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
Finished Product Manufacturer

PART 1	**GENERAL INFORMATION**
MANUFACTURERS DETAILS	
Name of the manufacturer	European Egyptian Pharmaceuticals Industries Co
Corporate address of the manufacturer	KM 25th, Alexandria-Cairo Desert Road, Amriya, Alexandria P.O. Box 111 El Mansheya, Egypt
INSPECTED SITE	
Name and address of the inspected manufacturing site	Same as above
Unit / block / workshop number	Oral Solid Dosage (OSD) area A – Tablets
INSPECTION DETAILS	
Dates of inspection	26 – 27 November 2025
Type of inspection	Routine inspection
INTRODUCTION	
Brief description of the manufacturing Activities	Manufacturing, packaging, and testing pharmaceutical products for human use of the following dosage forms: • **Solid dosage forms** o Tablets o Hard gelatin capsules o Soft gelatin capsules o Powder "effervescent & non-effervescent" filled in sachets • **Liquid dosage forms** o Internal use (syrup, suspension, drops) o External use (spray "nasal, topical", solution, lotion) • **dental supplies (hydroxyl Apatite)**
General information about the company and site	European Egyptian Pharmaceutical Industries (EEPI) is a pharmaceutical company located on the outskirts of Alexandria city, Egypt, and is a member of Pharco Corporate. The company indicated that no high-potency or potentially hazardous substances such as hormones and beta-lactam products are manufactured on-site.
Inspection History	EEPI had been regularly inspected by the Egyptian Drug Authority. In addition, several earlier WHO inspections were conducted at the site. The site was also inspected by the National Agency for Medicines and Medical Devices of Romania (2025), TMDA of Tanzania (2025) and ANVISA of Brazil (2025).

Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	**The following GMP elements were covered during the inspection:** • Pharmaceutical quality system (PQS) • Good manufacturing practices for pharmaceutical products • Sanitation and hygiene • Qualification and validation • Personnel • Personal hygiene • Premises and utilities • Equipment • Materials • Documentation • Good practices in production • Good practices in quality control **The following areas were visited during the inspection:** • Production areas • QC laboratories • Warehouse • Utilities including Water for Pharmaceutical Use and HVAC
Restrictions	Due to time limitation, some GMP elements were not covered during the inspection as indicated under part 2 of this inspection report.
Out of scope	Products and/or processes and facilities that are not under the scope of the WHO prequalification program.
WHO products numbers covered by the inspection	1. HP003 Sofosbuvir Tablet, Film-coated 400mg (Trade name: Gratiziano using Sofosbuvir NPP from PBIC. The product code was updated in light of the post-approval change submitted to and approved by WHO for replacing the API supplier from CAD in Saudi Arabia to PBIC in Egypt. The old product code was referencing Sofosbuvir from CAD).
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 air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
MF	Master formulae
MFT	Media fill Test
MR	Management review
NC	Nonconformity
NCA	National control authority
NCL	National control laboratory
NRA	National regulatory agency
OQ	Operational qualification
PDE	Permitted Daily Exposure
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**

1. Pharmaceutical quality system (PQS)

In general, a Pharmaceutical Quality System was established, documented and implemented, with written procedures covering essential quality elements being in place. The procedures that were reviewed during the inspection were generally of an acceptable standard. Production and quality control operations were independently managed and specified in written form. GMP requirements were essentially being met.

Product Quality Review (PQR)

PQRs were performed according to SOP "Annual product quality review". PQRs had to be compiled and approved within three months after the end of the evaluation period. Three product codes were listed for Sofosbuvir film coated tablets 400mg which included the following:

- Grateziano:
  - For local and export markets, By using Sofosbuvir API NPP from PBIC.
  - The earlier code for WHO prequalified product was invalidated/terminated according to the company. This was caused by cancellation of another Sofosbuvir API supplier which had been withdrawn from WHO PQ application.
- Gratsovir:
  - For local market.

The APQR of Sofosbuvir tablets (Grateziano) 400mg film coated tablet for the period from 01/10/24 to 30/09/2025 was reviewed.

Management reviews (MR)

The SOP "Integrated management review". was checked. MR was required to be performed annually with attendance of senior management. The last MR meeting was held on 05/01/2025 for the period of January to December 2024. The meeting agenda and the respective minutes of the meeting were available.

Quality risk management (QRM)

The quality risk management procedure was in place. The Risk assessment performed for PV of Sofosbuvir tablets was checked.

Handling of deviations

The SOP for deviations was in place. The SOP provided for roles and responsibilities, annotations, declaration, receipt, evaluation, risk analysis, investigation, and closure of deviations. The definition of deviations was comprehensive.

Another SOP complemented the deviation management namely the SOP for investigation, root cause analysis and CAPA. The scope of this SOP covered deviations, complaints, and recalls.

OOS/OOT management
OOS results obtained were investigated and documented according to SOP "Investigation and evaluation of OOS and OOT testing results" effective from 08/May/2025. The scope covered all analytical testing results of RM, packaging materials, finished products and stability testing. Laboratory error check list was available. The logbook for 2025 was verified.

CAPA management
A written CAPA procedure was in place. This was not checked in detail due to time constraints.

Change Control
The SOP for Change control was in place. The change controls were recorded and handled in the software application. The documentation related to changes were spot-checked.

Product Release
Product release was managed according to the final product release procedure. QA was responsible for the final review of all the relevant documents including BMR, BPR and batch testing record for the release finished product according to the SOP. The product release was spot checked in the above APQR.

2. Good manufacturing practices for pharmaceutical products
In general, EEPI applied the main concepts and principles of GMP aiming primarily at managing and minimizing the risks inherent in pharmaceutical manufacture to ensure the quality, safety and efficacy of products. Under GMP, the following activities were implemented:

- all manufacturing processes were clearly defined and systematically reviewed. However, the associated risks were not always properly assessed and managed in the light of scientific knowledge and experience.
- qualification and validation were performed.
- all necessary resources were provided, including sufficient and appropriately qualified and trained personnel, adequate premises and space, suitable equipment and services, appropriate materials, containers and labels, approved procedures and instructions, suitable storage and transport, adequate personnel, laboratories and equipment for in-process controls.
- instructions and procedures were written in clear and unambiguous language.
- procedures were carried out correctly and personnel are trained to do so.
- records were made during manufacture to show that all the steps required by the defined procedures and instructions had in fact been taken and that the quantity and quality of the product were as expected. Any significant deviations were fully recorded and investigated with the objective of determining the root cause and appropriate corrective and preventive action was implemented.
- records covering manufacture and distribution, which enable the complete history of a batch to be traced, were retained in a comprehensible and accessible form.

- the proper storage and distribution of the products minimized any risk to their quality and took account of good distribution practices (GDP).
- a system was available to recall any batch of product from sale or supply.
- complaints about marketed products were examined, the causes of quality defects were investigated and appropriate measures taken in respect of the defective products to prevent recurrence.

3. Sanitation and hygiene

In general, a high level of sanitation and hygiene was practised in every aspect of the manufacture of pharmaceutical products at EEPI. The scope of sanitation and hygiene covered personnel, premises, equipment and apparatus, production materials and containers, products for cleaning and disinfection, and anything that could become a source of contamination to the product. Potential sources of contamination were eliminated through an integrated comprehensive programme of sanitation and hygiene.

4. Qualification and validation

EEPI identified what qualification and validation work was required to prove that the critical aspects of their particular operation were controlled.

A validation master plan (VMP) was documented and clearly defined the key elements of a qualification and validation programme of EEPI. The VMP included a commitment to maintain continued validation status as well as clear roles and responsibilities to undertake the qualification and validation activities.

Qualification and validation established and provided documentary evidence that:

- the premises, supporting utilities, equipment and processes had been designed in accordance with the requirements for GMP (DQ).
- the premises, supporting utilities, equipment and processes had been built and installed in accordance with the requirements for GMP (IQ).
- the premises, supporting utilities, equipment and processes operated in accordance with the requirements for GMP (OQ).
- specific processed consistently produced a product meeting its predetermined specifications and quality attributes (PQ and PV).

The aspects of operation, including significant changes to the premises, facilities, equipment or processes, which may affect the quality of the product, directly or indirectly, were qualified and validated as appropriate.

Qualification and validation were not treated as one-time activities; instead, an ongoing programme was maintained following initial implementation, with periodic reviews conducted annually.

Qualification and validation activities were carried out in accordance with predefined and approved protocols. The results and conclusions were documented in comprehensive qualification and validation

reports. Processes and procedures were established on the basis of the results of the validation performed.

The VMP was reviewed and found to provide comprehensive guidance for qualification and validation activities including scope, validation approaches, revalidation, requalification.

A planner for the qualification and validation in 2025 was used to track related activities over the year. A record was also available indicating the qualification and validation activities completed in 2025.

Process validation
The SOP for process validation was in place.

The process revalidation of Sofosbuvir film coated tablets 400mg was ongoing at the time of this inspection. The PV protocol was reviewed. A risk assessment for PV was performed. CPPs and CQAs were documented and found to be acceptable. It was noted one PV batch was completed at the time of inspection.

The SOP "Operation and follow up of counting machine (Pharmapack)" was checked. The inspection and rejection of defect tablets in packaging operation were discussed.

Cleaning validation
The periodic cleaning re-validation protocol and report of Grateziano 400 mg were reviewed. The cleaning validation was executed for three batches of the product. Another cleaning validation study was performed for the worst-case product for cleaning based on a matrix for solubility, cleanability, toxicity and potency. The report of the latter study was reviewed. A new protocol was developed for refine the cleaning validation of Grateziano 400 mg considering the new acceptance criteria.

Validation of heating, ventilation, and air-conditioning systems
EEPI maintained the validated status of the HVAC systems including the air handling units and related cleanrooms through a requalification exercise which was performed on regular basis as per the relative GMP guidelines and ISO standards.

Validation of water systems for pharmaceutical use
The water generation/distribution system was requalified in 2024. The trend analysis of the water system was performed on an annual basis for chemical and microbiological parameters. The sampling plan for the water system was set as daily for the supply and return point, weekly for all other user points for microbiological parameters and monthly for the chemical parameters.

5. Complaints
Complaints were not checked in detail due to time constraints.

6. Product recalls
Product recall was not checked in detail due to time constraints.

7. Contract production, analysis and other activities

The production for the WHO PQ FPP Sofosbuvir Film-coated Tablets 400mg in the inspection scope was not contracted.

The contract laboratories were used for testing such as polymorph of Sofosbuvir API. Contract testing was not checked in detail due to time constraints.

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

The procedures for self-inspection, quality audits, and suppliers' audits were in place. This was spot checked in management review and not reviewed in detail.

9. Personnel

An organization chart was available. Key personnel responsibilities were required to be defined in job descriptions. The key personnel of the various department had pharmaceutical qualification and were well experienced in pharmaceutical manufacturing.

The Company employed 944 employees according to the company's SMF at the time of inspection. The number of personnel appeared adequate to the present activities. In general personnel met during the inspection are aware and follow the GMP principles with appropriate qualifications and experience.

10. Training

Training systems and procedures were in place but were not reviewed in detail in this inspection.

11. Personal hygiene

Personnel hygiene requirements were documented in written procedures. The requirements for entry Grade D cleanrooms were well documented, including pictorial drawings in change rooms. Staff observed in these areas were dressed in appropriate protective clothing.

12. Premises and utilities

The facility was multi-product and not dedicated. The premises and utilities at EEPI were well designed and maintained in support of different manufacturing activities.

Ancillary areas

Rest and refreshment rooms were separate from manufacturing and control areas. Facilities for changing and storing clothes and for washing and toilet purposes were easily accessible and appropriate for the number of users. Toilets were not directly connected to production or storage areas.

Maintenance workshops were separated from production areas. Parts and tools were stored in designated and dedicated rooms or lockers in the production areas.

Storage areas

Storage areas were of sufficient capacity and allowed orderly storage of the various categories of materials and products with proper separation and segregation: starting and packaging materials, intermediates, bulk and finished products, products in quarantine, and released, rejected, returned or recalled materials and products.

Storage areas were clean, dry, sufficiently lit and maintained within acceptable temperature limits. Storage conditions (e.g. temperature, humidity) were provided, controlled, monitored and regularly recorded.

Receiving and dispatch bays were separated from each other and protected the materials and products from the weather. Receiving areas were designed and equipped to allow containers of incoming materials to be cleaned before storage.

Quarantine areas were clearly marked, and their access restricted to authorized personnel. Special attention was paid to sampling and the safe and secure storage of printed packaging materials.

There were separate sampling areas, equipped with sampling booths, for starting materials which enabled sampling to be conducted in such a way as to prevent contamination or cross-contamination.

Weighing and dispensing areas
Separate weighing areas were available at EEPI (storage or production areas) and were used for the weighing of starting materials and the estimation of yield. The weighing areas were properly designed, operated and maintained for the intended use.

Production areas
At EEPI, Premises were laid out in such a way as to allow the production to take place in areas connected in a logical order corresponding to the sequence of the operations and to the requisite cleanliness levels. The interior surfaces of the production areas (walls, floors and ceilings) were smooth and free from cracks or open joints, did not shed particulate matter, and permitted easy and effective cleaning and, if necessary, disinfection.

Drains were of adequate size and designed and equipped to prevent back-flow. Open channels were avoided in production areas.

Production areas were effectively ventilated, with air-control facilities (including filtration of air to a sufficient level to prevent contamination and cross-contamination, as well as control of temperature and, where necessary humidity) appropriate to the products handled, to the operations undertaken and to the external environment. These areas were regularly monitored during both production and non-production periods to ensure compliance with their design specifications.

Production areas were well lit, particularly where visual online controls are carried out.

Quality control areas
QC laboratories were separated from production areas. Adequate storage space was provided for samples, reference standards, solvents, reagents and records. Retention samples were kept in a room with access control. The facility was in good condition.

Supporting utilities
The different utilities supporting the production and control areas including the Heating, Ventilation and Air-Conditioning (HVAC) utilities, the Water for Pharmaceutical Use (WPU) utilities and compressed gases utilities were well maintained and clean and were subject to regular monitoring and qualification activities.

13. Equipment
Equipment was located, designed, constructed, adapted and maintained to suit the operations to be carried out. The layout and design of equipment aimed to minimize the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build-up of dust or dirt, and, in general, any adverse effect on the quality of products.

Non-dedicated equipment was cleaned according to validated cleaning procedures between being used for production of different pharmaceutical products to prevent cross-contamination.

Defective equipment was removed from production and QC areas or clearly labelled as defective to prevent use.

14. Materials
Incoming materials and finished products were quarantined after receipt until released for use or distribution. Materials were managed by a computerised system to which the validation was completed in May 2025 according to the company information.

15. Documentation
Documentation was designed, prepared, reviewed and distributed according to approved procedures.

Approved, signed and dated testing procedures and specifications were available for starting and packaging materials and for finished products. They were spot checked during the inspection.

Master formulae
The master batch production record was reviewed. The list of approved suppliers was spot-checked, and it was found the PBIC was the sole supplier of Sofosbuvir NPP.

16. Good practices in production
Production operations including receipt and cleaning, quarantine, sampling, storage, dispensing and labelling, processing and packaging followed clearly defined procedures in accordance with the applicable manufacturing and marketing authorizations as well as WHO prequalification provisions and commitments. Deviations from instructions or procedures were documented, investigated and decided upon including provisions to extend the investigation to other batches of the same product and other products that might have been associated with the specific deviation.

Access to production premises was restricted to authorized personnel. No non-medicinal products were produced onsite.

Production records were reviewed as part of the approval process of batch release before transfer to the authorized person.

Prevention of cross-contamination and bacterial contamination during production
Cross-contamination was avoided by taking appropriate technical or organizational measures including conducting campaign production followed by appropriate cleaning and line clearance following validated procedures; providing appropriately designed airlocks, pressure differentials, and air supply and extraction systems; wearing protective clothing and personal protective equipment (PPE); using validated cleaning and decontamination procedures; and using cleanliness status labels on equipment.

Production areas underwent periodic environmental monitoring.

Processing operations
Before the start of any processing operation, area clearance was made to ensure the work area and equipment were clean and free from any starting materials, products, product residues, labels or documents not required for the operation.

After use, production equipment was cleaned without delay (within a limit established through dirty equipment holding time [DEHT]) according to validated cleaning procedures and kept under clean and dry conditions. Time limits for storage of equipment after cleaning and before use was established according to validated clean equipment holding time (CEHT).

Packaging operations
Different products were packaged in areas of close proximity with physical segregation. Area/line clearance was always performed before the beginning of packaging operations. The area/line clearance was performed according to a well-established procedure and checklist, and the clearance operations was documented in the respective records. The name and batch number of the product being handled was displayed at each packaging line.

Online verification of all labels by automated electronic means were in place and checks were made to ensure that any electronic code readers, and label counters were operating accurately. In addition, regular online in-process control of the product during packaging was implemented.

Checks on yields and reconciliation of packaged quantities were carried out to ensure that there were no discrepancies outside acceptable limits. Any significant deviation from the expected yield was recorded and investigated. Upon completion of a packaging operation, any unused batch-coded packaging materials were destroyed, and the destruction recorded.

17. Good practices in quality control
The QC function was independent of other departments. QC laboratories were located in the administration building. The microbiology laboratory was segregated from the chemistry laboratory.

Sample receiving and distribution

An access-controlled area for sample receival was available. Sample register and the information for receiving and distribution were checked. The traceability of raw data was available in the sampling records. Sampling was performed by QC for all materials and finished products.

Testing of starting material and finished products

The procedure for testing and release of API and finished product release procedure were available. The specifications, testing procedures and reference samples for WHO Sofosbuvir tablets 400 mg testing were spot checked. The working reference substance was managed following SOP "Qualification, handling and storage of WS in analytical labs".

Retention samples

Retention and retained samples were kept in a secured, temperature-controlled room. The retention sample register and samples of each batch were kept. Two full specification analyses reserve samples were stored in the same packaging system in which the FPP was stored. The sample retention time of API and FPP were defined.

Stability study

The SOP "Evaluation stability study protocol & report was check. Seven stability chambers were equipped with different conditions. The Stability study schedule for Sofosbuvir tablets 400 mg and register were available. WHO Sofosbuvir tablets 400 mg batch 210374A produced in 2025 was under the condition 30^0C/RH75%.

Instrumentation

The company has adequate numbers of instrument and equipment within the QC laboratories. The records and logs were adequately maintained. Status labels were attached to equipment and found acceptable. Calibration status and dates were acceptable. QC chromatographic analysis was operated and controlled with Empower 3 software with real time transfer. The SOP User's Privileges Assignments for Equipment" and "Back up & Restore system" were spot checked and discussed.

Microbiology Laboratory

The microbiology laboratory operated in compliance with GMP guidelines, with controlled facilities, qualified equipment, and validated test methods to ensure the reliability and integrity of microbiological results. Activities were performed by trained and qualified personnel in accordance with approved SOPs, with appropriate controls in place to prevent contamination, mix-ups, and data integrity issues. Environmental conditions, media, and reagents were monitored and qualified, and all results were documented, reviewed, and approved in line with GMP requirements.

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, ***European Egyptian Pharmaceuticals Industries Co,*** located at ***KM 25th, Alexandria-Cairo Desert Road, Amriya, Alexandria, P.O. Box 111 El Mansheya, Egypt*** was considered to be operating at an acceptable level of compliance with WHO good manufacturing practices for active pharmaceutical ingredients.

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.

The WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

PART 4	LIST OF GMP GUIDELINES REFERENCED IN THE INSPECTION REPORT

1. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eighth Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2.
   Short name: WHO TRS No. 986, Annex 2
   https://www.who.int/publications/m/item/trs986-annex2

2. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2.
   Short name: WHO TRS No. 957, Annex 2
   https://www.who.int/publications/m/item/annex-2-trs-957

3. WHO guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report. Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 9.
   Short name: WHO TRS 1010, Annex 9
   https://www.who.int/publications/m/item/trs1010-annex9

4. 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
   https://www.who.int/publications/m/item/annex-3-trs-1033

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
https://www.who.int/publications/m/item/annex-4-trs-929

6. 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. 1052), Annex 4.
Short name: WHO TRS No. 1052, Annex 4
https://www.who.int/publications/i/item/9789240091030

7. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 3.
Short name: WHO TRS No. 957, Annex 3
https://www.who.int/publications/m/item/trs957-annex3

8. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty Second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8.
Short name: WHO TRS No. 1010, Annex 8
https://www.who.int/publications/m/item/Annex-8-trs-1010

9. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditioning 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://www.who.int/publications/m/item/trs1019-annex2

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
Short name: WHO TRS No. 1044, Annex 4
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1044-annex4-technology-transfer-in-pharmaceutical-manufacturing.pdf

11. WHO good manufacturing practices for sterile pharmaceutical products. Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
Short name: WHO TRS No. 1044, Annex 2
https://www.who.int/publications/m/item/trs1044-annex2

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***
https://www.who.int/publications/m/item/trs943-annex3

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
https://www.who.int/publications/m/item/trs961-annex2

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
https://www.who.int/publications/m/item/trs981-annex2

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
https://www.who.int/publications/m/item/annex-3-trs-981

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
https://www.who.int/publications/m/item/tr961-annex14

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
https://www.who.int/publications/m/item/trs1019-annex3

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
https://www.who.int/publications/m/item/trs992-annex4

19. 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://www.who.int/publications/m/item/trs961-annex9-modelguidanceforstoragetransport

20. WHO Technical supplements to Model Guidance for storage and transport of time – and temperature – sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5.
Short name: WHO TRS No. 992, Annex 5
https://www.who.int/publications/m/item/trs992-annex5

21. WHO Recommendations for quality requirements when plant – derived artemisinin 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/trs-992-annex-6

22. 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
https://www.who.int/publications/m/item/annex-4-trs-1033

23. 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
https://www.who.int/publications/m/item/trs966-annex10

24. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 10.
Short name: WHO TRS No. 1010, Annex 10
https://www.who.int/publications/m/item/trs1010-annex10

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
https://www.who.int/publications/m/item/annex-2-trs-1033

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
https://www.who.int/publications/m/item/trs-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
https://www.who.int/publications/m/item/trs-1025-annex-3-water-for-injection

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/m/item/trs1025-annex4

28. Good trade and distribution practices for pharmaceutical starting materials. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 6.
Short name: WHO TRS No. 996, Annex 6
https://www.who.int/publications/m/item/annex-6-trs-996

29. WHO guidelines for preparing a laboratory information file. *WHO Expert Committee on Specifications for Pharmaceutical Preparations.* Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 13.
Short name: WHO TRS No. 961, Annex 13
https://www.who.int/publications/m/item/trs961-annex13

30. WHO good manufacturing practices for excipients used in pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-seventh Report. Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1052), Annex 1.
Short name: WHO TRS No. 1052, Annex 1
https://www.who.int/publications/i/item/9789240091030