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Prequalification Unit Inspection Services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Finished Pharmaceutical Product Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**Universal Corporation Limited (UCL)**
Corporate address of manufacturer	Strides Pharma Science Ltd Bilekahalli, Bannerghatta Road, Bangalore-560 076, India
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Club Road, Past Kikuyu Post Office P.O. BOX 1748-00902, Kikuyu town Kikuyu, Kenya GPS Coordinates: 1°14’ 26.64’’S, 36°39’38.83’’E
Inspection details	
Dates of inspection	2 – 6 September 2024 *Note: WHO participated in this inspection from 4 to 6 September 2024*
Type of inspection	Routine GMP inspection This was a joint inspection with UNICEF
Introduction	
Brief description of the manufacturing activities	The company is authorized by the Poison & Pharmacy Board of Kenya to manufacture tablets, hard gelatin capsules, liquids, dry syrups, powders, and semisolids for human use. Manufacturing activities for all dosage forms take place in the same building. No hazardous products are manufactured on site. Some Quality Control activities and tests may be outsourced at approved laboratories.
General information about the company and site	Universal Corporation Limited (UCL) is a subsidiary of Strides Pharma. The manufacturing site is located at Kikuyu Town, 21Km from Nairobi and 37Km from Jomo Kenyatta International Airport. The facilities cover an area of approximately 7,600m^2. The site started its operation in 2004. Manufacturing facilities were expanded during 2009-2010 (granulation, dispensing and storage areas). The first product was approved by WHO PQ in 2013. In 2016 Universal merged with Strides Pharma Care Limited.
History	This was the ninth WHO inspection. The last WHO inspection was carried out from 14 to 17 March 2023. The site is periodically inspected by the Poison & Pharmacy Board of Kenya.

Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	Implementation of CAPA related to the findings of the previous WHO inspection were reviewed. In addition, the following documents and procedures were reviewed: • Organization Chart. • Job descriptions for key personnel. • Personnel training and hygiene. • Product Quality Review. • Quality Risk Management. • Responsibilities of the quality units and production. • Complaints and Recalls. • Deviation control and change control. • CAPA. • OOS and investigation. • Material release. • Self-inspection and vendor qualification. • Validation and qualification. • Technology Transfer – Method Transfer. • Equipment calibration. • Data integrity. • Sampling and testing of materials. • Batch processing records. • Materials management system. • HVAC system. • PW system. Areas visited: • Starting materials, packaging materials and FPP warehouses • Manufacturing operations • QC laboratories
Restrictions	The inspection was restricted to products approved by WHO PQ and UNICEF
Out of scope	All other products and workshops were outside of the inspection scope and were not visited.
WHO products covered by the inspection	Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate tabs Film-coated 50mg/300mg/300mg (TLD) Artemether/Lumefantrine tabs 20/120mg Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg Artemether/Lumefantrine Tablet 80mg/480mg Pyrimethamine/Sulfadoxine tab, dispersible 12.50mg/250mg Pyrimethamine/Sulfadoxine tab, dispersible 25mg/500mg Pyrimethamine/Sulfadoxine + Amodiaquine (hydrochloride) tab, dispersible 25mg/500mg + 150mg Pyrimethamine/Sulfadoxine + Amodiaquine (hydrochloride) Tablet, Dispersible 12.5mg/250mg + 75mg

Abbreviations	Meaning
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
APS	Aseptic process simulation
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
CFU	Colony-forming unit
CIP	Cleaning in place
CoA	Certificate of analysis
CpK	Process capability
DQ	Design qualification
EDI	Electronic deionization
EM	Environmental monitoring
FAT	Factory Acceptance Test
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
IQ	Installation qualification
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
MF	Master formulae
MFT	Media fill Test
MR	Management review
NC	Non conformity
NRA	National regulatory agency
OQ	Operational qualification
PHA	Process hazard analysis
PLC	Programmable logic controller
PM	Preventive maintenance
PQ	Performance qualification
PQR	Product quality review
PQS	Pharmaceutical quality system
PW	Purified water
QA	Quality assurance

QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
RO	Reverse osmosis
SIP	Sterilization in place
SMF	Site master file
SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometer
VMP	Validation Master Plan
WFI	Water for injection

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

1. Pharmaceutical quality system

Since the merger of UCL with Strides Pharma Science Limited, UCL had implemented a QMS according to Corporate Quality Practices which aimed at harmonizing quality principles and approaches across all Strides sites.

Quality Manual

The global Pharmaceutical Quality System Manual was presented together with the minutes for the monthly site meetings and monthly corporate meetings. It was recommended that the company should consider including or referencing data integrity management.

Quality Risk Management

QRM principles were integrated into different aspects of the pharmaceutical system. A procedure for conducting risk assessments was in place and several procedures had integrated QRM principles as part of the process (e.g., handling of deviations, change management, equipment qualification).

Data Integrity

A Corporate Policy on Data Integrity was established. The commitment and support of senior management in the implementation of this policy was detailed in the document. The purpose of the document was to outline the key elements ensuring reliability and integrity of the QMS. According to the policy all employees had to be trained on the fundamental principles of Data Integrity. The policy took also into account risk management principles to identify critical data, assess the existing control levels, determine potential hazards, and implement appropriate mitigation measures. The policy further expanded in data governance, by describing the basic elements of data collection, analysis, reporting, and retention. There was refence to the ALCOA+ principles.

Product Quality Review

Product quality reviews were performed as outlined in a corporate procedure. The procedure was updated to include the review of co-packed products and primary packaging materials. According to the company's procedure, continuous process verification was to be performed when more than 25 batches were manufactured. In the case where less than 25 batches were produced, then only trends would be monitored. PQRS for the following products were reviewed:

- Terbinafine 1% cream, 15g tube for the period Oct 2022 – Sept 2023 with only one batch manufactured during the review period. On average, only one batch per year was manufactured. In 2022 there were no batches manufactured.
- Sulfamethoxazole/Trimethoprim 400mg/80mg tablets packed in blisters and bottles for the review period Feb 2023 – Jan 2024. 54 batches were manufactured during this review period, four complaints, seven deviations, three OOSs and two CAPAs were registered. Selected deviations, complaints and OOS reported in the PQR were reviewed and did not give rise to any comments.
- Pyridoxine 50mg tablets for the review period Apr 2023 – Mar 2024.
- Oral rehydration salts flavored 4 sachets for 0.5l +Zinc 20mg dispersible tablets, blister pack of 10 with semi-finished goods for the period Feb 2023 – Jan 2024. 32 batches were manufactured during this review period.
- Oral Rehydration Salt, flavored, 2 sachets for 1 L + Zinc 20mg dispersible tablets, blister of 10 with for the period Apr 2023 – Mar 2024. 87 batches manufactured during this review period.

Deviation Management

Deviations were handled as outlined in the corporate procedure. Deviations were logged in TrackWise and were classified into critical, major, or minor. Selected deviations categorized into each of these categories were reviewed and gave rise to typographical and misfiling errors.

All the non-compliances observed during the inspection were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

2. Good manufacturing practices for pharmaceutical products

Basic principles of good manufacturing practices were generally well defined in SOPs and implemented. Manufacturing processes were adequately described and documented in BMRs and BPRs. Records were made during manufacture. Qualifications and validations were performed according to prepared protocols. Records of equipment calibration, maintenance and cleaning were maintained. Required resources were available, including premises, equipment, and utilities as well as qualified and trained personnel.

All the non-compliances observed during the inspection were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

3. Sanitation and hygiene

Premises and equipment were generally maintained at an acceptable level of cleanliness, and they were appropriately labelled. There were cleaning procedures in place for facilities and equipment. In general facilities including warehouse and production areas were found to be tidy. Pictorials of gowning instructions were posted on personnel entry rooms. Appropriate areas for equipment and utensil cleaning were established. The procedures and records for utensils cleaning at the dispensary were reviewed in detail.

All the non-compliances observed during the inspection were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

4. Qualification and validation

A VMP was available. The corporate VMP provided the sequence of activities to ensure that facilities, equipment, systems, and utilities were maintained in a validated state. The VMP defined the different roles and responsibilities, and included among others, the validation policy, the management of the validation plan, the validation/qualification approach for facilities, equipment, systems, processes, utilities, cleaning, personnel, analytical methods, computerized systems, and vendors. The VMP also provided information on equipment qualification lifecycle and defined URS, DQ, FAT, IQ, OQ, and PQ. The 2024 annual validation/qualification planner was reviewed.

Fluid Bed Programmable Logic Controller (FBE PLC)

The FBE PLC verification protocol was presented. The verification was completed in February 2018. According to the periodic requalification schedule, the PLC was requalified (backup, audit trail) in September 2021 as part of the overall FBE requalification.

Process Validation

Process validation was performed as outlined in a written procedure. Process validation for the following products were reviewed:

- Terbinafine HCL 1% with batch size 200kg
- Acyclovir BP 5% with batch size 500kg
- ORS 20.56g with batch size 1522,30kg

All the non-compliances observed during the inspection were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

5. Complaints

A corporate procedure for the management of market complaints was presented. The SOP defined the process for receipt, registration, investigation documentation and disposition of a market complain including the identification and implementation of CAPA. The procedure further defined responsibilities of key personnel involved in the handling of a complaint. Complaints had to be logged in TrackWise within 24 hours of receipt. Upon registration in the system, the complaint coordinator had to classify the complaint based on its nature and description into critical, major, or minor. Definitions and examples for each of the classes were included in the procedure. After verifying the complaint, an acknowledgment letter was sent to the complainant within two working days and the relevant regulatory authority was informed, when necessary. The complaint was investigated and if any potential hazard to patient health was identified the relevant regulatory authority had to be informed

and withdrawal/recall of the product/batch from the market had to be considered. Timelines for handling of complaints were established and prioritization based on criticality and patient health impact were defined. Trending of complaints was performed annually. Three complaints for Dolutegravir/Lamivudine/Tenofovir tablets were registered in 2024 until the time of inspection. Two out of the three complaints were discussed in detail.

All the non-compliances observed during the inspection were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

6. Product recalls

Product recalls were handled according to a corporate procedure. The SOP provided a structured and documented way to withdraw a product/batch from the market and to minimize patient and business risks. TrackWise was used to register and manage product recalls. Criteria for the classification and urgency of recalls (Class I, II, III, or IV) were established and the different levels (depth) of recall were defined. The recall decision was taken by the Corporate Management Team and the relevant regulatory authority was notified. The recall implementation team was responsible for carrying out the recall in collaboration with the corporate management team. A Class II recall at the level of distributors for Fluconazole tabs 200mg was initiated on 06.05.2023 due to the receipt of several complaints regarding the presence of white spots on pink tablets and black marks on the PVC part of the blister. The root cause investigation indicated that the white marks were due to the Magnesium stearate used in the final blending step. The black marks on the PVC part of the blister were due to rubbing of the uncoated aluminum foil of the blister on the PVC. All affected batches were recalled. The recall was closed out on 28.08.2024.

All the non-compliances observed during the inspection were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

7. Contract production, analysis and other activities

Manufacture of WHO Prequalified products was not contracted out. According to the SMF, some analytical work could be contracted out but this was not applicable to WHO and UNICEF products. The list of qualified laboratories was included as Annex 3 of the SMF.

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

A corporate procedure on the evaluation and qualification of suppliers was available. The procedure described how new vendors were identified, selected, assessed, and approved. Suppliers were evaluated annually and requalified every three years. The evaluation was performed at corporate level and audits were carried out by experts employed at corporate level.

Due to time constraints self-inspection was not reviewed in detail.

9. Personnel

There were approximately 300 staff working on site. In general, personnel had the necessary qualification and practical experience. Responsibilities and duties of key personnel were adequately defined in job descriptions. Qualifications for each position were established. An organization chart depicting the reporting and administrative hierarchy was available and was discussed during the opening meeting.

10. Training

Training was provided in different ways including class-training, on the job-training, and computer-based training. For computer-based training the staff-member to be trained, received an Email describing the training that had to be completed on-line and the deadline for completion. Periodic reminders were also sent. Spot-checks on training records were made. The most recent on-line training on handling of complaints was reviewed in detail. The status of training was reviewed on-line and the list of people to be trained as well as the completion of training (completed or pending) was included in the list.

11. Personal hygiene

Personal hygiene at the facility was guided by written procedures. The SOPs described the various hygiene practices aimed at protecting product quality. The hygiene practices included hand washing and gowning instructions, reporting of illness, exclusion of certain practices in production areas. In general personnel followed good hygiene practices.

12. Premises

Since the previous WHO inspection, the following changes were made in relation to premises:

- Expansion of the finished goods warehouse and creation of a dispensed packing material storage area.
- Modification of the granulation area.
- Facility modification for liquids secondary packing, engineering stores and QA office.

Generally, premises were appropriately maintained. As noted in previous inspection reports, there were some limitations in facility design in terms of minimizing accidental errors of mix ups and contamination. Layouts of the facilities were made available. The tableting facilities were equipped with single pass air circulation system. Adequate pressure cascade was implemented to ensure containment whereas in powder generation areas negative pressure was maintained. AHUs supplying to a specific production area could be shut off only if the area was not in use and cleaning had already been performed. It is recommended that the company establishes the order of AHUs shut off and turn on to ensure that Differential Pressure (DP) cascade is not compromised. Spot-checks on the maintenance records of the AHU supplying fresh air to the coating area were performed. Preventive maintenance was performed quarterly. Filters were cleaned every month. DP limits for filters were established. There were general procedures in place for cleaning the facilities.

All the non-compliances observed during the inspection were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

13. Equipment

Since the previous WHO inspection some new equipment/instruments were installed in production. More specifically,

- Installation of a Metal detector in the Oral Rehydration Solution (ORS) line.
- Installation of an additional tray drier in the granulation area.

In general, equipment was installed and adequately maintained to suit the requirements for the dosage forms manufactured. Production equipment was of good standard and appeared to be well maintained. The workflow in the facility was appropriately designed, and the equipment appeared to be installed to facilitate production and reduce the risk of contamination and mix ups. All production equipment reviewed was identified as to its content or cleanliness status by appropriate labels.

All the non-compliances observed during the inspection were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR

14. Materials

There were procedures in place describing receipt, storage, and management of raw materials. Incoming materials were purchased from approved vendors, sampled, and tested according to specifications and testing procedures. Receipt of raw materials took place on the ground floor. A checklist was used to document the controls during receipt. There were separate areas for the storage of raw materials and packaging materials. Packaging materials were dispensed at the ground floor and then they were moved to the new dispensed packing material storage area before transferred to the packaging lines. Dispensing of raw materials took place in four dispensing rooms located on the first floor. The storage areas for quarantine and approved raw materials were visited. Generally, materials were labelled with the appropriate labels based on their status. An Enterprise Resource Planning system |(SAP) was used to generate these labels.

During the tour of the warehouse, it was noted that minor incidents at the warehouse (e.g., broken pallet, external container damage), were not logged and no CAPAs were documented. It is recommended that the company registers this type of incidents and performs the required investigations and applies CAPAs.

All the non-compliances observed during the inspection were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

15. Documentation

A documentation system was in place. Procedures defined and supported manufacturing and quality control operations. In general documents were approved, signed, and dated by appropriate responsible persons, reviewed, and kept up to date. Most SOPs were of the Global Quality type. Electronic documentation management systems were put in place for handling procedures, specifications, and records.

The corporate procedure for creation and release of process order was reviewed. This procedure also included the batch numbering system which was automatically issued in SAP. Specific instructions for the Combi product which includes two products and requires the creation of one extra batch number, were in place. There was a limitation in terms of the batch printing capability on the pack and tube of semi-solids since only 5 numbers could be printed. However, the full batch number including 8 characters was used in the CoA along with a declaration that the first 3 characters were omitted on the pack and tube.

Following up on CAPAs relating to observations made in the previous WHO inspection, it was noted that second level review and approval of records required further attention as missing documents, signatures and misfiling were identified.

All the non-compliances observed during the inspection were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

16. Good practices in production

A visit to production areas was made. At the time of the inspection there were ongoing production operations. Areas inspected included the dispensaries, the granulation area, the hoses/sieves/finger bags storage room, compression machines suites (7 compression machines), coating rooms, In-Process Control (IPC) laboratory, primary packaging in bottles and blisters, and secondary packaging. Line clearance was documented in BMRs. Metal detectors were used during compression and the detectors were challenged at the beginning and at the end of the process, and after any significant stoppage. Temperature, relative humidity, and pressure differentials were monitored. Rooms and equipment were appropriately labelled.

Spot-checks on BMRs were performed.

All the non-compliances observed during the inspection were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

17. Good practices in quality control

The procedure for handling OOS results was presented and discussed in detail. Similarly, a procedure for handling OOT results was in place.

Selected OOS results were reviewed and did not give rise to any comments.

Stability studies

A procedure for conducting stability studies was in place. Instructions for the receipt, incubation and withdrawal of stability samples were provided. The protocol of each study defined the stability indicating parameters, the conditions, the number of stability samples per test and the overall quantity for each time point, as well as the time points for withdrawing and testing samples. The stability protocol for Dolutegravir/Lamivudine/Tenofovir (TLD)300/300/50mg (90tabs in HDPE jars) was reviewed. The batch was incubated in three different conditions (30±2ºC/ 60±5%, 30±2ºC/ 75±5%, 40±2ºC/ 75±5%). The following documentation was reviewed:

- TLD Standard Test Procedure
- TLD Finished Product Specification
- TLD Analytical Report of TLD 300/300/50mg Finished Product.
- TLD Certificate of Analysis
- TLD Analytical Report – Stability, 3 months-accelerated
- TLD Analytical Report – Stability, 6 months-accelerated
- TLD Analytical Report – Stability, 3 months-long term 30ºC/75% RH
- TLD Analytical Report – Stability, 6 months-long term 30ºC/75% RH
- TLD Analytical Report – Stability, 9 months-long term 30ºC/75% RH
- TLD Analytical Report – Stability, 12 months-long term 30ºC/75% RH

All the non-compliances observed during the inspection were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

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 **Universal Corporation Limited (UCL)**, located at **Club Road, Past Kikuyu Post Office P.O. BOX 1748-00902, Kikuyu town, Kikuyu, Kenya** 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 2 years, provided that the outcome of any inspection conducted during this period is positive.

Part 4	List of WHO 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. Fifty-seventh Report. Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1044) Annex 2.
   Short name: WHO TRS No. 1044, Annex 2

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. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6.
   Short name: WHO TRS No. 961, Annex 6

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

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

24. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditionning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1019), Annex 2. **Short name: WHO TRS No. 1019, Annex 2**

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**

26. Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 6. **Short name: WHO TRS No. 1025, Annex 6**

27. Production of water for injection by means other than distillation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 3. ***Short name: WHO TRS No. 1025, Annex 3***

28. 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***