WHO Technical Report Series, No. 961, 2011, Annex 13.
    Short name: WHO TRS No. 961, Annex 13
    https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/quality-control/trs961-annex13-guidelines-preparing-laboratory-information-file.pdf?sfvrsn=54d1f397_2 https://www.who.int/publications/i/item/9789241209922

16. 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

17. 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

18. 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

19. Good chromatography practices. 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 Good chromatography practices
https://www.who.int/publications/m/item/trs1025-annex4

20. Good manufacturing practices: guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third report, Geneva, World Health Organization, 2020 (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

21. WHO model certificate of analysis. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second report, Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 4.
Short name: WHO TRS No. 1010, Annex 4
https://www.who.int/publications/m/item/trs1010-annex4

22. 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

23. Guidelines on pre-approval inspections. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-sixth report, Geneva, World Health Organization, 2002 (WHO Technical Report Series, No. 902), Annex 7
Short name: WHO TRS No 902, Annex 7
https://www.who.int/publications/m/item/trs902-annex7

24. Prequalification of quality control laboratories: procedure for assessing the acceptability, in principle, of quality control laboratories for use by United Nations agencies. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-first report, Geneva, World Health Organization, 2017 (WHO Technical Report Series, No. 1003), Annex 3
Short name: WHO TRS No 1003, Annex 3
https://www.who.int/publications/m/item/annex-3-trs-1003