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Prequalification Unit Inspection Services
WHO PUBLIC INSPECTION REPORT
WHOPIR
Active Pharmaceutical Ingredient Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	Pharco B International (2) for Chemicals (PBIC)
Corporate address of manufacturer	New Borg El Arab City, Second Industrial Zone No. 5, Block 22 Alexandria, 21934 Egypt
Inspected site	
Name & Address of inspected manufacturing site if different from that given above	Same as above
Synthetic Unit /Block/Workshop	Production block including: • Chemical processing area • Class D Area for API drying and packaging
Manufacturing license number	Serial No. 00091/2025 Technical license for operation for pharmaceutical plant Pharco B International (2) for the production of raw materials Code (LiHV2022074/0032016)
Inspection details	
Dates of inspection	23 – 25 November 2025
Type of inspection	Routine inspection
Inspection record number	INSP-API-2023-0010
Introduction	
Brief description of the manufacturing activities	Production and quality control of APIs and Herbal Extraction products.
General information about the company and site	Pharco-B international (2) for Chemicals (PBIC) was established in 2015 focusing on the production of Active Pharmaceutical Ingredients (APIs) and herbal extraction products. The site became operational in April 2016. The site is located in Borg El-Arab City, Alexandria, approximately 20 km from Borg El Arab International Airport. The overall area of the facility is approximately 17424 m^2. The site manufactured APIs and intermediates, including Sofosbuvir API, Ravidasvir Hydrochloride, Molnupiravir and Vildagliptin. The site also manufactured herbal extraction products and declared that no hormones, steroids, beta-lactams or cytotoxins were manufactured onsite.

	Three different quality grades of Sofosbuvir i.e. Sofosbuvir-NPP, Sofosbuvir form 6 and Sofosbuvir α, were manufactured by different processes at the site.
History	This was the third WHO PQT inspection with the latest inspection conducted in November 2022. The site was also inspected by the ANVISA, Brazil in January 2024 for a different API, and was periodically inspected by the Egyptian Drug Authority.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	Documents reviewed, including but not limited to: • Quality management • Personnel • Buildings and facilities • Process equipment • Documentation and records • Material management • Production and in-process controls • Packaging and identification labelling of APIs and intermediates • Storage and distribution • Laboratory controls • Validation • Change control • Rejects and reuse of materials • Complaints and recalls • Contract manufacturers (including laboratories) Site visited: • Production block • Warehouses • QC laboratories • HVAC system • Water system
Restrictions	NA
Out of scope	Products and/or processes and facilities that are not under the scope of the WHO prequalification program.
WHO APIs (including WHO API or APIMF numbers) covered by the inspection	• APIMF403 Sofosbuvir (Interna Code : Sofosbuvir NPP)
Abbreviations	**Meaning**
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
APR	Annual product review

BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
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
HEPA	High efficiency particulate air
HPLC	High performance liquid chromatography
HVAC	Heating, ventilation and air conditioning
IR	Infrared spectroscopy
IQ	Installation qualification
KF	Karl Fisher
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
MR	Management review
NC	Nonconformity
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
PSD	Particle size distribution
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
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. Quality management

A documented system for quality assurance was established, with procedures covering key quality elements in place. The Quality Department was divided into QA and QC and was separate from the Production Department. Operations were specified in written form and critical GMP requirements were essentially met. The procedures reviewed and discussed during the inspection were generally of an acceptable standard; however, in some cases, improvements appear to be necessary.

Product Quality Review (PQR)

PQRs were performed according to an established SOP for "Annual product quality review". The PQR was performed for batches manufactured in a period of 12 months. PQRs had to be compiled and approved within three months after the end of the evaluation period. The 2025 APQR schedule was available.

The Sofosbuvir-NPP APQR was reviewed.

Management review (MR)

The SOP "Integrated management system review" was checked. MR was required to be performed annually with attendance of senior management. The report for MR meeting held in 2025 for the period of January to December 2024 was reviewed. The meeting agenda and the respective minutes of the meeting were available.

Quality risk management (QRM)

The SOP "Risk management procedure" was available. Failure mode effects analysis (FMEA) and other quality risk management methodologies were described in the procedure. The QRM was used by the company in various aspects such as introduction of a new product, validation and qualification, change control and vendor qualification etc. A QRM periodic review plan template was attached.

A risk assessment log was kept. Risk assessment report "Prevention of contamination and cross contamination", was reviewed and discussed.

Product release

Product release was managed according to the "Batch review and release" which was checked. The release of "API or intermediate" was the responsibility of QA. Starting materials were released by QC.

QA manager and a delegated QA person were responsible for the final review of all the relevant documents including BMR, BPR and batch testing records for the finished product release according to the procedure.

It was noted that WHO grade Sofosbuvir API was released according to in-house specifications with additional control on polymorphism. A product code with WHO specifications was established at the time of inspection.

2. Personnel

An organogram was presented at the opening meeting with clear separation between production/operations and quality-related activities. The quality assurance and quality control activities at the site were assigned to two different appointed managers. The managers reported functionally to the Corporate Quality Unit.

Personnel qualification

Personnel met during the inspection were adequately qualified based on education, experience and training. The responsibilities of key personnel were detailed in the relevant job descriptions, and the hierarchical and administrative structures were depicted in the organization chart. The formal delegation of this task was verified. Minimal qualifications were defined for the various tasks, with verification performed for the education of the QC manager and one HPLC analyst.

The site employed a total of 106 staff and did not employ any temporary or seasonal staff.

Personal hygiene

In general, as observed during the site tour and witnessing of actual manufacturing activities, personnel followed good sanitation and hygiene practices. Proper gowning was observed before access to production and control areas. Signage and pictorials were not available for the gowning requirements before entering the clean areas.

3. Buildings and facilities

Production

There was one production block on the site. Sofosbuvir was manufactured in the non-dedicated production facility and lines. Both chemical and clean area in the production block were inspected.

QC laboratories

Laboratory areas were separated from production areas. Nevertheless, laboratory areas, in particular microbiological laboratory were located within the same block of the production areas with separate access doors.

Utilities

In general, all utilities impacting the product quality of the products (e.g. steam, gases, compressed air, and heating, ventilation and air conditioning) were qualified and appropriately monitored. Drawings for these utility systems were available.

The last annual qualification report of the cleanroom was reviewed. It comprised HEPA filter integrity test, air change test, particle count test, recovery time test, temperature and humidity, pressure and viable count. No deviation was reported during the qualification study.

Nitrogen

No nitrogen generation system was available at PBIC. Rather, nitrogen was supplied by a qualified supplier and stored in a tank of 10 m^3 capacity. The nitrogen distribution system was tested on monthly basis. Annual qualification was also considered.

Water

Water used in the manufacture of the APIs was of purified water (PW) quality and was demonstrated to be suitable for its intended use. Water treatment equipment was qualified and the PW generation system was validated and monitored with appropriate action limits.

The purified water layout was reviewed. The testing reports of the routine monitoring of the PW were spot checked.

Lighting

Adequate lighting was provided in all areas to facilitate cleaning, maintenance, and proper operations.

4. Process equipment

Design and construction

Equipment used in the manufacture of intermediates and the API was non-dedicated. Generally, the equipment was appropriately identified for its intended use and maintenance.

Equipment maintenance and cleaning

Written procedures were established for the cleaning of equipment and its subsequent release for use in the manufacture of intermediates and APIs. The SOP related to "Sofosbuvir equipment cleaning" was checked.

Equipment was divided into three groups for cleaning.

- Group A: SS or GL reactors with jacket, stirrer and heat exchanger
- Group B: SS with jacket and stirrer
- Group C SS reactors with stirrer only

Equipment cleaning was classified into:

- Minor: Batch to batch
- Major: After campaign or product changeover.

The SOP for the planned maintenance schedule of the equipment was in place. A planner of the monthly, quarterly and semi-annually maintenance schedule was established and its implementation was tracked accordingly.

HVAC maintenance

The SOP for operation and preventive maintenance of the air handling unit and exhaust unit was in place. The records of the monthly preventive maintenance checklist of the air handling unit AHU01 serving the cleanrooms in the production area, as well as the exhaust of the same, were spot-checked.

Calibration

Production and analytical equipment, including balances, sensors, and other measuring devices, contained a unique identifier, along with calibration dates. Calibration stickers were available on the equipment with clear indication of the date of the last and the due date for subsequent calibration activities. Balances were verified on daily basis (when in use).

Computerized systems

The computerized system validation master plan was in place. The procedure provided for life cycle management of computerized systems including validation, review and monitoring. The list of computerized systems for corporate purposes, as well as the site-specific purposes, was provided. Two computerized systems were listed as corporate related computerized systems (an enterprise resource management and change management system). Both computerized systems were considered category 4. The review frequency for this category was set for 3 years. The change management system was validated in 2023.

The SOP for periodic review of computerized systems was also available. The SOP was not implemented as no computerized system was used and reached the due date for periodic review (3 years for category 4 and category 5 systems; and 5 years for category 3 computerized systems).

5. Documentation and records

Documentation system and specifications

Documents related to the manufacture of intermediates or APIs were prepared, reviewed, approved, and distributed according to written procedures. The issuance, revision, superseding and withdrawal of documents were controlled with maintenance of revision histories. The site used a manual record system while a computerized system limited to the material management and QC-laboratory activities, i.e., HPLC, GC, etc.

The risk assessment study for data management and data integrity implementation was spot-checked.

Equipment cleaning and use of records

Records of major equipment use, cleaning, and maintenance were available and included the date, product and batch number of each batch processed in the equipment, and the person who performed the cleaning and maintenance.

Equipment logbooks were bound and serialized to ensure traceability and compliance with data integrity.

Master production and control records

The SOP for issuance and controlling batch manufacturing and batch cleaning record was in place. The SOP provided for batch numbering which comprised a serial number with no letters. This new batch numbering was used since 2025 with the introduction of an enterprise management system for materials. There was a change control for the change related to the batch numbering system along with the introduction of the enterprise management system.

The master batch production and control records of Sofosbuvir were reviewed:

- Master batch production record of stage I. This MBPR was established based on the latest process validation of the production process of stage I.
- Master batch production record of stage I. This MBPR was established for the bigger batch size of stage I.
- Master batch production record of stage II. This MBPR was revised to consider some minor process and documentation improvements.
- Master batch production record of stage III. This MBPR was revised to consider some minor process and documentation improvements.

Batch production and control records

The batch production and control records of one batch of Sofosbuvir stage I were spot-checked. The batch record documented batch related activities. The BMR of the original intermediate (crude Sofosbuvir) as well as a reprocessed batch was reviewed.

6. Materials management

Receipt and quarantine

Incoming starting materials and finished API products were quarantined after receipt until released for use or distribution. The "Material supplier list" was in place. The status of raw material was indicated, with respect to material under quarantine or approved. The material label and status were checked.

Sampling and testing of starting materials and finished APIs

Both starting materials and finished Sofosbuvir API were sampled in the warehouses. Sampling rooms located in the warehouses were equipped with LAF and access control was in place. A secured area for return and rejected materials was established. The starting materials and finished goods were managed through the enterprise management system with a barcode on the material label.

Storage

The following warehouses were visited during the inspection.

- Warehouse for solid materials and packaging materials
- Warehouse for solvents, which were stored in drums. All solvents used in manufacturing were stored in drums, and a solvent tank farm was not available at the site.
- Warehouse for finished API products

Materials and finished API products were stored in different warehouses under specified conditions which were inspected. Warehouses appeared clean and materials were placed in good order.

Supplier management

The procedure for Material supplier management was in place. Supplier evaluation was made primarily through a vendor questionnaire with the provision of an on-site audit for critical suppliers. Re-audit of the supplier was planned based on risk assessment considering the material criticality, annual evaluation of the supplied material/service and date of the last audit. A list of critical suppliers was available and several supplier evaluations were reviewed.

The supplier agreements had a clause for the notification of changes if applicable along with the rights of the contract giver to audit the contract receiver when needed.

7. Production and in-process controls

Written procedures were established to monitor the progress and control the critical and major process parameters that may cause variability in the quality characteristics of intermediates and APIs. In-process controls and their acceptance criteria were defined.

Raw materials were weighed and measured using appropriately accurate devices. Three quality grades of Sofosbuvir APIs were produced, distinguished by coding, each with distinct process and specifications.

The manufacturing of WHO PQed Sofosbuvir from intermediates Sofo-C2 and SOFO-1 was carried out at Pharco-B International (2) for Chemicals and divided into three stages and each stage involved intermediate testing of the material or, respectively, the finished API. Blending batches of Sofosbuvir API batches were not performed for the WHO-grade Sofosbuvir.

One batch at Stage III was in operation during the WHO inspection. The relevant production areas were inspected and the BMR was checked. The processing status was indicated on the equipment. Stage III production in chemical and clean area (class D) involved manufacturing Sofosbuvir through purification, crystallization, isolation and drying. Contamination control in production of the API was checked and discussed.

8. Packaging and identification labelling of APIs and intermediates

The SOP for activities in the production finishing areas was in place. The SOP provided for line clearance prior to operation and a template for finishing area cleaning and clearance checklist was utilized. The checklist was issued by QA along with the BMR issued for each individual batch.

Packaging operations were not in operation at the time of inspection. Packaging and labelling were not inspected in detail due to time constraints.

9. Storage and distribution

Warehousing procedures

Adequate facilities were available for the storage of materials under appropriate conditions. Records of these conditions were maintained.

Distribution procedures

APIs were released for distribution to third parties only after approval by the Quality Unit.

WHO grade Sofosbuvir API batches were solely distributed to European Egyptian Pharmaceutical Industries (EEPI) upon the agreement between the two companies.

10. Laboratory controls

Physicochemical Laboratory

Written procedures were established for the sampling, testing, approval or rejection of materials and finished API products. Specifications, sampling plans, schedules, and test methods under the responsibility of QC were in place. Separate rooms or areas for receiving samples, GC, HPLC, Karl Fischer Titration, reference standards and retention samples were available. Several sampling and testing procedures were checked.

It was noted that the instrument for testing particle size distribution, polymorphism was not equipped in the laboratory and the testing was contracted out.

OOS/OOT management

OOS results obtained were investigated and documented according to SOP entitled "Handling of OOS results in chemical lab". The procedure was checked and found to be accepted.

OOS registers were checked. A number of OOS investigations were spot-checked but not reviewed in detail due to time constraints.

Stability study

The stability samples were kept in the stability study chambers at EEPI site. The stability study chambers were not available on the site.

The SOP for stability study of drug substance and intermediate was in place. The procedure provided for selection of stability study batches for finished API and intermediates, test procedures and specifications, testing frequency, packing and labelling of stability samples, data evaluation and trend analysis and notification of stability failures.

The hold time stability study protocol for SOFO-C1 MAC was reviewed.

A documented, ongoing testing programme was designed to monitor the stability characteristics of APIs and the results were used to confirm appropriate storage conditions and retest or expiry dates. The stability-indicating testing procedures were validated.

The ongoing stability study protocol for one batch of Sofosbuvir finished API was spot-checked. This was the first batch of the finished API produced in 2025. The 3-month testing interval was reviewed and found compliant with the product specifications.

Reserve/retention samples

Retention samples of each batch of Sofosbuvir API were retained for 10 years. Two full specification analyses reserve samples were stored in the same packaging system in which the API was stored. The area was under the same room temperature of QC Chemical laboratory.

Environmental Monitoring and microbiological testing

There were SOPs and logbooks available for the various processes required for the environmental monitoring of the controlled areas of manufacturing, microbiological testing of nitrogen, compressed air as well as the microbiological testing of the finished API.

11. Validation

Validation documentation

There was an established requirement for documentation of the validation and qualification activities, including through protocol and related reports. The template of the qualification and validation reports included dedicated sections for approval, conclusion and deviations (if any).

Qualification

The SOP for equipment qualification was reviewed. The procedure provided for lifecycle management of equipment qualification, including DQ, IQ, OQ and PQ.

Process Validation (PV)

The SOP for PV was in place. The procedure guided different stages of PV, including process design, process qualification and continued process verification. The SOP also provided for different PV approaches, including prospective and concurrent PV. The procedure was silent on retrospective PV, noting that by the time of the inspection, no retrospective PV was considered. The policy for process revalidation was set as once every 5 years if not mandated earlier (e.g., due to change or based on PQR).

The PV protocol and report for Sofosbuvir were reviewed. The original batch size for stage I involved 4 batches, each of 250 Kg. The additional batch size for stage I involved 4 batches, each of 45 Kg. The mentioned protocol and report were related to the new batch size which in turn was managed through a change control. CPP and CQA were defined prior to the commencement of the PV study and these were verified during the PV study, among other IPC parameters.

The batch manufacturing records of one of the four PV batches of stage I of SOFO-C1 MAC were reviewed. In addition, the BMR of one batch of the original intermediate (crude Sofosbuvir) as well as the reprocessed batch were reviewed.

Actual yields were compared with expected yields at designated steps in the production process and the same was documented in the batch production and control records. Expected yields with appropriate ranges were established based on the validated manufacturing process.

Periodic review of validated systems

Systems and processes were periodically evaluated to verify that they were still operating in a valid manner. Revalidation was also considered in case of major changes to the validated systems.

Cleaning Validation (CV)

The SOP for cleaning validation was in place. The procedure provided for roles and responsibilities of CV activities, acceptance criteria, matrixing for selection of the worst-case scenario among the produced APIs, sampling methods (rinse and swapping) and CV documentation including CV protocols and reports.

The CV protocol and report were reviewed. The PDE data was provided by a qualified and approved toxicologist. The three runs of the CV were completed by end of 2022 and early 2023 considering an API (other than sofosbuvir) was worst case scenario.

12. Change control

A change management procedure was available. Several changes were documented in the APQR.

13. Rejection and re-use of materials

Rejection

Intermediates and APIs failing to meet established specifications were identified as such and quarantined. These intermediates or APIs could possibly be reprocessed or reworked as described below.

Reprocessing

The SOP for reprocessing and reworking was in place. The Procedure allowed reprocessing and reworking of batches not meeting preset specifications. Reworked batches were required to be validated (concurrent approach) and declared to regulatory authorities along with stability data prior to sale.

The list of reprocessed batches was provided.

The BMR of the original intermediate (crude Sofosbuvir) as well as the reprocessed batch was reviewed.

Reworking

Please refer to "Reprocessing" subsection. The manufacturer declared that no reworking was performed at PBIC so far.

Recovery of materials and solvents

No solvent recovery was considered for the manufacturing of Sofosbuvir at PBIC.

Returns

Returned intermediates or APIs were identified as such and quarantined in a dedicated and well segregated area.

14. Complaints and recalls

Customer complaint and product recalls were managed according to written procedures. No complaints and recall on Sofosbuvir were reported as there were no commercial batches of WHO grade Sofosbuvir have been distributed since last inspection.

15. Contract manufacturers (including laboratories)

PBIC did not outsource any production activities. On the other hand, several QC activities were outsourced by PBIC to third parties.

All outsourced laboratory activities were controlled through quality agreements as guided by the supplier qualification procedure.

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, **Pharco B International (2) for Chemicals (PBIC)** located at **New Borg El Arab City, Second Industrial Zone No. 5, Block 22 Alexandria, 21934 Egypt,** was considered to be operating at an acceptable level of compliance with WHO good manufacturing practices guidelines.

All the non-compliances observed during the inspection that were listed in the full report as well as those reflected in the WHOPIR, were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

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

Part 4	**List of GMP guidelines referenced in the inspection report**

1. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eight 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. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1.
   Short name: WHO TRS No. 957, Annex 1

https://www.who.int/publications/m/item/trs957-annex1

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. Fifties 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
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