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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	Sequent Scientific Limited
Corporate address of manufacturer	Corporate: 301, 'Dosti Pinnacle', Plot No. E7, Road No.22, Wagle Estate Industrial Area, Thane(W), Mumbai – 400604, India
Inspected site	
Name & Address of inspected manufacturing site if different from that given above	Sequent Scientific Limited Plot no: B-32, G-2&G-3, MIDC, Mahad, Dist. Raigad -402309, Maharashtra, India
Synthetic Unit /Block/ Workshop	Plant 1, Plant 2 and Plant 3
Inspection details	
Dates of inspection	29 August - 02 September 2022
Type of inspection	Initial inspection (New site)
Introduction	
Brief description of the manufacturing activities	Production, quality control of intermediates and API products.
General information about the company and site	Sequent Scientific Limited (Mahad site) was established in the year of 2001. It is one of the Sequent Scientific Group of company. No beta-lactam antibiotics and high potent drug substances are manufactured on the site.
History	This was the initial WHO GMP inspection.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	• Quality management system • Production blocks • Solvent recovery plant • Warehouses • Physical and chemical quality control laboratory • Microbiology laboratory • Water system

Restrictions	The inspection was restricted to the production of the product 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 427 Albendazole
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**

1. Quality management

The quality management system was generally well established, documented and implemented. The site organizational structure was presented and was acceptable. Quality-related activities were defined and documented. The quality assurance department was independent from production. The persons authorized to release products were specified.

Annual Product Quality Review (PQR)

The Company had a procedure for annual product quality review. The APQR was required to be prepared from January to December and the compilation was to be completed before the end of March of the subsequent year in principle.

At the time of the inspection, Albendazole API has not been prequalified by PQ. The APQRs for Albendazole 2021 and 2020 for the other quality grades were reviewed. The Company utilized one manufacturing process to produce API with different quality specifications supplied to commercial markets. The list of testing parameters differs based on the customer requirements or pharmacopeial (EP/BP/USP/IP) specifications. The APQR reported the key elements for the review period and was in general acceptable.

It was noted that the stability study data for Albendazole batches applied for WHO PQ were generated at another site: Sequent Research Limited located at 120 A&B, Industrial Area, Baikampady, New Mangalore – 575 011, India.

Quality Risk Management

Quality risk management and risk assessment was handled and performed according to an approved procedure. Risk assessment register for 2021 was checked and discussed.

Management review (MR)

Quality management review followed an approved procedure. MR meeting minutes dated July 2022 and the presentation prepared for the meeting were reviewed and found to be generally acceptable.

Deviations

Deviations were managed according to an approved procedure. The procedure and deviation management in Albendazole APQR 2021 were reviewed and found generally acceptable.

CAPAs

The CAPA events were handled with an established procedure. The QA department was responsible for issuing the CAPA number. The review of the CAPA register, CAPA effectiveness and trending of CAPA were performed. The CAPA procedure and flow chart depicted the steps leading change control raised to inform permanent changes.

Product release

The QA department was authorized to release the finished API batches manufactured at the Mahad site. The SOP for API product batch release and dispatch were reviewed and discussed.

Internal Audits:

The procedure for internal audits described the audit plan and the requirement for audits to be conducted. The audit form was used and included the check points to be audited for each department which was found acceptable.

2. Personnel

Personnel qualifications

An organization chart was available. 370 people were employed by the company at the time of the inspection. There appeared to be a sufficient number of personnel for the current manufacturing activities. Personnel were qualified through qualifications, experience, and training. Responsibilities in position descriptions for key personnel were reviewed. The positions of the Head Production and Head Quality were separate with independent responsibilities.

Training

The procedures for training and assessment of staff were reviewed and found acceptable. Training program for staff was in place with criteria for trainers established. The training protocol and record for an analytical analyst reviewed showed that the analyst met the criteria and was deemed competent to perform HPLC analyses.

Personnel hygiene

Personnel were required to wear protective clothing suitable for the type and stage of manufacturing. Suitable sanitation and change room facilities were provided.

3. Buildings and facilities

Design and construction

The buildings and facilities inspected were generally designed and constructed to facilitate cleaning, maintenance, and operations as appropriate to the type and stage of manufacture. Manufacturing areas provided adequate space for the placement of equipment.

Albendazole API manufacturing took place within three separate production plant units. A Grade D clean area was located in one of the plants for the final drying and packaging activities. The recovery of solvents was performed in the distillation facility on the site.

HVAC System

The company had established procedures for environmental control. The following documents were checked and found acceptable.

- The SOP for HVAC re-qualification for the ISO 8.
- The HVAC P&ID
- The qualification an AHU with the parameters results which supported the re-qualification of the AHU for ISO 8 criteria.

Water System

Purified water (PW) was used in the production and QC laboratory and PW was not used in the final purification stage of Albendazole API manufacture.

Portable water was supplied by the local government. The PW Generation and Distribution P&ID was checked. The company had sampling points for the generation and distribution system as indicated on P&ID. The detailed sampling plan was available for each sampling point. The re-qualification of PW system and the annual purified water monitoring report was check and was found acceptable.

Containment

The final synthesis, purification, and packaging of Albendazole API took place in a dedicated facility.

Lighting

The lighting in all warehouses and production areas, and the QC laboratory was suitable.

Sanitation and maintenance

All areas inspected were clean and appeared to be well maintained.

4. Process equipment

Equipment used in the manufacture of Albendazole API was dedicated and appeared to be of appropriate design and size for its intended use, cleaning, and maintenance. In general, equipment appeared to be well maintained. Measuring equipment was required to be labelled with its calibration status and all examples viewed were within their calibration dates.

The company had a preventive maintenance and serving procedure for equipment in place and was prepared annually and generated by SAP. The records were kept by the engineering department. The cleaning of the dust extractor collector filters was checked. The cleaning was required to be conducted on a regular basis and the integrity check for the filters should be covered.

5. Documentation and records

The company had corporate QA procedures for good documentation practices. The site had procedures and record control established. A procedure for the preparation, revision, and distribution was in place. Appropriately designed forms were used for the management of documents and records. QA department was responsible for the document control and retention of archival documents. The procedure for the disposal of documents was reviewed and found acceptable.

Batch numbering system

The batch numbering system was reviewed. There were several product codes assigned to Albendazole APIs corresponding to the different quality specifications.

Batch manufacturing and packaging records

BMR documents were prepared, reviewed, and approved according to written procedures. QA was responsible for the review of records and approval for the release of API batches produced. The SOP for issue and retrieval of batch manufacturing and packing record was reviewed and discussed.

Several BMRs of Albendazole API were briefly reviewed. The quantity of input materials was recorded and verified. The instructions were provided for the operators. The manufacturing activities were verified by the production supervisor. The holding time of the materials and in-process control were checked and discussed.

6. Materials management

The material management system was in place for the receipt and tracking of inventory. Starting materials and finished goods were stored in a dedicated area within the warehouse. There was a tank farm for the receipt of solvents and an external drum store. These appeared to be tidy and well managed and appropriately labelled. The raw material warehouse and finished goods warehouse were visited during the inspection.

Raw Materials

Procedures were established for managing all starting materials and packaging materials, received by approved suppliers. The company utilized the SAP system for materials management. The quarantined, approved and rejected material status were applicable and indicated by affixed labels.

The rejected raw material storage area was secured, no materials were stored in the area during the inspection. The rejected/returned raw material registered was checked and discussed.

Finished Products

There were two finish product warehouses on the site. The temperature was controlled below 25^0C. The products stored during the inspection had customer dispatch labels.

Vendor qualification

A qualification system for starting material suppliers had been established. The procedures for the supplier audit and the quality agreement with suppliers were available. A supplier audit report for key staring material and the quality agreement were checked and found acceptable.

7. Production and in-process controls

The production was in operation at the time of inspection. The production block Plant 1, 2 and 3 were visited. The manufacturing processes of Albendazole API were performed and recorded according to instructions in the batch production records. The SOP for blending batches was reviewed and discussed.

8. Packaging and identification labelling of APIs and intermediates

The primary packaging operation was carried out in a Grade D environment. The labelling of the API was performed according to an approved procedure. The finished API product was packed in HDPE polybags and Fibre drums. The drums were sealed with unique seal number. Product labels were attached to the drums.

9. Storage and distribution

The APIs and intermediates were stored in a designated warehouse and held in quarantine until released for distribution by QA department.

10. Laboratory controls

The company had an established QC laboratory with wet chemistry, chromatography, and separate microbiology laboratory. Sample receiving and distribution, retention sample room were spot checked during the inspection.

Physical and chemical Laboratory

The laboratory operations had the LIMS electronic management system, however the analytical instruments were all managed as standalone equipment, and data was manually transferred to LIMS. The chromatographic analyses procedure for integration and the HPLC analysis for WHO grade Albendazole batch were checked.

The data integrity management procedures were established, e.g. the instrument procedure for access management, project creation, roles/privileges and audit trial review which was reviewed and discussed. The calibration status of the QC equipment was spot check, and found acceptable.

OOS and OOT management

The procedure for OOS and OOT was reviewed. A flow chart outlined the steps for investigations. Trending was performed for OOS events. The OOS register and the investigation of an OOS of a Albendazole batch (IP) were reviewed and discussed.

Microbiology laboratory

The company had a small microbiology laboratory established. It was briefly visited. The PW microbiological limit test was checked. The results for the annual microbiological monitoring for purified water were discussed.

11. Validation

Validation policy

The validation policy was described in the VMP. The company had validation policies, procedures established and documented validation records.

Process Validation

The SOP for process validation was in place and reviewed. The process validation protocol and report for Albendazole API with three process validation batches were reviewed. The PV protocol and report for Albendazole micronization were also checked and discussed.

Cleaning validation:

The equipment line was dedicated for the Albendazole production. The SOP for cleaning validation, the cleaning validation protocol and report of Albendazole were reviewed during the inspection.

The periodic cleaning procedure of the equipment used for manufacturing of Albendazole was checked. The procedure defined the conditions and requirements for a complete equipment cleaning to be performed.

Analytical Method Validation

The analytical method validation for EP Grade Albendazole was available as described in the protocol and report. This validation was performed at Mangalore Site. The transfer of the analytical method was discussed.

Computerised Systems:

The company had a SAP system for material management and QC laboratory LIMS with Server and Acronis Cloud Backup procedures. The validation plan presented a full life cycle approach of the systems. The procedure for computerized system validation was reviewed and addresses the validation components to ensure data security, integrity and disaster recovery. There was an annual review for re-validation and systems to be migrate and data secured.

12. Change Control

An approved procedure for change control was established. The change controls for increased batch size of the API production and a CC for the trial conducted to use a recovered material were reviewed and discussed during the inspection.

13. Rejection and re-use of materials

The company had a procedure for re-use of materials. Albendazole manufacturing involved the use of recovered solvents. The specifications set for the recovered solvents to be used in the Albendazole production were available.

Reprocessing and reworking for the API production was allowed as per the company's procedure. The APQR 2020 for Albendazole API reported reprocessed batches.

14. Complaints and recalls

Procedures were established for complaints, returns, and recalls.

Complaints

The procedure and record for complaints was reviewed and found acceptable. The complaint register was available and the investigation of the reported complaints of Albendazole API were checked and discussed.

Recalls

The procedure for recalls was reviewed and found acceptable. QA was responsible for the recall process. Recall class 1, 2, 3, and the triggers for recalls were described. A flow chart directed the procedure. The recall register showed no Albendazole recall. The company conducted a mock recall periodically for Albendazole.

15. Contract manufacturers (including laboratories)

A contract laboratory Sequent Research Limited, 120 A&B, Industrial Area, Baikampady, New Mangalore – 575 011, India was used for analytical method validation and stability study.

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, ***Sequent Scientific Limited*** located at ***Plot no: B-32, G-2&G-3, MIDC, Mahad, Dist. Raigad -402309, Maharashtra, 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)