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Prequalification Unit Inspection Services
WHO PUBLIC INSPECTION REPORT
WHOPIR
Desk Assessment of Finished Product Manufacturer

Part 1	**General information**
Company information	
Name of Manufacturer	Aspiro Pharma Limited
Corporate address of the manufacturer	Plot No. 23, Sy. No. 321, Biotech Park Phase – III, Karkapatla (Village) Markook Mandal, Siddipet (Dist.) Telangana – 502281, India Web: www.aspiropharma.com Mail: info.aspiro@aspiropharma.com Tel: +91–9959644055
Inspected site	
Name & address of manufacturing site	Aspiro Pharma Limited Plot No. 23, Sy. No. 321, Biotech Park, Phase–III, Karkapatla (Village) Markook Mandal, Siddipet (Dist.) – 502281 Telangana (State), India Tel: +91–9959644055 Land Line: 08454-245600 Fax: 08454-245662 Latitude: 17.6825° N Longitude: 78.7292° E
Production Block/Unit	Block-1, specifically the Ground floor, houses the lyophilized, Liquid injectable, Prefilled Syringes production lines, The first floor houses ophthalmic solutions & Injectable Suspensions along with the associated clean utilities and support areas. Products Manufactured: - Liquid Injectables (Aseptically Filled & Terminally Sterilized) - Lyophilized Injectables - Prefilled Syringes - Ophthalmic solutions & Injectable Suspensions
Manufacturing license number	Aspiro Pharma Limited holds a valid manufacturing license issued by the Drugs Control Administration, Telangana, India. The license was issued in Form-28 on 5 February 2014, authorizing the manufacture, sale, and distribution of pharmaceutical formulations. The license was valid until 03/02/2029.
Desk assessment details	
Start and end dates of review	5-8 May 2025

Products covered by this desk assessment	Remdesivir Powder for solution for injection 100mg/vial (with WHO ePQS no. CV001)	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments**	
USFDA	Dates of inspection:	1 - 11 August 2023
	Type of inspection:	For-cause GMP and Pre-Approval Inspection
	Block/Unit:	The inspection primarily covered Block 1, where sterile manufacturing operations, including lyophilized and liquid injectable production, took place.
	Type of products/Dosage forms covered:	The inspection covered lyophilized injectables and liquid injectables, including both aseptically filled and terminally sterilized dosage forms.
EU-DUTCH (Netherlands)	Dates of inspection:	12 – 15 June 2023
	Type of inspection:	GMP inspection to verify compliance with EU GMP requirements, specifically under the framework of Directive 2001/83/EC and the EU Guidelines to Good Manufacturing Practice (EudraLex Volume 4)
	Block/Unit:	The GMP inspection primarily covered Block-1, where the sterile manufacturing operations are located, including lyophilized and liquid injectable production on filling lines 1 to 4. It also included Block 2, which houses quality control laboratories, packaging operations, and visual inspection areas.
	Type of products/Dosage forms covered:	The following types of products and dosage forms were included in the scope of inspection: • Lyophilized injectables • Liquid injectables • Sterile products processed by both aseptic filling and terminal sterilization
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	Aspiro Pharma Limited was not subject to any onsite inspection by WHO. A desk assessment was performed by WHO in 2020.	
Summary of manufacturing activities	Aspiro Pharma Limited is a sterile pharmaceutical manufacturing facility dedicated to producing finished dosage forms for human use. The site complies with international GMP standards, including USFDA, EU, WHO, and Indian Schedule M. Its manufacturing scope includes liquid injectables	

	(aseptically filled and terminally sterilized), lyophilized injections, prefilled syringes, ophthalmic solutions, and injectable suspensions. The site does not handle Penicillins, Cephalosporins, or cytotoxic products. The facility is structured into two main blocks. Block-1 houses core production operations with six injectable lines, compounding areas, clean utilities (PW, WFI, pure steam), and a microbiology lab. Block-2 contains QA, QC, visual inspection, packaging lines, cold storage, and stability chambers. Accessory buildings support ancillary functions such as HR, engineering, and warehousing. Production follows detailed master batch records and SOPs, covering all steps from material handling to sterile filtration, aseptic filling, lyophilization, and final packaging. Manufacturing occurs in classified cleanrooms with HEPA filtration and controlled environments (Grade A–D). In-process controls ensure quality at all critical stages. Electronic systems like SAP, LIMS, and Empower support documentation, inventory, and data integrity. Equipment is fully qualified and calibrated, and a robust validation program ensures process reliability and compliance.
General information about the company and manufacturing site	Aspiro Pharma Limited is a sterile pharmaceutical manufacturing facility located within Biotech Park, Phase III, Karkapatla Village, Telangana, India. Spanning approximately 10 acres, the site is reportedly equipped with modern infrastructure, clean utilities, and controlled environments designed to meet global Good Manufacturing Practice standards. It operates under a quality management system and has been inspected by several national and international regulatory authorities, including the USFDA, EU-Dutch (Netherlands), WHO-GMP (via CDSCO and DCA India), SAHPRA (South Africa), NAFDAC (Nigeria), and SMDC (Ukraine). The facility is well-connected to Hyderabad, supporting both regulatory compliance and commercial supply.
The focus of the last WHO inspection	Not applicable
Areas inspected	The product reviewed during the previous desk assessment was associated with Blocks 1 and 2.
Out of scope and restrictions (last WHO inspection)	Not applicable.
WHO products covered by the previous WHO Desk Assessment	Remdesivir Powder for solution for injection 100mg/vial
Additional products to be	None

covered by this desk assessment:	
Abbreviations	**Meaning**
AHU	Air handling unit
API	Active pharmaceutical ingredient
BMR	Batch manufacturing record
BPR	Batch Packing record
CAPA	Corrective and preventive action
CC	Change control
FPP	Finished pharmaceutical product
GMP	Good manufacturing practices
NC	Non-conformity
NRA	National regulatory agency
PQR	Product quality review
PQS	Pharmaceutical quality system
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
SMF	Site master file
SOP	Standard operating procedure
SSCC	Serial shipping container code

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

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

The list of regulatory inspections performed in the last five years was documented in Annexure 3 of the SMF, as follows:

Regulatory Agency	**Date(s) of Inspection**
WHO - Geneva (Desk Assessment)	31-08-2020 to 16-10-2020
EU - DUTCH (Netherlands)	12-06-2023 to 15-06-2023
Kenya - Pharmacy and Poisons Board	02-05-2022
ZAZIBONA (Zambia, Zimbabwe, etc.)	12-05-2022 to 13-05-2022
Schedule M GMP, DCA - Telangana, INDIA	24-02-2025
WHO-GMP - CDSCO & DCA Telangana	22-07-2024 to 24-07-2024
EU - Netherlands (Dutch)	12-06-2023 to 15-06-2023
USFDA	01-08-2023 to 11-08-2023
Schedule M GMP, DCA - Telangana, INDIA	30-01-2024
Uganda - National Drug Authority	28-02-2024 to 01-03-2024
Ukraine – SMDC	04-03-2024 to 09-03-2024

CDSCO & DCA Joint Inspection	22-07-2024 & 23-07-2024
SAHPRA - South Africa	11-11-2024 to 15-11-2024
NAFDAC – Nigeria	28-11-2024 to 29-11-2024
BELARUS - EAEU Countries	03-02-2025 to 07-02-2025
Schedule M GMP, DCA - Telangana, INDIA	24-02-2025
ZAZIBONA (Zambia, Zimbabwe, etc.)	28-03-2025 to 02-04-2025

The outcomes of all inspections conducted in the last three years have been reported as positive in a separate document submitted to the WHO. There is no indication that any previous inspections resulted in a different outcome.

b) Manufacturing authorization granted by national authorities:

Authority	License No. & Form	Issued To	Address	Validity	Scope
Drugs Control Administration, Telangana	Form 28	Aspiro Pharma Limited	Sy. No. 321, Biotech Park, Phase-III, Karkapatla Village, Siddipet District, Telangana, India	Valid until 03/02/2029	Manufacturing for sale/distribution of approved drugs (per GMP under Schedule M)
Drugs Control Administration, Telangana	Form 28A	Hetero Labs Ltd (at Aspiro site)	Same as above (Loan license basis)	Valid until 26/11/2029	Manufacture of Remdesivir injections (liquid & lyophilized) for Domestic and Export markets

Hetero Labs Ltd holds a loan license (Form 28A) permitting the manufacture of Remdesivir formulations at the GMP-compliant site of Aspiro Pharma Limited. This allows the use of an established manufacturing facility for production under regulatory oversight, ensuring compliance with national standards while facilitating market and export demands. This arrangement is applied under Indian Drugs and Cosmetics Rules and is commonly used for flexibility in manufacturing and scale-up, especially for time-sensitive or high-demand products like Remdesivir.

c) Site master file:

The Site Master File of Aspiro Pharma Limited has been prepared in line with the format and guidance provided in WHO Technical Report Series No. 961, Annex 14. It comprehensively described the facility, operations, quality systems, and regulatory compliance status, supporting transparency and readiness for GMP inspections by national and international authorities. It also records the site's regulatory inspection history and licensing status. The document is scheduled for periodic review and update, with the next review due by October 2026.

The review of the submitted SMF revealed no non-conformities.

d) List of all the products and dosage forms manufactured on-site:

Aspiro Pharma Limited manufactured a wide range of sterile pharmaceutical products, primarily in the form of:

- Lyophilized Injectables (e.g., Rabeprazole Sodium, Remdesivir, Tigecycline, Micafungin)
- Liquid Injectables (e.g., Propofol, Levetiracetam, Acetaminophen, Sugammadex, Lidocaine)
- Ophthalmic Solutions & Injectable Suspensions (e.g., Timolol Maleate, Brimonidine Tartrate, Bromfenac)
- Prefilled Syringes **(**Naloxone)

As per the list submitted to the WHO, the site handles 135 products, including general injectables, anesthetics, anti-infectives, antiepileptics, non-oncology-related substances, and ophthalmic, spanning multiple volumes, strengths, and preservative types. The list was prepared, verified, and signed on 15 April 2025.

e) Most recent product quality review(s) (PQR)(s) of the concerned WHO product(s):

Product Quality Review Summary – Remdesivir for Injection 100 mg/vial

Review Periods:

- July 2020 – June 2021
- July 2021 – June 2022
- July 2022 – June 2023

Aspiro Pharma Limited has submitted three consecutive PQRs for Remdesivir for Injection 100 mg/vial, in accordance with GMP principles and ICH Q10 expectations. The purpose of these reviews was to verify that the product remains within a state of control throughout its lifecycle, based on a comprehensive assessment of batch data, deviations, OOS, quality trends, and stability outcomes.

The annual Product Quality Reviews demonstrated that Remdesivir for Injection 100 mg/vial has been manufactured, tested, and monitored in accordance with GMP principles. Where production occurred, all quality parameters remained in a state of control. Stability results further confirm the product's consistency over its lifecycle. There was no evidence of recurring deviations, product quality concerns, or systemic failures during the review periods.

f) Batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant product(s):

A recent batch of Remdesivir for Injection (100 mg/vial, lyophilized) was manufactured, tested, and packaged in compliance with GMP requirements. The batch was produced under validated conditions, following all standard procedures for sterile manufacturing, including solution preparation, aseptic filling, lyophilization, and visual inspection. No deviations or quality issues were reported during manufacturing or packaging.

The packaging process adhered to specified configurations, with full reconciliation of materials and accurate overprinting of batch-related data. Analytical testing confirmed the batch met all required specifications for identity, assay, pH, impurities, particulate matter, sterility, and other quality

attributes. Two Certificates of Analysis were provided, one internal and one for regulatory/customer purposes, both showing consistent results.

All documentation was complete, compliant with relevant procedures, and deemed acceptable for GMP review.

g) Master batch manufacturing and packaging record(s) of the product(s) of interest:

The manufacturing and packaging of Remdesivir for Injection 100 mg/vial at Aspiro Pharma Limited were based on formally approved and version-controlled Master Batch Manufacturing Records (MBMR) and Master Batch Packing Records (MBPR).

Both master records defined validated and detailed instructions for each stage of the manufacturing and packaging processes. They included information on designated equipment, material specifications, sampling points, in-process controls, and reconciliation steps. Relevant SOPs were referenced throughout, covering critical activities such as line clearance, gowning, sterilization, dispensing, labeling, coding, and shipper configuration. Each document was formally reviewed and signed by responsible production and quality assurance personnel, confirming their approved and controlled status.

The MBMR encompassed all key manufacturing stages, including dispensing, solution preparation, sterile filtration, lyophilization, sealing, visual inspection, and yield reconciliation. The MBPR outlined the complete packaging process, covering labeling, cartooning, shipper configuration, tamper-evidence measures, and carton weight verification, along with controls for serialization and overprinting.

h) Recalls in the past three years related to products with quality defects:

Aspiro Pharma Limited has formally declared that no product recalls due to quality defects have occurred in the past three years. This included all pharmaceutical products manufactured at their facility located at Biotech Park, Phase III, Karkapatla Village, Telangana, India.

The statement was documented and signed by the Associate Vice President – Quality, and dated 21 April 2025, confirming the site's consistent compliance with product quality standards and regulatory requirements.

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

Aspiro Pharma Limited has confirmed, via a signed declaration dated 16 April 2025, that a periodic self-inspection program is actively implemented under the appliable SOP. These self-inspections were conducted by senior Quality Assurance representatives as a continuous quality oversight mechanism, covering all drug products manufactured at the site.

j) Copy of any warning letter, or equivalent regulatory action, issued by any authority to which the site provides or has applied to provide the product:

Aspiro Pharma Limited has confirmed that no warning letters or equivalent regulatory actions have been issued by any health authority at its manufacturing site. While a Form FDA 483 was issued following an FDA inspection in August 2023, the company submitted a corrective and preventive action plan, which was reviewed and accepted by the FDA. A subsequent EIR was issued, confirming that the inspection was closed and no further regulatory action was deemed necessary.

k) Out-of-stock situations:

According to a signed statement dated 16 April 2025, there were no ongoing or foreseen out-of-stock situations affecting the manufacturing or distribution of its commercial drug products. This included all products manufactured at the Karkapatla site, Telangana, India (i.e., the site in the scope of this desk assessment).

The company affirmed a stable supply chain and production planning to support the uninterrupted availability of its marketed pharmaceutical products.

l) Additional documents submitted:

No inspections or audits by competent national or international regulatory authorities were scheduled to take place at the manufacturing site within the next six months as per the document dated 16 April 2025, provided by the site. It indicated that there were no inspections scheduled through October 2025 according to the site's knowledge.

Part 5	**Conclusion – Desk assessment outcome**

Based on the previous WHO inspections and the GMP evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. the site ***Aspiro Pharma Limited*** located at ***Survey No. 321, Biotech Park Phase III, Karkapatla village, Markook Mandal, Siddipet, Telangana 502281, India*** is considered to be operating at an acceptable level of compliance with WHO GMP 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 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 TRS No. 986, Annex 2***
   https://digicollections.net/medicinedocs/documents/s21467en/s21467en.pdf

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***
   untitled (digicollections.net)

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://digicollections.net/medicinedocs/documents/s23457en/s23457en.pdf

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
   9789240020900-eng.pdf (who.int)

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://digicollections.net/medicinedocs/documents/s21440en/s21440en.pdf

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**
   https://digicollections.net/medicinedocs/documents/s23455en/s23455en.pdf

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
   https://digicollections.net/medicinedocs/documents/s20108en/s20108en.pdf

8. 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. 961, 957), Annex 1***
https://digicollections.net/medicinedocs/documents/s18681en/s18681en.pdf

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 3. ***Short name: WHO TRS No. 957, Annex 3***
https://digicollections.net/medicinedocs/documents/s22358en/s22358en.pdf

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***
https://digicollections.net/medicinedocs/documents/s19959en/s19959en.pdf

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***
https://digicollections.net/medicinedocs/documents/s18677en/s18677en.pdf

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***
https://digicollections.net/medicinedocs/documents/s18683en/s18683en.pdf

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***
https://digicollections.net/medicinedocs/#d/s21438en

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***
https://digicollections.net/medicinedocs/documents/s18682en/s18682en.pdf

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
https://digicollections.net/medicinedocs/#d/s20177en/

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
https://digicollections.net/medicinedocs/#d/s20175en/

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. 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://digicollections.net/medicinedocs/documents/s23697en/s23697en.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***
Essential Medicines and Health Products Information Portal (digicollections.net)

21. 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***
9789240020900-eng.pdf (who.int)

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. 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

24. Guidelines on heating, ventilation, and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation, and air-conditioning 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://digicollections.net/medicinedocs/documents/s23699en/s23699en.pdf

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**
9789240020900-eng.pdf (who.int)

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**
9789240001824-eng.pdf (who.int)

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-detail/978-92-4-000182-4

28. 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