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

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**Aurisco Pharmaceutical Co., Ltd.**
Corporate address of manufacturer	Badu Industrial Park Zone, Tiantai, Zhejiang Province, 317200, P.R. China
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Badu Industrial Park Zone, Tiantai, Zhejiang Province, 317200, P.R. China GPS: 29.118706 N, 121.055335 E DUNS: 545319522
Synthetic unit /Block/ Workshop	Workshop 805
Inspection details	
Dates of inspection	25-28 October 2019
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	Aurisco Pharmaceutical Co Ltd is engaged in the production and quality control of APIs and intermediates. From the presentation at the Opening Meeting, the Aurisco Pharmaceutical Co Ltd, Tiantai site produces the following APIs and intermediates: - Eplerenone - Fluticasone Propionate - Fluticasone Furoate - Mometasone Furoate - Flumethasone - Betamethasone - Abiraterone Acetate - Tenofovir Disoproxil Fumarate - Tenofovir Alafenamide Fumarate - Pregabalin - 16-beta Methyl Epoxide(DB11) - 16-alpha-hydroxyprednisolone (16HP)
General information about the company and site	Aurisco is a private pharmaceutical company founded in 1998. The company has three production sites. The site in Tiantai in Zhejiang Province, which is the subject to this inspection, was put in use in 2008. It occupied an area of 53,000 m^2 land and is located in Badu Industrial Park

	Zone. The site is surrounded by light industry. There are no other chemical or pharmaceutical manufacturers in the immediate vicinity. This site produces Tenofovir Disoproxil Fumarate and its intermediate PMPA in Workshop 805. It also supplies intermediates to other API synthesis companies. The site also produces several steroidal APIs. These are manufactured in Workshop 806. The 2nd Aurisco site which produces finished dosage forms, APIs and intermediates of different products is in Yangzhou, Jiangsu Province. Construction of a third production site, also located in Yangzhou, started in 2015. At the time of inspection, the company employed 414 people at the Tiantai site, including 12 in QA, 42 in QC, 192 in the production department, 11 in the warehouse and 157 other departments.
History	This was the third WHO inspection of the Tiantai site. The previous inspections were conducted in April 2017, and in January/February 2018. The site had also been inspected by USFDA in 2013 & 2018 and Behörde für Gesundheit und Verbraucherschutz der Freien und Hansestadt Hamburg, Germany in 2016 & 2018, with positive outcomes. However, the product scope and production blocks involved in those inspections were different from those of the WHO inspections.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The inspection covered most of the sections of the WHO GMP for APIs, i.e. - Quality management - Personnel - Buildings and facilities - Process equipment - Documentation and records - Materials management - Production and in-process controls - Packaging and identification labelling of APIs and intermediates - Storage and distribution - Laboratory controls - Validation - Change control - Rejection and reuse of materials - Complaints and recalls - Contract manufacturers (including laboratories) Areas visited included the: - Warehouses - Workshop 805 - QC laboratories
Restrictions	N.A.
Out of scope	API products other than Tenofovir Disoproxil Fumarate (APIMF320) manufactured at this site, were outside the scope of this inspection.

WHO APIs covered by the inspection	Tenofovir Disoproxil Fumarate (APIMF320) • company's internal code: B2 • company's internal code -intermediate 1: PMPA
Abbreviations	**Meaning**
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
CIP	Cleaning in place
CoA	Certificate of analysis
CpK	Process capability
DQ	Design qualification
EDI	Electronic deionization
EM	Environmental monitoring
FMEA	Failure modes and effects analysis
FPP	Finished pharmaceutical product
FTA	Fault tree analysis
GMP	Good manufacturing practices
HEPA	High efficiency particulate air
HPLC	High performance liquid chromatography (or high performance liquid chromatography equipment)
HVAC	Heating, ventilation and air conditioning
IQ	Installation qualification
KF	Karl Fisher
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
MR	Management review
NC	Non conformity
NRA	National regulatory agency
OQ	Operational qualification
PHA	Process hazard analysis
PLC	Programmable logic controller
PM	Preventive maintenance
PQ	Performance qualification
PQR	Product quality review
PQS	Pharmaceutical quality system
PW	Purified water
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory

QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
RO	Reverse osmosis
SMF	Site master file
SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometer

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

1. Quality management

A formal documented system for quality assurance was in place, with procedures covering all key quality elements. Operations were specified in a written form and GMP requirements were essentially met. The procedures that were reviewed and discussed during the inspection were generally of a satisfactory standard. Managerial responsibilities were appropriately specified in written job descriptions. Product and processes were monitored, and these results were considered during batch release. Regular monitoring and reviews of the quality of pharmaceutical products were conducted according to documented schedules and procedures.

Product quality review

Product quality review (PQR) was performed on a calendar year basis, taking into consideration the provisions stated in the WHO GMP for API. PQRs were completed by March of the following year for the products manufactured in the preceding year. The 3-sigma criteria was used for the calculation of process robustness, while the CpK, using Minitab software, was used for the calculation of the process capability. The PQR of Tenofovir Disoproxil Fumarate (TDF) for 2018 was discussed.

Deviation management

Deviation handling procedure was discussed. A process flow chart was part of the procedure. The deviations were categorized into critical, major and minor. The investigations into the deviations were performed using various tools such as the 5 WHY's and the fish-bone diagram.

Corrective action and preventive action (CAPA)

CAPA management procedure was in place. It was noted that the procedure ad been applied to CAPA arising from deviations, complaints, recalls, non-conformance, return, GMP inspections, self-inspections, product quality review and quality risk management. The procedure described the mechanism to ensure effectiveness of CAPA on a retrospective basis, e.g. document review, site visits etc. An Excel spread-sheet was used for the tracking of CAPA, and this was done every first 10 days of the month.

Quality risk management procedure (QRM)
QRM procedure was in place. The risk assessment was performed using a lifecycle approach and applied to all quality system elements. The procedure described various tools to be used for risk assessment. It was clarified that the introduction of new molecules and new equipment etc., will trigger change controls, and risk assessments were part of change controls. A logbook or risk register on QRM was maintained.

Management review (MR)
MR procedure was in place and it was performed once a year. The review meeting was chaired by the Quality Director and the review included discussions on PQR, self-inspections, regulatory inspections, safety, health and environment, new equipment, new process, new material, change control system and environmental monitoring. From the minutes of MR meeting dated 8 April 2019, it was noted that although the minutes had recommended areas for improvement.

Internal audits
Internal audit or GMP self-inspection procedure was in place. The procedure stated that internal auditors shall not conduct audit of their own department to ensure no conflict of interest. The deficiencies observed during self-inspections were classified into critical, major or minor. A list of qualified auditors from the different departments had been maintained in a register. Internal audits or self-inspections were performed at least once per year. In order to cover all departments involved, internal audits were performed once every four months. The GMP self-inspection schedule was in place for 2019.

The issues noted from this section have already been addressed and will be verified during future inspections.

2. Personnel
At the time of the inspection, 414 people were employed by the company. There appeared to be sufficient number of competent personnel with appropriate qualifications, experience and training. A programme for routine GMP training had been put in place. Personnel were required to wear protective clothing that were suitable for the type and stage of manufacturing. Appropriate sanitation and change room facilities were provided. Smoking and eating were not permitted in manufacturing areas.

In general, the training program appeared satisfactorily.

3. Buildings and facilities

The buildings and facilities inspected were designed and constructed to facilitate cleaning, maintenance and operations as appropriate to the type and stage of manufacture. Manufacturing areas were spacious to allow placement of equipment.

The chemical and clean area in Workshop 805 were inspected. Workshop 805 also included a general chemical synthesis area and a clean area (classified as Grade D) for crystallization, harvesting and packaging – the latter not dedicated to only B2 APIs. The design of the rooms, placement of equipment and maintenance thereof appeared suitable for the processes involved in the synthesis of B2.

HVAC System

A 100% fresh air HVAC system was used in Workshop 805 clean area. Workshop 805 was stated to have a dedicated AHU equipped with G3 Prefilter, F5 Filter and HEPA final filter.

Water system

Purified water (PW) was not used in the final purification stages of B2 API, but for equipment washing purpose in the clean area only. The system was designed using double reverse osmosis to produce purified water. The PW generation system was linked to two distribution loops, one was dedicated for Workshop 805 (B2 line) and the second for all other workshops.

Containment

The final synthesis, purification and packaging of B2 API took place in a non-dedicated facility shared with other products. The workshop is well segregated from those producing steroidal APIs.

Lighting

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

Sanitation and maintenance

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

The issues noted from this section have already been addressed and will be verified during future inspections.

4. Process equipment

Equipment used in the manufacture of B2 API appeared to be of appropriate design and size for its intended use, cleaning and maintenance.

In general equipment and facilities 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.

Computerized systems were not used for material or production control but used in QC lab for HPLC and GC networking.

5. Documentation and records

Documents were managed according to written procedures. Activities were documented in SOPs and other appropriate documents such as batch manufacturing records (BMRs) and logs. Those reviewed were seen to be appropriately approved and version controlled. All records and other documentation requested during the inspection were promptly available following request.

The QA was responsible for management of document control.

6. Materials management

Manual systems were in place for the receipt and tracking of inventory. Raw materials and finished goods were stored in a dedicated area within the warehouse. There was a tank farm for the receipt of solvents and other liquid reagents as well as an external drum store. These appeared to be tidy and well managed and appropriately labelled.

Solid materials were required to be verified upon their receipt, including checking for damage and confirmation that the supplier had been approved/qualified. Following these checks, the received materials were placed in quarantine, and labelled with the storage location. Bulk liquids were received from either dedicated tankers or tankers accompanied by a cleaning certificate.

Production materials were sampled by QC in a designated sampling area according to a defined sampling plan. After testing by QC, the materials were released with an appropriate label incorporated on to each container. The records of materials viewed were satisfactory. There were two sampling rooms used for raw material sampling, one for steroids and the other for other non-steroidal materials.

7. Production and in-process controls

The inspection team visited Workshop 805 and covered the following areas:

- Material storage area
- Dispensing area (solid and liquids)
- Synthesis area, covering reactors, centrifuges and crystallizers
- Clean room, covering centrifuges, crystallizers, drying, milling sifting and packing activities

Synthesis and production of B2 took place in Workshop 805 chemical area. Final purification, crystallization, drying and packaging were performed in the clean area. The intermediate PMPA used in house and for sales, were also manufactured in the chemical area. There were 6 different quality grades of B2 manufactured using a single process. There were two crystallizers in the clean area. Currently one is dedicated to crystallization of B2.

In-process sampling was performed at defined and documented stages during processing, and the samples were tested in the QC laboratory.

B2 API synthesis, purification, crystallization, drying and packaging were performed in non-dedicated facilities. Adequate precautions were in place to minimize the likelihood of contamination during production, including the final stages taking place in a Grade D controlled environment. The procedure for cleaning equipment had been validated. Final crystallization was performed from non-aqueous media in stainless steel reactors to limit risks of glass and microbial contamination.

8. Packaging and identification labelling of APIs and intermediates

Packaging materials were appropriately stored and subjected to quality control testing before release.

The primary packaging was carried out in Grade D environment whereas secondary packaging was performed in an uncontrolled environment.

9. Storage and distribution

Finished APIs were stored in a designated warehouse and held in quarantine until released by the Authorized Person. APIs and intermediates were released for distribution after release by the Quality Unit.

10. Laboratory controls

The Quality unit comprised the QA department and QC laboratory. The QC laboratory was responsible for testing of raw materials, intermediates and finished APIs as well as in-process controls. The laboratory was spread over a three-story building, and was divided into the following sections:

- First floor (including rooms for storing retention samples and reference standards, microbiology laboratory)
- Second floor (including the instrumentation laboratory equipped with HPLC, GC, FTIR and weighing balances)
- Third floor (including the physio-chemical laboratory and room for stability chambers)

Overall, the company had an organized and suitably equipped QC laboratory for API testing.

11. Validation

The validation policy for B2 was described in a Validation Master Plane (VMP) with validation management described in a written procedure.

Process validation

The manufacturing process was revalidated in June 2019 after the introduction of capacity increasing in parts of equipment for B2CP. This was handled through a change control. Six batches were taken as part of the validation study to produce three batches of B2. The results of the finished API were compared against previously validated batches and found to be identical for critical quality attributes. There were also changes made to the validated process of PMPA. The process was revalidated in 2018 using three batches of PMPA.

Analytical method validation

It was confirmed that the R&D Centre is responsible for analytical validation and process development activities, and the Centre reported directly to the General Manager. The analytical method validation (AMV) was performed on the HPLC, GC and titration methods using all test parameters. The analytical validation documents are reviewed and approved by QA. The AMV for related substance test for B2 was in place. The validation included specificity, linearity, LOQ & LOD, accuracy, range, intermediate precision, method repeatability, robustness, solution stability. The LOD & LOQ was performed and the signal to noise ratio was established. The assessment for robustness included validation performed on different days using the same Agilent HPLC.

Cleaning validation

The procedure on cleaning validation and its guideline principles was in place. The procedure referred to LD50 and PDE approach.

12. Change control

Change control management procedure was in place. The procedure was described in the process flow diagram for the change control. The changes were classified into minor (i.e. changes that may not have any impact on quality, safety and efficacy, e.g. replacement of same type equipment, facility), and major (i.e. changes that may have an impact on the quality, safety and efficacy of the product, e.g. scale up of production batch size) and critical (such as a change of manufacturing process which impact on the quality, safety and efficacy of the product, where investigation and validation are required to be performed). It was indicated by the company that change controls were reviewed following their implementation.

13. Rejection and re-use of materials

The use of solvents such as Dimethylformamide (DMF), Triethylamine (TEA) and Nitromethyl Pyrrolidine (NMP) in the synthesis of B2 (TDF) were not recovered, while the mother liquor was discarded. Three solvents (methylene chloride, isopropyl alcohol and cyclohexane) used for centrifugation and crystallization, were recovered (via distillation

14. Complaints and recalls
The company confirmed that there were no complaints and recalls in 2018

15. Contract manufacturers (including laboratories)
No contract manufacturers or contract laboratories were used for routine production and testing.

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, ***Aurisco Pharmaceutical Co. Ltd***, located at ***Badu Industrial Park Zone, Tiantai, Zhejiang Province, 317200, China*** was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines for APIs.

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

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

Part 4	List of GMP Guidelines referenced in the inspection report

1. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. ***Short name: WHO GMP for APIs or WHO TRS No. 957, Annex 2***
   http://apps.who.int/medicinedocs/documents/s20119en/s20119en.pdf

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*** or ***WHO TRS No. 986, Annex 2***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

3. WHO good manufacturing practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-sixth Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2.
   Short name: WHO TRS No. 970, Annex 2
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/

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

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 HVAC Guidelines*** *or* ***WHO TRS No. 1010, Annex 8***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en/

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

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

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

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

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

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

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

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

14. WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2. ***Short name: WHO TRS No. 981, Annex 2***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/
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***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/
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. WHO Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 3. ***Short name: WHO TRS No. 992, Annex 3***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

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

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

21. Guidance on good data and record management practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 5.
Short name: WHO GDRMP guidance or WHO TRS No. 996, Annex 5
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf

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 Multisource guidance or WHO TRS No. 996, Annex 10
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

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
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf