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Prequalification Unit Inspection Services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Active Pharmaceutical Ingredients Manufacturer

Part 1	**General Information**
Manufacturers details	
Name of manufacturer	Lupin Ltd, Tarapur
Corporate address of manufacturer	Kalpataru Inspire, 3rd FLR, Santacruz (E), Mumbai - 400 055 (Maharashtra), India
Inspected site	
Name & Address of inspected manufacturing site if different from that given above	T-142, M.I.D.C Tarapur, Boisar (Via), Taluka & District. Palghar, Maharashtra-401 506, India.
Production Unit	T1, T2 and T3
Inspection details:	
Dates of inspection	27-31 March 2023
Type of inspection	Routine re-inspection
Introduction	
Brief description of the manufacturing activities	Production, Quality control and distribution of fermentation based, synthetic non-Sterile API and intermediates
General information about the company and site	Lupin was founded in the year 1968. Lupin Tarapur site was in operation since 1992. The site is located at Tarapur via Boisar in the state of Maharashtra, near the coast of Arabian Sea and about 120 km away from Mumbai airport. Human resources, Administration and Safety functions were common for T1, T2 & T3 facility.
History	The site had been inspected by WHO several times. The last WHO onsite inspection was held in August 2017. The site was inspected by US FDA in April 2022, a warning letter was issued.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	• Quality management system • Production Blocks • Warehouses • Quality control laboratories • Stability study • Water system
Restrictions	The inspection was restricted to the production of the products listed in the inspection scope.

Out of scope	All other products and production facility on the site were outside of the inspection scope and were not visited.
WHO APIs (including WHO API or APIMF numbers) covered by the inspection	1. APIMF040, WHO API-040: Pyrazinamide (Withdrawn after the inspection) 2. APIMF028, WHO API-028: Rifampicin 3. APIMF447 Rifapentine (under assessment) 4. APIMF093, WHO API-093: Ethambutol HCl (No commercial batches manufacture) 5. APIMF317, WHO API-317: Tenofovir Disoproxil Fumarate (No commercial batches manufacture) 6. APIMF385 Abacavir Hemisulfate (No commercial batches manufacture)
Abbreviations	**Meaning**
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
CIP	Cleaning in place
CoA	Certificate of analysis
CpK	Process capability
DQ	Design qualification
EDI	Electronic deionization
EM	Environmental monitoring
FMEA	Failure modes and effects analysis
FPP	Finished pharmaceutical product
FTA	Fault tree analysis
GMP	Good manufacturing practices
HEPA	High efficiency particulate air
HPLC	High performance liquid chromatography (or high-performance liquid chromatography equipment)
HVAC	Heating, ventilation, and air conditioning
IQ	Installation qualification
KF	Karl Fisher
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
MR	Management review
NC	Nonconformity
NRA	National regulatory agency
OQ	Operational qualification
PHA	Process hazard analysis

PLC	Programmable logic controller
PM	Preventive maintenance
PQ	Performance qualification
PQR	Product quality review
PQS	Pharmaceutical quality system
PW	Purified water
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
RO	Reverse osmosis
SMF	Site master file
SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometer
WFI	Water for injection

Part 2	**Summary of the findings and comments (where applicable)**

1. Quality management

The quality management system was generally well established, documented and implemented. The quality assurance department was independent from production. The site organizational structure was presented. Quality-related activities were defined and documented. -

Product Quality Reviews (PQRs):

The APQR procedure for drug substances and saleable intermediates was checked. It described purpose and application of the procedure. Various elements of quality systems and products were reviewed on an annual basis and were completed within 30 working days upon the review schedule. Process capability was calculated using the software Mini tab. CpK based on quality attributes was calculated and assessed. Separate APQR reports were generated if a product was produced using different manufacturing processes.

The following APQRs of WHO API products were reviewed and discussed. The OOS, deviation, change control and CAPAs etc. were reviewed in the following APQRs.

- APQR Pyrazinamide 2021-2022
- APQR Rifamycin S, 2022-23,
- Rifampicin IP/BP/EP/ USP 2020
- APQR Rifapentine 2021-22

Quality Risk Management

Quality risk management and risk assessment were performed according to an approved written procedure. The logbook of risk assessment 2023 for T1 was checked and discussed.

Management review (MR)

Quality management review followed an approved procedure which required MR to be performed at the site, corporate and global level. The site level MR performed on a monthly basis was responsible by the site head and site QA. The minutes and presentations of site MR meeting held in February 2023 were reviewed and discussed.

Deviations

Deviation was managed according to a written procedure. Deviations were reported in the QMS system and classified into critical, major, and minor supported with examples for each class. The deviations reported in 2022 were checked. The investigation was required to be closed within 30 working days according to the SOPs.

The deviation and subsequent CAPAs in respect that several Rifapentine API batches was reviewed and discussed.

Out of specifications (OOS) and out of trending (OOT)

The SOP for OOS management was checked. It was applicable for physical, chemical, instrumentation and microbiology testing. Microbiology OOS handling procedure was separate. The SOP for OOT was available. The reported OOSs and trending for OOT for 2022 were spot checked.

CAPA management

CAPAs were managed electronically with the QMS software. The procedure described the details for taking corrective and preventive actions for non-conformances, handling complaints, deviations, OOS, audit finding, OOT, laboratory incidents and annual product reviews.

The CAPA log for year 2022 were reviewed. They were raised from deviations, OOS and audits.

Self-inspection (Internal quality audits)

The SOP for self-inspection was checked. It described the objective, scope, reference document, definitions, procedure etc. The self-inspection was performed twice a year and a schedule of 2023 was available. Cross functional team along with QA carried out self-inspections. As a policy, internal audit reports cannot be shared with any inspectors, so the WHO team was unable to review self-inspection reports.

Product release

Authorized QA persons were responsible for release of the finished API batches manufactured at the site. The SOP for product release of API and intermediates was reviewed. The release of Rifapentine API batches was reviewed and discussed. Non-compliances observed during the inspection that was listed in the full report regarding product release were addressed by the manufacturer to a satisfactory level.

2. Personnel

Personnel qualifications

968 people were employed by the company at the time of the inspection. There appeared to be an adequate number of personnel who were qualified through qualifications, experience, and training. An organization chart was available. Production and Quality department were separate with independent responsibilities.

Personnel hygiene

Personnel were required to wear protective clothing suitable for the type and stage of manufacturing. Suitable sanitation and change room facilities were provided.

3. Buildings and facilities

The site had three facilities i.e.T1, T2 and T3 which contained manufacturing plants, solvent recovery units and three Quality Control laboratories.

Water

Potable water supplied by MIDC and PW generated at the site were used in equipment cleaning and process steps. PW plant was visited. P&ID of PW generation and distribution system checked were approved and documented. Online conductivity meter and PH meter were equipped in the PW system. The controls appeared satisfactory.

Nitrogen

Nitrogen used in process was produced on site. Oxygen analyser and dew point meter were equipped online.

4. Process equipment

Design and construction

Equipment used in the manufacture of APIs and intermediate appeared to be of appropriate design and size for its intended use. In general cleaning and maintenance appeared satisfactory.

Equipment cleaning and maintenance

The SOP for equipment cleaning was reviewed. There were two types of cleaning:

- Type A cleaning: Batch to batch cleaning, and dirty and clean holding time specified.
- Type B cleaning: Product change over and periodic through cleaning.

The SOP for equipment preventive maintenance procedure was reviewed. Equipment maintenance was performed quarterly and yearly in accordance with the procedure.

5. Documentation and records

The SOP for document control, review, modification and numbering procedure was reviewed. It described in detail how to handle Lupin documents and to prepare master batch records and copies.

The SOP for assignment of batch number, manufacturing date and retest/expiry date and SOP for preparation, review, approval, issuance, and control of batch production record by SAP system

were reviewed. The batch number was generated by SAP system. The batch history and traceability for reprocess and reworking batches were checked and discussed.

BMRs and batch analysis records were archived for specified period in accordance with the SOP.

The response to the dossier deficiencies received from WHO PQ was reviewed and discussed.

1. Materials management

Supplier (vender) qualification

The SOP for suppliers' qualification was reviewed. The SOP was applied to suppliers for all incoming materials including starting materials and packaging materials. Before material supplier was qualified, samples were tested for qualification with the assistance of corporate / global quality.

The company performed the vendor audits based on risk assessment and conducted within the specified timeline. The risk assessment was performed after each audit of the vendor. Remote audit procedure is mentioned in the SOP. Vendor audit reports for two key starting materials used for WHO APIs' manufacturing were checked and found acceptable.

7. Production and in-process controls

The production blocks used for processing of each WHO API product were identified and documented.

Rifapentine

The Production Block for Rifapentine API were visited. The areas inspected was found to be of suitable standard, clean and logically organized to suit their intended purpose. Micritization and blending operation were applied when needed.

The cleaning procedures in microbiology seed laboratory and sterilization of glassware and garments
were checked. Justification of location for environmental monitoring was available and found to be acceptable.

Pyrazinamide

The production block for Pyrazinamide was inspected. The product was exposed to the air in the clean area but this area was unclassified. The Pyrazinamide API had been withdrawn from this site after this inspection.

Abacavir Hemisulfate

Abacavir production block was visited. Tray dryers were used in intermediate and final API drying process. Dust generation and its control in the material drying and unloading rooms were discussed.

Blending batches of intermediates or APIs

Blending of API batches was permitted. The SOP for operation of blender was available for review. The SOP for handling of tail-end material was checked.

In-process sampling and controls

In-process sampling was performed at defined stages during processing.

8. Packaging and identification labelling of APIs and intermediates.

Packaging materials and labels were subjected to quality control before release. Line clearance in the packaging area was spot checked. Packaging and labelling were not in operation at the time of inspection.

9. Storage and distribution

Lupin Tarapur site has three warehouses, located in T1, T2, and T3. The SOP for storage, issuance of finished products and SOP for receipt and storage of raw and packing materials in warehouse was reviewed. There was an entry procedure with SOPs and pictures together with relevant logbooks.

Dispensing activities were controlled by warehouse personnel and the staff followed steps described in the SOPs. Material dispensing were carried out in dispensing rooms equipped with LAFs. The accessories used for sampling and dispensing materials were validated for cleaning. The cleaning method was checked.

10. Laboratory controls

The three quality control laboratories located in T1, T2, and T3 were inspected. Laboratories space and equipment were adequate for the tasks being conducted.

Samples (In process, finished APIs, key starting materials and intermediate) were received according to written procedures. Retention samples were managed according to the SOP for retention sample management and kept one year after expiry date, or three years after market distribution, whichever is longer.

Full calibration plan for 2023 was presented. A HPLC was taken as example, and it was calibrated for pump, flow rate, gradient composition, auto sampler (linearity and accuracy) detector (noise, drift, lamp intensity, wavelength accuracy) and it was acceptable.

The SOP for audit trail and computer access control was reviewed and discussed. All HPLCs and GCs were networked and operated using Chromeleon software.

Microbiology laboratory

Cultures were received in mother culture as agar slant and then hydrated according to a written procedure. Four passages were allowed to be perform and this was confirmed by checking the logbook for consumption of the cultures.

Method validation for microbial limit tests (Suitability test) was documented in the product validation reports using both positive and negative controls. A growth promotion test was performed for each preparation.

The SOP for environmental monitoring of the powder processing area described the media used, plate exposure time, conditions for incubation etc. The alert and action limits were defined based on historic data.

An OOS in respect to the environmental air monitoring results in the colling zone in the glass washing area in the microbiology laboratory was reviewed and discussed.

11. Validation

Validation and qualification policy and requirement were described in the Validation Master Plan (VMP).

Process validation (PV)

The SOP for process validation was reviewed. The PV was required to be performed on three consecutive batches, and revalidation could be triggered by changes.

Rifapentine PV

The following documents were reviewed,

- Quality risk management protocol and report for Rifapentine in 2020.
- PV protocol, PV report for signed in 2021, with three PV batches.
- Holding time study protocol and report for Rifapentine wet materials.

Computerized Systems validation (CSV)

The SOP for validation of computerized system was available for review. Computerized systems were used for QMS, QC lab, material management or production control including,

- Caliber for QAMS (quality assurance management system)
- SAP for material management and quality modules
- WMS for warehouse management system
- Chromeleon for chromatographic data handling in QC Lab
- Minitab for data trending and statistical evaluation
- DAS/CDAS data acquisition system for temperature/pressure/humidity monitoring
- LIMS for Laboratory (under implementation)
- EDMS and DMS for SOPs upload for printing and viewing

The validations were performed periodically from three to five years based on the risk assessment outcomes.

Qualification

Qualification of key equipment was a prerequisite for process validation. Qualification protocols and reports were available for key equipment. These were cross-referenced in the process validation documentation.

Cleaning validation

Cleaning validation policy and equipment cleaning methods were defined in VMP. SOP, protocol, cleaning validation for equipment were available for review. They were not checked in detail because time constrains.

12. Change control

The SOP for change control was reviewed. The procedure described the types of changes related to building and facility, process, packaging, QC specification and methods, documents, also computer software. The change was classified as major or minor. All CCs were managed by QA electronically including effectiveness of change, review and documentation. Several changes in respect to production block and equipment for API manufacturing were checked. They were handled adequately.

13. Rejection and re-use of materials

Reprocessing and Reworking

Reprocessing and reworking were managed according to an in-house SOP which was reviewed and discussed.

Recovery of materials and solvents

Solvents were recovered in the various stages of the production. The SOP for handling of recovered and distilled solvents was reviewed. Validation of solvent recovery processes was required.

The company confirmed no external solvent recovery plant was used, all solvent recovery was performed on the site and the recovered solvents were not used for WHO grade of Rifapentine API.

14. Complaints and recalls

Complaints

The SOPs for handling of market complaints for drug substance and intermediates were reviewed. Complaints were classified into critical, major or minor based on investigation report and were managed through the QMS system. The product quality related complaints reported during 2022 were checked. No complaints were reported for WHO products.

Recalls

Recall of APIs/saleable intermediates were handled according to an SOP. This SOP provided a procedure to recall / remove products from the market. It stated that mock recall was carried out for at least one batch of any product dispatched for sale or export, to test the effectiveness of the recall procedure.

15. Contract manufacturers (including laboratories)

Technical contracts with the external testing laboratories involved in the materials' testing for Lupin were checked and discussed during the inspection.

Part 3	Conclusion – Inspection outcome

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, ***Lupin Limited*** located at ***T-142, M.I.D.C Tarapur, Boisar (Via), Taluka & District. Palghar, Maharashtra-401 506, India*** was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines.

All the non-compliances observed during the inspection that were listed in the full report as well as those reflected in the WHOPIR, were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

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

Part 4	List of GMP guidelines referenced in the 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-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://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