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

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**Suheung Co., Ltd (Osong Plant)**
Corporate address of manufacturer	Suheung Co., Ltd Janghan-Ro 40 Dongdanun-Gu, Seoul, Republic of Korea
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Suheung Co., Ltd (Osong Plant) 61, Osongsaengmyeong-ro, Osong-eup, Heungdeok-gu, Cheogju-si, Chungcheongbuk-do, Republic of Korea DUNS: 687943324
Unit / block / workshop number	A, B, D
Inspection details	
Dates of inspection	11-13 September 2023
Type of inspection	Routine GMP Inspection
Introduction	
Brief description of the manufacturing activities	The site is authorized to manufacture hard empty capsules and oral solid dosage forms: soft gel capsules, uni/multi dose form (tablets, hard capsules, powders). Additionally, products containing toxic and hazardous materials (cyclosporine) are manufactured in dedicated areas. The Clofazimine 100mg soft gel capsules (bulk product) were manufactured on-site. The capsules were packaged, tested, and released by Dong-A ST.
General information about the company and site	Suheung Co. Ltd. was founded in 1973 and is one of the major manufacturers of empty hard capsules and soft gel capsules. The site was commissioned in 2012 and is located in a Life Science Park. The facilities were certified in 2022 for ISO 14001 and ISO 45001 by SGS.
History	The site was last inspected by WHO in November 2019 and is periodically inspected by MFDS. The site was also inspected by TGA in 2019.

Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	Documents reviewed included but were not limited to: • Quality Manual – management review meetings • Organization Chart • Job descriptions for key personnel • Personnel training and hygiene • Product Quality Review • Quality Risk Management • Responsibilities of the quality unit and production • Complaints and Recalls • Deviation handling and CAPA • Change control • OOS and OOT investigations • Material release • Self-inspection and vendor qualification • Validation and qualification • Equipment calibration • Data integrity • Sampling and testing of materials • Batch processing records • Materials management system • Analytical methods – stability • HVAC system • PW system Areas visited: • Starting materials, packaging materials and FPP warehouses • Sampling and dispensing areas • Soft gel capsules manufacturing operations • QC laboratories
Restrictions	N/A
Out of scope	Products and manufacturing activities not related to WHO-PQ products were not covered
WHO products covered by the inspection	Clofazimine Capsules, soft 100mg
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	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**

1. Pharmaceutical quality system

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 being met. The procedures reviewed and discussed during the inspection were generally of an acceptable standard

Quality Manual

The Quality Manual of the site was reviewed. According to the Quality Manual, top management was committed to maintaining and controlling the quality system. Responsibilities of key personnel and the documentation hierarchy were defined. The Quality Manual was reviewed by the Standardization Committee and approved by the CEO. Copies were distributed to all relevant departments. The distribution list for the current QM version was checked. The responsibilities of the Standardization Committee were described in a written procedure.

Management Review

Management review meetings were held annually, and included evaluation of internal quality audit results, non-conformities, follow up actions from the previous management meeting, and preventive actions for quality control. The minutes were submitted to the standardization committee.

Product Quality Review

The PQR procedure was reviewed. The scope of the PQR included, but was not limited to, raw materials, packaging materials, in-process data, statistical evaluation of product quality attributes, finished product analysis data, deviations, OOS, changes, stability, and CAPA. The PQR for the product Clofazimine soft capsules 100 mg for the year 2022 and the year 2021 were reviewed.

Deviations

There was a procedure in place for managing deviations. The SOP adequately described the steps for reporting, assessing, investigating, applying remedial actions, documenting, and closing out a deviation. It was applicable to all GMP related activities and operations on-site when a departure from an approved instruction or established standard or an incident in which a non-conformance or failure was observed. Deviations were categorized into three levels (critical, major, or minor) based on criticality and impact. Root cause investigations had to be completed within twenty days. No deviations for Clofazimine were registered in 2022 since no batches were manufactured. Similarly, no deviations for Clofazimine were listed in 2023 until the time of inspection. The deviation logs for 2022 and 2023 (until the time of inspection) were reviewed. Examples of deviations were reviewed.

Change control

The change control procedure provided guidance on the management and impact of changes and was applicable to new changes including, but not limited to, changes related to products, production processes, analytical methods, equipment, utilities, facilities, materials, and systems. The effectiveness of changes was evaluated after implementation.

The introduction of a new supplier of lecithin for the Clofazimine soft gel caps. 100mg was reviewed. The introduction of LIMS was also reviewed. At the time of inspection, qualification was still on-going. The OQ phase had been completed.

In addition, the change of the Clofazimine soft gel caps 100mg shelf-life to 36 months was checked.

Quality Risk Management

QRM was integrated in Suheung's PQS and a procedure was in place describing the systematic process for managing and mitigating risks associated with processes and systems. Different risk management tools could be used, and the relevant SOP included sufficient details on each of the risk tools used by the company. The following risk assessments were reviewed:

- The manufacturing process of Clofazimine soft gel cap 100mg.
- Sharing the PW loops C and E with the food facility.

Batch release

Batch release was performed according to a written SOP. The Qualified Legal Pharmacist was responsible for certifying and releasing a batch. An example of a Clofazimine batch release was reviewed in detail.

Any observations related to this section have been adequately addressed and the implementation of CAPA will be verified at the next inspection.

2. Good manufacturing practices for pharmaceutical products

Good manufacturing practices were generally implemented. Manufacturing processes were generally defined in SOPs and systematically reviewed. Necessary human resources and adequate premises, equipment and utilities were provided for the current manufacturing activities. Qualifications/ validations, calibrations, and maintenance were performed according to prepared protocols and followed the relevant established procedures. The manufacturing processes followed procedures as defined and documented in the BMRs.

The company used cotton cloths for removing foreign matter from soft gel capsules during tumbling and drying. The company stated that these cloths were dedicated to Clofazimine soft gel caps. The procedure for cleaning the fabric used for swiping the capsules was reviewed. Additionally, the fabric certificate was reviewed as well as the cleaning validation protocol and report.

Any observations related to this section have been adequately addressed and the implementation of CAPA will be verified at the next inspection.

3. Sanitation and hygiene

Premises and equipment were generally maintained to an acceptable level of cleanliness, and were appropriately labelled, and records maintained. Procedures for gowning and hygienic behavior in

production areas were available. There was appropriate gowning in all areas for staff and visitors, including pictorials, hand washing and sanitization before entry to production areas.

Any observations related to this section have been adequately addressed and the implementation of CAPA will be verified at the next inspection.

4. Qualification and validation

Validations and qualifications were performed according to the site policy and documented procedures. The 2023 VMP was presented. It was structured based on the relevant SOP. Necessary resources in production were provided, including qualified and trained personnel, adequate premises, equipment, and services, appropriate materials, approved procedures and instructions, laboratories and equipment for in-process and other controls.

Qualification – Calibration of Equipment

The qualification of the metal detector was reviewed. The metal detector was calibrated for the detection of ferrous, non-ferrous, and stainless steel using 5 sizes of metal test pieces for 3 runs each, at different positions, using 4 levels of sensitivity detection.

The calibration of two scales (dispensing of bulk capsules) was checked. They were calibrated on 06.01.2023.

The requalification of the encapsulation machine was also reviewed. Requalification was performed every five years. Calibration certificates for standard equipment were included in the report. Parameters like temperature for the formation of the gelatine spread/film, speed, and noise were measured and found to be within the established limits.

HVAC qualification

The 2022 annual trend analysis of the HVAC system was reviewed. The purpose of the report was to verify the correct operation of the air handling unit and dehumidifier. These units supplied air to the encapsulation area (11 rooms) and the tumbler area (9 rooms). Parameters like air temperature and humidity at the point of generation, noise and vibration, pipe leak, filter differential pressure, and air volume were measured during the year.

Cleaning Validation

Cleaning validation was described in the "Validation" procedure. The worst case was chosen based on the daily dosage, the toxicity, the solubility, and the difficulty to clean. Each factor was given a different weight.

The cleaning validation protocol for the Standard Encapsulation Machine was reviewed. The company's cleaning validation approach had changed to identifying the worst-case scenario based on PDE values. Examples of the implementation for the selection of the worst case based on PDE, and calculation of the MACO, were reviewed. Additionally, the analytical validation and the calculation of recovery factor were discussed in detail.

Any observations related to this section have been adequately addressed and the implementation of CAPA will be verified at the next inspection.

5. Complaints

Complaints were handled according to a written procedure. Complaints could be received by any communication method, such as phone, E-mail and/or conversation. The sales department was

responsible for collecting information and reporting of complaints to the QA department. The QA department filled in the complaint report, categorized the complaint (critical, major, or minor), performed a root cause analysis, and initiated the investigation with the concerned department(s). The root cause analysis was performed according to a written SOP. This process had to be concluded within 7 days. The QA department informed the sales department within 14 days from the date of complaint receipt and relevant CAPAs were identified. Corrective and Preventive Actions were determined based on the principles described in a procedure. The CAPAs were issued by the QA department and due dates were assigned. The head of the concerned department was responsible for implementing the CAPAs and the QA department was responsible for the verification of the CAPAs. Effectiveness of the CAPAs was also foreseen.
The complaints lists for 2022 and 2023 were presented, and examples of complaints were reviewed.

Any observations related to this section have been adequately addressed and the implementation of CAPA will be verified at the next inspection.

6. Product recalls

Product recalls were performed according to a written procedure. A committee was responsible for taking the decision to recall. The QA department was responsible for handling the recall process and notifying the authorities (including WHO). Recalls were to be initiated within 24 hours and distributors were notified as soon as possible. The recall process was monitored and, for Class I recalls, an evaluation report had to be issued after 5 days from the recall date and communicated to the local authorities. A mock recall was foreseen in the SOP and was performed at least once per year.
The most recent mock recall (13/4/2023) was reviewed along with the evaluation of its effectiveness

Any observations related to this section have been adequately addressed and the implementation of CAPA will be verified at the next inspection.

7. Contract production, analysis, and other activities

The contract between Seheung Co. Ltd and Dong-A ST for the manufacture of bulk Clofazimine soft gel caps 100mg, was reviewed. The contract defined in detail the responsibility of each party (please, refer to the Dong-A ST inspection report for more details).

Any observations related to this section have been adequately addressed and the implementation of CAPA will be verified at the next inspection.

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

Suppliers were evaluated and qualified in accordance with a written SOP. The R&D Team was responsible for the initial evaluation of a new supplier. The Head of the QA Team was responsible for evaluating the suppliers and maintaining the relevant documentation. The QA manager was responsible for establishing a risk-based audit plan to re-assess suppliers. Examples of supplier qualification were reviewed.

Any observations related to this section have been adequately addressed and the implementation of CAPA will be verified at the next inspection.

9. Personnel

There was an adequate number of personnel suitably qualified by education and training to perform and supervise the manufacture of FPPs. The personnel met during the inspection appeared to be knowledgeable about GMP. An organization chart was available. Key personnel responsibilities were defined in job descriptions which also included qualifications for the different posts. The following job descriptions were checked:

- Quality Assurance Manager – Responsible Pharmacist (Quality – Manufacturing Manager)
- Warehouse Manager (Storage Management Manager)
- Team Leader of the production department
- Manager of production 2 (packaging)

Any observations related to this section have been adequately addressed and the implementation of CAPA will be verified at the next inspection.

10. Training

There were procedures in place for personnel training defining the training system, training types, and training plans. Induction-orientation training was provided to newly recruited personnel within 3 months of recruitment. Contract personnel received the same induction training as permanent personnel. Continuous and repeated training was also provided based on identified needs according to training plans established at the end of the year for the following year. Existing employees had to receive at least 12 hours of training per year, including repeated training on general GMP principles, hygiene, and data integrity among others. On the job training was also provided, where necessary, to improve work techniques or to address problems. Training plans were established according to a written procedure. The 2023 annual plan was presented, and it included both internal and external training. Oral tests were conducted for each training session and written tests were conducted every quarter covering the training topics of the quarter. Passing criteria were established.

Any observations related to this section have been adequately addressed and the implementation of CAPA will be verified at the next inspection.

11. Personal hygiene

The personal hygiene at the facility was considered appropriate regarding the manufacturing and packaging operations carried out, and in line with the GMP guidelines. There were procedures in place adequately defining the concepts of occupational health, hygiene, and safety. Personnel hygiene was described in two SOPs. The SOPs referenced good hygiene practices, steps to be followed for employees with health issues, and medical examinations upon recruitment and on a periodic basis (annually). Relevant records were reviewed.

Any observations related to this section have been adequately addressed and the implementation of CAPA will be verified at the next inspection.

12. Premises

Layouts of the facilities were made available. The warehouses for raw and packaging materials as well as FPPs were located on the first floor, together with the dispensary and the sampling areas. Personnel gowning took place on the second floor. Production operations were carried out on the 4th floor while storage of the bulk product, capsule inspection and bulk packaging took place on the 3rd floor. Sliding doors were installed in some production rooms on the 4th floor. The 5th floor included two levels where

dispensing of shell raw materials and colours took place. In general, premises were constructed, designed, and maintained to suit the operations to be carried out and prevent the risk of contamination of materials and products. At large, the design of premises was such as to minimize the risk of errors and permit effective cleaning and maintenance.
Toxic materials (cyclosporine) and related products were manufactured in dedicated areas and equipment and were transferred in sealed containers through the production corridor.
Detailed instructions regarding the operation of the sampling area (preparation, sampling and cleaning) were reviewed.
Trend analysis on environmental monitoring and HVAC parameters was performed on an annual basis. The relevant documents were reviewed.

Any observations related to this section have been adequately addressed and the implementation of CAPA will be verified at the next inspection.

13. Equipment
In general, production equipment was of appropriate standard and records of preventive maintenance were kept. The equipment appeared to be installed to facilitate production and reduce the risk of contamination and mix ups. All production equipment reviewed were identified as to their content or purpose with cleanliness status identified by appropriate labels. Cleaning records were presented. Procedures for the set up and operation of production equipment were made available. There was a dedicated encapsulation machine for Clofazimine.
Examples of preventive maintenance records for production equipment were reviewed.
Additionally, the SOP on maintenance of small utensils in the weighing area was spot-checked.

Any observations related to this section have been adequately addressed and the implementation of CAPA will be verified at the next inspection.

14. Materials
Written procedures for the receipt identification, quarantine, storage, handling, sampling, approval, or rejection of materials were checked. Material receipt operations were inspected in detail, including the controls and areas during receipt. The materials were sampled and labelled appropriately according to their status (e.g., quarantine, sampled, released, rejected).
The procedure for quarantine and approval of materials received from contract givers (sampled and tested) was reviewed.

Any observations related to this section have been adequately addressed and the implementation of CAPA will be verified at the next inspection.

15. Documentation
A documentation system was in place including procedures for the creation, issuance, review, approval, and withdrawal of quality documents. The relevant activities were performed according to an SOP. The different levels of the documentation hierarchy were adequately defined. Records were appropriately completed and maintained.

Any observations related to this section have been adequately addressed and the implementation of CAPA will be verified at the next inspection.

16. Good practices in production

In general, there were procedures in place providing appropriate instructions for the activities, operations and processes taking place in the manufacturing areas. Manufacturing and packaging batch records were maintained and completed contemporaneously. Daily calibrations were registered in logbooks and preventive maintenance records were readily available.
Operators performed visual inspection of Clofazimine soft gel caps before bulk packaging.

Any observations related to this section have been adequately addressed and the implementation of CAPA will be verified at the next inspection.

17. Good practices in quality control

The Quality control laboratories were separated from the production areas and tasked with the physical, chemical, instrumental, and microbiological analysis of starting, packaging, and intermediate materials, as well as finished pharmaceutical products. The QC laboratory was appropriately organized and equipped. Analytical equipment was installed in separate rooms and logbooks for use and maintenance of equipment were presented. Test reports and methods for the bulk Clofazimine soft, gel caps., wax, lecithin, gelatine, and glycerine were reviewed.
The raw material retained sample area was visited. Logbooks for storage of retained samples were made available. Temperature and relative humidity were controlled and monitored.

The PW sampling and testing SOP was reviewed. The site had one PW generation system and three loops (C, D and E). D loop served only the food facility while the other two served both the pharmaceutical facility and the food facility. A risk assessment for sharing the loops with the food facility had been conducted. Sampling was performed once a month between the 8th and 12th day. The last point on the return loop as well as certain user points in the manufacturing area were tested every month, while, for user points in the cleaning area, periodic sampling was scheduled during the year. Appearance, conductivity, TOC, and microbial limit test were performed. The August 2023 trend report was reviewed.

Any observations related to this section have been adequately addressed and the implementation of CAPA will be verified at the next inspection.

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, ***Suheung Co. Ltd. (Osong Plant)***, located at ***61, Osongsaengmyeong-ro, Osong-eup, Heungdeok-gu, Cheogju-si, Chungcheongbuk-do, Republic of Korea*** 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 until 30/09/2025, 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://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. 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
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. Fifties Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 6.
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