World Health Organization

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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
of the FPP manufacturer

Part 1	**General information**
Manufacturers Details	
Company information	
Name of manufacturer	Technolog Private Joint Stock Company (Group of pharmaceutical companies Lekhim)
Address	8, Stara prorizna Street, Uman city, Cherkassy Region, 20300, Ukraine 48°44'40.9"N 30°12'41.2"E 365918676
Corporate address of manufacturer	23, Shota Rustaveli street, Kyiv, 01033, Ukraine (Lekhim JSC) Tel: + 38 (044) 521-86-50 Fax: + 38 (044) 287-62-76
Inspected site	
Address of inspected manufacturing site if different from that given above	As above
Workshop	Vitamin products workshop, building No. 9
Inspection details	
Dates of inspection	4 - 7 December 2018
Type of inspection	Initial
Introduction	
Brief summary of the manufacturing activities	Manufacture of: • Hard gelatin capsules, granules, dragees, tablets, cutaneous liquids, oral liquids, syrups, active pharmaceutical ingredients (API, substances, active/drug substances); • Bulk products; • Packaging of API for further sale to the license holders which carry out the economic activity on manufacturing of the medicinal products in pharmacy conditions.
General information about the company and site	In 2009, Private Joint Stock Company "Technolog" became a part of a "Group of pharmaceutical companies Lekhim". In 2010, PJSC "Technolog" received the approval of compliance with quality standards ISO 9001: 2009. In 2012, the enterprise obtained GMP certificate No. 033/2012/SAUMP/GMP.

<table>
<tr><td></td><td>The dietary supplements, food supplements and disinfectants are manufactured on the site according to the approved technical requirements.

Solid dietary supplements and food supplements are manufactured in the workshop of vitamin preparations (VP).
Liquid dietary supplements are manufactured in the workshop of the liquid medicines (LM).
Disinfectants are manufactured in the workshop of the liquid medicines (LM) in the unit for cutaneous preparations manufacture: Requirements to the manufacture meet the GMP regulations.

Veterinary preparations of solid form and in liquid form are planned for production at the site under construction.</td></tr>
<tr><td>History</td><td>This was the first WHO inspection.
The site was inspected by the following authorities:

<table>
<tr><th>Authority</th><th>Dates of inspection</th></tr>
<tr><td>State Service of Ukraine on Medicines and Drugs Control</td><td>August, 2015</td></tr>
<tr><td>State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania</td><td>August, 2017</td></tr>
<tr><td>Center for Examinations and Tests in Health Service of the Ministry of Health of the Republic of Belarus</td><td>October, 2017</td></tr>
<tr><td>Analytical Expertise Center for Medicines of the Republic of Azerbaijan</td><td>December, 2017</td></tr>
<tr><td>State Service of Ukraine on Medicines and Drugs Control</td><td>August, 2018</td></tr>
</table></td></tr>
<tr><td>Brief report of inspection activities undertaken</td><td></td></tr>
<tr><td>Scope and limitations</td><td></td></tr>
<tr><td>Areas inspected</td><td>See Part 2 below</td></tr>
<tr><td>Restrictions</td><td>Products out of scope of WHO PQ</td></tr>
<tr><td>Out of scope</td><td>Manufacturing workshops of liquid medicines and solid dosage forms</td></tr>
<tr><td>WHO product numbers covered by the inspection</td><td>Protionamide Tablet, Film-coated 250 mg</td></tr>
</table>

Abbreviations

ADE	acceptable daily exposure
AHU	air handling unit
ALCOA	attributable, legible, contemporaneous, original and accurate
API	active pharmaceutical ingredient
APQR	annual product quality review
AQL	acceptance quality limit
BDL	below detection limit
BMR	batch manufacturing record
BPR	batch packaging record
CAPA	corrective actions and preventive actions
CC	change control
CoA	certificate of analysis
Cpk	process capability index
DQ	design qualification
EM	environmental monitoring
FAT	factory acceptance test
FBD	fluid bed dryer
FG	finished goods
FMEA	failure modes and effects analysis
FMECA	failure mode, effects and criticality analysis
FPP	finished pharmaceutical product
FTA	fault tree analysis
FTIR	Fourier transform infrared spectrometer
GC	gas chromatograph
GMP	good manufacturing practice
HACCP	hazard analysis and critical control points
HPLC	high-performance liquid chromatograph
HVAC	heating, ventilation and air conditioning
ID	identity
IPC	in-process control
IQ	installation qualification
IR	infrared spectrophotometer
ISO	International Organisation for Standardisation
KF	Karl Fisher
LAF	laminar air flow
LIMS	laboratory information management system
LoD	limit of detection
LOD	loss on drying
MB	microbiology
MBL	microbiology laboratory
MF	master formulae

MHRA	Medicines and Healthcare Products Regulatory Agency
MR	management review
NIR	near-infrared spectroscopy
NMR	nuclear magnetic resonance spectroscopy
NRA	national regulatory agency
OQ	operational qualification
PC	personal computer
PDE	permitted daily exposure
Ph. Eur.	European Pharmacopoeia
PM	preventive maintenanceprocess method
Ppk	process performance index
PQ	performance qualification
PQR	product quality review
PQS	pharmaceutical quality system
PRC	product release certificate
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
RH	relative humidity
RM	raw materials
RS	reference standard
SFG	semi-finished goods
SMS	short message service
SOP	standard operating procedure
STP	standard test procedure
T	temperature
TAMC	total aerobic microbial count
TFC	total fungal count
TLC	thin layer chromatography
TMC	total microbial count
TOC	total organic carbon
UPS	uninterruptible power supply
URS	user requirements specifications
USP	United States Pharmacopeia
UV	ultraviolet-visible spectrophotometer
VMP	Validation Master Plan
WS	working standard

Part 2	Brief summary of the findings and comments

1. Quality system

Principle

Production and control operations were specified in written form and GMP requirements were essentially being met. Managerial responsibilities were specified in written job descriptions. Product and processes were monitored, and the results were reviewed as part of the approval process of batch release. Regular monitoring and reviews of the quality of pharmaceutical products were being conducted according to documented schedules and procedures.

Quality assurance department

Document "Quality assurance policy" was briefly discussed. QA main responsibilities were, but not limited to:

- Organization of training
- QA documentation
- Production documentation
- Organization and performance of internal audits and external audits,
- Organization and performance of calibration of equipment, facilities and utilities
- Organization and performance of validation
- Preparation of PQRs

Management review (MR)

Document "Senior management responsibility" and its flow chart were briefly discussed. According to the document, MR should be carried out bi-annually.

Quality Risk Management (QRM)

Document "Quality risk management" was briefly reviewed and discussed.
QRM was performed as part of the following:

- Quality Control system
- Pharmaceutical development
- Technical - Equipment and systems
- Materials management
- Technological process
- Laboratory control and stability tests
- Packing and labelling

The following SOPs were used for risk assessments:

- Methods of quality risk assessments
- Applying quality risk assessment methods (FMEA, FMECA)
- Applying quality risk assessment methods (HAZOP)

Reviewed and discussed the QRM - Record of analysis of risks for Protionamide Tablet, Film-coated 250 mg which was performed during pharmaceutical development.

Product Quality Review (PQR)

Document "Product quality review" was briefly discussed. PQRs were prepared according to the sliding schedule. As an example, PQR for Pancreatin 18.01.2017 01.2018 (top product) was briefly discussed.

Process capability was evaluated by using Cpk (calculated by excel). Document "Process reproducibility analysis" was briefly discussed.

PQR for Protionamide Tablet, Film-coated 250 mg (2016) was briefly discussed. This medicine was manufactured for the Ukrainian market.

Deviations

Document "Deviation management", its flow chart and deviation registers 2017 - 2018 were briefly discussed. Deviations were classified as:

- Critical
- Major
- Minor

The document also specified root cause analysis. No critical deviations were registered. A number of major deviations were briefly discussed.

Corrective actions and preventive action (CAPA)

Document "Corrective actions" and "Preventive actions" and its flow chart were briefly discussed.

Change control (CC)

Document "Change management", its flow chart and register for 2018 were briefly discussed. Changes were classified as:

- Critical
- Major
- Minor

According to the document, risk assessment should be carried out for critical and major changes. A number of changes were briefly discussed.

Supplier qualification

Documents "Purchase of materials" and "Approval of the manufacturers and vendor of raw materials and other materials" were briefly discussed.

The QA Manager together with other relevant departments was responsible for the approval of suppliers.

A quality risk assessment was performed to determine which suppliers warranted auditing. The supplier audit plan "Audit of API and Materials Manufacturers" for 2017 was reviewed. Seventeen (17) supplier audits were planned and all were conducted.

Complaints

Document "Complaints management" and registers for 2017 - 2018 were briefly discussed. Complaints were classified as:

- Critical
- Major
- Minor

No critical or major complaints were registered, no complaints regarding product quality.

Product recalls

Document "Recall management" was briefly discussed. Recalls were classified as:

- Class I - Initiation within 24 hours
- Class II Initiation within 24 hours
- Class III Initiation within 3 - 5 calendar days

According to the SOP, effectiveness of the procedure was evaluated by mock recall, performed annually. According to the company, there was no recalls in the company history.

Product returns

Document "Returns management" and register were briefly discussed.

Reprocessing and rework

Document "Repackaging of products" was briefly discussed. According to the company explanation, rework of the products was not allowed.

Batch release

Documents "Batch release procedure" and "Analytical protocols of intermediate, bulk, finished product testing) were briefly discussed. Batch release was performed by the Qualified Person.

Personnel

The company had an organogram which was part of the Site Master File which clearly indicated the reporting lines and level of responsibility. The site employed 354 employees.

The Director General was responsible for the appointment of key personnel.

The duties and responsibilities were clearly defined in job descriptions which included the responsibilities and requirements. The responsibilities were delegated, and the acceptance was acknowledged in writing. The person responsible for production, the person responsible for Quality Assurance and the person responsible for Quality Control, were different persons of equal level of authority, neither of whom were responsible to the other, but all had responsibility for achieving the required quality.

The job description for the Qualified Person was discussed and reviewed. The responsibilities of the Qualified Person were to confirm that each batch of finished product complied with the regulatory requirements and cGMP related to the quality of the finished product and approved the release of the finished product batch for sale. Two Qualified Persons were appointed.

Training

According to the document "Personnel Training", the following types of training were carried out within the organization:

- General orientation training for newly recruited personnel
- Work-specific initial training (job introduction)
- Ongoing training which was either scheduled (GMP principles, ISO 9001 and ISO 22000 and job-specific training) or unscheduled (new equipment, new operational methods, method transfer, new documents changes to documents) or external training (refresher training or participation in conferences, seminars, webinars etc.)

All training was registered on an electronic data base as per document "Working with personnel training data base".

The training records of the chemist was reviewed and discussed.

Personal hygiene

Document "Personnel Hygiene" described the requirements for personal hygiene.

Document "Medical examination and help" required all personnel, prior to and during employment, to undergo health examinations. A personal government medical card was issued for each employee.

An obligatory daily examination of personnel was conducted by the medical staff. A register for each workshop and QCD was completed by the medical staff. The examination comprised of the following:

- No symptoms of apparent illness
- No fever
- No open lesions on the skin
- Other health issues

Personnel that had an apparent illness or open lesions that may adversely affect the quality of products was not permitted to handle starting materials, packaging materials, in-process materials or medicines products until the condition was no longer judged to be a risk.

Document "Providing personnel with special clothes, footwear and PPE" detailed the clothing requirements for personnel. Clothing was only ordered from suppliers that were granted status "Qualified" or "Acceptable". The requirements to process clothing was documented and every piece of gowning was marked, and a label attached for the counting of the washing cycles.

In order to prevent contamination/cross contamination, the microbiology laboratory handled their own clothing as per document "Order of process clothing preparation for the microbiological laboratory workers".

All personnel were trained by QA in the practices of personal hygiene.

Documentation

The documentation system was generally established. The documentation system was described in the document "Documentation Management".

The documentation system consisted of four levels.

Documents were initiated by specialists with the appropriate qualification and experience. The documents became effective, once approved by the responsible personnel and agreed with management. Documents were then distributed by copying the originals in the required quantity. Issuance of each copy for use in the organization units was registered. The previous document versions were withdrawn upon revision and the originals were archived.

Personnel were trained when new documents were issued or when documents were revised by completing an "Acquaintance check".

Documents related to the manufacture of intermediates and APIs were prepared, reviewed, approved and distributed according to written procedures. The SOPs were also displayed at appropriate points.

2. Production system

Production operations followed defined procedures. Significant deviations from the initial protocol were recorded and investigated, root causes were determined and CAPAs were implemented where necessary. Checks on yields and reconciliation of quantities were carried out. Access to production premises was restricted to authorized personnel.

Inspectors visited the following production rooms were visited:

- Dispensing
- Granulation room with adjacent binder preparation room
- Blending room
- Compression room
- Coating room
- Equipment cleaning room
- Cleaned equipment storage room and clean bins storage room
- Tools storage room

3. Facilities and equipment system

Production premises were located, designed, constructed, adapted and maintained to suit the operations to be carried out. The layout and design of premises minimized the risk of errors and permitted effective cleaning and maintenance. Premises were cleaned and disinfected according to detailed written procedures, records were maintained. Production equipment were connected to a password protected PC. All PCs, except FBD had already pre-defined recipes installed.

HVAC system

There were X AHU units. AHU No. YY serving air to the dispensing room re-qualification report was briefly discussed.

Purified Water (PW)

Each manufacturing workshop was equipped with a self-contained treated water generation, storage and distribution system. PW was prepared by two-stage reverse osmosis and complied with the requirements of the European Pharmacopoeia (Ph. Eur.).

The required velocity (0.9 - 1.5 m/s) and temperature (< 25 °C) was maintained in the closed loop circuit. UV lamps were installed in the distribution water system to prevent microbiological contamination.

Sanitization of the treated water storage and distribution system was carried out, the frequency was based on the validation results and if the action limit was exceeded.

Cleaning validation

Different cleaning methods were used for cleaning processing equipment, namely

- Manual cleaning of detachable equipment parts
- Clean-in-Place (CIP) using vacuum cleaners and CIP systems

Cleaning procedures were in place for the different pieces of equipment, for example:

- "Cleaning and washing of dryer-granulator"
- "Cleaning and washing of rotary tablet machine"
- "Cleaning and washing of tablet dedusters"

Sampling methods and analytical tests were developed and validated.

A "bracketing" approach to cleaning validation was adopted. The "worst case" relating to the product resulted in the selection of XX - Cleaning validation protocol YY.

Computerized systems

Document "Back up of data" was briefly discussed. Automatic back up of data was performed once in 24 hours using program "Acronis Backup Advanced 12.5. Active backup for business".

4. Laboratory control system

The QC function consisted of QC Analytical and QC Microbiology departments.

During inspection Protech (Protionamide) 250 mg tablets analytical raw data was cross checked with instruments usage logs, reference standard usage log. Company was asked to re-calculate excel sheet calculations manually. Cross checks proved calculations.

Out of specifications (OOS)

Document "Order of OOS results investigation" and its flow charts and register were briefly discussed. The SOP was applicable to all raw materials, in-process tests, packaging materials and finished products.

Sampling

Document "Sampling of raw materials and primary packaging materials" was briefly discussed. 100 % identity tests were performed using NIR.

Analytical balances

Analytical balances verification was preformed daily and weekly by laboratory staff. Monthly calibration was performed by the metrological department according to the USP Chapters <41> and <1250>.

Reference standards

Working standards (WS) were calibrated against pharmacopeia standards and dispensed in amber colour single use vials.

Dissolution apparatus

Dissolution apparatus used for comparative dissolution test was checked. Mechanical calibration was carried out every 6 months. Calibration kit was presented to the inspectors.

5. Materials system

During inspection raw materials, packaging materials and finished goods warehouses were inspected. There was a total of six warehouses, namely:

- Storage of starting materials
- Storage of primary packaging materials
- Storage of chemical reagents and precursors
- Storage of finished product
- Storage of the secondary packaging materials
- Storage of manufacturing wastes

Raw materials and primary packaging materials sampling was carried out in one room under LAF. Rejected and returned goods room was locked, no materials were in the room during inspection.

6. Packaging and labelling system

During inspection, Protex 250 mg primary and secondary packaging was carried out. Primary packaging line was equipped with a sensor which detected empty blisters, empty "pocket", and color of tablets. Secondary packaging line was equipped with a pharma code reader.

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 ***Private Joint Stock Company Technolog, located at 8, Stara prorizna Street, Uman city, Cherkassy Region, 20300 Ukraine*** was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines.

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

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

Part 4	List of WHO Guidelines referenced in the inspection report

1. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Eighth Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. ***Short name: WHO TRS No. 986, Annex 2***
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/
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 GMP for APIs*** or ***TRS No. 957, Annex 2***
   http://www.who.int/medicines/publications/44threport/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 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 GPPQCL Guidelines or ***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 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 TRS No. 996, Annex 10
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

23. WHO guidance on 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 guidance on Stability testing or WHO TRS No 1010, Annex 10**
https://extranet.who.int/prequal/sites/default/files/documents/TRS1010_Annex10.pdf