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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	**Guilin Pharmaceutical Co. Ltd**
Corporate address of manufacturer	Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd., Building A, No.1289, Yishan Road, Shanghai 200233, P.R. China
Inspected site	
Name & Address of inspected manufacturing site if different from that given above	Guilin Pharmaceutical Co. Ltd – API No 43, Qilidian Road, Guilin, Guangxi, 541 004, China
Synthetic Unit /Block/ Workshop	API workshop I (API-I) and API workshop II (API-II)
Inspection details	
Dates of inspection	25-28 September 2023
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	Guilin Pharmaceutical Co., Ltd. is engaged in the manufacturing of various finished product dosage forms including tablets, capsules (soft capsules, hard capsules), injectables (powder for injections and small-volume parenteral (SVP) injections) and active pharmaceutical ingredients. This inspection specifically focused on manufacturing of non-sterile APIs.
General information company and site	Guilin Pharmaceutical Co., Ltd. is a subsidiary of the Shanghai Fosun Pharmaceutical (Group) Co., Ltd since 2003. Since the previous WHO inspections (October 2021~ August 2023), several major changes have been executed including a new product application, changes related to formula and process, specification, premises, equipment, facility and company organization structure etc..
History of previous regulatory inspections since 2021 pertaining to the API site	

Inspectorate	**Dates of inspection**	**Scope of inspection**
WHO	2021.09	API-I, API-II,
US FDA	2023.08	OSD-I

Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	**Document Review included but not limited to:** - Quality management system

	- Documentation system - Validation and qualification **Site areas visited:** - Production workshop API-I - Production workshop API-II - Quality laboratory - Warehouse: Automated, Printed Packaging Components and Packaging material - Purified water system
Restrictions	The inspection was restricted to the production of the products listed in the inspection scope.
Out of scope	The API site inspection was limited to WHO Prequalified APIs manufactured in API-I and API-II workshops. Products and production areas outside of the inspection scope were not inspected.
WHO APIs (including WHO API or APIMF numbers) covered by the inspection	1. WHOAPI-181 (APIMF181, Artemether) 2. WHOAPI-278 (APIMF278, Pyrimethamine) 3. WHOAPI-279 (APIMF279, Sulfadoxine) 4. WHOAPI-355 (APIMF355, Artesunate) 5. WHOAPI-459 (APIMF459, Dihydroartemisinin) (Under assessment)

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 (or high-performance liquid chromatography equipment)
HVAC	Heating, ventilation and air conditioning
IQ	Installation qualification
KF	Karl Fisher
LAF	Laminar airflow

LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
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
SMF	Site master file
SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometer
WFI	Water for injection

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

1. Quality management

The quality management system was generally established, documented and implemented. The quality management system was common to sterile and non-sterile active pharmaceutical ingredients and finished pharmaceutical products operations. The site organizational structure was presented and was generally acceptable. The Organigram identified the Quality and Production department operating under different leadership with the Qualified Person reporting into Head of Quality. According to the Organigram, Finished API Product release was shared between QA Manager and Qualified Person. In general, Quality-related activities were defined and documented. The Quality Assurance department was independent of production.

Management review

Management review was performed following the documented procedure. Quarterly management review meetings for discussion of quality matters i.e., audits, complaints, recalls, APQR's, production were conducted. Management meetings were attended by heads of the various units, with

minutes and attendance register available and kept. Meeting minutes of July 2023 were reviewed. Trend Analysis was performed for OOS, Deviations and reported at quarterly management committee meetings.

Product release

The SMP for product release was reviewed and discussed in relation to the overall final responsibility for the batch release of finished products.

Deviation control

The SMP for Deviation controls was briefly discussed. The deviation reported for the period 1 April – June 2023 was documented. The investigation of a deviation related to the autoclave located in the quality control laboratory was reviewed and discussed.

OOS investigation

The SMP for OOS investigations was briefly discussed. The OOS reported for the period 1 April – June 2023 was documented. The investigation of OOS and the CAPA executed were checked.

CAPA's and investigation

The SMP for CAPA investigations was briefly discussed. The CAPAs raised for the period 1 Jan – March 2023 was reviewed.

Quality Risk Management

The SMP for QRM investigations was discussed. Risk Priority Number was determined based on Probability (P), Occurrence (O) and Severity (S). The risk associated with the manufacturing of product in a multipurpose product manufacturing site taking into account HBEL was checked. HBEL risk for all current products were conducted and completed. Information as per Risk Register for OSD1 was noted.

Annual Product Quality Review (APQR):

The PQR procedure was in place which described the process for the review of product performance and consistency of the manufacturing process. Various elements of the quality system and products were reviewed every 12 months as per the procedure. Process capability was calculated whereas CpK more than 1.3 was considered robust, CpK less than 1.3 required investigation.

Internal audit

Self-inspection for utilities and water conducted in May 2023 was reviewed. An audit plan for the inspection was prepared according to the SOP. The audit team led by QA included representation from QA, QC, Production etc. A typed report followed various handwritten reports that were completed according to an inspection template.

2. Personnel

The responsibilities of staff and their specific duties were recorded in written job descriptions. Personnel interviewed during the inspection were aware of the principles of GMP. Organization charts and job descriptions were available. Job descriptions of the QA Manager, QA Assistant Manager and QP were reviewed and discussed.

Gowning and laundry:
Changing and washing before entry to production areas followed written procedures. Direct contact was avoided between the operator's hands and starting materials, primary packaging materials and intermediate or bulk products. The level of hygiene observed, and the measures taken to maintain hygiene requirements were found to be satisfactory.

Training
Training was managed according to written procedures. Training was divided into induction training, cGMP, on the job training and external training. Training was evaluated through questionnaires and a passing grade were set. Assessment records following training were available. For purposes of Laboratory training, SOP on qualification verification and laboratory staff competence was checked. Training received by staff members were verified and found acceptable.

3. Buildings and facilities

The premises for manufacturing, storage and quality control of the inspected API products were generally of a satisfactory standard. The inspected production blocks API-I and API-II are multipurpose plants. The plants and the facilities inspected were seen to be in good condition. Manufacturing areas included chemical areas and grade D clean areas. They were generally designed, and constructed to facilitate cleaning, maintenance, and operations as appropriate to the type and stage of API manufacture. All finished API's manufactured in both API-I and API-II were used as starting material in the production of Finished Product (OSD or INJ).

Penicillin API, OSD and injections were previously manufactured on site in three dedicated blocks. Penicillin production ceased with manufacturing being contracted out and the Penicillin manufacturing block decontaminated. The area was being recommissioned for purposes of manufacturing for the domestic market, storage of spare parts and archiving of documentation. During the inspection it was observed that commissioning of PEN-I API was still ongoing.

4. Process equipment

Equipment used in the manufacture of intermediates and APIs was of appropriate design and adequate size, and suitably located for its intended use, cleaning, sanitization and maintenance. Equipment was constructed so that surfaces that contact raw materials, intermediates or APIs did not alter the quality of the intermediates. Permanently installed processing lines were appropriately identified. A set of current drawings was maintained for equipment and critical installations. Schedules and procedures were established for the preventive maintenance of equipment. Records of calibrations were maintained.

Written procedures were established for cleaning of equipment and its subsequent release for use in the manufacture of intermediates and APIs. Equipment and utensils were cleaned, stored and sanitized to prevent contamination or carry-over of a material that would alter the quality of the intermediate or API. Equipment was identified as to its contents and its cleanliness status.

Written procedures were established for equipment maintenance. Control, weighing, measuring, monitoring and test equipment was calibrated according to written procedures and an established schedule. Equipment calibrations were performed using standards traceable to certified standards.

5. Documentation and records

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 all documents was controlled with maintenance of revision histories available.

A procedure was established for the retention of documents, with specified retention periods..

Records of major equipment use, cleaning, sanitization and maintenance showed the date, time, product and batch number of each batch processed in the equipment, and the person who performed the cleaning and maintenance.

Laboratory control records included complete data derived from all tests conducted to ensure compliance with established specifications and standards, including examinations and assays.

Batch production records and batch testing records were kept and available. They were reviewed and results were considered during batch release. BMRs were completed contemporaneously with records available at the point of production. BMRs were verified during the conduct of the inspection.

6. Materials management

Incoming materials were purchased from approved suppliers, sampled, and tested according to specifications and testing procedures. Receipt, warehousing, and release of starting materials were managed with WMS (Warehouse Management System) as per the SOP. Approved, signed and dated testing procedures and specifications were available for starting material, packaging materials and for finished products.

7. Production and in-process controls

The production process followed documented procedures and instructions. Production processes were conducted in the specified facilities and equipment. Written procedures were established to monitor the progress and control the performance of processing steps that cause variability in the quality characteristics of intermediates and APIs. Class D clean areas were available for the final steps of the API's manufacture and were maintained at a satisfactory level. The manufacturing of APIs in block API-I and block API-II was visited, including the chemical area and clean rooms. In-process controls and their acceptance criteria were defined. IPQC testing was conducted by QC.

8. Packaging and identification labelling of APIs and intermediates

Containers provided adequate protection against deterioration or contamination of the intermediate or API that may occur during transportation and recommended storage. In the area where packaging operations were performed the material flow of API, personnel and packaging materials were controlled. A brief inspection of the API I and API II workshop packaging area was undertaken. Labels were issued to the packaging line with batch information handwritten on the label. All API material was for in-house use to manufacture finished products. During inspection, no packaging/labelling was carried out.

9. Storage and distribution

Incoming materials, quarantine and acceptance/rejection in the warehouse was controlled by a computerized system. A brief inspection of the warehouse for chemicals was undertaken. The access control to the sampling room, gowning/de-gowning of personnel and the material status labels were checked.

10. Laboratory controls

The QC laboratories were separated from production areas. The laboratories have been designed and equipped with facilities for chemical, instrumental, microbiological and stability chambers. A new LIMS system was under development.

Sample receiving

Testing samples receiving and allocation to analysts were conducted formally and recorded as per the SMP. Logbooks for received API, raw materials, IPC samples and finished products were checked.

Laboratory equipment

Most of the laboratory equipment was linked with computerized software, with some standalone instruments such as UV, ICP, IR and AAS. Information was saved in real time on a separate laboratory server and the general server of the company. The SOP for the computerized system management was checked and discussed.

Calibration of laboratory equipment

Calibration of analytical weighting balance was assessed. Calibration of dissolution apparatus was verified. Mechanical and chemical calibration was performed. Equipment usage log and maintenance records were available. Calibration and system suitability tests for IR apparatus were verified.

Microbiology laboratory equipment

Full set of data was available and was checked for calibration of balances, incubators, fridges, laminar air flow benches. Standard weights were externally calibrated according to the External calibration program.

Stability monitoring

Stability was performed followed the SOP with samples stored in a Walk-in stability chamber. Temperature and humidity mapping was carried out periodically. Temperature and humidity were monitored electronically. Stability chambers were equipped with alarm systems. Stability was performed annually on one batch of product.

Reference material

Working reference standards were prepared in house with expiry dates indicated. Usage of reference materials were recorded. Expiry dates for pharmacopeial reference standards were checked online. The log recording expiry dates of chemicals and reference standards were checked and discussed.

Retention samples

Retention samples were kept in the same packaging for commercial use. Samples were visually inspected every year.

11. Validation

Validation and qualifications were described in the Validation Master Plan. Process validation was performed according to an in-house validation procedure. The process validation was required to be performed either prospective or concurrent. Before validation activities were started appropriate qualification of critical equipment and ancillary systems was completed.

12. Change control

The SMP for change control was briefly discussed. During the inspection, change controls executed were reviewed and effectiveness verified.

Change control to penicillin blocks for API and FPP were checked, followed up and CAPA verified following from the last inspection. The CC was still ongoing and had not been closed at the time of inspection.

13. Rejection and re-use of materials

The procedure for intermediates or APIs reprocessing and reworking was checked. The final disposition of rejected materials were recorded.

The procedure for recovered solvents and recovered materials in the API manufacturing centre was reviewed. The list of recovered solvents was documented as required by the procedure.

14. Complaints and recalls

The management procedure for handling of customer complaints was established. No market complaints were received between January – 10 September 2023.

The management procedure for recalls provided appropriate instructions to recall/remove products from the market. No recalls had been initiated between January – 10 September 2023.

15. Contract manufacturers (including laboratories)

For purpose of API manufacturing, Guilin has entered into various Technical Agreements with suppliers of material and consumables. External contract laboratory testing was used for a limited number of specialist analytical procedures.

Quality agreements were spot-checked. Contracts permitted the contract giver to audit the contract acceptor's facilities for compliance with GMP. Subcontracting was not allowed. Contract acceptor and contract giver responsibilities were clearly defined.

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, ***Guilin Pharmaceutical Co Ltd-API***, located at ***No 43 Qilidian Road, Guilin, Guangxi, 541 004, China***, was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines.

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

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

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

1. 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 GMP for APIs*** or ***TRS No. 957, Annex 2***
   untitled (digicollections.net)

2. 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 GMP Guidelines o***r ***WHO TRS No. 986, Annex 2***
   https://digicollections.net/medicinedocs/documents/s21467en/s21467en.pdf

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://digicollections.net/medicinedocs/documents/s23457en/s23457en.pdf

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
   9789240020900-eng.pdf (who.int)

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

6. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty Second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8. **Short name: WHO TRS No. 1010, Annex 8**
   https://digicollections.net/medicinedocs/documents/s23455en/s23455en.pdf

7. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4.
   Short name: WHO TRS No. 937, Annex 4
   https://digicollections.net/medicinedocs/documents/s20108en/s20108en.pdf

8. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1.
   Short name: WHO TRS No. 961, 957), Annex 1
   https://digicollections.net/medicinedocs/documents/s18681en/s18681en.pdf

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

10. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6.
    Short name: WHO TRS No. 961, Annex 6
    https://digicollections.net/medicinedocs/documents/s19959en/s19959en.pdf

11. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7.
    Short name: WHO TRS No. 961, Annex 7
    https://digicollections.net/medicinedocs/documents/s18677en/s18677en.pdf

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

13. General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-First Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3. ***Short name: WHO TRS No. 943, Annex 3***
    https://digicollections.net/medicinedocs/#d/s21438en

14. WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2.
    Short name: WHO TRS No. 961, Annex 2
    https://digicollections.net/medicinedocs/documents/s18682en/s18682en.pdf

15. WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2.
Short name: WHO TRS No. 981, Annex 2
https://digicollections.net/medicinedocs/#d/s20177en/

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

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

18. Good Manufacturing Practices: Guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Third Report Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3. ***Short name: WHO TRS No. 1019, Annex 3***
https://digicollections.net/medicinedocs/documents/s23697en/s23697en.pdf

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

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

21. Guideline on data integrity. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 4. ***Short name: WHO TRS No. 1033, Annex 4***
9789240020900-eng.pdf (who.int)

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

23. WHO Recommendations for quality requirements when plant – derived artemisin is used as a starting material in the prosecution 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
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

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
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

25. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditionning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Third Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1019), Annex 2. **Short name: WHO TRS No. 1019, Annex 2**
https://digicollections.net/medicinedocs/documents/s23699en/s23699en.pdf

26. Points to consider when including Health-Based Exposure Limits in cleaning validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 2. **Short name: WHO TRS No. 1033, Annex 2**
9789240020900-eng.pdf (who.int)

27. Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fourth Report Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 6. **Short name: WHO TRS No. 1025, Annex 6**
9789240001824-eng.pdf (who.int)