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Prequalification Unit Inspection Services
WHO PUBLIC INSPECTION REPORT
Finished Product Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**Shanghai Desano Bio-Pharmaceutical Co., Ltd.**
Corporate address of manufacturer	1479 Zhangheng Road, China (Shanghai) Pilot Free Trade Zone, Shanghai 201203, China.
Inspected site	
Name & address of inspected manufacturing site if different from that given above	1479 Zhangheng Road, Zhanjiang, High-Tech Park, Shanghai 201203, Peoples Republic of China
Unit / block / workshop number	Block No.2
Inspection details	
Dates of inspection	15, 18-20 March 2024
Type of inspection	Follow up and new application
Introduction	
Brief description of the manufacturing activities	Manufacturing, packaging and quality control of OSD FPPs.
General information about the company and site	Shanghai Desano Bio-Pharmaceutical Co., Ltd. is a private company founded in 2000 in Shanghai. The site was licensed by the Shanghai Drug Administration. Licensing covers FPP of solid dosage forms, including tablets and hard-shell capsules. No hormones, steroids, beta-lactams or cytotoxin products were produced on the site.
History	The site has been regularly inspected by the WHO. The last WHO on-site inspection was performed on 10 – 14 July 2023.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	• Quality management system • Production Block No.2 • Utilities • CAPAs to the deficiencies made in the last inspection
Restrictions	The scope of the inspection was restricted to the following FPPs in the WHO PQ programme.
Out of scope	Products out of prequalification

WHO product numbers covered by the inspection	**PQR number**	**Name**
	HA655	Lamivudine/Zidovudine Tablets, 150 mg/300 mg
	HA658	Efavirenz Tablets, 600 mg
	HA694	Dolutegravir (Sodium) Tablets, 50mg
	HA749	Atazanavir (sulfate)/Ritonavir Tablets, 300 mg/100 mg
	HA746	Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablets, 50mg/300mg/300mg (DTL)

	HA787	Ritonavir Tablets, 100mg
	CV019	Molnupiravir Capsules, hard 200mg
	CV026	Nirmatrelvir Tablet + Ritonavir Tablet, 150mg + 100mg

Abbreviations	**Meaning**
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
APS	Aseptic process simulation
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
CFU	Colony-forming unit
CIP	Cleaning in place
CoA	Certificate of analysis
CpK	Process capability
DQ	Design qualification
EDI	Electronic deionization
EI	Elementary impurity
EM	Environmental monitoring
FMEA	Failure modes and effects analysis
FPP	Finished pharmaceutical product
FTA	Fault tree analysis
GMP	Good manufacturing practices
GPT	Growth promotion test
HEPA	High efficiency particulate air
HPLC	High performance liquid chromatography (or high-performance liquid chromatography equipment)
HVAC	Heating, ventilation and air conditioning
IQ	Installation qualification
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
MF	Master formulae
MFT	Media fill Test
MR	Management review
NC	Non conformity
NCA	National control authority
NCL	National control laboratory
NRA	National regulatory agency
OQ	Operational qualification
OOS	Out of specifications
OOT	Out of trends
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 were reported, investigated, and recorded. An appropriate level of root cause analysis was applied during 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. Periodic management reviews were carried out. A 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 procedures covering personnel, premises, equipment and apparatus, production materials and containers, and products for cleaning were in place.

4. Qualification and validation

The company validation policy and key elements of the qualification and validation programme were defined and documented in the validation master plan (VMP). Follow-up of VMP plan execution was reviewed in the MR meeting. Process revalidation and utility requalification including PW, HVAC and compressed air were required to be performed periodically.

Process validation

Process validation was performed according to an approved validation management procedure. The process validation of CV019 Molnupiravir 200 mg capsules and HA749 Atazanavir (sulfate) /Ritonavir Tablets, 300 mg/100 mg_were reviewed and discussed. The CAPAs to the deficiencies in respect of process validation made in the last WHO inspection were verified.

Equipment qualification

Equipment qualification procedure was available for review. The qualification of the tablet compression machine and primary packaging machine in the production block was checked and discussed.

Cleaning validation

The cleaning validation procedure, cleaning validation protocol and report for the compressing machine and granulator were reviewed were found to be acceptable.

Analytical methods validation

Analytical method validation for Dolutegravir residue testing and for the related substance of Nirmatrelvir tablets were performed and found to be acceptable.

Computerised system (CS) validation

Computerized systems were used in the QC laboratory, QMS and material management. HPLC and GC were networked by CS, and the company had the data integrity controls in place for the systems. Production equipment was generally reliant upon the manual setting of set points on PLC systems rather than the use of recipe-based systems.

Computerized system validation was not reviewed in detail due to time constraints.

HVAC system

The procedures for clean area environmental monitoring were checked. After the previous inspection, action and alert limits were tightened for TAMC. The AHUs used for air supply to the tablet compressing rooms were spot checked. The management procedure for air conditioning in the production area was discussed.

Water system

The water system located in the production building was visited. The PW was produced by double RO followed by EDI in ambient temperature. The sanitization to the system was performed regularly. The flow velocity, conductivity and TOC were monitored online. The annual review of the purified water system was performed and reviewed.

Compressed air

The compressed air system was visited. The procedure for compressed air monitoring and the report for installation and operation of compress air system were checked. Microbiological sampling and analysis were carried out from sampling points in contact with products.

5. Complaints

The procedure for customer complaint management was checked. QA personnel was responsible for handling the complaints. Complaints were received by the marketing department. A final decision was QP's responsibility. Complaints were classified as:

- Critical
- Major
- Minor

Consideration was given to whether other batches were also affected, and recall should be initiated. The complaint registers of 2023 and 2024 were maintained. Complaints were checked.

6. Product recalls

The procedure for product recall was checked. Recalls were classified as:

- Class 1 – recall within 24 hours
- Class 2 – recall within 48 hours
- Class 3 – recall within 72 hours

There were no recalls recorded. According to the SOP mock recall should be performed annually.

7. Contract production, analysis and other activities

The SOPs for contract production and contract laboratory were available. Manufacturing of PQ products was not contracted out. An approved list of contract laboratories was presented. Contract giver and acceptor responsibilities were clearly defined.

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

The procedure for self-inspection was checked. The procedure specified the departments/items should be inspected. The annual self-inspection plan was available. A Self-inspection report was checked. After completion of the self-inspection the report was written, CAPAs were proposed by inspected departments and evaluated by QA.

Supplier's audits were performed according to the procedure for Supplier management. According to the procedure checked, suppliers were classified as critical vendors and other suppliers. Risk assessment was used to determine which type of audits should be performed. Supplier's audit schedule for 2023 and 2024 was checked.

9. Personnel

Desano had an adequate number of personnel with the necessary qualifications and practical experience. Job descriptions were available. 216 staff work for the site at the time of this inspection.

The authorized person was nominated and was responsible for compliance with technical or regulatory requirements related to the quality of finished products and the approval of the release of the finished product for sale or supply. Steps were taken to prevent unauthorized people from entering production, storage and QC areas.

10.Training

The procedure for training management was checked. GMP and job-specific training according to the written procedure and schedule was provided to all personnel. Newly recruited personnel received training appropriate to the duties assigned to them. Approved training programmes were available, training records were kept. Training effectiveness was evaluated.

11.Personal hygiene

The procedure for personnel hygiene management was checked. Personnel was trained in the practices of personal hygiene according to the written procedure. Any person shown at any time to have an apparent illness or open lesions that may adversely affect the quality of products was not allowed to handle starting materials, packaging materials, in-process materials or medicines. Direct contact was avoided between the operator's hands and starting materials, primary packaging materials and intermediate or bulk products. Personnel wore clean body coverings including hair covering. Smoking, eating, drinking, chewing, and keeping plants, food, drink, smoking material and personal medicines were not permitted in production, laboratory and storage areas.

12.Premises

Premises were located, designed, constructed, adapted and maintained to suit the operations to be carried out. The layout and design of the premises minimized the risk of errors and permitted effective cleaning and maintenance.

Production operations were carried out in Production Block No.2. It was suitably designed and constructed to facilitate manufacturing and good sanitation. A logical flow of materials and personnel was ensured. Electrical supply, lighting, temperature, humidity and ventilation were appropriate.

Storage areas appeared to have acceptable capacity for the current range of products being handled. Segregation was provided for the storage of rejected, recalled, or returned materials or products. Safe and secure storage was provided for printed packaging materials.

QC laboratories were separated from production areas. QC laboratories were designed to suit the operations to be carried out. Sufficient space was given to avoid mix-ups and cross-contamination. Suitable storage space for samples, reference standards, solvents, reagents and records were provided.

The microbiological laboratory (MBL) was separated from the QC laboratory and had separate rooms for working with live cells and microbiological tests. Relevant SOPs and photos of entry procedure were on display.

13.Equipment

Equipment was located, designed, constructed, and maintained to suit the operations to be carried out. Current drawings of critical equipment and support systems was maintained. Fixed pipework was clearly labelled to indicate the contents. Balances and other measuring equipment of an appropriate range and precision were available for production and control operations and were calibrated according to a fixed schedule. Production equipment was cleaned according to a fixed schedule.

Laboratory equipment and instruments suited to the testing procedures undertaken. UV and IR instruments were stand-alone; HPLC/GCs were connected with a computerised software. The calibration schedule for QC lab equipment was checked.

14.Materials

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

Starting and packaging materials for drug products and FPP were stored in different warehouse rooms. They were managed by a computerized system. The procedures for staring material and packaging materials receiving and delivering, as well as the procedure for the computerized system for material management were checked. The CAPAs to the deficiencies made in the last inspection were verified.

15.Documentation

Documents were designed, prepared, reviewed and distributed with care. Documents were approved, signed and dated and had unambiguous contents. Documents were regularly reviewed and kept up to date. Records were made or completed when any action was taken.

The procedures for product batch numbering system and for batch record management were reviewed. BMR/BPR and Laboratory work sheet issuance was controlled. Batch manufacturing records and batch analysis records were checked by QA by using checklists.

Specifications were available for starting and packaging materials, intermediate and finished products. The procedure for audit trail review in QC laboratory and the procedure for laboratory documentation was checked with a focus on the CoA issuance procedure.

16.Good practices in production

Production operations followed clearly defined procedures in accordance with manufacturing and marketing authorizations. Handling of materials and products, such as receipt and cleaning, quarantine, sampling, storage, labelling, dispensing, processing, packaging and distribution were done in accordance with written procedures and instructions and recorded. Checks on yields and reconciliation of quantities were carried. During processing materials, bulk containers, major items of equipment, rooms and packaging lines being used, were labelled with the product or material being processed, its strength and the batch number. In-process controls were performed within the production area.

Entrance to the production floor was via change rooms, relevant SOPs and photos of entry procedure were on display. Entry to dispensing, compression, granulation, blending, coating, and primary packaging was via additional airlocks. Airlocks were interlocked. Pressure differentials and T&RH were online monitored by the EMS system and manually recorded in BMRs. Procedures were in place to avoid mix-ups and contamination and cross contamination. Periodic environmental monitoring of production areas was carried out. The procedure for return product handling was checked. The SOP was revised after the inspection.

17. Good practices in quality control

Adequate facilities, trained personnel and approved procedures were available for sampling, inspecting, and testing of starting materials, packaging materials, and intermediate, bulk, and finished products, and where appropriate for monitoring environmental conditions. Records were available demonstrating that required sampling, inspecting and testing procedures have been carried out and that deviations have been recorded and investigated. Out-of specification results obtained were investigated in accordance with an approved procedure.

Stability testing

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.

Retention sample

Retention samples were kept for each of every batch of FPP products at the specified condition. The annual inspection records to retention samples were maintained and checked.

OOS and OOT management

The procedure for handling OOS and the procedure for handling OOT were checked. The OOS procedure was applicable to APIs, finished products, IPC samples, raw materials, stability studies, packaging materials, cleaning samples, PW and compressed air samples. OOS registers and OOT registers were checked.

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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, ***Shanghai Desano Bio-Pharmaceutical Co., Ltd.,*** located at ***1479 Zhangheng Road, China (Shanghai) Pilot Free Trade Zone, Shanghai 201203, Peoples 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 GMP 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://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1010-annex8-who-gmp-heating-ventilation-airconditioning.pdf?sfvrsn=c77698e2_0

6. 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
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7. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-seventh Report, Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1052), Annex 4.
Short name: WHO GPPQCL Guidelines, TRS No 1052, Annex 4
https://www.who.int/publications/i/item/9789240091030

8. 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

9. 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

10. 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

11. 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***
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12. General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-First Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3. ***Short name: WHO TRS No. 943, Annex 3***
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13. WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2.
Short name: WHO TRS No. 961, Annex 2
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Short name: WHO TRS No. 981, Annex 2
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15. WHO guidelines on variation to a prequalified product. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 3.
Short name: WHO TRS No. 981, Annex 3
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16. WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14.
Short name: WHO TRS No. 961, Annex 14
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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

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

19. 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)

20. 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

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***
TRS 1033 - Annex 4: WHO Guideline on data integrity

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
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23. 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
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24. 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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25. Points to consider when including Health-Based Exposure Limits in cleaning validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 2. **Short name: WHO TRS No. 1033, Annex 2**
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26. Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fourth Report Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 6. **Short name: WHO TRS No. 1025, Annex 6**
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27. Production of water for injection by means other than distillation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 3. ***Short name: WHO TRS No. 1025, Annex 3***
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