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Prequalification Team Inspection Services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Active Pharmaceutical Ingredient Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**Hetero Labs Ltd (HLL), Unit III (intermediate division)**
Corporate address of the manufacturer	Hetero Corporate RMZ Nexity, Survey No. 83/1, Knowledge City Raidurg Village, Serlingampally, Adjacent to ITC Kohenur Hyderabad – 500081 Phone: +91-40-23704923 Ext.: 6901 Mobile: +91-8008002882
Name & address of inspected manufacturing site if different from that given above	Unit 3, Survey No.120, 128, 150 (Part), 150/1, 151/2,&158/1, N. Narasapuram (Village), Nallamattipalem (V) Nakkapalli (Mandal), Anakapalli (District), Andhra Pradesh 531 081, India GPS Coordinates Longitude & Latitude Coordinates of the site: 82° 343' 07. 72”E, 17° 22' 50.70”N
Synthetic unit /Block/ Workshop	Manufacturing blocks: - D, E, G - H, J, and P
Inspection details	
Dates of inspection	29-30 November 2025
Type of inspection	For-cause inspection
Introduction	
Brief description of the manufacturing activities	HLL Unit III intermediate division has a total area of 125681 square meters. The manufacturer confirmed that the USFDA did not inspect the Unit III intermediate division (or the Unit III API division). From the opening meeting presentation, it was noted that the site is dedicated to intermediate manufacturing for their captive consumption. Mainly key starting materials (KSM) and a few intermediates were manufactured on this site. HLL Unit III intermediate division does not fall under the SEZ, Andhra Pradesh, unlike Unit IX. The intermediates manufactured for WHO PQ APIs were produced in Unit III, intermediate division, in accordance with ICH Q7. The quality management system remains the same as for other Hetero Labs facilities. The site has multiple warehouses for storing various materials (liquids and KSM). The finished intermediates were stored in Warehouse V.
General information about the company and site	Hetero Labs Limited, Unit-III, intermediate division, is engaged in the manufacture and distribution of key chemical starting materials & Intermediates that are distributed to API manufacturers for API manufacturing.

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History	The manufacturing site was last inspected by PQ Inspection Services in October 2017. A desk assessment was conducted in October 2022, and the site was declared GMP-compliant. The site was also inspected by the USFDA in August 2014 and November 2018, and was classified as VAI and NAI, respectively. The site was also inspected by the Pharmaceuticals and Medical Devices Agency- PMDA JAPAN in September 2022 and was classified as approved.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: - Quality management - Laboratory controls - Process equipment - Production areas - Finished intermediate warehouse
Restrictions	None
Out of scope	The intermediates not manufactured for the WHO APIs were out of the scope of this inspection.

WHO APIs covered by the inspection

Product Name	APIMF Number	API Name	Manufacturing Block
(4R,12aS)-7-methoxy-4-methyl-6,8-dioxo-3,4,6,8,12,12a-hexahydro-2h-pyrido [1',2',4,5] pyrazino[2,1b] [1,3]oxazine-9-carboxylic acid **(DOL)**	APIMF400	Dolutegravir Sodium	P
(2R-CIS)-5-(4-amino-1,2-dihydro-2-oxo-1-pyrimidinyl)-1,3-oxathiolane-2-carboxylic acid (2S,5R)-menthyl ester **(PNG)**	APIMF123 for LU series APIMF404 for LM series	Lamivudine	E
4-amino-n-(2r,3s)(3-amino-2-hydroxy-4-phenyl butyl)-n-isob.utylbenzene Sulfonamide **(DRI)**	APIMF410	Darunavir Ethanolate	G, D, J
(2,5-dioxopyrrolidin-1-yl((3R,3aS.6aR)-hexahydro [2,3-b] furan-3-yl)carbonate **(HDP)**	APIMF410	Darunavir Ethanolate	D
4-Amino-N-((2R, 3S)-3-Amino- 2-Hydroxy-4-PhenylButyl)-N-Isobutyl Benzene Sulfonamide **(AHS)**	APIMF550	Darunavir Ethanolate	G
(3R, 3aS, 6aR)-Hexahydrofuro [2,3-B]Furan-3-yl (4-Nitrophenyl) Carbonate **(HNC)**	APIMF550	Darunavir Ethanolate	G, H & D

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	(R)-9-[2-(phosphono methoxy) propyl] adenine **(TFD)**	APIMF098	Tenofovir Disoproxil Fumarate	E

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
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	Non conformity
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

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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

Part 2	**Summary of the findings and comments**

1. Quality management

The quality management system at HLL, Unit III, for KSMs and intermediates was implemented in line with the ICH Q7 requirements. Though Unit III had separate procedures, the QA reported to the same corporate QA as for their API sites. The manufacturing site, Unit III, has the following electronic systems:

- Caliber LIMS for sample receiving, testing, release, and overall laboratory activities
- QMS spectrum (change management, CAPA, incident, and laboratory incidents)
- Warehouse management portal system (WMPS) for material receiving, issuance, dispensing, distribution, reconciliation, and generation of labels
- CAPS used for tracking of equipment, qualification, preventive maintenance, and calibration schedule of manufacturing and engineering equipment
- User management system for the creation of user IDs, modification, and deletion.

The procedures for product quality review, quality risk management, management review, CAPA, and incidents were reviewed. Also, an impact assessment of the USFDA inspection on Unit III, intermediate division, was reviewed. The impact assessment confirmed the traceability of the manufactured batches to the laboratory records.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

2. Personnel

From the opening meeting presentation, it was noted that the site employed 1926 employees in the following areas:

Production	1056
Quality Control	140
Warehouse	97
Quality Assurance	125
Engineering	284
Others (EH&S, HR, TSD, R&D, IT)	225

The manufacturing site operated 24/7 in three shifts (A, B, and C) and a general shift.

3. Buildings and facilities

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The site has a total area of 125681 square meters and comprises the following sections:

- Warehouses – Solid, Liquid Raw Materials, and Bulk Solvent Storage yard
- Production Blocks, namely Block- C, D, E, G, H, I, J, K, L, N, P, Intermediate Drying Section (IDS)
- Intermediate Storage Area
- Quality Control
- Quality Assurance
- Engineering
- Human Resources
- Water systems – Potable Water
- Environmental Health and Safety
- Information and Technology

Potable water

The manufacturing site used potable water generated by the chemical sanitation reverse osmosis (RO) system. The desalinated water was used as feed water. It is used in the initial stages of the process & cleaning. The potable water was tested for chemical and microbial parameters, as well as for Nitrite and nitrate content.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

4. Process equipment

From the opening meeting presentation, it was noted that the site was well equipped with various process equipment, including but not limited to the following:

S. No.	Equipment	Capacity / Range
1	Stainless Steel Reactors	250 L to 35,000 L
2	Glass Lining Reactors	250 L to 25,000 L
3	Hastelloy Reactors	100 L to 5000 L
4	Centrifuges	36” to 60.”
5	Agitated Nutsche Filter Driers (ANFDs)	1000 L to 10000 L
6	Tray Dryers	12 - 96 Trays
7	Vacuum Tray Dryers	12-24 trays
8	Roto Cone Vacuum Dryers	500 L – 4000 L
9	Blenders	4000 L & 10000 L

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During the visit to various manufacturing blocks, the process equipment were found to be adequately maintained.

5. Documentation and records

The documents were prepared, reviewed, approved, and distributed in accordance with the document control procedure. A manual system was in place for managing documents. The intermediates were manufactured in accordance with the approved batch production records.

During the visit to the intermediate manufacturing areas, the process-related activities were recorded directly on the batch production records. Due to time constraints, only a limited number of documents were reviewed during the inspection.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

6. Materials management The warehousing facilities comprised four warehouses:

- Solid Raw Materials: Consists of Raw material receiving area; De-dusting area; Separate areas for Quarantine, Approved and Rejected materials; Dedicated areas for – Sampling, Dispensing, Storage of Catalysts, Packing materials, Intermediates, Returned Materials.
- Bulk solvents storage area: Dedicated tanks and lines for loading and transfer of solvents.
- Drum Storage Area for Liquids: Dedicated areas for Liquid Sampling & Dispensing
- Intermediate storage area: For Intermediate Chemicals

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

7. Production and in-process controls The inspector visited the manufacturing blocks (G, D, E, and P) within the scope of the inspection. Various intermediates were manufactured in different manufacturing blocks for their captive consumption. Batch-to-batch cleaning, product changeover, and periodic cleaning were performed in accordance with the approved procedures. The cleaning limit of 100ppm was established. In most cases, closed systems were used to transfer materials from one stage to another. For charging materials through the manhole, hoppers were also used to minimize contamination and cross-contamination, as well as safety risks. The intermediates were manufactured in the synthesis areas, whereas no classified environment was required.

The temperature sensors, indicators, vacuum, and pressure gauges were calibrated once every 6 months. At the time of the visit to Block D, no product related to the PQ was running, whereas in Block E, PNG-II was being manufactured. This block was used to manufacture intermediates for Tenofovir Disoproxil Fumarate and Lamivudine.

In general, the manufacturing areas were clean and adequately maintained.

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8. Packaging and identification labelling of APIs and intermediates

None of the manufacturing blocks required powder processing of the intermediates. Hence, no facility for powder processing was provided. The intermediates were packed in accordance with the approved requirements.

9. Storage and distribution

The inspector visited the finished intermediate storage area, which was accessed through a biometric system. The area was maintained below 35°C, and temperature mapping was performed, identifying a hotspot for routine monitoring. The status of materials was manually updated, and segregation was maintained. The rejected intermediate storage area was also visited; it was found locked, with keys held by the QA personnel.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

10. Laboratory controls

The quality control laboratory was staffed with 140 personnel and equipped with 16 HPLC and 10 GC systems. The in-process samples (IPCs) were collected by production, sent to the laboratory for testing, and then logged into the physical logbooks. Caliber LIMS was used for laboratory activities, and the remaining samples (other than IPCs) were logged. The competency matrix was maintained, and LabSolution was used for chromatographic analysis. The chromatographic data systems (CDS) were networked, whereas non-CDS instruments were not connected to any network.

The SOP for resolving out-of-specification results was reviewed and applies to the analysis of raw materials, intermediates, packaging materials, hold-time study samples, and Potable water. The procedure was not applicable to in-process tests, samples received from vendors as part of the qualification. A flowchart was provided as part of the procedure, and the investigation was conducted in phases. A hypothesis study was required as part of the investigation. Resampling and additional testing were described in the procedure. Trend analysis was performed every quarter.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

11. Validation

The process validation for the intermediates was performed in accordance with the site-specific process validation SOP. The process validation was performed using a life-cycle approach (process design, process qualification, and continued process verification). The flow diagram for the process validation was part of the procedure. In addition, validation requirements for blending, drying, and physical modification were described in the separate annexures part of the process validation SOP. Due to time constraints, other validation-related aspects were not inspected.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

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12. Change control

The SOP for change controls was discussed, providing guidance on managing change controls. The change controls were handled through the QMS application. The changes were categorized as permanent or temporary and further classified as major or minor. For major changes, a risk assessment will be conducted as part of the impact assessment. Examples of the types of changes and their classifications were described in the procedure. A 45-day timeline was established for the closure of the changes. An electronic logbook was available within the QMS software. Changes related to process & cleaning validation, procedure, and specification updates, as well as others, were raised and closed in line with the timeline.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

13. Rejection and re-use of materials

Returned goods

SOP detailed the Handling of Returned Goods. This SOP was specific to HLL Unit-III, Intermediate Division. Logbook for the last 03 years verified.

Reprocessing

SOP detailed the reprocessing of finished intermediates and starting materials. This SOP was specific to HLL Unit-III, Intermediate Division. However, the scope of the document was not specified for the Intermediate division. Note: Reworking was not possible for any failed product obtained during the manufacturing process and not in the scope of Hetero Labs Limited, Unit-III manufacturing process. Reprocessing logbook of the last three years verified.

Recovered solvents:

It is part of the Process validation SOP, detailing the recovery solvent procedure from sections 4.15.1 to 4.16 of said SOP. The SOP Procedure on the usage of recovery solvents. During the inspection, the firm informed that the following solvents were recovered from the WHO PQ API intermediates:

1. PNG- Menthol
2. DOL- Acetonitrile and Methanol
3. DRI - IPA, Methanol
4. TFD – Toluene, Dimethyl Formamide, Methylene Dichloride

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

14. Complaints and recalls

Complaints

SOP detailed the Handling of customer complaints. This SOP was specific to HLL Unit-III, Intermediate Division. However, the scope of the document did not specify the Intermediate division. The manufacturer has provided the format for the complaint investigation summary report, the acknowledgement of customer complaint, the logbook, the complaint investigation report, etc., along with the SOP. Compliant Handling was not upgraded to the QMS Lite application. Manually documented QA Control. Complaint Logbooks for the last three years (2023, 2024 & 2025) were verified, and it was

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observed that the firm received no market complaints regarding intermediates, i.e., DOL, PNG, DRI, HDP, AHS, HNC, and TFD.

Recalls

SOP detailed the product recall procedure. This SOP was specific to HLL Unit-III, Intermediate Division. However, the scope of the document was not specified for the Intermediate division. Recall log format was in place. The logbook was unavailable, as no recall was conducted for any of the intermediates manufactured at the HLL Unit-III, Intermediate division. This was confirmed by the manufacturer during inspection.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

15. Contract manufacturers (including laboratories)

The manufacturer confirmed that no contract manufacturing was carried out for any of the intermediates used in the WHO API manufacturing. The approved list of contracted laboratories was maintained, while some samples were sent to HLL's R&D for testing.

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, ***Hetero Labs Limited, Unit III, Intermediate Division***, located at ***Unit III, Survey No.120, 128, 150 (Part), 150/1, 151/2 &158/1, N. Narasapuram (Village), Nallamattipalem (V), Nakkapalli (Mandal), Anakapalli (District), Andhra Pradesh 531 081, India,*** was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines for APIs.

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

2. 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*** http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

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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
   http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

4. 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
   http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

5. 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***
   http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

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

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

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
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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. 961), Annex 9. ***Short name: WHO TRS No. 961, Annex 9***
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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11. 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
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

12. 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

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***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

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***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

15. WHO Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 3. ***Short name: WHO TRS No. 992, Annex 3***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

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***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

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***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

18. 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 Multisource guidance or ***WHO TRS No. 996, Annex 10***
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

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19. 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**
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en/

20. 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

21. 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
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22. 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
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23. 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
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24. Points to consider when including Health-Based Exposure Limits (HBELs) 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 1033, Annex 2***
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations¨

25. 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 1033, Annex 3***
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

26. 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://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations