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Prequalification Unit Inspection services

WHO PUBLIC INSPECTION REPORT (WHOPIR) Finished Product Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	Dr. Reddy's Laboratories Ltd
Corporate address of manufacturer	8-2-337, Road No. 3 Banjara Hills Hyderabad - 500034 Telangana State India
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Formulations Technical Operations - Unit 2 (FTO - Unit 2) Dr Reddy's Laboratories Ltd Survey No. 42, 45 & 46 Bachupally Village Bachupally Mandal Medchal Malkajgiri District Telangana State India - 500090
Unit / block / workshop number	Formulations Technical Operations - Unit 2 (FTO - Unit 2)
Inspection details	
Dates of inspection	20 to 24 June 2022
Type of inspection	Initial inspection
Introduction	
Brief description of the manufacturing activities	Production, quality control and release of solid oral dosage forms including tablets, capsules, and pellets.
General information company and site	Dr Reddy's Laboratories Ltd is a global pharmaceutical company which has several API and FPP manufacturing facilities according to the company's information. FPP manufacturing facilities FTO - Unit 2 and FTO - Unit 3 were located on the same site (Bachupally campus). FTO - Unit 2 employed 509 people at the time of this inspection. Some corporate/central functions and facilities were also situated in the Bachupally campus according to the company's information.
History	This was the first WHO inspection of this site.

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Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	• Pharmaceutical quality system • Production block • Warehouses • QC including Chemical and Microbiological Laboratories • Water system
Restrictions	• The inspection was restricted to the production of the product listed in the inspection scope. • The product dossier was under assessment by WHO medicines PQ programme and product specification and testing method etc. had not been accepted by WHO at the time of inspection.
Out of scope	• Small batch size of Molnupiravir Capsules, hard 200mg initially submitted in dossier was voluntarily withdrawn from the inspection scope and dossier by the company. • All other products and production facilities on the site were outside of the inspection scope and were not visited.
WHO products numbers covered by the inspection	Molnupiravir Capsules, hard 200mg (under assessment)
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
CFU	Colony-forming unit
CIP	Cleaning in place
CNC	Clean non classified
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
GPT	Growth promotion test
HEPA	High efficiency particulate air
HPLC	High performance liquid chromatography (or high performance liquid chromatography equipment)
HVAC	Heating, ventilation and air conditioning

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IQ	Installation qualification
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
MF	Master formulae
MR	Management review
NC	Non conformity
NCA	National control authority
NCL	National control laboratory
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

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

1. Pharmaceutical quality system

A documented system for quality assurance was established, with procedures covering key quality elements in place. The procedures of the quality management system included SOPs managed at corporate and site levels. The quality assurance department was independent from production. Quality-related activities were generally defined and documented. The persons authorized to release products were specified. The procedures reviewed and discussed during the inspection were generally acceptable.

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Product Quality Review (PQR)

SOP for Product Quality Review was reviewed. APQR was performed for commercial product. The procedure was generally considered satisfactory. The product quality review of Molnupiravir Capsules, hard 200mg (CV009) was unavailable at the time of inspection as the product had not been approved by WHO PQ and commercialised for supplying to market.

Management Review (MR)

The SOP for Quality Management Review was available for review. The procedure specified that management reviews were performed monthly by the Quality Head/PQA and Plant Head. A site management review held in April 2022, including the presentation and meeting minutes were reviewed and discussed.

Quality Risk Management (QRM)

The SOP for Quality Risk Management was reviewed. This SOP discussed various approaches to risk assessment, but the focus was on utilizing the FMEA model, which was explained by QA staff during the inspection. Quality Risk Assessment reports for Molnupiravir Capsules 200mg were reviewed. A qualitative method was used for this risk assessment with no high risks identified.

Change Control

The SOP for Change Management System and Criteria for Classification was available for review. Changes were classified as "Temporary" or "Permanent" as well as "Major" or "Minor". Changes were initiated according to an Action Plan. The Change Control Log for 2021 was checked. The following Change Controls were reviewed, e.g.,

- New product introduction of Molnupiravir Capsules 200mg.
- Execution of confirmatory batch for Molnupiravir Capsules 200mg at FTO - Unit 2 for India and emerging markets.

Deviations

The company's quality system handled deviations defined in WHO GMP as incidents or temporary changes. The SOP for Handling of Incidents was checked. Different categories of incidents had different timelines for close-out. Category and number of incidents were noted in the 2021 Management Review. Trends were performed as required by the SOP. An incident in mock recalls was reviewed during the inspection.

CAPA

The SOP for CAPA Management was reviewed. The sources of CAPA mentioned in the procedure were checked and discussed.

OOS/OOT

The SOP for Handling of OOS Results and SOP for Handling of OOT Results were checked and generally found acceptable. OOS trends were noted in the 2021 Management Review.

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Product release

FPP batch release was managed according to an approved SOP. Batch record review and release were performed electronically in the computerized system "Manufacturing Execution System (MES)". The persons authorized to perform product release was documented in an approved name list.

Product release of Molnupiravir Capsules 200mg was reviewed. During walk-through of the FG warehouse, the product status of Molnupiravir Capsules 200mg was checked. It was noted that batches of WHO grade Molnupiravir Capsules 200mg had been manufactured according to the information from SAP. Non-compliances observed during the inspection listed in the full report regarding product release were addressed by the manufacturer to an acceptable level.

2. Good manufacturing practices for pharmaceutical products

Good manufacturing practices were generally implemented. Necessary human and physical resources with adequate premises, equipment and utilities were provided for the current operational level of FPP activity. Manufacturing processes and procedures were defined and documented in the eBMR and eBPR. Product and processes were monitored, and the results were required to be checked as part of the approval process for batch release.

3. Sanitation and hygiene

Premises and equipment in the FPP production area appeared to be maintained at a satisfactory level of cleanliness at the time of the inspection.

4. Qualification and validation

Process validation

Process validation was performed according to an approved SOP. According to the dossier for Molnupiravir Capsules, hard 200mg, submitted to WHO PQ, the process validation protocol and process validation report were checked.

Equipment qualification

The following documents were reviewed and found acceptable.

- Re-Qualification Report for Vertical Autoclave used in the Microbiology laboratory
- Performance verification of LAF Hood in the Microbiology laboratory.

Cleaning validation

Cleaning validation was performed according to an approved SOP. Equipment in FTO - Unit 2 used in Molnupiravir Capsules 200mg production was non-dedicated. Several products shared the granulator and some of the other equipment of the production line inspected.

The Cleaning Validation Protocol and Report for Molnupiravir Capsules, hard 200mg were checked. The company introduced a PDE-based approach for setting allowable residue limits after cleaning. The carryover of the worst-case product shared on the line was identified based on cleaning validation matrix. No objectional comments were made.

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Analytical Method validation

The SOP for Analytical Method Validation was checked. Method Validation Protocol for Assay of Molnupiravir Capsules 200mg and Method Validation Report for Assay of Molnupiravir Capsules 200mg was reviewed.

Method Validation Protocol for Related Substances by HPLC for Molnupiravir Capsules 200mg and Method Validation Report for Related Substances by HPLC for Molnupiravir Capsules 200mg were reviewed and found to be generally acceptable. However, WHO PQ had not accepted API and FPP specifications at the time of this inspection. The company was required to update the method validation and STP when necessary to meet the specifications and analytical methods once finalized.

5. Complaints

The SOP for Handling of Market Complaints was reviewed. Complaints were required to be closed with CAPAs. Complaint records were required to be kept perpetually according to the SOP for Retention Period for Various Documents. Complaint Log for 2021 was checked and discussed.

6. Product recalls

Product recall

SOP for Product Recall and Market Withdrawal was available for review. A mock recall was required to be performed at a specified time period. Checked a mock recall performed in 2021 and a product recall initiated in 2021. An incident report related to the mock recall was reviewed.

Product return

The procedure for handling of returns was available for review. No batches of WHO grade Molnupiravir Capsules 200mg were returned as it has not yet been approved for supply to markets.

7. Contract production, analysis, and other activities

Production was not contracted out. However, specific QC tests, validation services and the FG warehousing were contracted to external laboratories or companies. The SOP for Qualification of External Testing Laboratories was available for review. The qualifications of the service providers for testing and FG warehousing were checked.

8. Self-inspection, quality audits and suppliers' audits and approval

Self-inspection

The SOP for Self-Inspection was checked. Self-inspections were carried out at least once in a calendar year. The team was from cross-functional departments. The departments were audited per the schedule. QA monitored and tracked the CAPAs. Checked List of Qualified Auditors for Self-Inspection, Auditor Qualification Record - Self Inspection, Internal Audit Schedule and Self-Inspection Reports.

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Suppliers' management

The SOP for Vendor Management and SOP for Vendor Audit and Compliance Program was checked. All raw and packaging materials must be sourced from approved vendors. The vendor qualification for Molnupiravir API and a primary packaging were checked.

9. Personnel

The personnel met during the inspection appeared to be knowledgeable about GMP. Organization charts were documented and presented in the opening meeting.

Key personnel responsibilities were defined in job description (JD) per SOP. The JDs of key personnel such as Head of Unit 2, Quality Department, Production department, Manufacturing Science and Technology (MSAT), QA and a team leader were reviewed and found acceptable in general.

10. Training

SOP for Employee Training was checked. Training activities were carried out using "Learning Management System" (LMS) which is an electronic system. Checked the training records for employees.

11. Personal hygiene

The procedure for Personnel Hygiene was checked. All employees were required to undergo a medical examination when joining the company, followed by an annual checkup. In the event of contagious or infectious disease, the employee would not be allowed to work in the production area.

Suitable washing and changing areas were provided. Each employee entering the production area was required to wear factory-issued footwear and a uniform. A secondary gowning procedure was followed before entering the Grade D manufacturing areas and primary packaging areas.

12. Premises

Production areas

Premises were located, designed, constructed, and maintained to suit the operations to be carried out. The layout and design of the premises minimized the risk of errors and permitted effective cleaning and maintenance to avoid cross-contamination. Premises were designed and constructed to facilitate good sanitation.

FTO - Unit 2 was a multi-product non-dedicated OSD facility, including starting materials and FG warehouses, dispensing booths and production modules for manufacturing and packaging. The classified areas were monitored for temperature, relative humidity, and pressure differentials with BMS system for environmental control.

A contract warehouse for FG was also used but was not covered by this inspection due to time constraints.

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Utilities

Adequate ventilation, air filtration and exhaust systems were provided. The HVAC system provided filtered air to the Grade D cleanrooms. BMS and EMS system was available. This was not inspected in detail in this inspection.

Purified water

Purified water was produced from mains drinking water by double ROs followed by EDI. The system was equipped with one generation system and two distribution loops. Water system was visited during the inspection. The following documents were reviewed:

- P & ID for Purified Water Generation and Distribution System
- SOP for Monitoring of Water Quality
- Microbiological sampling and testing in 2021

The PW system appeared well designed and maintained, under good control, and suitable to produce PW for FPP production.

13. Equipment

Equipment installed in the production block FTO - Unit 2 was multi-purpose, and each piece of equipment had a unique identification number. The equipment viewed during the inspection appeared to be of suitable design and construction for the allocated process and maintained in good condition.

Equipment calibration

Inspectors reviewed the quarterly calibration of the micropipette used in the Microbiology Laboratory which was performed according to SOP for Operation and Calibration of Micropipette and found acceptable.

Computer System (CS)

Computerized systems were used in quality management, warehouse (WMS), production, engineering (BMS),the laboratories (LIMS), SAP for material management and LMS (Learning Management System) for employee training. The CS validation was not inspected in detail due to time constraints.

14. Materials

Starting materials

All raw materials, capsules and primary packaging materials were received at the warehouse through a single receiving bay and managed according to approved SOPs. All materials were stored in the respective warehouses with specified temperature and relative humidity requirements. Molnupiravir API used by the company was supplied from different manufacturing sites. Only one site, at the time of inspection, was submitted in the dossier for WHO PQ. As a result, it was not interchangeable with the APIs from the other sources which were checked and discussed with the company during the inspection.

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Secondary packaging material warehouse

The secondary packaging material warehouse was situated alongside the FG warehouse. The secondary packaging materials were received through a single receiving bay.

Finished Goods Warehouse

Finished Goods Warehouse located in the FTO - Unit2 was inspected. Finished products should be held in quarantine until final release. Segregated Rejected, Recall and Return hold areas were available. The finished product status was managed by computerised system with barcode reader.

An external FG warehouse used to store FG, including Molnupiravir Capsules 200 mg, was not covered by this inspection.

15. Documentation

Documents were available for product/process specifications, raw material specifications, packaging component specifications, analytical methods, and QA procedures. Documentation was managed by computerized system.

Document review was managed according to SOP for Electronic Document Management. QA had overall responsibility for ensuring preparation, issuing and retrieval of all documents for manufacture. SOP for Allotment of Location and Batch Number was reviewed. Batch Production Records (MES) were stored electronically.

Tentative Molnupiravir Specifications and Standard Test Procedures (STPs) were available during the inspection. At the time of this inspection, the specifications had not been finalised and accepted by WHO PQ. The company is expected to re-review the relevant testing data against the specifications and test methods when finalised in the approved WHO dossier of Molnupiravir API and FPP for those batches already tested and blocked based on tentative in-house specifications and test methods.

16. Good practices in production

Production of Molnupiravir Capsules, hard 200mg was not in operation at the time of inspection. Material dispensing and the production operation in the modules inspected for other products was viewed from CNC corridors. The production appeared to operate at a satisfactory level.

The SOP for Procedure for Dispensing of Raw Materials was checked. Cleaning and line clearance were required as per company procedure.

17. Good practices in quality control

The QC function was independent of other departments. FTO - Unit 2 QC laboratory was separated from production areas. LIMS was used in the QC, HPLC and GC were networked with software.

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Testing of starting materials and finished products

The SOP for Sampling and Testing of Raw Materials was available and reviewed. Samples kept in QC were checked.

Reviewed the following documents:

- Total Degradation Products
- SOP for Management of Analytical Standards
- General Test Procedure - Determination of Water

Reference substance

The reference substance of impurity standard RS used for Molnupiravir Capsules testing was checked. Non-compliances observed during the inspection listed in the full report regarding its original batch number and characterization, were addressed in CAPAs by the manufacturer to a satisfactory level.

Stability monitoring of FPPs

Stability study samples were required to be withdrawn from the stability study chambers according to the stability study programme. Molnupiravir Capsules 200mg stability study batches were documented. Stability study samples were stored under the following conditions:

- 25 ± 2˚C/60 ± 5 % RH
- 30 ± 2˚C/75 ± 5 % RH

Due to time constraints, the stability testing data for Molnupiravir Capsules 200mg was not checked in detail.

Reserve/retention samples

There was a designated temperature-controlled area for storage of retention FPP samples. It was visited during the inspection. Access to this area was restricted. A sample of each batch of FPP manufactured was kept. The SOP for Collection, Storage, Retrieval, Review and Disposition of Reserve Samples was available for review. The inspection record for retention samples and retention samples of WHO grade Molnupiravir Capsules 200mg was checked and discussed.

Microbiology laboratory

The Microbiology laboratory was separate from the production area. Access was restricted to authorized personnel only. The laboratory activities, such as media and equipment preparation, testing, handling of reference cultures, enumeration of microorganisms, decontamination were segregated.

The media was prepared in-house. Growth promotion testing was done on all media for every batch. The performance of the media was checked regarding recovery of the target organisms. In addition, pH was also measured. Reference cultures were used to establish the acceptable performance of all media and validate the microbiological methods used.

The following documents were reviewed:

- SOP for Management of Media in Microbiology Laboratory
- SOP for Management of Standard Microbial Cultures in Microbiology Laboratory
- Record for Stock and Reconciliation of Ready to use Cultures

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- Record for Receipt, Enumeration, Purity Check and Identification of Ready to Use Cultures
- SOP for Operation, Cleaning, Calibration and Validation of Autoclave
- Description of Load Pattern and Parameters
- Logbook for Vertical Autoclave
- SOP for Management of Biological Indicators in Microbiology Laboratory
- Drug Product Method - Molnupiravir Capsules 200mg

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, ***Formulations Technical Operations - Unit 2, Dr Reddy's Laboratories Ltd,*** located ***at Survey No. 42, 45 & 46, Bachupally Village, Bachupally Mandal, Medchal Malkajgiri District Telangana State, India - 500090*** 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-eighth 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 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/trs-1025-annex-4

4. 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 1019, Annex 3
https://www.who.int/publications/m/item/trs1019-annex3

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
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. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-sixth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 2.
Short name: WHO TRS No. 1044, Annex 2
https://www.who.int/publications/i/item/9789240063822

9. WHO guidelines on transfer of technology in pharmaceutical manufacturing. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-sixth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
Short name: WHO TRS No. 1044, Annex 4
https://www.who.int/publications/i/item/9789240063822

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
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs961-annex9-modelguidanceforstoragetransport.pdf?sfvrsn=b80e925f_5

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
https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/production/trs981-annex2-who-quality-risk-management.pdf

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://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs981-annex3-who-variations-prequalified-product.pdf?sfvrsn=809e81b_2

15. 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://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs992-annex4.pdf?sfvrsn=2a1980f0_2

16. 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://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs992-annex5.pdf?sfvrsn=99aedfbe_2

17. 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***
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/regulatory-standards/trs966-annex10.pdf?sfvrsn=5d94f486_2

18. 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/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1010-annex8-who-gmp-heating-ventilation-airconditioning.pdf?sfvrsn=c77698e2_0

19. 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://extranet.who.int/pqweb/sites/default/files/documents/TRS1010_Annex10.pdf

20. 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

21. 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

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

23. 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
9789240020900-eng.pdf (who.int)

24. 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

25. 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