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Prequalification Unit-Inspection Services
WHO PUBLIC INSPECTION REPORT
of the FPP manufacturer

Part 1	**General information**
Manufacturers Details	
Name of manufacturer	Medopharm Private Limited
Corporate address of manufacturer	MEDOHOUSE, No.25, Puliyur 2nd Main Road, Trustpuram, Chennai - 600 024. Tamil Nadu, India
Inspected site	
Name and Address of inspected manufacturing site if different from that given above	Medopharm Private Limited No. 50, Kayarambedu Village, Guduvanchery - 603 202, Tamil Nadu, India
Unit / block / plant number	Unit II
Inspection details	
Dates of inspection	6 – 9 January 2025
Type of inspection	Routine inspection
Introduction	
Brief description of the manufacturing activities	Manufacture, Packing (Primary and Secondary), quality control and release of solid dosage forms – tablets, coated and uncoated for human use.
General information about the company and site	• Medopharm was established in 1970. The company was in the field of pharmaceutical formulations manufacturing since last five decades. Medopharm has two units (Unit I and Unit II) located at Guduvanchery Chennai Tamil Nadu site. QC laboratories were common for both Units. • Unit I was a dedicated facility for manufacturing Beta-lactam Oral Dosage Formulations and produces tablets, capsules, and dry powders for suspension formulations. • Unit II in this inspection scope was for the manufacture of General category Tablets. The distance between the two Units is about 100 meters.

<table>
<tr><td>History of Regulatory Inspections</td><td>The site has been inspected by the WHO PQT team in November 2021. The site was inspected by the following authorities in recent years according to the company information.
<table>
<tr><th>Authority</th><th>Dates of inspection</th><th>Type of inspection</th><th>Facility covered by inspection</th></tr>
<tr><td>Medicines Control Authority, Zimbabwe</td><td>26 – 27 September 2022</td><td rowspan="6">On site GMP inspection</td><td rowspan="6">Unit II</td></tr>
<tr><td>Tanzania Medicines and Medical Devices Authority</td><td>5 – 6 September 2022</td></tr>
<tr><td>National Drug Authority, Uganda</td><td>27 – 28 October 2022</td></tr>
<tr><td>Pharmacy, Medicine and Poison Board, Malawi</td><td>23 – 24 November 2022</td></tr>
<tr><td>National Authority of Regulations of Medicines of Mozambique</td><td>15 – 16 July 2023</td></tr>
<tr><td>Medicines Regulatory Authority, Zambia</td><td>1 – 6 December 2023</td></tr>
</table></td></tr>
<tr><td></td><td></td></tr>
<tr><td>Areas inspected</td><td>Documents reviewed:
• Quality management
• Personnel
• Buildings and facilities
• Sanitation and hygiene
• Documentation and records
• Materials management.
• Process equipment and utilities.
• Qualification and validation.
• Change control.
• Production and in-process controls
• Packaging and labelling of FPPs and intermediates.
• Return and reprocessing of products.
• Storage and distribution.
• Laboratory controls.
• Complaints and recall

Site areas visited:
• General production block of Unit II
• Warehouses
• QC laboratory—Physical, chemical, and microbiological
• Water system
• HVAC
• Stability chambers</td></tr>
<tr><td>Restrictions</td><td>The product scope of the inspection for WHO was restricted to the NT012 Albendazole Tablets, Chewable 400 mg.</td></tr>
</table>

Out of scope	Facilities and products which are not under the scope of this inspection.
WHO product number covered by the inspection	NT012 Albendazole Tablets, Chewable 400mg

Abbreviations

ADE	acceptable daily exposure
AHU	air handling unit
ALCOA	attributable, legible, contemporaneous, original and accurate
API	active pharmaceutical ingredient
APQR	annual product quality review
AQL	acceptance quality limit
BET	bacterial endotoxin test
BDL	below detection limit
BMR	batch manufacturing record
BPR	batch packaging record
CAPA	corrective actions and preventive actions
CC	change control
CFU	colony-forming unit
CoA	certificate of analysis
CoS	certificate of suitability
Cpk	process capability index
DQ	design qualification
EM	environmental monitoring
EU	endotoxin unit
FAT	factory acceptance test
FG	finished goods
FMEA	failure modes and effects analysis
FPP	finished pharmaceutical product
FTA	fault tree analysis
FTIR	Fourier transform infrared spectrometer
GC	gas chromatograph
GMP	good manufacturing practice
HACCP	hazard analysis and critical control points
HPLC	high-performance liquid chromatograph
HVAC	heating, ventilation and air conditioning
ID	identity
IR	infrared spectrophotometer
IPC	In process control
IQ	installation qualification
KF	Karl Fisher
LAF	laminar air flow
LIMS	laboratory information management system
LoD	limit of detection
LOD	loss on drying
M	meter
MB	microbiology
MBL	microbiology laboratory
MF	master formulae

MR	management review
NIR	near-infrared spectroscopy
NMR	nuclear magnetic resonance spectroscopy
NRA	national regulatory agency
OQ	operational qualification
Ph. Eur	European Pharmacopoeia
PHA	preliminary hazard analysis
PM	preventive maintenance
Ppk	process performance index
PQ	performance qualification
PQR	product quality review
PQS	pharmaceutical quality system
PRC	product release certificate
PW	purified water
QA	quality assurance
QC	quality control
QCL	quality control laboratory
QMS	quality management system
QRM	quality risk management
RA	risk assessment
RABS	restricted access barrier system
RCA	root cause analysis
RH	relative humidity
RM	raw materials
RS	reference standard
SAP	system applications products for data processing
SFG	semi-finished goods
SMS	short message service
SOP	standard operating procedure
STP	standard test procedure
T	temperature
TAMC	total aerobic microbial count
TFC	total fungal count
TLC	thin layer chromatography
TMC	total microbial count
TOC	total organic carbon
UPS	uninterruptible power supply
URS	user requirements specifications
USP	United States Pharmacopeia
UV	ultraviolet-visible spectrophotometer
VMP	Validation Master Plan
WFI	water for injections
WS	working standard

Part 2	Summary of the findings and comments

1. Pharmaceutical quality system

Production and control operations were specified in written forms and GMP requirements were generally met. Product and processes were monitored, and the results were checked as part of the approval process for batch release.

PQRs

The company had in place a procedure for performing product quality reviews. Product Quality Review was performed annually of all pharmaceutical products following SOP "Product Quality review". The APQRs Albendazole Chewable tablets 400 mg January – December 2022 PQR (bio-batch for WHO) and Albendazole Chewable tablets 400 mg January – December 2023 PQR: (bio-batch for WHO) were reviewed. The BE study was repeated in 2022 as required by WHO PQ program. After the new BE study, no batches of WHO grade product were manufactured.

QRM

The SOP for "QRM" was applicable to QMS (major deviations, CC or quality failure), development, manufacturing, distribution, submission / review process of drug products, use of starting materials, packaging and labelling materials. Ishikawa diagram was used to identify the risks. Steps for RA:

- Risk assessment
- Risk control
- Risk review
- Risk communication

FMEA was used for risk evaluation. The acceptance criteria of RPN were defined. The risk logbook for 2024 was checked.

The risk assessment report performed of Beta lactam cross contamination from Unit I to Unit II was checked. The risk of potential contamination from air exhaustion from Unit 1 was discussed.

DIRA

The SOP "Data integrity" was available. The SOP explained ALCOA and ALCOA + principles and data governance procedures, for example, electronic data management, design of new systems, periodic review and monitoring, data integrity, data backup and restoration etc.

The SOP "Electronic data management in the laboratory" was checked. SOP was applicable for software-based systems as: HPLC, GC, IR, UV auto titrator, and stability chambers. Privileges of the software Users for HPLC was checked. The privileges assigned to Analyst, Reviewer, Manager, and Admin were discussed.

Management review (MR)

The SOP "Procedure for quality system review" was checked. According to the SOP, core quality system review meeting shall be held regularly. Head QA was responsible for organizing the meeting. Meeting was chaired by the Chief operation officer in consultation with CEO and attended by all department heads. Agenda was specified. It was noted that KPIs were established for deviations, CAPAs, change controls, OOS etc.

The minutes of last quality system review meeting held in December 2024 reviewed. Presentations covered current review period as well as periods from the beginning of year. Presentations reviewed were seen to be well organized and detailed.

Change Controls (CC)
The SOP "Change Control System" was checked. Changes were managed through a computerized system. Risk assessment was required to be performed mandatory for critical and major change. Changes were classified as Critical, Major, or Minor. Selected CCs were verified.

OOS investigation
The SOP "Out of specification investigation" and flow charts were checked. SOP was based on MHRA guidelines. SOP explained phase IA and phase 1B investigations as well as phase II and phase III investigations. OOS results were trended annually. Selected OOSs were reviewed.

OOT investigations
The SOP "Out of trend investigation" was checked. OOTs were trended annually.

Deviations
Deviations management was outlined in the SOP. The scope of the procedure included the handling of deviations during manufacturing, packaging, storage, and internal distributions. The company had classified deviations as either planned or unplanned. Deviations were then further classified as either critical, major, or minor. Selected deviations were reviewed and included unplanned deviation and planned deviations.

The SOP "Handling of laboratory deviations" was checked. Trending was performed annually. Trends for 2024 were checked. Laboratory deviations log sheet for 2024 was checked.

Root Cause Analysis
How the company managed root cause analysis was reviewed as part of the complaint management processes during this inspection.

CAPA
Selected CAPA implementations were reviewed as part of the company's complaint investigations.

2. Good manufacturing practices for pharmaceutical products
Good manufacturing practices were generally implemented. The necessary human and physical resources, including adequate premises, equipment, and utilities were provided for the current operational level of FPP activity. Manufacturing processes were generally adequately defined. The manufacturing processes followed procedures as defined and documented in the BMRs and BPRs. The personnel were appropriately qualified and adequate training was conducted.

3. Sanitation and hygiene
Sanitation and hygiene procedures covering personnel, premises, equipment and apparatus, production materials and containers, products for cleaning were in place.

4. Qualification and validation
Validation master plan (VMP)
The company had a policy to qualify and validate the manufacturing facility. The Procedure for preparation of VMP and VMP for 2025 were available. The PV status and planner for the process validation for WHO grade Albendazole tablets were checked and discussed.

Process validation

The SOP "Process validation" was checked. The procedure described that the process validation activities are carried out in three stages.

- Stage 1 - Process Design:
- Stage 2 - Process Qualification:
- Stage 3 - Continued Process Verification:

There were two batch sizes submitted in the dossier for WHO grade Albendazole chewable tablets 400mg. Their PV status was verified, and the relevant batch manufacturing records were spot checked.

Cleaning Validation

The SOP "Cleaning validation" was checked. The cleaning validation shall be conducted on three consecutive batches for selected worst-case product. The acceptance criteria described included PDE, 10 ppm and daily dose and the lowest limit was taken for validation study. The cleaning validation for the compression machine on which WHO product was manufactured were checked and discussed.

Validation of computerized systems

A computerized system was used in QA and QC. Change control, deviations and CAPAs were managed by eQMS. The computerized system validation followed the policy described in the VMP. The computerized system validation was not reviewed in detail in this inspection due to time constraints.

5. Complaints

The SOP "Handling of Market Complaints" was available. Complaints were classified into critical, major, and minor. At the time of the audit there were no complaints raised for 2025. The complaints reported from 2021 to 2024 were available. Selected complaints together with root cause analyses, change controls and CAPA plans were reviewed.

6. Product recalls

The SOP "Product recall" was checked. Head QA was responsible for initiation of the recall and for informing the recall committee. According to the SOP Head QA and recall committee collectively investigate and determine the level and extent of the recall.

- Category I – execution within 24 from confirmation of the recall
- Category II – execution within 72 hours from confirmation of the recall
- Category III - execution within 15 days from confirmation of the recall
- Category IV (directives from drug authorities)
- Category V (voluntary recall)

Recalls were also classified as levels:

- Type A – All suppliers of medicines (all distribution points)
- Type B – Wholesalers, hospital services, retail outlets, doctors
- Type C – Patient level

The effectiveness of the procedure was evaluated by mock recall executed yearly for domestic and export markets.

7. Contract production, analysis, and other activities

No contract production activities were used by the company for the product under inspection. Contract testing laboratories were used, and a list was available.

For distribution activities, the company made use of two dedicated transportation companies which were qualified as outlined in SOP "Transporter Qualification". The contract with the transport service providers were verified.

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

Self-inspection/internal audit

The SOP "Self-inspection" was briefly checked. Self-inspection was carried out by certified auditors. A department-wise checklist was used. Inspection report was approved by the chief auditor, CAPA implementation was checked and approved by Head QA. The self-inspection outcome was discussed in the management review meeting.

Suppliers' approval and audits

There was an onsite team responsible for the supplier's approvals and audits. There were two supplier approval levels. Level I was approving suppliers only based on a document review. This was done for tertiary packaging material suppliers. Level II was to approve suppliers based on both a document review and manufacturing site audits. Level II suppliers include API, excipients, primary packaging, printed packaging, and other container closure suppliers such as the HDPE jars and caps. The company performed vendor appraisals to assess the performance of their suppliers. Suppliers were requalified following the company procedure.

The company made use of third-party audit agencies to perform audits of suppliers outside of India. There was a signed agreement between Medopharm and the third-party audit agency.

9. Personnel

The site had an adequate number of personnel with the necessary qualifications and practical experience; job descriptions were available. According to the company presentation, the number of personnel employed at the site was 136 at the time of inspection.

10.Training

The SOP "Training of personnel" was checked. GMP and job-specific training were provided to all personnel, including contract workers. Newly recruited personnel received training appropriate to the duties assigned to them.

The SOP "Training and validation of analytical chemists" was checked. Analysts were allowed to perform analysis until they were certified as validated chemists. The qualification of the QC analysts was assessed by comparing test results of already released samples. Acceptable RSDs were specified for different type of analysis.

11.Personal hygiene

Procedures for medical check-up of all staff were in place. All staff were required to undergo physical examinations, eye checks, x-rays, and test for sulphamethoxazole allergy. New staff required medical check ups prior to employment, whereas all existing staff had to have medical check-ups every year.

The procedure for personnel health and hygiene requirements were available and found to be acceptable.

12.Premises

Production

On site there were two production blocks. Unit I was dedicated to the manufacturing of non-sterile penicillin solid dosage forms and Unit II for General OSD products.

The Unit II facility was a multi-product and not dedicated facility. Exposed surfaces were smooth, impervious, and unbroken to minimize the shedding or accumulation of particles or microorganisms and permitted ease of cleaning. Access to production premises was restricted to authorized personnel. The environmental monitoring of the classified areas in Unit II including temperature, relative humidity, and pressure differentials were controlled manually. They were checked during the visit to Production Block Unit II.

QC laboratories

QC laboratories including Physicochemical laboratory and Microbiology laboratory were separated from production areas. Adequate storage space was provided for samples, reference standards, solvents, reagents and records. Both QC laboratories were common to Unit I and Unit II. The QC management such as change control, and equipment requalification of the QC labs was managed under QMS of Unit I.

Utilities

P&ID drawing for the HVAC system and schematic drawing of the purified water generation & distribution system were provided in the SMF and checked onsite. Manufacturing areas were ventilated with air control units. The filter cascade was documented. Filters pressure differentials were monitored. Alarm system was provided and challenged. HVAC system was found clean and well maintained.

The following procedures were checked.

- SOP "Procedure for operation of AHU and ventilation units"
- SOP "Environmental monitoring by settle plate method"
- SOP "Environmental monitoring by air sampling method"

Purified water

The P&ID and schematic drawing of purified water generation & distribution system provided in the SMF were checked onsite. PW system was seen to be clean and maintained in good order.

The raw water sourced from the bore well. The raw water was treated through the pretreatment system followed by RO unit. RO water (portable water) was used for equipment and area cleaning.

PW was distributed to user points via a continuous circulation loop. Online monitoring: conductivity supply/return, flow rate, and temperature at the return point.

The SOP "Sampling and testing of water" was checked. Sampling was carried out by IPQA personnel. The sampling schedule and acceptance criteria for test parameters were specified. Alert and action limits of microbiological limit were established based on historical data. Trending was performed. Trending results for December 2024, return loop were reviewed. All results were within alert specifications.

Compressed air

The P&ID drawing for compressed air generation and distribution system was checked. After drying compressed air was filtered via filters. Where compressed was used in contact with product additional filters were installed. Filter integrity check and replacement were performed by an external agency. Re-qualification of the system was performed following the company procedure.

Lighting

Lighting was adequate in all areas visited during the inspection.

13.Equipment

Equipment installed in the facility was multi-purpose and each piece of equipment had a unique identification number. Equipment was located, designed, constructed, adapted, and maintained to suit the operations to be carried out. The equipment viewed appeared to be of suitable design and construction for the allocated process in general.

Equipment qualification and maintenance

The SOP "Requalification of equipment & instrument" was checked. The Engineering department manager supervised the equipment qualification and maintenance for both Unit I and Unit II. The qualification of the compression machine used to produce WHO Albendazole tablets and the qualification of a blister packing machine were reviewed.

The guidance on the frequency of performing preventative maintenance on equipment was outlined in SOP on "Planned Preventative Maintenance". The preventive maintenance of a compression machine, a high shear mixer and a blister packing machine together with the maintenance records were checked.

Equipment cleaning

The equipment cleaning of a compression machine stored in the production area was checked during the inspection.

14.Materials

Incoming materials and finished products were quarantined after receipt or processing until they were released for use or distribution. Materials and products were stored under the specified conditions established by the manufacturer.

Starting materials were purchased from approved suppliers. Receiving of materials was protected from weather. A checklist was used for receiving raw materials and packaging materials. Materials were sampled under RLAF in the sampling room. Sampling was performed by QA personnel. Rejected materials were under QA control. Materials dispensed for each batch of the final product were kept together and conspicuously labelled as such. Materials management was done manually using a stock register.

Primary packaging materials store and secondary packaging store were briefly visited. All warehouses visited were seen clean and in good order. Finished products central warehouse was common for Unit I and Unit II as for other Medopharm units.

15.Documentation

Documents were designed, prepared, reviewed and distributed with care. Documents were approved, signed, and dated. Documents were regularly reviewed and kept up to date. Records were required to be made or completed when any action was taken.

The following procedures were reviewed.

- SOP "Issue, completion, review of BMR, BPR and batch release"
- SOP "Testing and release/rejection of intermediate and finished products"
- SOP "Verification and approval of analytical reports"
- SOP "Document and data control"

Batch numbering system and BMR management.

Batch numbering was managed following the SOP "Batch numbering system".
The SOP "Creation, completion, review of BMR/BPR and batch release" was checked. The BMR and BPR of an Albendazole tablets were reviewed.

Material Code management

The SOP on "Coding System" outlined how to assign item codes for the individual raw materials, excipients, packaging materials, bulk, and finished product. Product codes were entered into a product identity register logbook.

16.Good practices in production

Production operations followed defined procedures. Handling of materials and products was done in accordance with written procedures and recorded. Deviations were approved through software in writing by a designated person. Checks on yields and reconciliation of quantities were carried out. Operations on different products were not carried out simultaneously or consecutively in the same room or area. During processing, materials, bulk containers, major items of equipment, rooms and packaging lines being used, where appropriately labelled Access to production premises was restricted to authorized personnel.

The company performed hold time studies for dispensed materials and then from blended bulk onwards. Albendazole tablets primary and secondary packaging was done manually.

Reprocessing and reworking

The following procedures were checked and discussed.

- SOP "Operating procedure off rapid pack blister de-foiling machine"
- SOP "Handling of rejects generated during processing"
- SOP "Handling of reprocessable recovery of semi-finished and finished goods"

Return of products

The SOP "Handling of returned products" was in place.

17. Good practices in quality control

The QC function was independent of other departments. The QC laboratories were separated from production areas. The microbiology laboratory was segregated from the chemistry laboratory. QC laboratory was seen to be clean and in good order. QC laboratory was common for Unit II and Unit I. QC personnel were not allowed to enter raw materials and packaging materials warehouses and Unit II production premises.

Incoming samples were registered in separate logbooks and kept in locked metal cabinets. Wet solutions made in the laboratory were seen to be appropriately labelled. HPLC columns were kept in locked metal shelves and were seen to be stored in good order. HPLC columns were product dedicated, usage was recorded in logbooks.

The testing data of WHO Albendazole tablets bio-batch and 24 M stability studies was checked with original HPLC chromatograms retrieved from the IT server. Chromatograms were briefly checked.

The following procedures were verified.

- SOP "Bracketing of standards in chromatographic methods"
- SOP "Good chromatographic procedures" were checked
- SOP "Sampling of raw materials"
- SOP "Sampling of packaging materials"
- SOP "Sampling of packaging of blend, bulk and finished product"
- SOP "Acceptable quality limit for tablet attributes"
- SOP "Handling and maintenance of analytical standards"

Instrument calibration

Several QC instruments calibration records were briefly checked. Instruments were serviced and calibrated at pre-specified intervals and records were maintained. Instrument calibration labels indicate date of calibration and servicing and the date when recalibration is due. Balances of an appropriate range and precision were available. Standards used for calibration were traceable.

Class "A" volumetric glassware was used in the laboratory. Upon receipt, 100 % calibration was performed on each item of volumetric glassware.

Instrument maintenance

The instrument maintenance of Milli-Q water system was spot checked and showed the cartridge filter maintained in line with the required schedule.

Retention samples

Retention samples (control samples) from each batch of finished product in their final packaging were kept for at least one year after the expiry date. Samples of active starting materials were retained for six years. Samples were of a size sufficient to permit at least two full analyses. Retention samples were visually checked once per year.

Stability study

The company had available walk-in stability chambers for long-term stability studies at the condition of 40 °C/75%RH, 30°C/75%RH, 25°C/60%RH and another as backup. Chambers were qualified in accordance with in-house procedure. The stability study sample of a batch for WHO BE study were in warded in the chamber controlled at 30°C/75%RH.

Microbiology Laboratory

The Microbiology laboratory carried out the microbiological testing and approval of incoming materials, intermediate products, finished products, water, and environmental monitoring samples. The layout and clean zone grades, gowning procedure, media growth promotion test and PW microbial limit testing procedure were spot checked and discussed.

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 deficiencies listed in the Inspection Report, a decision on the compliance of **Unit *II, Medopharm Private Limited,*** located at ***No. 50, Kayarambedu Village, Guduvanchery - 603 202, Tamilnadu, 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-eighth Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. ***Short name: WHO TRS No. 986, Annex 2***

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***

3. 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

4. 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

5. 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***

6. 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

7. WHO good practices for pharmaceutical quality control laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1.
   Short name: WHO TRS No. 961, 957), Annex 1

8. 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

9. 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

10. WHO guidelines on technology transfer 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

11. 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***

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***

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

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

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

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

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***

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***

19. 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***

20. WHO Recommendations for quality requirements when plant – derived artemisin 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

21. Guideline on data integrity. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 4. ***Short name: WHO TRS No. 1033, Annex 4***

22. WHO general guidance on variations to multisource pharmaceutical products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10.
Short name: WHO TRS No. 996, Annex 10

23. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 10.
Short name: WHO TRS No. 1010, Annex 10

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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***

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