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Prequalification Team Inspection Services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Active Pharmaceutical Ingredient Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**Chongqing Kangle Pharmaceutical Co., Ltd**
Corporate address of the manufacturer	No. 4 Huazhong Road, Chongqing (Changshou) Chemical Industrial Park, Chongqing 401 221, China
Inspected site	
Name & address of inspected manufacturing site if different from that given above	No.4 Huazhong Road, Chongqing (Changshou) Chemical Industrial Park, Chongqing 401 221, China
Synthetic unit /Block/ Workshop	Area A (administrative office, QC, and QA) Area B (manufacturing/production areas) 1. Building 1 (B001), Workshop No. 1, 101 production line for Piperaquine Phosphate 2. Building 2 (B002), Workshop No. 3, 301 production line for Sulfadoxine Area A: Latitude 29º48'48'', Longitude: 106º59'54'' Area B: Latitude 29.813461º, Longitude: 106.997353º
Inspection details	
Dates of inspection	29 April – 3 May 2024 24 – 27 March 2025
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	The manufacturing site comprises two areas, designated as A and B. Area A includes the administrative building, a quality control laboratory, a finished goods warehouse, a packaging material warehouse, and the R&D department. Area/building B comprises buildings used to manufacture APIs and intermediates, e.g., for Piperaquine Phosphate in 101, B001, and Sulfadoxine in 301, B002.
General information about the company and site	Chongqing Kangle Pharmaceutical Co., Ltd. was founded in 1988 and is located at No. 4 Huazhong Road, Chongqing (Changshou) Chemical Industry Park (Latitude: 29.813461 ° and Longitude: 106.997353 °), which is a national chemical industry park. The company shareholder is Tongfang Pharmaceutical Group Co., Ltd. (Tongfang Pharmaceutical Group Co., Ltd. is held by Shanxi Construction Investment Group).
History	The WHO PQ inspection services have regularly inspected the manufacturing site since October 2014, with the last inspection taking place

	in April 2024. The April 2024 inspection revealed several major deficiencies, prompting a follow-up inspection in March 2025.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: 1. Quality management system 2. Production and packaging operations 3. Personnel and training 4. Self-inspection and supplier audits 5. Laboratory areas 6. Documentation review 7. Premises and equipment 8. On-site verification of CAPA
Restrictions	None
Out of scope	The APIs and intermediates, not submitted for WHO PQ, were outside the scope of this inspection; accordingly, the respective areas were also outside the scope of this inspection.
WHO APIs covered by the inspection	1. Piperaquine Phosphate (APIMF248) 2. Sulfadoxine (APIMF496)
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 air flow
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

Part 2	**Summary of the findings and comments**

1. Quality management

The site had a formal, documented quality system that met most of the current WHO Good Manufacturing Practice (GMP) requirements for APIs. The QA and production departments were independent of each other and reported directly to the General Manager. The Vice General Manager, Quality Director, and Production Director reported directly to the General Manager. All the site procedures discussed during the inspection were in Chinese. Products and processes were monitored, and results were considered during batch release. The entire quality management system was manually managed, as no electronic system was used.

The Product Quality Review (PQR) procedure was reviewed. The PQR was prepared for the Jan-Dec period. If no batches were produced during this period, the PQR would still be prepared. If the same API has different manufacturing processes, a separate PQR would be required. If the specification is different, a common PQR would be prepared. The PQR should be completed by the end of March every year. The company produces 9 APIs and 7 intermediates. A unique number was assigned to each PQR. The PQRs of the products in question were discussed.

The SOP for Quality Risk Management (QRM) was reviewed, and tools, such as FMEA and HACCP, were described in the procedure. The logbooks were maintained for the risk analysis performed. In 2023, a total of 22 risk assessments were conducted, whereas in 2024, a total of 8 risk assessments were performed.

The data integrity management SOP was discussed. The procedure was applied to both paper-based and electronic data, describing the ALCOA principles and requirements related to access management, audit trails, data review, data storage, archiving, and backup.

The deviation investigation management procedure was discussed. The procedure defined different types of deviations:

- Minor deviation, which has no impact on the quality of the product.
- Moderate deviation, which may cause a reparable impact on the quality of the product.
- Critical deviation, which affects the quality of the product, such as reprocessing or rework.

The process for detecting, recording, and reporting deviations that occurred during production was described in the procedure, along with a decision tree.

A self-inspection management procedure was available. The topics covered were personnel, facility, equipment, materials, finished products, qualification and validation confirmation, documentation management, quality control, quality assurance, contracted activities (production and quality testing), distribution, and recalls. The self-inspection schedule for 2023 and 2024 was presented.

The CAPA management procedure was available. The procedure outlined the topics to be covered, responsibilities, process, and reporting requirements. A register for all the CAPAs handled in 2023 was available.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

2. Personnel

The job descriptions of the key personnel were reviewed and found to be adequate.

The SOP for GMP training was reviewed. The QA was responsible for approving the GMP training plan. The SOP defined five categories of training: new employee training, new post-training, regular training, retraining (in the event of deviations or out-of-specification (OOS) conditions), and continuous training. The training plans for 2023 and 2024 were presented.

The company had approximately 270 employees as follows:

- QA: 11
- QC: 41
- Production: 99
- RA: 3

- Equipment: 29
- Warehouse: 13
- R&D: 27

Following the last WHO inspection in April 2024, the manufacturer has strengthened its QC, QA, and production departments by recruiting four personnel each in QC and QA, and 13 personnel in production.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

3. Buildings and facilities

The manufacturing site was divided into two wings, A and B. Wing A primarily handled administrative activities, including the quality control laboratory. Wing B was located across Wing A on No.4 Huazhong Road, where production activities were carried out. The production activities were access-controlled. Sulfadoxine and Piperaquine Phosphate were manufactured in lines 301 and 101, respectively. The manufacturer did not have a dedicated solvent recovery plant; the materials and solvents were recovered in the production areas. Also, the company did not have solvent tank farms, as all solvents were received in drums.

Since the last WHO inspection, the manufacturer installed audio-visual alarms in the cleanrooms to prevent multiple doors from being opened simultaneously. No significant changes were made to the buildings and facilities.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

4. Process equipment

The production and packaging area featured stainless steel reactors (SSR), glass-lined reactors (GLR), centrifuges, filters, crystallizers, dryers, a multi-mill, a sifter, and other equipment. Since the last WHO inspection, the manufacturer has not purchased or installed any new process equipment.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

5. Documentation and records

The company has a paper-based documentation system. The SOP for the GMP document was available. The procedure described the architecture of the documentation system, which included SOPs, specifications, responsibilities, and the SOP numbering system (consisting of three letters for the document type, one digit for the management classification code, four digits for the serial number, and two digits for the version number). The quality director defined the document's effective date according to the training needs. The review period was every three years.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

6. Materials management

The SOP for the supplier management procedure was reviewed and recently revised to clarify the procedure. The suppliers were qualified based on the paper assessment, questionnaire, and on-site audit. The manufacturers of the critical materials (e.g., key starting materials) were on-site audited. The suppliers were reaudited once every three years. An annual supplier audit plan was prepared at the beginning of the year, and a yearly evaluation was required, followed by a rating.

There were no significant changes in the materials system since the previous WHO inspection.

7. Production and in-process controls

The inspector visited Workshop 3, B002, Production Line 301, where Sulfadoxine was manufactured. The process flow chart of Sulfadoxine submitted as part of the dossier was verified during the inspection. Sulfadoxine was manufactured in 4 stages. The inspector also visited the workshop 1, production line 101 of building 1, where the Piperaquine Phosphate was manufactured. At the time of the visit, no production activities were conducted for Piperaquine Phosphate.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

8. Packaging and identification labelling of APIs and intermediates

The final purification, packaging, and labeling activities were conducted in the cleanroom, classified as Grade D. During the visit, no packaging activities were carried out. No changes have been made since the last WHO inspection, held in April 2024.

9. Storage and distribution

The company had four (4) warehouses divided into Area A and Area B. The inspector visited Area B, where three storage rooms were located. The procedure was followed for receiving and storing the incoming materials. The inspectors visited the storage area and noted that the material offloading area was provided with a canopy/shelter as one of the corrective actions in response to the last WHO inspection held in April 2024.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

10. Laboratory controls

The quality control laboratory was located on both the first and second floors. The QC lab was staffed with a manager, an assistant manager, supervisors, and analysts. The laboratory was divided into six teams: physical/chemical testing, HPLC, GC, microbiology, GMP compliance, and IPQC lab. The first floor has a microbiology lab, a reagent preparation area, stability study chambers, and a retention sample room. In contrast, the second floor has the instrumentation room (comprising 13 HPLCs, 4 GCs, TOC analyzer, pH meter, FTIR, KF apparatus, analytical balances, Malvern Mastersizer, and others. The samples were received on the 2nd floor and logged into the registers. The product-wise logbooks were maintained. The samples were stored in the cupboards, and the temperature (15-30℃) was maintained. It was confirmed that temperature mapping was performed.

The inspectors visited the physical, chemical, and microbiology laboratories and verified the changes made since the last WHO inspection held in April 2024. In particular, it was noted that a new analytical balance had been installed and was in use, ensuring traceability. The stability chambers were installed and in use. In the microbiology laboratory, a double-door autoclave was installed, located in the Grade C area where microbial limit tests were performed.

The out-of-specification (OOS) procedure was revised to ensure no inconsistency between the procedure and the flow diagram. Since the last WHO inspection, a total of 13 OOS (11 invalid and 2 valid) were raised, and all have been closed. Training activities were scheduled to train analysts on invalid out-of-specification (OOS) results.
The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

11. Validation

The validation master plan was discussed, which provided objective, scope, responsibilities, content (validation organization, validation work procedure, scope of validation, references, methodology, acceptance criteria, requirement for validation document, validation schedule for 2024, and follow-up implementation and maintenance status. The VMP outlined validation requirements for the facility, including the utility (clean area and purified water), analytical method validation, and cleaning validation, among others. The manufacturing processes have not been validated due to no production activities in 2023. The inspectors reviewed the cleaning validation, computerised system validation, and analytical method validation.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

12. Change control

The change control management procedure was discussed. Three types of change were categorized: minor, moderate, and major. The flowchart for managing change was presented. There were two levels of changes (document changes and other changes). The quality director was responsible for approving the change request and categorizing it. The change control logbook for the document changes initiated in 2022 and 2023 for Piperaquine Phosphate was presented. The change control procedure was revised to include a document change control form and a document change control logbook. Also, the change control notification procedure was revised to provide better clarity. The requirement for impact assessment was strengthened, and additional guidance was provided. Since the last WHO inspection, a total of 59 change controls have been raised, with 57 closed and two remaining open.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

13. Rejection and re-use of materials

The company confirmed that no specific procedure was available for the blending activities. The blending was handled according to the instructions provided in the respective batch production record.

The SOP for handling the rejected materials was discussed. The procedure stated that rejected materials cannot be issued without adequate assessment, whereas rejected packaging materials should not be used.

The SOP for reprocessing and reworking was discussed. The procedure described the definitions of both reprocessing and reworking. Reprocessing was allowed when specific tests, such as loss on drying or solvents, were out of specification, and the last purification step was repeated. The reprocessed batches were subjected to additional testing and stability studies as applicable. The procedure stated that reworking was not allowed for any product.

The SOP for recovery material management was discussed, and instructions were provided on handling recovered materials and solvents. Recovered materials should be used at the same stage or an earlier stage. The number of recoveries should be defined, and recovered materials should not be used once the campaign is completed. Validation was required for the use of recovered materials and solvents.

The SOP for returning products was discussed and reviewed as part of the periodic review. There were no returns since the last WHO inspection.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

14. Complaints and recalls

The SOP for customer complaints was revised following the last WHO inspection. In particular, provisions were introduced to handle feedback, such as damaged cartons or packages, as complaints. Investigation methods were implemented, and the effectiveness of CAPA was verified. Since the last WHO inspection, no complaints have been received by the manufacturer.

The SOP for product recall was updated in accordance with the GMP guideline and drug recall management procedure to include the definition and classification of recalls. The responsibility for recall was defined, including the archiving of documents and other relevant information. No recall was executed since the last WHO inspection. A mock recall was performed.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

15. Contract manufacturers (including laboratories)

The manufacturer confirmed that no manufacturing activity for Piperaquine Phosphate and Sulfadoxine was outsourced. The XRPD test was outsourced to contracted laboratories, and it was confirmed that two approved laboratories were audited following the ISO/IEC 17025 standard.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

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, ***Chongqing Kangle Pharmaceutical Co., Ltd.***, located at ***No. 4 Huazhong Road, Chongqing (Changshou) Chemical Industrial Park, Chongqing 401 221, China*** was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines for APIs.

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 TRS No. 957, Annex 2*** http://www.who.int/medicines/publications/44threport/en/

2. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eighth Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. ***Short name: WHO TRS No. 986, Annex 2***
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

3. 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
   http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

4. 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
   http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

5. 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***
   http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

6. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1.
   Short name: WHO TRS No. 957, Annex 1
   http://www.who.int/medicines/publications/44threport/en/

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
   http://www.who.int/medicines/publications/44threport/en/

8. 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
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

9. 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
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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***
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

11. 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
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12. 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

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***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

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***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

15. WHO Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 3. ***Short name: WHO TRS No. 992, Annex 3***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

16. 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

17. 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***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

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

19. 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**
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en/

20. 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

21. 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.
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22. 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.
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25. 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 1033, Annex 3***
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

26. 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 1033, Annex 4***
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