World Health Organization

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

Part 1	**General information**
Manufacturers Details	
Company information	
Name of manufacturer	Micro Labs Limited – Goa – ML06
Corporate address of manufacturer	Micro Labs Limited 27, Race Course Road, Bangalore - 560 001, India Contact number: 080-2237 0451 Fax number: 080-2237 0463
Inspected site	
Address of inspected manufacturing site if different from that given above	Micro Labs Limited – Goa-ML06 Plot No. S-155 to S-159 & N1 Phase III & IV, Verna Industrial Estate, Verna, Salcette Goa, 403 722, India North latitude: 15°21'49.709" East longitude: 73°56'55.287" D-U-N-S: 91-579-3658
Unit / block / plant number	N/A
Manufacturing license number	• License no. 651 for drugs other than those specified in schedule C, C(1) and X, to the Drugs and Cosmetics Rule 1945 • License no. 652 for drugs specified in schedule C and C(1) excluding those specified in schedule X, to the Drugs and Cosmetics Rule 1945
Inspection details	
Dates of inspection	25-29 July 2022
Type of inspection	Routine
Introduction	
Brief summary of the manufacturing activities	Micro Labs Limited was established in 1973 with the Goa manufacturing facility situated at Verna Industrial Estate, starting operations in 2004. Operations in expanded building were started in 2013. Plans are underway to expand on the Micro Laboratory with the expansion of the QC lab completed in 2022. The facility is commissioned to produce non- sterile Oral Solid Dosage Forms for human use. The site supplies product only to the Export market.
General information	Manufacture and quality control of tablets and hard capsules

about the company and site	
Brief report of inspection activities undertaken	All areas involved with the manufacture of products submitted to WHO for prequalification or that have received PQ status were inspected.
Scope and limitations	Routine GMP inspection conducted. Areas and products not within the WHO Prequalification submissions were excluded.
Areas inspected	See Part two below
Restrictions	All production areas, quality control laboratory and micro laboratory areas together with documentation storage and warehouse facilities involved with the manufacturing of the WHO products were inspected. The Misoprostol suite was briefly visited. Areas not involved with the WHO products were excluded from the inspection.
Out of scope	Areas and products not within the WHO Prequalification submissions were excluded.
WHO product numbers covered by the inspection	• MA132 Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg • MA133 Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg • MA133 Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg • HA483 Zidovudine Tablet, Film-coated 300mg • HA485 Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg • HA536 Lamivudine Tablet, Film-coated 30mg • HA537 Zidovudine Tablet, Film-coated 60mg • HA555 Lamivudine/Zidovudine Tablet, Film-coated 30mg/60mg • HA567 Nevirapine Tablet 20mg • HA568 Nevirapine Tablet 50mg • HA569 Nevirapine Tablet 100mg • HA570 Nevirapine Tablet 200mg • HA620 Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 300mg/300mg • HA629 Lamivudine/Nevirapine/Zidovudine Tablet, Film-coated 150mg/200mg/300mg • HA631 Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 200mg/300mg • HA633 Efavirenz Tablet, Film-coated 600mg • HA644 Lamivudine Tablet, Film-coated 150mg • HA674 Abacavir (sulfate) Tablet, Dispersible 60mg • HA598 Trimethoprim and Sulfamethoxazole BP 80mg/400mg • HA599 Trimethoprim and Sulfamethoxazole BP 160mg/800mg • HA751 Dolutegravir Tablets 50mg • HA755 Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumerate Tablets 50mg/300mg/300mg • HA763 Abacavir and Lamuvidine Dispersible Tablets 120mg/60mg • HA767 Efavirenz, Lamivudine and Tenofovir disoproxil Fumerate Tablets 600mg/300mg/300mg

- HA760 Lopinavir and Ritonivir Tablets USP 100/25 mg
- HA761 Lopinavir and Ritonivir Tablets USP 200/50 mg

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
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	Brief summary of the findings and comments (where applicable)

1. Quality system,

Principle

Production and control operations were specified in written form and GMP requirements were essentially being met. Managerial responsibilities were specified in written job-descriptions. Product and processes were monitored, and the results considered during batch release; regular monitoring and reviews of the quality of pharmaceutical products were being conducted according to documented schedules and procedures. Six monthly senior management review meetings as per the applicable SOP were conducted following monthly site management meetings and a monthly governance forum meeting. Feedback from the various Site Production was reported by Corporate QA at the Senior Management Review meeting. Corporate QA was represented full time on site. The latest Senior Management Review Agenda and Minutes were reviewed.

Quality Risk Management

Quality Risk Management had been implemented via the requirement for Risk Assessments (RA) to be performed during the evaluation of change controls, validation activities, data integrity assessments and other quality system elements. These were recorded in a consistent manner.

Data Integrity

A Data Integrity Policy signed by senior management was communicated across the facility and was supported by SOP.

Out of Specification results (OOS)

OOS registers and trends were briefly discussed. Trending was performed quarterly.

Out of trends (OOT)

OOT results, flow chart and register for 2021 were briefly discussed.

Product Quality Review (PQR)

Product quality review (PQR) was discussed. The timeline for PQR was 12 months from date of product launch. Some PQR was discussed.

Deviations

Handling of deviations, deviation register, and trends were briefly discussed. Scope was "manufacturing, packaging, storage and internal distribution". Deviations were classified as:

- Minor
- Major
- Critical

Deviations should be closed within 30 days, if not possible an extension should be obtained. Trending was performed quarterly. Trending for 2021 was investigated. Deviation Investigational Team should be appointed appropriate to the required deviation and investigation. Key performance Indicators were listed as:

- Closure on time - within 30 days.
- Recurring deviation - Specification limit of 5%.

Some deviations were briefly discussed.

Change control (CC)

Change control system, CC registers, "Key performance indicators to be covered in quality system review", and trends were discussed. The SOPs referred to different types of changes including temporary and permanent changes. Changes were classified as:

- Minor
- Major
- Critical

Changes were trended annually.

KPIs for changes were "time" related with a change to be completed within 30 days. Two systems exist for CC, a manual system that requires 30days for completion and an ePortal system that allows for a 45 day completion period. Accordingly, the manual system was in the process of being phased out but will be used when the electronic system is not available.

CAPA

Handling of Corrective and Preventative Action and corresponding registers for 2021 were briefly discussed. CAPA's can be triggered from any noncompliance including Audits, Lab Deviation, Training, PQR, Trend Report, deviations, OOS, CC. CAPA were divided into

- Phase I - Initiation
- Phase II- Implementation and Closure
- Phase III - Effectiveness

Timelines for implementation of CAPA was stated as 30 days. One request for extension of CAPA timelines was allowed. All CAPAs were reviewed by Corporate QA thorough e-System and during Site Management meetings. Trending was performed quarterly. KPIs were identified which related to % on-time completed, effective monitoring and %, on time completion of regulatory observations. Some CAPAs were inspected.

Risk Assessment

Risk Assessment Reports were reviewed, observations made and addressed by site.

Batch Manufacturing Records and Batch Release:

The SOP for creation completion, review of Batch Manufacturing Records and Batch Release, was reviewed. Batch numbering system was addressed.

SOP for Batch Release was verified against an actual product batch release and found compliant.

2. Good manufacturing practices for pharmaceutical products

Required resources were available, including adequate premises, equipment, utilities and personnel. In general, production operations followed defined procedures. Manufacturing processes were adequately defined and documented in BMRs and BPRs. Qualifications and validations were performed according to prepared protocols. Significant deviations from the initial protocol were recorded and investigated, root causes were determined and CAPAs were implemented where necessary. Checks on yields and reconciliation of quantities were carried out. Access to production premises was restricted to authorized personnel. A risk assessment for cross contamination in shared facilities based on the HBEL approach was presented supporting the current product range to be manufactured in a dedicated facility without any shared services.

Products were dispatched with the inclusion of Data loggers to check transportation conditions to allow customers to read the data loggers.

Disaster Management and Security of Computerized Systems

A Disaster Recovery Plan in place, was evaluated and found acceptable.

3. Sanitation and Personal Hygiene

Pre-employment and annual medical examinations were performed for all staff followed by training in the importance of personal hygiene and the reporting of illness.

Change rooms for general, primary, and secondary manufacturing zones were provided for staff garment and shoe changes. Dedicated shoes and colour coded garments per zone were provided daily for staff as per the different operating zones.

4. Qualification and Validation

Product Process validation

Product Process validation of specific tablets was inspected following OOS and to allow for the scale up of pre-submission batches to commercial batch sizes. Reason for validation – batch size increase.

Computer System Validation

The validation of computerized systems was governed by a Validation plan for the Goa site which addressed specific systems and processes.

The validation reports reviewed all addressed the major GMP requirements were comprehensively executed. Some observations were made which were addressed satisfactory.

Cleaning Validation

A comprehensive cleaning validation system was in place based on the calculation of Health Based Exposure limits represented by the permitted daily exposure limit (PDE) calculated by a contracted Toxicologist and verified by an internal subject matter expert.

The cleaning of production equipment and small items was performed via three distinct protocols

- Type A – Product change over
- Type B – Batch change over
- Type C – End of shift cleaning

The limits for cleaning validation are calculated via a commercial software package which considers various parameters including PDE, solubility, cleanability, minimum therapeutic dose, strength of product, specific toxicological risks and the surface area of the equipment. The PDE based limits were compared to the traditional limits with the worst case used for cleaning validation studies using specific analytical techniques for each API and the cleaning agent as well as microbiological limit testing. Following the optimization of the cleaning method and validation of the effectiveness for each worst-case molecule for each piece of equipment, a verification of cleaning effectiveness was performed for all Type A cleaning activities on an ongoing basis.
The program was supported by the establishment of detailed cleaning methods, recording of cleaning parameters and critical steps, the training of staff and the establishment of equipment clean and dirty hold times.

5. Complaints
Handling of market complaints together with the complaints registers and compliant trends were inspected. Trending was carried out quarterly. Complaints were classified as:

- Critical
- Major
- Minor

According to the SOP complaints should be closed within 30 days. For critical complaints a decision on recall had to be made within 3 days and completed within 7 days. The maximum time for the review of a complaint was 150 days. All complaints were evaluated by the Pharmacovigilance Dept to allow for input. Trending was done quarterly, and yearly. Yearly trends were reviewed for the past 3 years. Complaints are discussed in the Management review.

The Yearly market complaints trend for 2021 was inspected with some complaint investigations reviewed. No critical complaints were received during 2021.

6. Product Recalls
Product recall for export market was inspected. Recalls classification and execution of recall was done by Corporate QA and Head of Corporate QA via the Site QA representative. Effectiveness of the recall was investigated. Recalls were classified as:

- Class I – recall should be initiated within 24 hours
- Class II – recall should be initiated within 48 hours
- Class III – recall should be initiated within 10 working days

Recall Committee is appointed with appropriate representation. The Recall was depended on the degree of hazard and extend of distribution and was classified into:

- Level I - Consumer
- Level II - Retailer
- Level III - Wholesaler

Effectiveness checks are based on Recall strategy which is defined:

- Level A – 100
- Level B – Some %
- Level C – 10 %
- Level D - 2% of Total number of consignees
- Level E – No check

Specific procedure for WHO products and Mock Recall was available. Mock Recall was executed for each market of one product during 2021. The execution of the latest recall was inspected.

Product rejects / Non-conforming products

Control and tracking of non-conforming products was discussed. An appropriate action is implemented following conclusion of any investigation. The non-conforming products registers for 2021 (manual document) was inspected.

Product returns

Handling of returned products which may also include a recalled product was discussed. Product are stored in the return goods area for decision making. Products could be reworked. If decision to destroy, it will be sent to the rejected area. There were no return products in 2021 and 2022.

7. Contracts, Self-inspection, quality audits and approved vendors

Self-audits were conducted as per the appropriate SOP. Self-audits were conducted according to a six-system approach and covered 1 area every 6 months. Audit Teams were identified by QA. Nonconformities were classified as Critical, Major or Minor. The Self-audit report conducted for February 2022 was available. Check list was used as audit tool.

Internal Quality Audit was conducted as per an appropriate SOP. Audit was aimed at sites within the Micro Lab family. Audit schedule and Audit Team were defined by Corporate QA. Compliance rate of each site after audit to determine the follow-up cycle. Competence Checklist was used as audit tool. The conduct of Internal quality audits was verified. The audit team was appointed by CQA and consisted of corporate QA staff. Audit reports were available and inspected.

Vendor auditing was conducted as per SOP in support of Outsourcing of activities for Quality control testing, destruction of waste material (Antimicrobials), Micro Labs R&D and API. Some outsourced activities were inspected.

8. Personnel

An appropriate number of staff employed in various units within the plant was employed.
Manufacturing capacity allows for three shift operations.

- Manufacturing 3 shifts,
- Lab and packaging 2 shifts

9. Training

The training procedure, and Annual training plan for 2022, together with the corresponding job description and training records were spot checked. SOP calls for Self-reading and Classroom training. Effectiveness of training was verified. Training classified into Orientation training, Hands on training (job specific training) and Ongoing training. Refresher training was limited to self-reading of predefined SOP's. Annual training plan for 2022 available. Training records for specific staff were verified and found compliant.

10. Premises

The manufacturing facility consists of the original manufacturing block (Existing) built in 2004 and a second manufacturing block (Expanded) added in 2013. The two manufacturing blocks were joined by a corridor to provide approximately 16000 square meters of manufacturing and warehousing space and approximately 2400 square meters of QC/QA space.

The lay out of the primary and secondary manufacturing areas and work in process storage areas supported the unit processes performed and were suitably laid out to provide for a unidirectional flow of materials and to minimize the risks of cross contamination and product mix ups.

The primary manufacturing areas were of an appropriate design and finish to facilitate cleaning and were generally in good condition. The primary manufacturing areas were controlled in terms of temperature and humidity via recirculating HVAC units with primary filtration of the return air in the manufacturing room (low level) with terminally mounted HEPA filters on the supply side (high level). Temperature and humidity readings from room mounted devices were recorded in logbooks.

The primary manufacturing rooms opened directly onto the adjacent corridors with appropriate pressure differentials and additional staff change facilities provided to minimize the potential for cross contamination. Pressure differentials were manually recorded in logbooks and were found to be in specification.

The chemical and microbiological control laboratories were well equipped and well maintained. Stability chambers for all required conditions were provided.

Materials were stored in a fully automated warehouse and an adjacent finished goods store which were both monitored for temperature and humidity via an automated monitoring system. The temperature and humidity mapping of the warehouse was completed on a regular basis which confirmed the positioning of the routine monitoring probes and no deviations for out of specification results had been raised in the past 2 years.

Utilities

The facility was supported by sufficient square meters of engineering utilities space. The HVAC units and the purified water plant servicing the existing facility were found to be in good condition with appropriate labeling, maintenance, and calibration. Compressed air was supplied via a stainless-steel loop and storage system with final filtration at the point of use.

Water was supplied via a combination of local government and borewell sources and underwent pretreatment, de-mineralization and ultrafiltration prior to storage and circulation in a stainless-steel ambient temperature loop with weekly high temperature sanitization. The performance of the system was monitored via a combination of online measurement and offline sampling with subsequent QC chemical and microbiological testing. The engineering and quality control records for the water system for the period January 2021 to December 2022 indicated that the system was under control.

The facility was supplied with electricity by the local government supported by sufficient (excess) on site power generators to run the facility during power outages.

Packaging and labeling Systems

The issuing, control and reconciliation of bulk tablets and printed packaging materials were completed as per the BPR's. Records for line clearance and line opening activities as well as online checks and challenges were comprehensive and accurately completed. Suitable samples of printed packaging prior to and after the printing of batch specific details were retained.
The packaging areas were conditioned to less than 25C with manual recording of the data.

13. Equipment

The facility was adequately equipped to produce a wide range of tablets and capsules in a range of batch sizes. The granulation equipment was in good condition and varied in terms of the levels of automation and containment. The compression and coating equipment were all of a modern design with extensive computer-based feedback systems.
A planned preventative maintenance program was in place for all equipment and analytical instruments which was up to date and supported by adequate records. A similar program was in place for calibration which had a clear distinction between the calibrations required for critical and noncritical instruments. Calibration was generally outsourced to approved service providers with the records and appropriate certificates checked by a company representative prior to approval. The records reviewed were found to be in order.
A range of modern blister packaging equipment fitted with appropriate automated checking systems were in place in the primary packaging rooms connected directly through the wall to secondary packaging equipment which included camera driven auto rejection systems as well as serialization capabilities at individual unit as well as shipper level.

14. Materials

Starting and packaging materials were well managed on receipt via a combination of the SAP system and a bar code driven automated materials management and labeling system (MTS) supported by handheld scanners for material transactions from receipt up until the dispensing process. Dedicated sampling booths were provided for starting materials and packaging materials which met expectations. All materials were stored in an orderly manner and were well controlled.
Solvents were dispensed into pressure vessels in a dedicated room as per batch requirements after which they were moved into the production area.
Retained samples of starting material and retention samples of finished goods were stored in a secure system of movable racks and were well controlled.

15. Documentation

SOP's were generated, approved, controlled and retired in a computerized document management system (DMS) which formed part of the software system used across the site. The distribution of SOP's to the shop floor was done via an inhouse developed "eSOP" system which had not been validated. SOP's contained sufficient step wise instructions for the operations performed. Cleaning SOP's included detailed photographs of critical steps.

Batch manufacturing and packing documents (BMR's & BPR's), protocols, logbooks and laboratory worksheets were printed from the DMS system and authorized by QA before distribution. These documents were well designed with sufficient instruction and adequate space for the recording of key activities.

The storage and archiving of paper based documentation was facilitated by a bar code tracking system prior to allocation of storage locations in a well-equipped document storage area which was conditioned and fire protected

16. Good practices in production

The production activities were performed in an orderly manner in accordance with the BMR's and supportive SOP's. All documents reviewed were accurately and contemporaneously completed with the attachment of the required supportive data such as cleaning labels and equipment print outs.
Fixed equipment was cleaned as part of the room cleaning activities while the movable and small parts were cleaned in a cleaning area with separate clean and dirty entry points as well as storage areas for product dedicated change parts. Washing and drying facilities were provided for FBD "finger bags" along with product specific storage cabinets. Cleaning labels containing the "expiry" of the cleaning status were attached to the polybags containing the cleaned parts which were then affixed to the BMR for subsequent verification.
Compression machine punches were securely stored in a dedicated room linked to a punch cleaning station with adequate record keeping.

17. Good practices in Quality Control

The QC function consisted of QC Analytical and QC Microbiology departments. As reported by the company chromatographic instruments (HPLCs & GCs) were operated through network-based software. No standalone chromatographic system was in place.

SOP, Sampling of raw Material, identify the sampling requirements, including separate sampling for micro testing. Sampling Requirements were defined in the e-sampling plan. 100% sampling was required for the identification of starting materials while pooling of samples was allowed for additional testing. The SOP included provision for pooling of samples for Micro testing.

The following laboratory systems were evaluated and found to be compliant.

- Receipt and storage of samples
- Allocation of samples and the printing of analytical work records (AWS) from the LIMS system
- Storage of reference samples, columns, and reagents
- Verification of analytical balances
- Standardization of volumetric solutions and analytical standards
- Data integrity and selected systems
- Access and privileges
- Control of audit trails, re integration and aborted runs
- Good chromatography practices
- Review of batch specific analytical raw data & Stability sample
- Entry of data into the LIMS system and accuracy of the resultant COA
- Reduced testing of API samples

The out of specification procedure was reviewed with no major concerns. The examples reviewed were investigated as per the SOP and were well recorded with the required level of scientific rigor.

Microbiological Laboratory:
The Micro laboratory was inspected. SOP for Microbial Culture management, and Microbial media management, were available and challenged. Preparation of media, incubation and reading of results were inspected and found compliant. Compliance of autoclaves were inspected.

Part 3	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, the site ***Micro Labs (Goa) – ML06,*** located at ***Plot No. S-155 to S-159 & N1 Phase III & IV, Verna Industrial Estate, Verna, Salcette Goa, 403 722, India*** complies with WHO good manufacturing practices for pharmaceutical products guidelines for the manufacture of medicines.

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.

DEFINITIONS

Critical deficiency
A *critical* deficiency may be defined as an observation that has produced, or may result in a significant risk of producing, a product that is harmful to the user.

Major deficiency
A *major* deficiency may be defined as a non-critical observation that:

- has produced or may produce a product that does not comply with its marketing authorization and/or prequalification application (including variations);
- indicates a major deviation from the GMP guide;
- indicates a failure to carry out satisfactory procedures for release of batches;
- indicates a failure of the person responsible for quality assurance/quality control to fulfil his or her duties;
- consists of several other deficiencies, none of which on its own may be major, but which together may represent a major deficiency and should be explained and reported as such.

Other deficiency
A deficiency may be classified as other if it cannot be classified as either critical or major, but indicates a departure from GMP. A deficiency may be other either because it is judged as minor or because there is insufficient information to classify it as major or critical.

Classification of a deficiency is based on the assessed risk level and may vary depending on the nature of the products manufactured, e.g. in some circumstances an example of another deficiency may be categorized as major.

Part 4	List of GMP Guidelines used for assessing compliance

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.
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/
   Short name: WHO TRS No. 986, Annex 2

2. 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

3. 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/

4. WHO Good Manufacturing Practices: water for pharmaceutical use. *WHO Expert Committee on Specifications for Pharmaceutical Preparations.* Fourth-sixth Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2
   Short name: WHO TRS No. 970, Annex 2
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/

5. WHO guidelines for sampling of pharmaceutical products and related materials. *WHO Expert Committee on Specifications for Pharmaceutical Preparations.* Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4
   Short name: WHO TRS No. 929, Annex 4
   http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

6. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations.* Fifty-second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8
   Short name: WHO TRS No. 1010, Annex 8
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en/

7. Supplementary guidelines on good manufacturing practices: validation. *WHO Expert Committee on Specifications for Pharmaceutical Preparations.* Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4
Short name: WHO TRS No. 937, Annex 4
http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

8. WHO Good Practices for Pharmaceutical 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/

9. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. *WHO Expert Committee on Specifications for Pharmaceutical Preparations*. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2
Short name: WHO TRS No. 957, Annex 2
http://www.who.int/medicines/publications/44threport/en/

10. 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

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

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

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

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

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

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