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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	**PT SANBE FARMA (hereafter PT Sanbe)**
Corporate address of manufacturer	PT. Sanbe Farma, Sterile preparation plant Jalan Taman Sari no. 10 Bandung West Java, Indonesia
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Unit 3 Sterile Preparation Plant Jl. Industri Cimareme No. 8 Padalarang, Bandung, Indonesia
Unit/block / workshop number	Unit 3 (small volume parenteral)
Inspection details	
Dates of inspection	14-18 August 2023
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	PT. Sanbe Farma, a Sterile Preparation Plant, produces sterile products in the following forms: solution for infusion, liquid for injection, dry powder for solution for injection, eye drops, ear drops, eye ointment, fat emulsion, and medical devices. Separate units producing oncology and biological products were in the same location. The building was constructed in 2003 and started operation in 2006. The building area is 35,606 square meters.
General information about the company and site	PT. Sanbe Farma was established in 1975 in Indonesia to conduct activities related to the formulation development, production, packaging process, and marketing of medicines. PT. Sanbe Farma, Sterile Preparation Plant has its head office located in Jalan Taman Sari no. 10 Bandung West Java, Indonesia.
History	The manufacturing site has previously been inspected by WHO PQ in November 2014, February 2017, and May 2018.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	Documents reviewed included but were not limited to: o Product Quality Review o Quality risk management

	○ Complaints ○ Media fill ○ Qualification and requalification ○ Equipment calibration Areas visited: ○ Ampoule filling line ○ Ampoule washing ○ QC laboratories, including chemical and microbiological ○ HVAC and Water for injection system
Restrictions	The inspection was restricted to Oxytocin injection, 10IU/ml.
Out of scope	All other products and production facilities on the site were outside of the inspection scope and were not visited
WHO products covered by the inspection	RH050 (Oxytocin Solution for Injection 10 IU/mL)
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 airflow
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 (where applicable)**

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 met. The procedures reviewed and discussed during the inspection were generally acceptable.

The product quality review procedure was reviewed and noted that the procedure was referenced to the PIC/S GMP Guide, Indonesian GMP Guide, WHO TRS 986 Annex-2, and ISO 9001:2015. The PQR was performed annually, and the Head of Quality was responsible for reviewing and approving the PQR. Various products were reviewed based on their approval date/anniversary date. The schedule for Unit 3/SVP was available, identifying 98 products manufactured in SVP on various lines. The data for 12 months were collected, 2 months for scheduling, and 3 months for performing PQR. The SOP described the CpK criteria using Minitab.

The SOP on change management provided guidelines for handling changes in the production process, starting and packaging materials, analysis methods, equipment procedures, utilities, specifications, etc. The changes were classified into Level 1 and Level 2. They were handled using a change control form, and risk was assessed to evaluate the potential risks associated with the proposed change. Provision was made to notify the respective regulatory authorities and seek approval before implementing the proposed change. In general, the procedure for handling changes was found adequate.

The SOP on deviation investigation guided the analysis, reporting, decision, and impact of the deviations on the quality of the products. The QA manager ensured deviations were investigated and reported and appropriate CAPAs were implemented. The deviations were classified based on the criticality of the deviation, and RPN was calculated based on the severity, probability, and risk detection. The deviations were classified into critical, major, and minor. The root cause analysis was performed using the Ishikawa diagram, and 5 Whys and timelines were established for each deviation category. In general, the procedure for handling deviations was found adequate.

A procedure called “how to use tools for root cause analysis” was reviewed. It was noted that the procedure described investigation tools such as 5-Whys, Ishikawa diagram, FMEA, and HACCP. The complaint investigation was performed using the Ishikawa diagram.

The QRM was discussed. It was performed by cross-functional team members from QA, QC, production, engineering, PPIC, validation, and other departments. The procedure was recently revised, and a periodic review of QRM was added. The procedure was developed based on the ICH Q9 guideline, and risks were identified, analyzed, and evaluated. The risks were assessed using the FMEA. The risk assessment was performed based on quality defects.

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

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 MPA injection manufacturing activities. The manufacturing processes follow procedures as defined and documented in the BMRs. The personnel were appropriately qualified. PT Sanbe is a multiproduct facility wherein around 40 products containing different active substances were produced on the same ampoule filling machine together with Oxytocin injection. The existing aseptic practices were reviewed during the visit to the ampoule filling machine, and ampoule washing area. Media fill video recordings were also reviewed. The site also produces antibiotics, among other products.

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

3. Sanitation and hygiene

Clean areas were frequently disinfected following the SOP. More than one type of disinfecting agent was used. The disinfectants were sterilized before being used in Grade A and B areas. The hygiene facilities established on the site appeared to be acceptable.

4. Qualification and validation

Validations and qualifications were performed according to the site policy and documented procedures. 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.

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

5. Complaints

The SOP on product complaint handling was discussed. The complaints were received from the marketing team and logged into the logbooks. Complaints were broadly described as quality-related complaints and adverse reaction-related complaints. Before initiating an investigation, details about the product, including associated communication, were verified and supported with examples. The investigation considered raw materials, packaging materials, finished products, the environment, and other aspects. The complaints were trended annually.

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

6. Product recalls

It was noted that the company had recalled Ranitidine injection due to nitrosamine impurities in 2019 based on the instructions from the local authority, BPOM. Since then, there have not been any recalls. The mock recalls for the domestic and export markets had been performed.

7. Contract production, analysis, and other activities

Not inspected due to time constraints

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

The SOP for self-inspection was briefly discussed. According to the SOP, there were three categories of audit:

- First-party audit/ self-inspection and internal audit,
- Second-party audit/ vendor and distributor audit,
- Third-party audit/ external audit.

Self-inspection was an internal assessment carried out by the department supervisor. It was carried out monthly using the general Self-Inspection Form as guidance for all departments. The manager was responsible for checking the result and approving the corrective action. The action with the submitted evidence would be verified by the QA Inspector, and the completed Self-Inspection Form would be approved by the QA Manager. CAPA could be addressed by the same person who carried out the inspection.

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

9. Personnel

Organograms were available for the site and other functional departments. The head of quality was responsible for the quality function, including validation activities. The head of quality and SVP plant manager separately reported to the Technical Operations Director.

10. Training

The training program included induction, basic training, specific training, and continuous in-house training for all employees. The training was provided based on the updated internally developed procedures.

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

11. Personal hygiene

The SOP for the entry and exit procedure of Grade B and C production rooms was discussed. Changing and washing before entry to production areas followed written procedures. Direct contact between the operator's hands, starting materials, and primary packaging materials was avoided. The protective clothing washing and sterilization operations followed standard operating procedures.

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

12. Premises

In general, exposed surfaces of production areas were generally smooth, impervious, and unbroken to minimize the shedding or accumulation of particles or microorganisms. The IPQA personnel performed environmental monitoring of the production areas. The clean rooms for Oxytocin injection were surrounded by a Grade D corridor that gave good visibility to the ampoule filling line. In filling, the frontal view was good, but there was no view of the rear side of the machine. Also, there was no external visibility of critical aseptic operations such as dispensing, compounding, autoclaving, filtration, and other areas. Changing rooms were designed as airlocks and used to provide physical separation between the different stages of changing. Changing rooms were flushed with filtered air. The final stage of the

changing room was the same grade as the area into which it leads. Changing rooms were equipped with crossover benches and mirrors. QC laboratories for microbiological and chemical testing were separated from production areas. Entering QC was access-controlled.

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

13. Equipment

The ampoule line was a multi-purpose line that manufactured Oxytocin injection including a range of other ampoule products. The line consisted of a conventional integrated aseptic filling line from ampoule washing to filling. The ampoule line was installed with the grade A zone protected from personnel intrusion via solid barriers with glove ports (RABS). The line was operational during the audit.

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

14. Materials

Incoming materials and finished products were quarantined after receipt until they were released for use, or distribution. Starting materials and packaging materials in the scope were purchased from approved suppliers. Materials and products were stored under the specified conditions.

15. Documentation

The documentation system was paper-based and was controlled by the QA department. Documentation was generally designed, prepared, reviewed, and distributed according to a documented procedure. Approved, signed, and dated testing procedures and specifications were available for starting and packaging materials and finished products.

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

16. Good practices in production

In general, the change rooms were found adequate as separate changerooms were provided for both men and women. Adequate handwashing and drying facilities were provided before entering the controlled areas. After the second change room, an air shower facility was provided. Adequate gowning for different grades of areas was provided, also different color gowning was provided for operators working in different grades of the manufacturing areas. The Italian-made ampoule filling machine, Corima, had been in use for more than 15 years. The filling machine was equipped with three nozzles. Open-RABS and PVC curtains were used as barriers, especially extended LAF was supported with PVC curtains. Glove ports were installed from the side of the filling machine whereas no glove port was installed from the front of the machine due to the potential risk of fire due to flame used to seal ampoules. At the time of the inspection, a Trovensis injection containing Ondansetron was being produced. Two probes, one each in Grade A and B, were seen used for continuous particle monitoring. Similarly, viable monitoring

was performed, and settle plates were seen inside Grade A and B areas. Filled and sealed ampoules were manually transferred to the conveyer for labelling and packing.

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

17. Good practices in quality control

The QC laboratory was staffed with 57 personnel for physical, chemical, and instrumentation testing, whereas the microbiology laboratory was staffed with 46 personnel. The laboratory was located on the first floor of the main building, separated from the production areas. Biometric access was provided. The laboratory analyzed incoming starting materials, bulk products, finished products, and stability study samples. The incoming samples were logged in separate logbooks and assigned a unique QC ID. There were separate logbooks for microbiology and physicochemical samples. The laboratory was generally equipped with eye splashers and showers; however, adequate containment was not provided where high-potent substances were handled.

The microbiology laboratory analyzed sterility testing, microbial limit test, endotoxins, antibiotic assay etc. The sterility testing was performed under LAF with a Grade B background. Separate MAL and PAL were provided for the sterility testing area. Top-loading autoclaves were used for media Sterilization.

The retained and stability samples for Oxytocin injection were stored in the same refrigerator. As per qualification mapping, the temperature was continuously monitored using a temperature logger, and the refrigerator was equipped with an audio-visual alarm.

The deficiencies raised in this section have been 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, ***PT Sanbe Farma, located at Jl. Industri Cimareme, No. 8, Block A, Bandung Barat, 40553, Indonesia***,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 artemisin 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***
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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-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**
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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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