World Health Organization

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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	China Resources Zizhu Pharmaceutical Co., Ltd
Corporate address of manufacturer	No.27, Chaoyang North Road, Chaoyang District, Beijing 100024, PR of China
Inspected site	
Name & address of inspected manufacturing site if different from that given above	China Resources Zizhu Pharmaceutical Co., Ltd. No.27, Chaoyang North Road, Chaoyang District, Beijing 100024, PR of China
Unit / block / workshop number	W-F-E Workshop
Inspection details	
Dates of inspection	16 to 20 October 2023
Type of inspection	Routine inspection
Introduction	
Brief description of the manufacturing activities	China Resources Zizhu manufactures FPPs including Tablets (hormones, contraceptives), Hard capsules (hormones, contraceptives), Small volume injections, Patches (hormones), Membranes, Ophthalmic preparation (eye drops), Therapeutic biological products, and Gels. The site also engaged in the extraction of Traditional Chinese Medicine.
General information about the company and site	China Resources Zizhu was established in 1969. The site in Beijing manufactures finished pharmaceutical products. Key buildings on the site include the Complex Pharmaceutical Preparation Building, the W-F-E Workshop, Warehouses, QC laboratories and the Power Station.
History	The manufacturing site has been regularly inspected by WHO-PQT. This was the fourth WHO PQ inspection. The site has also been previously inspected by the State Service of Ukraine on Medicines and Drugs Control and by the Beijing Drug Administration.
Brief report of inspection activities undertaken --Scope and limitations	
Areas inspected	• Quality management system • Production block: W-F-E Workshop • Warehouse • QC laboratories • HVAC system • Water system • Compressed air
Restrictions	The scope of the inspection was restricted to the following FPPs in the WHO PQ programme.
Out of scope	Products out of WHO Prequalification Programme

WHO products numbers covered by the inspection	**PR number**	**Product**	**Status**
	RH052	Mifepristone 200mg Tablet	Prequalified
	RH048	Misoprostol 200mcg Tablet	Prequalified
	RH089	Mifepristone + Misoprostol Tablet 200mg + 200mcg	Prequalified

Key persons met

Abbreviati	**Meaning**
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
APS	Aseptic process simulation
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
CFU	Colony-forming unit
CIP	Cleaning in place
CoA	Certificate of analysis
CpK	Process capability
DQ	Design qualification
EDI	Electronic deionization
EM	Environmental monitoring
FMEA	Failure modes and effects analysis
FPP	Finished pharmaceutical product
FTA	Fault tree analysis
GMP	Good manufacturing practices
GPT	Growth promotion test
HEPA	High efficiency particulate air
HPLC	High performance liquid chromatography (or high-performance liquid chromatography equipment)
HVAC	Heating, ventilation and air conditioning
IQ	Installation qualification
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
MF	Master formulae
MFT	Media fill Test
MR	Management review
NC	Nonconformity
NCA	National control authority
NCL	National control laboratory
NRA	National regulatory agency
OQ	Operational qualification
PHA	Process hazard analysis
PLC	Programmable logic controller
PM	Preventive maintenance

PQ	Performance qualification
PQR	Product quality review
PQS	Pharmaceutical quality system
PW	Purified water
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
RO	Reverse osmosis
SIP	Sterilization in place
SMF	Site master file
SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometer
WFI	Water for injection

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

1. Pharmaceutical quality system

The quality management system was established and maintained. Production and control operations were specified in written forms and GMP requirements were essentially being met. Managerial responsibilities were specified in written job descriptions. Product and processes were monitored, and the results were checked as part of the approval process for batch release. Regular monitoring and reviews of the quality of pharmaceutical products were being conducted according to documented schedules and procedures. Controls on starting materials, intermediate products, and bulk products and other in-process controls, calibrations and validations were carried out. A change control system was in place. Deviations, suspected product defects and other problems were reported, investigated, and recorded. An appropriate level of root cause analysis was applied during such investigations. The effectiveness of CAPAs were monitored. Regular reviews of the quality of pharmaceutical products were conducted. The procedure for self-inspection was in place. Continual improvement was explained in the Quality Policy. Periodic management reviews were carried out. Quality risk management procedure was in place.

The deficiencies raised in this section have been addressed satisfactorily.

2. Good manufacturing practices for pharmaceutical products

Good manufacturing practices were generally implemented. Necessary human and physical resources with adequate premises, equipment and utilities were provided for the current operational level of FPP activity. Manufacturing processes were adequately defined and were shown to be capable of consistently manufacturing pharmaceutical products of the required quality that comply with their specifications. The manufacturing processes follow procedures as defined and documented in the BMRs and BPRs. The personnel were appropriately qualified and adequate training was conducted.

3. Sanitation and hygiene

Sanitation and hygiene procedure covering personnel, premises, equipment and apparatus, production materials and containers, products for cleaning and disinfection were in place. Potential sources of contamination were eliminated through an integrated programme of sanitation and hygiene.

4. Qualification and validation

Validation master plan

An approved validation master plan (VMP) and validation plan for 2023 were available and reviewed. The company qualification and validation policy and programme were defined and documented in the VMP.

Process validation

Process validation was performed according to an approved validation procedure. The process validation for primary packaging of RH089 Mifepristone + Misoprostol Tablet 200mg + 200mcg were reviewed and discussed.

Equipment qualification

Equipment qualification procedure was available for review. The qualification of the packaging machines in W-F-E workshop was checked and discussed.

Cleaning validation

The approach to cleaning validation mentioned in VMP was acceptable. The cleaning re-validation protocol and report reviewed for the compressing machine and deduster in the W-F-E Workshop were found to be acceptable.

Analytical methods validation

The analytical method validation for Misoprostol residue testing was performed and found to be acceptable.
The Equipment clean holding time has been defined based on validated results.

The deficiencies raised in this section have been addressed satisfactorily.

5. Complaints

The SOP "Management Procedure of Customer Communication and Complaint" was checked. Designated person from QA was responsible for handling the complaints. Complaints were classified in quality and no-quality complaints. Complaints concerning a product defect were recorded and investigated. Registers for 2022 and 2023 were checked. Complaints and other information concerning potentially defective products were reviewed according to written procedures and the corrective action were taken.

6. Product recalls

The SOP "Management Procedure of Drug Recall" was checked. A system to recall from the market, promptly and effectively, products known or suspected to be defective was in place. A qualified person was nominated for the execution and coordination of recalls. Recalls were classified into three classes. Effectiveness of the arrangements for recalls was tested and evaluated by a mock recall that was performed periodically. Recall protocol and summary report were available.

7. Contract production, analysis, and other activities

Contract manufacturing was not carried out. Several external contract laboratories were used. The testing service agreement with contract laboratories were available and checked. The contract giver and contract acceptor responsibilities were specified.

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

Written instructions for self-inspection were established to provide a minimum and uniform standard of requirements. SOP "Management Procedure of GMP Self-inspection" was checked. Self-inspection team was selected from experienced and trained staff members. List of approved self-inspectors was presented. After completion of self-inspection, a report was written, CAPAs were submitted and evaluated and if required follow up inspection was conducted.

Suppliers' audits

The SOP "Supplier Audit and Evaluation Procedure" and "Suppliers management procedure" were checked. Suppliers were categorized into different categories based on their performance. The Supplier audit schedule for 2023 was available and presented. The on-site audit report for the supplier of Mifepristone API was checked and found to be acceptable.

9. Personnel

There were organograms available for the site and other functional departments. China Resources Zizhu had an adequate number of personnel with the necessary qualifications and practical experience, job descriptions were available. The number of personnel was 504 at the time of this inspection.

An authorized person was nominated and was responsible for ensuring compliance of the product with technical and regulatory requirements. and the approval of the release of the finished product for sale or supply. Products were released for sale or supply after certification by the qualified person. The job description for Quality Director (Qualified Person (QP) was checked.

10. Training

SOP "Management Procedure of Staff Training" was checked. Training in accordance with a written programme was provided for all personnel whose duties were performed in manufacturing areas or into control laboratories. Newly recruited personnel received training appropriate to the duties assigned to them. Continuing training was given, and its practical effectiveness was periodically assessed. Approved training programs were available. Training records were kept.

SOP "Management Procedure of Analyst Training and Assessment" was checked. Analyst's competency list was available and presented to the inspectors.

11. Personal hygiene

The personnel gowning procedure was appropriate and was generally followed. Instructions and pictorials to be followed were sufficiently clear and were available in the change rooms. For new personnel including contract personnel, medical examinations were conducted before joining the company and repeated yearly. Direct contact between the operator's hands and starting materials, primary packaging materials and intermediate or bulk product was avoided. Smoking, eating, drinking, chewing, and keeping personal medicines was forbidden in production, laboratory, and storage areas.

12. Premises

Zizhu had following facilities relative to the products in the inspection scope:

- W-F-E (hormone OSD)
- W-F-E warehouse

Entrance to the W-F-E workshop was via a cascade of changing rooms. Exit from the workshop was separated from the entrance. Separate rooms were provided for storage of spare parts. The premises were designed and constructed to suit the operations for the manufacture of products in the workshop. The layout of the premises was designed to avoid the risk of contamination and cross-contamination. Production premises were seen to be clean and well maintained.

Purified water

The inspectors visited the PW generation system. Source water was potable water provided by the city. The potable water passed through multimedia filter, softener, 5μm filter, two reverse osmosis and EDI. Sampling and testing of PW were performed following the SOP "Processing water monitoring procedure". Trending was performed quarterly and annually. Alert and action limits were specified and based on historical data. PW system was seen to be clean and well maintained.

Utilities

The SOP "HVAC system management procedure" and "Operation manual of HVAC system" were checked. The building management system (BMS) was used to monitor AHU performance. BMS had audio-visual alarm system. Alarms were registered in a logbook. The AHU system was briefly visited and the AHUs for air supply and air exhaustion were checked. They were observed to be clean and well maintained.

Compressed air

The compress air suppling to W-F-E workshop was briefly checked, included the P & ID of Compress air generation system, PQ protocol and report. SOP for daily compression air routine management procedure was in place.

13. Equipment

Equipment was located, designed, and constructed to suit the operations to be carried out. The layout and design of equipment permitted effective cleaning and maintenance. Fixed pipework was clearly labelled. Balances and other measuring equipment were available for production and control operations and were calibrated. Laboratory equipment and instruments suited to the testing procedures were undertaken. Calibration labels indicated calibration date and due date were available.

14. Materials

Incoming materials were managed in accordance with SOP "Material management" and SOP "Material code management". A list of approved suppliers was available and presented to the inspectors.

Warehouses were visited during the inspection. Separate storage warehouse was provided for storage of API, excipients and packaging materials used for production in W-F-E workshop, as well as for finished products storage. Separate rooms were provided for returned, rejected materials and reagents. Quarantine areas were clearly indicated. Printed packaging materials were stored in locked location. The warehouse was seen to be clean and managed in good order.

Temperature and humidity were continuously monitored on-line and manually checked and recorded daily. Receiving and dispatch bays were separated and were protected from weather conditions.

Sampling and dispensing were carried out in LAF cabinet. SOP "Standard Operation Procedure of Sampling" was checked. Entrance to the sampling/dispensing room was via change rooms, pressure differentials were specified and recorded.

Waste from production and AHUs were stored in hazardous warehouse and afterwards sent to certified entity for destruction. The hazardous warehouse was visited during the inspection.

The deficiencies raised in this section have been addressed satisfactorily.

15. Documentation

Documents were designed, prepared, reviewed, and distributed with care. Documents were approved, signed, and dated by the appropriate responsible persons. Documents had unambiguous contents: the title, nature and purpose were stated. Documents were laid out in an orderly fashion. Reproduced documents were legible and clearly marked.

SOP "Records management procedure" was checked. The QA department was responsible for documents managements as: issuance, copying, distribution. Issuance of records was recorded in a logbook. The procedures for Batch numbering system and BMR management were checked. BMR issuance logbooks were maintained.

The deficiencies raised in this section have been addressed satisfactorily.

16. Good practices in production

Production operations followed defined procedures in accordance with marketing authorization. Deviations from instructions or procedures were investigated and CAPAs applied. Checks on yields and reconciliation of quantities was carried out.

The production and packaging area of WFE workshop were visited during the inspection. Misoprostol 200mcg Tablets were under manufacture, the batch starting material dispensing and primary packaging and secondary packaging were observed. The usage of punch and die, IPC and BMR were checked during the inspection.

17. Good practices in quality control

The QC function was independent of other departments. QC laboratories were separated from production areas. Adequate resources were available to ensure that all the QC functions are carried out. Adequate facilities, trained personnel and approved procedures were available. Sufficient samples of starting materials and products were retained to permit future examination. Samples of APIs and excipients were retained for one year after the expiry date of finished products. Samples of finished products were retained one year after the expiry date in its final pack. Retention samples were visually inspected annually. Retention samples room and stability samples rooms were seen to be clean and were in good order. Access to these rooms was limited to nominated persons.

Sample receiving and distribution

Sample register and the information for receiving and distribution were checked. The traceability of raw data was available in the sampling records.

Certificate of analysis (CoA)

SOP "Quality test and control procedure" was checked. SOP explained procedure to be followed to issue CoA. Responsible persons from QC summarized analytical data and prepared CoA. CoA was checked by another person from QC. Final approval of CoA was by QC supervisor. CoA was signed by all three persons.

OOS/OOT management

SOP "OOS/OOT investigation" was reviewed. OOS registers were maintained. OOS, OOT annual review of year 2022 was checked.

Stability study

Stability chambers for different temperature and humidity conditions were available. The monitoring records of temperature and humidity were maintained and checked. An on-going stability program was in place. The

sample withdrawal schedule was available and presented to the inspectors. The stability study procedure and protocol for PQ products were checked and discussed.

Retention samples

Retention and retained samples were kept in a secured and temperature-controlled room. The retention sample register and samples of each batch were kept. Annual check for the sample was performed according to the company procedure.

Microbiology Laboratory

Microbiological laboratory was briefly visited. The laboratory was adequately equipped and appeared to be of an acceptable standard for non-sterile products.

The deficiencies raised in this section have been addressed satisfactorily.

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, ***China Resources Zizhu Pharmaceutical Co., Ltd.,*** located at ***No.27, Chaoyang North Road, Chaoyang District, Beijing 100024, People's Republic of 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 WHO Guidelines referenced in the inspection report

1. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eight Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. ***Short name: WHO TRS No. 986, Annex 2***
   https://digicollections.net/medicinedocs/documents/s21467en/s21467en.pdf

2. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. ***Short name: WHO TRS No. 957, Annex 2***
   untitled (digicollections.net)

3. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 3.
   Short name: WHO TRS No. 1033, Annex 3
   9789240020900-eng.pdf (who.int)

4. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
   Short name: WHO TRS No. 929, Annex 4
   https://digicollections.net/medicinedocs/documents/s21440en/s21440en.pdf

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

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

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

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

9. WHO guidelines on technology transfer in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Sixth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 1044), Annex 4.
   Short name: WHO TRS No. 1044, Annex 4
   TRS 1044 - Annex 4: WHO guidelines on technology transfer in pharmaceutical manufacturing

10. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-

Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9. ***Short name: WHO TRS No. 961, Annex* 9**
https://digicollections.net/medicinedocs/documents/s18683en/s18683en.pdf

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

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

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

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

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

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

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

18. WHO Technical supplements to Model Guidance for storage and transport of time – and temperature – sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5. ***Short name: WHO TRS No. 992, Annex 5***
Essential Medicines and Health Products Information Portal (digicollections.net)

19. WHO Recommendations for quality requirements when plant – derived 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/who-recommendations-for-quality-requirements-when-plant-derived-artemisinin-is-used-as-a-starting-material-in-the-production-of-antimalarial-active-pharmaceutical-ingredients---trs-992---annex-6

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

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

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

23. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-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://digicollections.net/medicinedocs/documents/s23699en/s23699en.pdf

24. Points to consider when including Health-Based Exposure Limits in cleaning validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report

Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 2. **Short name: WHO TRS No. 1033, Annex 2**
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25. Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fourth Report Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 6. **Short name: WHO TRS No. 1025, Annex 6**
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26. Production of water for injection by means other than distillation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fourth Report. Geneva, World Health
Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 3. Short name: WHO TRS No. 1025, Annex 3
https://www.who.int/publications-detail/978-92-4-000182-4

27. Good chromatography practice. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 4. ***Short name: WHO TRS No. 1025, Annex 4***
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