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Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)

Active Pharmaceutical Ingredient Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	MSN Life Sciences Private Limited, UNIT II
Corporate address of manufacturer	MSN House Plot C-24, Industrial Estate, Sanath Nagar, Hyderabad-500018 T.S. India
Inspected site	
Name & Address of inspected manufacturing site if different from that given above	MSN Life Sciences Private Limited, Unit-II, Sy. No: Parts of 454, 455, 457, 458 & 459, Chandampet (Village), Shankarampet-R (Mandal), Medak District, Telangana, Pin code: 502 255
Block/ Workshop	Block A, C, D, E, G, H & I
Manufacturing license number	17/MD/TS/2014/B/G
Inspection details	
Dates of inspection	22-26 August 2022
Type of inspection	Initial Inspection (New site)
Introduction	
Brief description of the manufacturing activities	• Manufacturing and quality control of Intermediates and APIs: • Peptide Research & Development and Peptide Manufacturing (Dedicated facility)
General information about the company and site	MSN Life Sciences Private Limited, Unit-II belongs to the MSN Group of companies. The facility responsible for the manufacturing of APIs and intermediates was established in 2014. According to the company's information, no beta-lactam antibiotics and high-potency drug substance are manufactured on the site.
History	The current inspection was the initial WHO inspection.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	• Quality management system • Block: A, D &H • Quality Control laboratories: Physical, chemical and microbiology labs • Utilities: Water and HVAC system • Warehouses

Restrictions	The inspection was restricted to the production of the products listed in the inspection scope.
Out of scope	All other products and production facility on the site were outside of the inspection scope and were not visited.
WHO APIs (including WHO API or APIMF numbers) covered by the inspection	APIMF 381 Darunavir APIMF 448 Bedaqualine
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
WFI	Water for injection

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

1. Quality management

A documented system for quality assurance was established, with procedures covering key quality elements in place. Operations were specified in written form and critical GMP requirements were essentially being met. The quality system allows for corporate and site QA SOPs. Most of the quality management procedures were managed at the corporate level since 2021. The procedures reviewed and discussed during the inspection were generally of an acceptable standard.

Annual Product Quality Review (PQR)

SOP for Product Quality Review was reviewed. The APQRs of Bedaqualine API/2020 and Darunavir API/2021 were reviewed. The two APIs in the inspection scope have not previously been PQed at the time of this inspection. WHO grade of the API products have not been supplied to the market.

Quality Risk Management (QRM)

A quality risk assessment system had been established. The procedure for QRM, the risk assessment protocol and the report for Darunavir production was reviewed and found acceptable.

Management review

The company has established a management review system. The Management Review procedure, the minutes of meetings and the management review reports for Jan-Jun 2022 were reviewed and found to be acceptable.

OOS and OOT management

Several procedures for OOS and OOT management and the 2021 OOS/OOT annual review were checked and found to be generally acceptable.

Deviations

Deviation management procedure and deviation investigation records for the two APIs in the inspection scope were checked and found in general to be acceptable.

CAPAs

CAPA management procedure and the CAPA for an OOS Report were reviewed and found acceptable.

Product release

The procedure for batch release and the procedure for handling batch production records and analytical raw data, as well as the release of a batch of Darunavir Amorphous, were reviewed and found acceptable.

2. Personnel

The MSN Unit II had a total of 784 staff members on the whole site. An organigram of the MSN company was presented. For the activities of Unit II, the number of personnel appeared adequate for the present activities on the site. The key personnel of the various departments and staff met during the inspection appeared adequate in education and experience to their jobs. The site head took full operational responsibility for Unit II. The positions of the head of production and head of quality were separate with independent responsibilities. Job descriptions of the site Head, QA head and QC head were reviewed and found to be acceptable.

Training

The company has a training centre for staff training available in the QC section. Analysts training was checked. No objectional comments was made.

3. Buildings and facilities

Production blocks

MSN Unit II site was designed in different blocks for manufacturing activities. The synthesis, purification, and packaging of the two APIs in the inspection scope took place in a non-dedicated facility and shared with other chemical products. Several procedures to avoid contamination and cross-contamination during production were reviewed. Blocks A, D and H relevant to the production of Darunavir API and Bedaqualine API were inspected. They were maintained at an acceptable level in general.

Water system

The water system was visited. The P&ID of the water system was checked. TOC, PH, and conductivity were monitored. The sampling and testing for the water as the source of water for production was discussed. The purified water APQR-2021 and standard testing procedures and testing results were reviewed. An alarm logbook was available for the water production area. Micro alert limit and action limit were specified.

Air Handling Unit

The company had procedures and reports for environmental control and the Air Handling Units testing for the clean room in Block A was in place and found acceptable. HVAC verification was performed periodically. The daily monitoring of the clean rooms, temperature, relative humidity, and differential air pressures were performed and found to be acceptable.

Computerized systems

Computerized systems were not used for material management or production control.

A computer system was used in the QC lab for HPLC and GC networking. The QC analytical instruments utilized primarily Empower 3 and Lab Solutions BD computerized software systems. The SOP for electronic data back-up, retrieval and disaster recovery was in place. The validation was not checked in detail in this inspection.

4. Process equipment

The process equipment installed in the production blocks was for multi-purpose manufacturing and was in general adequality labelled with unique identification numbers. The procedures, protocols, and records for equipment qualification and requalification were available. The requalification was performed periodically. A tray dryer used in Block A was reviewed for temperature mapping which showed uniform distribution.

The company had an equipment preventative maintenance procedure, plan and schedules. The maintenance record of a centrifuge was checked.

Equipment calibration for a balance in the finished goods warehouse was checked and found to be acceptable.

5. Documentation and records

Documentation system

The company had a documentation system established as an essential part of Quality Assurance.

Documentation was designed, prepared, reviewed, and distributed according to a documented procedure. Documentation was managed through manual and electronic procedures for different types of documents. Master Documents and records for production, QA/QC were adequately controlled and were archived in QA. The management of documents was in general acceptable.

Batch numbering system

A batch numbering procedure was in place. Batches reprocessed, and reworking/recovered were indicated in the batch number. Several SOPs as below were reviewed and found to be acceptable generally.

- SOP for the batch numbering system.
- SOP for the handling of batch production records and analytical raw data
- SOP for assigning manufacturing date and retest/expiry period.

6. Material management

The company had procedures in place to manage the reviewed incoming raw materials and packaging materials. QC sampled materials from the sampling room in the warehouse and recorded in the sampling logbook. Different raw materials, and packaging materials for API products were stored in different warehouses with temperature and humidity control if required. A manual based system for inventory material management system was used. Warehouses including RM, packaging materials, solvent tank farm, active carbon room and finished API warehouse were inspected during the inspection.

Raw Material Warehouse

Incoming raw materials were placed under quarantine after receipt until they were released for use or distribution. The materials sampled by QC for testing had sampling labels attached to the containers. The company used a manual procedure for the control of the raw materials. Temperature mapping was performed and monitoring was in place. QC rejected the material store had no material kept during the time of the inspection and was locked. The register was available for rejected material.

The solvent tank farm was visited and found to be acceptable. Colour coding and identification of solvents were in place. Solvent transfer hoses were protected from contamination.

Supplier approval

The procedure for the qualification and approval of suppliers was reviewed. The procedure described the procedure for new suppliers, renewal, and cancellation of approval. The supplier audit report for the supplier of a key starting material for Darunavir API was reviewed and discussed.

7. Production and in-process controls

The production process of the Darunavir and Bedaqualine took place in the specified production blocks by following the process submitted in the dossier. Key starting materials were synthesized on-site and obtained from approved suppliers.

The documentation for manufacturing & packaging batch records for process validation of Darunavir was reviewed and found acceptable. The CoA was checked against the QC results in the BMR for correctness. The batch production records for Darunavir API reviewed were found to be acceptable.

8. Packaging and identification labelling of APIs and intermediates

Packaging materials

Packaging materials were appropriately stored and subjected to quality control testing before release. The company used approved suppliers of primary and secondary packaging.

Packaging and labelling operations

Packaging and labelling were not in operation at the time of inspection. Labelling and packaging management procedure and packaging and labelling operations were checked in batch packaging records and discussed.

9. Storage and distribution

Finished API product warehouse

The warehouse access was controlled. Products were labelled as "approved" or "under test" (quarantine). The area was under temperature control. The returned and rejected final product material store was locked. Several Bedaqualine API batches were seen in the warehouse and their status label was checked and discussed.

Distribution procedures

APIs and intermediates were released for distribution after they had been released by QA. Darunavir and Bedaqualine API release specifications for different markets with different quality grades were in place.

10. Laboratory controls

General controls

The company had an organized and suitably equipped QC laboratory for starting material and API testing. The QC facility consisted of the wet chemistry laboratory, the chromatography laboratories, the stability study chambers and the retention and reference sample area. The microbiology testing area was separate from the chemical analyses.

Sampling and testing of intermediates and APIs

Sampling and testing activities were performed by following several approved procedures according to approved material/product specifications. No testing was conducted during the inspection in the wet chemistry section.

The chemistry laboratory had procedures in place with acceptable labels for the equipment regarding calibrations. Access to the instrumentation, audit trail, and USB port access was spot checked and found acceptable.

The column register showed that the dedicated column was used for Darunavir HPLC analyses. The column register and the column performance procedure were available and discussed.

Stability study

The stability chambers were locked and secured with additional electronic pad pass-code control. The chambers had a response alarm upon failure of a chamber and regular alarm challenges were performed. The qualification and preventative maintenance for the stability chambers in different temperatures and relative humidity conditions were performed periodically. The register for each chamber indicated which products were placed on stability. The WHO stability batch of Darunavir API and stability samples for ongoing stability were viewed.

Reference Standards

The procedure for the management of reference standards was reviewed and discussed. The primary reference substance and preparation of reference working standards of Darunavir were checked.

Microbiological laboratory

The Microbiological laboratory is restricted to authorized personnel only. The laboratory activities, such as media preparation, testing, incubation, and enumeration of microorganisms etc. was viewed from the corridor. The procedure and record for the microbial limit test of PW water were spot checked.

11. Validation

Validation master plan

An approved VMP was available and reviewed. The qualification and validation policy and programs were defined and documented.

Process validation

Process validation was performed according to the in-house validation procedure.

Darunavir Amorphous

The process validation of Darunavir Amorphous (WHO grade) and Darunavir API micronization PV was performed. The relevant PV protocols and reports were reviewed and were generally acceptable.

Bedaqualine API PV

Process validation including manufacturing and packaging of Bedaqualine API and Bedaqualine API micronization PV were reviewed together with validation batches' BMRs and BPRs. The risk assessment performed for Bedaqualine PV was reviewed and found to be generally acceptable.

Cleaning validation

The company had a cleaning validation policy, supported by procedures, protocols and records. The procedure for cleaning validation and the cleaning validation report, cleaning records for the equipment used for Darunavir's final manufacturing process conducted in the clean room were reviewed and found acceptable.

Analytical method validation (AMV)

An AMV report on impurity content in Darunavir generated by R & D unit at another site was checked and discussed.

12. Change control (CC)

Changes were managed according to the SOP for change control and the SOP for handling temporary change. The CC registers for 2021 and 2022 were available for review. Several CCs in respect of documents, testing method, equipment, and production for the APIs in the inspection scope were reviewed and found to be generally acceptable.

13. Rejection and re-use of materials

Rejection

The company has procedures for rejected material and re-use of materials in place for review.

Reprocessing and reworking

The SOP for reprocessing and reworking was reviewed. The procedure allowed reworking but stated that the reworking batch shall not be dispatched to regulated markets and customers.

Recovery of material

The SOP for the recovery of solvents and materials was reviewed. The company stated that in the manufacturing of Darunavir API, no recovered solvents or recovered materials are used in the API's manufacturing process.

14. Complaints and recalls

The company had procedures for handling complaints and recalls. The QA department was responsible for handling complaints and recalls. The recall procedure had the classifications (critical, major, minor), times lines for the investigation, communications and share information with customers and regulatory authorities, CAPA, reconciliation of product recalled and closing of the event. Mock recalls are performed periodically.

The product APQR reported no complaints and recalls for Darunavir API during 2020-2022. No complaint or recall for Bedaqualine API of WHO grade as it has not been approved and supplied to markets at the time of this inspection.

15. Contract manufacturers (including laboratories)

There was no contract manufacturing that took place for the two APIs in the inspection scope. The company had a qualification system for suppliers and procedures for contract service providers. Register for approved testing laboratories exist. Testing laboratory Register showed that other MSN sites were involved in the testing of the Darunavir API product.

Part 3	**Initial 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, ***MSN Life Sciences Private Limited Unit-II*** located at ***Sy No: *Parts of 454, 455, 457, 458 & 459, Chandampet (Village), Shankarampet-R (Mandal), Medak District, Telangana, 502255, India*** was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines.

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

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

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

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

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

3. WHO guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report. Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 9. ***Short name: WHO TRS 1010, Annex 9***
https://digicollections.net/medicinedocs/documents/s23457en/s23457en.pdf

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23. WHO Recommendations for quality requirements when plant – derived artemisin is used as a starting material in the prosecution of antimalarial active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 6
Short name: WHO TRS No. 992, Annex 6
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

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

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

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

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