20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

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

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**Svizera Labs Pvt. Ltd**
Corporate address of the manufacturer	Plot No. 29/33 Govandi, Mumbai, 400 043, India
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Plot D-16/6, TTC Industrial Area, MIDC, Turbhe, Navi Mumbai, 400 703, India DUNS: 72-533-7690 GPS details: 19.0538 (latitude) and 72.99777 (longitude)
Unit/block / workshop number	WHO PQ products are produced at building 1 (plot number D-16/6) containing Rifampicin and non-Rifampicin products. The company has constructed another manufacturing facility named Building 2 on plot number D-16/5. The company intends to produce "white" or non-Rifampicin products in building 2 for WHO and other markets.
Inspection details	
Dates of inspection	20-23 March 2023
Type of inspection	GMP inspection
Introduction	
Brief description of the manufacturing activities	The manufacturing plant was constructed in 1998 and has been used since 2001. The plant has buildings 1 and 2 for manufacturing tablets, capsules, and powder for sachets.
General information about the company and site	Svizera Labs Private Limited was set up in 1998 in Navi Mumbai, India, and is part of Maneesh Pharmaceuticals Limited. The manufacturing plant produces tablets, capsules, and powder/granules for, sachets and products are packed in blisters, strips, jars, sachets and bulk packs. These products are manufactured for WHO and other markets.
History	This was a follow-up inspection, whereas a routine GMP inspection was conducted in April 2022. In addition, the manufacturing site had been regularly inspected by WHO PQ. The Portugal agency inspected the site from 13 to 17 March 2023 for Metformin tablets and Fluoxetine capsules (not according to DCP but national procedure). The Hungarian authority and UK MHRA inspected the manufacturing site in 2017 and 2019 respectively. Upon verification of the EudraGMDP website, it was noted that the Hungarian authority inspected

	the site in December 2019 (expired 31 July 2021). The UK MHRA inspected the site in June 2017.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: 1. Pharmaceutical quality system 2. Personnel and training 3. Production (building 1 and 2) 4. Quality control laboratories 5. Utilities
Restrictions	None
Out of scope	This was the follow-up inspection of Svizera Labs Pvt Ltd. The scope of the inspection was limited to the on-site verification of CAPA for the products in the WHO Prequalification Program.
WHO products covered by the inspection	1. TB189 Isoniazid/Rifampicin Tablet, Film-coated 75mg/150mg 2. TB192 Ethambutol hydrochloride/Isoniazid/Rifampicin Tablet, Film-coated 275mg/75mg/150mg 3. TB193 Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin Tablet, Film-coated 275mg/75mg/400mg/150mg 4. TB392 Isoniazid Tablet 300mg (under assessment)
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
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 airflow
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
WFI	Water for injection

Part 2	**Summary of the findings and comments (where applicable)**

1. Pharmaceutical quality system

This was a follow-up inspection of Svizera Labs Pvt Ltd. The routine GMP inspection was conducted in April 2022. The PQS was upgraded by revising the SOPs, improving the change control systems, incident reporting, CAPA reporting and their effectiveness. The senior management is now more involved in strengthening the PQS and external consultants were appointed to guide the company to comply with WHO cGMP requirements. In general, the changes made since the last inspection were acknowledged by the inspection team. The senior management had appointed more personnel from the last inspection to attain quality objectives.

Annual product quality review (APQR)

The SOP has provided the purpose, scope, responsibility, and procedure for product quality review. The information/data that shall be compiled and reviewed were identical to as described in the WHO GMP Guide. The procedure also stated that process capability shall be performed on the assay of the finished product which is not adequate. The company is required to perform process capability for all those parameters which can affect the consistency of the process.

Management review

The SOP for quality system management review was reviewed. A structured meeting takes place at regular intervals to discuss the functioning of the quality system, which has to take action to correct issues when necessary. The last summary report of the management review, from November 2021 to January 2022 was presented.

Change control

The SOP for the change management system was reviewed. It describes the initiation, evaluation, review, approval or rejection, closure, regularization and post-evaluation of the proposed changes. At the time of inspection, 39 changes had been initiated (143 in 2021). Most of the changes listed in 2022 (around 80%) were related to SOPs revision. Change control related to Building 2 (plot number D16/5) was created for additional capacity on the same plot. Currently, the company has planned to manufacture "white products". A change control was raised on 22/07/2021 for this change. A new production facility was created on the second floor of the plot (D-16/5) as per business needs. The change control has not been closed yet as granulation-1 and 2 have not been created (machines are yet to come). The company have started using this newly created area for "white products" only. Currently, granulation is carried out in Building 1 whereas blending, compression, and packing unit operations are being carried out in a new Building 2.

Handling of deviation procedure had described how deviation should be reported and investigated including initiation, investigation, evaluation, approval, rejection and CAPA. The procedure is applied to all departments. The deviations were classified as critical, major and minor and were supported with examples. The procedure was supported with a flowchart, templates for deviation report form and logging deviations.

Quality risk management (QRM)

Risk assessment SOP was discussed. The principles of risk assessment were adopted from ICH Q9. The procedure delineated the methodology for initiating risk management using a cross-functional team. The risk was assessed using the severity of impact, probability of occurrence and ability to detect the risk. A risk priority number was calculated by multiplying the scores of severity, occurrence and detection of risk. The procedure also described other tools such as FMEA, FTA, HAZOP, PHA, and HACCP. A risk assessment tracking sheet was in place identifying the name of the risk assessment, risk assessment report and approval date. A comprehensive risk assessment of the facility was discussed. This risk was raised to provide documented evidence for the assessment of the risk involved in the entire manufacturing. The risk assessment included risks associated with the premises. All risks identified were reported below RPN criteria of less than 27. Hence, no further action was taken.

The deficiencies noted from the pharmaceutical quality system section have been addressed satisfactorily and the same will be verified during future PQ inspections.

2. Good manufacturing practices for pharmaceutical products

Basic principles of good manufacturing practices were described and implemented. Manufacturing processes were generally defined and documented in BMRs and BPRs.

The Svizera Labs Pvt Ltd (Building 1 and 2) is a multi-purpose manufacturing facility which produces finished pharmaceutical products of different therapeutic areas. At the time of the last inspection, it was noted that the company uses manual and open processes for various unit operations. During the follow-up inspection, some improvements were observed by tidying up the areas.

During the visit to Building 1, the company made several changes to maintain differential pressure between the core processing areas and the corridor. During a quick visit to building 2, it was noted that the design and the space were found adequate, and the company have taken into account the current GMP requirements such as separate material airlock and personnel airlock, use of a pressure transfer system for transferring materials/in-process materials from one unit operation to another unit operation etc. It should be noted that building 2 is not used for producing any WHO PQ and under-assessment products. The company is planning to file a variation to include building 2 for WHO products without containing Rifampicin.

The deficiencies noted in this section have been addressed satisfactorily and the same will be verified during future PQ inspections.

3. Sanitation and hygiene

The procedure relating to sanitation and hygiene for personnel, premises, equipment, and production areas has been updated since the last PQ inspection.

The SOP for health and hygiene provided requirements for the health and hygiene of personnel working in the manufacturing facility. The company is required to cross-reference other procedures related to the health and hygiene of the personnel.

A separate procedure for the preparation of sanitization solution was reviewed. The company uses 1.0% Dettol solution, 3.0% Savlon solution and 70% filtered IPA wherein Dettol and Savlon were rotated weekly, and 70% IPA was used as hand sanitiser. The company validated 70% IPA in 2008.

The deficiencies noted in this section have been addressed satisfactorily and the same will be verified during future PQ inspections.

4. Qualification and validation

A validation master plan was available. The processes were validated using a three-batches concept.

Cleaning validation

The SOP for cleaning validation/verification of manufacturing equipment was discussed. The procedure stated that the cleaning matrix shall be updated, and an impact assessment should be performed on MACO when a new molecule and or a new or existing product, change in batch size, new equipment and modification of equipment is introduced. The cleaning validation report for Clonidine Hydrochloride Tablets 25mcg was reviewed and noted that Clonidine was identified as a worst-case product. The PDE value of Clonidine was reported as 0.01 mg/day (10 ug/day) and hence it was identified as worst-case. The company revised the new product introduction procedure and also implemented the use of the HBEL approach.

The deficiencies noted in this section have been addressed satisfactorily and the same will be verified during future PQ inspections.

5. Complaints

The SOP on "Complaint Handling and Product Recall" was reviewed. It includes the system of receiving, classifying and responding to all complaints and deciding on any actions, CAPAs etc. It also includes a system for possible recalls and performing mock recalls. The logbook for Complaints for 2022 has been checked and 5 complaints were received.

The deficiencies noted in this section have been addressed satisfactorily and the same will be verified during future PQ inspections.

6. Product recalls

The SOP on "Complaint Handling and Product Recall" was reviewed. There has been no recall for several years. A mock Recall concerning the Doxycycline HCl in the European market was conducted by the customer. The report was reviewed and the mock recall was found compliant.

The deficiencies noted in this section have been addressed satisfactorily and the same will be verified during future PQ inspections.

7. Contract production, analysis and other activities

The contract agreement with Maneesh Pharmaceuticals was updated and now it included the stability studies performed by Maneesh Pharmaceuticals for Svizera Labs Pvt Ltd.

The deficiencies noted in this section have been addressed satisfactorily and the same will be verified during future PQ inspections.

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

The Procedure for Self-Inspection (Internal Audits) was reviewed. It included a detailed description of the planning and performing of the internal audits, covering twice per year all the departments and taking care that the auditors are independent of the auditee department. An extended questionnaire is used for the internal audits of each department. An annual schedule is composed in December every year. The

Internal Audit at the QA Department on 22 February 2023 was reviewed and it followed the procedure, had the relevant questionnaire filled in and 5 minor non-conformities were observed. On 6 March the QA department informed the auditors about the completed CAPAs. The review of any deficiencies observed by any authority that inspected Svizera in the previous year and checks on the relevant CAPAs were missing.

Vendor approval was performed according to the SOP.

The deficiencies noted in this section have been addressed satisfactorily and the same will be verified during future PQ inspections.

9. Personnel

Since the last WHO PQ inspection, the company adopted a reward and recognition policy through the company's human resource department to motivate employees. The company believes that this new policy will help to recognize efforts put in by the employees in terms of performance, attitude and achievements. In addition, the company recruited new staff members in different departments.

The deficiencies noted in this section have been addressed satisfactorily and the same will be verified during future PQ inspections.

10. Training

The SOP on "Training and Development of Plant Personnel" was reviewed. It included induction training, technical training, on-the-job, refresher training etc. The list of internal trainers includes trainers from different departments who are certified accordingly. The training calendar for 2023 was reviewed and includes internal and external training in various GMP topics and regulations.

The deficiencies noted in this section have been addressed satisfactorily and the same will be verified during future PQ inspections.

11. Personal hygiene

Personnel received training in the practices of personal hygiene. The procedure on personal hygiene provided clear instructions about illness and open lesions. Similarly, instructions were provided, and training was imparted to the personnel about smoking, the use of tobacco products, jewellery, phones etc.

The deficiencies noted in this section have been addressed satisfactorily and the same will be verified during future PQ inspections.

12. Premises

The inspectors visited the warehouse, building 1 and building 2. The warehouse used for storing incoming materials including packaging materials was not maintained adequately. The air conditioner was not functioning appropriately during the inspection and personnel should have raised deviations or work orders when it broke down. The balances (e.g. pallet trolley) used for verifying the incoming

materials were not adequately calibrated to cover their operating range. The company is required to look into their existing building 1 in a more holistic manner and rectify issues related to no interlocking, no closing of doors, differential pressure out of the limit and or just at the lower limit.

A visit to building 2 was made which is located adjacent to existing building 1 and produces WHO-prequalified products. The plot number of building 2 is D-16/5. The change control related to building 2 was raised in July 2018 whereas the company started using the warehouse (materials and products) in 2021 for WHO-prequalified products. The company manufacture Metformin tablets for the UK market as well as intends to manufacture products for the Portuguese market. Both buildings 1 and 2 were inspected by INFARMED in March 2023 for Metformin tablets, Fluoxetine capsules and Sodium Picosulfate sachets. The company intends to manufacture only "white products" in their new Building 2 whereas existing Building 1 continues to produce Rifampicin-containing products. Building 2 was designed and constructed following the current cGMP requirements, in particular, separate MAL, PAL, use of gravity feed, vacuum transfer systems, racking system in the warehouse, and glass panels to view manufacturing activities without entering the core processing areas. Building 2 is much more spacious in size and well-lit.

The deficiencies noted in this section have been addressed satisfactorily and the same will be verified during future PQ inspections.

13. Equipment

The equipment used in the manufacturing, processing, and packaging was of appropriate design. The equipment was placed in a suitable location to facilitate operations for their use, cleaning, and maintenance.

The protocol for requalification of air handling units has been revised to include the detailed methodology and found compliant. The raw data of the requalification by Cool Tech company was reviewed and found compliant. An SOP was composed "Disaster Management and Response for natural and man-made disasters" that provided an analysis of possible disaster cases. Training has been organized on Aug 10, 2022.

The deficiencies noted in this section have been addressed satisfactorily and the same will be verified during future PQ inspections.

14. Materials

The materials were received through the receiving bay. Upon receipt, the incoming materials were verified for weight, and supplier apart from other details before being stored in the quarantine area. An approved supplier list was maintained. A manual system of the status label was in place for sampling, under-test and approved materials. The changes made following the April 2022 inspection were verified and found satisfactory.

The deficiencies noted in this section have been addressed satisfactorily and the same will be verified during future PQ inspections.

15. Documentation

The company is using a manual and electronic system for the management of documents. The QA is responsible for controlling the documents handled on-site. In addition, the document control system (DCS) was in use for the printing of batch manufacturing records, batch packaging records, test data sheets and others.

The deficiencies noted in this section have been addressed satisfactorily and the same will be verified during future PQ inspections.

16. Good practices in production

Upon a visit to the production areas within Building 1, the company made some changes in unit operations such as the sifting of materials. The capacity of the air handling units has been improved to ensure sufficient differential pressure is achieved at all times in all critical processing areas. The company was committed to continue working on the differential pressure system and to ensure that the screws of the magnehelic gauges were locked at all times and adequate monitoring was monitored and recorded on differential pressures. The personnel have been trained to raise work orders and or deviations when differential pressure was observed out of the limit.

The deficiencies noted in this section have been addressed satisfactorily and the same will be verified during future PQ inspections.

17. Good practices in quality control

The inspectors visited the quality control laboratory located on the 2nd floor. The company have purchased and installed two new HPLC systems. These were qualified (performance qualification) in February 2023. A unique username (employee code) and password were used by the responsible personnel for Chromeleon and six HPLCs and one GC were running on the Chromeleon 7.3.1 version.

The following new equipment and instruments were procured by the company from the last PQ inspection:

- Dissolution apparatus (12 vessels from Electrolab)
- Polarimeter (LabIndia)
- Melting point apparatus (Electrolab),
- Vacuum chamber for loss on drying
- Stability chamber for 40/75%
- Incubator for microbial limit test

As part of the response to a deficiency raised in April 2022, the company have started purchasing active substances from the API manufacturers to prepare working standards in their quality control laboratory. In one such example, the Rifampicin working standard was prepared from Rifampicin purchased from Lupin.

The deficiencies noted in this section have been addressed satisfactorily and the same will be verified during future PQ inspections.

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, ***Svizera Labs Pvt Ltd***, located at ***Plot D-16/6, TTC Industrial Area, MIDC, Turbhe, Navi Mumbai, 400 703, 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 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-eight Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. ***Short name: WHO TRS No. 986, Annex 2***
   https://digicollections.net/medicinedocs/documents/s21467en/s21467en.pdf

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***
   untitled (digicollections.net)

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
   9789240020900-eng.pdf (who.int)

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
   https://digicollections.net/medicinedocs/documents/s21440en/s21440en.pdf

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**
   https://digicollections.net/medicinedocs/documents/s23455en/s23455en.pdf

6. WHO good practices for pharmaceutical quality control laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1.
   Short name: WHO TRS No. 961, 957), Annex 1
   https://digicollections.net/medicinedocs/documents/s18681en/s18681en.pdf

7. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 3.
   Short name: WHO TRS No. 957, Annex 3
   https://digicollections.net/medicinedocs/documents/s22358en/s22358en.pdf

8. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-six Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 2.
   Short name: WHO TRS No. 1044, Annex 2
   TRS 1044 - Annex 2: WHO good manufacturing practices for sterile pharmaceutical products

9. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Six Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
   Short name: WHO TRS No. 1044, Annex 4
   TRS 1044 - Annex 4: WHO guidelines on technology transfer in pharmaceutical manufacturing

10. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9. ***Short name: WHO TRS No. 961, Annex 9***
    https://digicollections.net/medicinedocs/documents/s18683en/s18683en.pdf

11. 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***
    https://digicollections.net/medicinedocs/#d/s21438en

12. 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
    https://digicollections.net/medicinedocs/documents/s18682en/s18682en.pdf

13. WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2.
    Short name: WHO TRS No. 981, Annex 2

https://digicollections.net/medicinedocs/#d/s20177en/

14. WHO guidelines on variation to a prequalified product. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 3.
Short name: WHO TRS No. 981, Annex 3
https://digicollections.net/medicinedocs/#d/s20175en/

15. WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14.
Short name: WHO TRS No. 961, Annex 14
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

16. 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***
https://digicollections.net/medicinedocs/documents/s23697en/s23697en.pdf

17. WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4. ***Short name: WHO TRS No. 992, Annex 4***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

18. 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***
Essential Medicines and Health Products Information Portal (digicollections.net)

19. 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
https://www.who.int/publications/m/item/who-recommendations-for-quality-requirements-when-plant-derived-artemisinin-is-used-as-a-starting-material-in-the-production-of-antimalarial-active-pharmaceutical-ingredients---trs-992---annex-6

20. 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***
9789240020900-eng.pdf (who.int)

21. WHO general guidance on variations to multisource pharmaceutical products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10.
Short name: WHO TRS No. 996, Annex 10
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

22. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 10.
Short name: WHO TRS No. 1010, Annex 10
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

23. 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**
https://digicollections.net/medicinedocs/documents/s23699en/s23699en.pdf

24. 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**
9789240020900-eng.pdf (who.int)

25. 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**
9789240001824-eng.pdf (who.int)

26. Production of water for injection by means other than distillation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 3. ***Short name: WHO TRS No. 1025, Annex 3***
https://www.who.int/publications-detail/978-92-4-000182-4

27. Good chromatography practice. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 4. ***Short name: WHO TRS No. 1025, Annex 4***
https://www.who.int/publications-detail/978-92-4-000182-4