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

Part 1	**General information**
Manufacturers Details	
Company information	
Name of manufacturer	Qilu Pharmaceutical Co., Ltd.
Corporate address of manufacturer	No. 317, Xinluo Road, High-Tech Zone, Jinan, Shandong Province, China, 250101 Tel: +86-531-83126268 Fax: +86-531-83126002 North latitude: 36.681916 East longitude 117.144306 D-U-N-S 421279342
Inspected site	
Address of inspected manufacturing site if different from that given above	The same as above
Unit / block / plant number	Building K002, Workshop No. X Building K004, warehouse Building K02, QA & QC
Manufacturing license number	Lu 20160001 Scope of licence: production, packaging, quality control and release of powder for injection, SVP, tablets, granules, hard capsules, eye drops, Inhalants, sterile APIs, psychological drugs
Inspection details	
Dates of inspection	16 – 20 January 2017
Type of inspection	Initial
Introduction	
Brief summary of the manufacturing activities	Production, packaging, quality control and release of powder for injection, small volume parenterals (SVP), tablets, granules, hard capsules, eye drops, Inhalants, sterile APIs, psychological drugs

<table>
<tr><td>General information about the company and site</td><td>Qilu Pharmaceutical Co., Ltd. was established in 1958 and is a comprehensive large-scale pharmaceutical manufacturing enterprise in China. Qilu has eight manufacturing sites:

Six sites have been inspected and approved by US FDA, EDQM, MHRA (United Kingdom), TGA (Australia), MCC (South Africa), MFDS (Korea), PMDA (Japan).

Seven sites have been inspected and approved by the CFDA (China), and one site was under construction during the inspection.

Qilu Pharmaceutical Co., Ltd., located in High-Tech Zone, is mainly for the production of finished dosage forms and sterile APIs. This site covers an area of 67185 m^2. During inspection there were seven separate buildings. SVPs were manufactured in the building K 002. The building for finished products manufacturing have been in operation since 2006.</td></tr>
<tr><td>History</td><td>This was the first WHO inspection.
The site has been inspected by the following regulatory authorities:
<table>
<tr><td>Feb. 2012, Approved</td><td>Cephalosporin Powder for Injection and Small Volume Parenterals</td><td>TGA, Australia</td></tr>
<tr><td>Mar, 2012, Approved</td><td>Capsule and Eye Drops</td><td>CFDA, China</td></tr>
<tr><td>May, 2012, Approved</td><td>Powder for Injection (General category) and Small Volume Parenteral Injection</td><td>CFDA, China</td></tr>
<tr><td>Aug, 2012, Approved</td><td>Small Volume Parenteral Injection</td><td>CFDA, China</td></tr>
<tr><td>July, 2013, Approved</td><td>Cephalosporin Powder for Injection, tablets</td><td>USFDA</td></tr>
<tr><td>May, 2014, Approved</td><td>Cephalosporin Powder for Injection and Small Volume Parenterals</td><td>TGA, Australia</td></tr>
<tr><td>May, 2015, Approved</td><td>Cephalosporin Powder for Injection, tablets</td><td>USFDA</td></tr>
<tr><td>Aug, 2015, Approved</td><td>Cephalosporin Powder for Injection</td><td>MHRA</td></tr>
<tr><td>June, 2016, Approved</td><td>Small Volume Parenteral Injection</td><td>CFDA</td></tr>
<tr><td>Aug, 2016, Approved</td><td>Cephalosporin Powder for Injection</td><td>CFDA</td></tr>
<tr><td>Nov, 2016, Approved</td><td>Cephalosporin Powder for Injection, SVP</td><td>MHRA</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</td></tr>
<tr><td>Restrictions</td><td>N/A</td></tr>
<tr><td>Out of scope</td><td>N/A</td></tr>
</table>

WHO product numbers covered by the inspection	TB Amikacin (sulfate) Solution for injection 500mg

Abbreviations

AHU	air handling unit
ALCOA	attributable, legible, contemporaneous, original and accurate
API	active pharmaceutical ingredient
APQR	annual product quality review
BDL	below detection limit
BMR	batch manufacturing record
BPR	batch packaging record
CAPA	corrective actions and preventive actions
CC	change control
CFU	colony-forming unit
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
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
IR	infrared spectrophotometer
IPC	In process control
IQ	installation qualification
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
MR	management review
NIR	near-infrared spectroscopy
NMR	nuclear magnetic resonance spectroscopy
NRA	national regulatory agency
OQ	operational qualification

PHA	preliminary hazard analysis
PM	preventive maintenance
PpK	process performance index
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
RH	relative humidity
RM	raw materials
RS	reference standard
SAP	system applications products for data processing
SFG	semi-finished goods
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
URS	user requirements specifications
UV	ultraviolet-visible spectrophotometer
VMP	Validation Master Plan
WFI	water for injection
WS	working standard

Part 2	Brief summary of the findings and comments (where applicable)

Brief summary of the findings and comments

1. Pharmaceutical quality system (PQS)

Principle

Production and control operations were specified in written form and GMP requirements were generally followed. Managerial responsibilities were specified in job-descriptions. Product and processes were monitored and the results taken into account in batch release; regular reviews of the quality of pharmaceutical products were conducted.

Quality Risk Management

The SOP "Quality Risk Management" was discussed.

The following tools were specified:

- Design of experiments (DoE)
- Pareto charts
- Fault tree analysis (FTA)
- Failure modes and effects analysis (FMEA)
- Hazard analysis and critical control points (HACCP)

The register of risk assessments performed in 2016 was presented.

Risk assessment for computerized systems used in production workshop X was discussed.
Cross contamination risk assessment for SVP line Y was spot checked.

RA registers were dedicated to the workshops and laboratories.

Product Quality Review (PQR)

The SOP "Annual product quality review" was discussed. According to the SOP, PQR should be finished by the first quarter of the next year. In case products were not manufactured during review period PQRs were performed to cover complaints, stability studies, technical agreements etc.

Management review

The SOP "Quality system review" was discussed. According to the SOP quality system review shall be performed quarterly. The SOP was applicable, but not limited to:

- Deviations management
- CC
- Customer requires /complaints
- Returns
- Rejects
- Reprocess and rework
- Inspection
- PQR
- Recall
- Validation /qualification
- Stability program
- Documentation management
- CAPA

Deviations

The SOP "Management of production deviation" and flow chart were discussed. Deviations were classified:

- Critical
- Non-critical

The SOP was applicable for planned deviations to all departments. Deviations classification was carried out by respective departments and approved by QA. Deviations were trended quarterly. Manufacturing process deviations were recorded in respective batch manufacturing records (BMR).

Registers/logs were maintained separately for deviations related to the different departments.
QA issued deviation report forms to departments, maintained the registers.

Periodic trending of deviation was in place. Timeline of one month for investigation of the deviation was specified.

Deviation register was presented to the inspectors.

Corrective actions and preventive action (CAPA)

The SOP "Management of Corrective actions" was discussed. This SOP was applicable to all departments. There was a quarterly review of CAPAs related to different quality systems. A risk grade of high, middle and low was outlined in the procedure.

Change control (CC)
The SOP "Change control" and flow chart were discussed. SOP was applicable for any GMP related changes.

Changes were classified:
- Permanent
- Temporary

and
- Minor
- Moderate
- Major

CC registers were maintained by individual departments.

2. Good manufacturing practices for pharmaceutical products
Manufacturing processes were defined and reviewed. Qualifications and validations were performed. Significant deviations were recorded and investigated, root causes were determined and CAPAs were implemented. Systems were in place for handling complaints and recalling any batch of product from sale or supply.

3. Sanitation and hygiene
The company had an SOP as the basis for its approach to personal hygiene and sanitation in its production facilities. Microbial monitoring was performed.

4. Qualification and validation
Autoclave validation
Autoclave No X, used for product sterilization, and autoclave No Y, used for tools sterilization, validation protocols and reports were discussed.

Autoclave No Z for hard goods qualification report was discussed.

Depyrogenation tunnel qualification
Ampoules depyrogenation tunnel No X qualification report was spot checked.

Temperature mapping
Temperature mapping for warehouses was performed every 2 years in winter and summer periods. The T mapping report for the warehouse X was spot checked.

Clean room qualification

The following tests were performed:

- Particle size
- Air changes per hour
- Velocity
- Air flow pattern
- Pressure differential
- T & Relative humidity (RH)
- Clean up time
- HEPA filter integrity test

Cleaning validation

Cleaning validation report No Y was discussed. Swab and final rinse water samples were tested for bioburden, chemical residuals and total organic carbon (TOC). Recovery studies were performed.

Hold time studies

Amikacin (sulfate) Solution for injection 500 mg/2ml solution hold time studies report was discussed. Hold time studies were performed starting from the dissolution of the API to the end of the filling.

Leak test validation

For leak test, blue dye solution diluted with purified water was used. The leak test validation had been performed by water for injection (WFI). Defective ampoules were detected by the manual visual inspectors. The manual visual inspectors were qualified for this operation.

5. Complaints

The SOP "Complaints management" was discussed. Complaints were classified as:

- Critical
- Major
- Minor

Complaints were trended yearly.

6. Product recalls

The SOP "Product recall management" was discussed. Recalls were classified as:

- Grade I - recall within 24 hours
- Grade II – recall within 48 hours
- Grade III – recall within 72 hours

A person from QA was appointed for dealing with recalls. QP had overall responsibility for dealing with recalls.

Recall effectiveness was evaluated by mock recall.

7. Contract production, analysis and other activities

Manufacturing operations, if required, were contracted out to Qilu Hainan site. Technical agreement (TA) with Hainan site was discussed.

Contract laboratory was used for packaging materials analysis. TA with contract laboratory was discussed

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

The SOP "Self inspection" was discussed. Inspection was carried out by team. Self-inspectors were trained annually and qualified after training. Check lists were used to perform self-inspection. Observations were classified as:

- Critical
- Major
- Minor

Inspection report was written by the team and CAPAs addressed by the inspected department.

The SOP "Management of supplier" was discussed. CAPA implementation was checked by the QA. Annual self-inspection schedule was presented to the inspectors.

Suppliers' audits and approval:

The management of the suppliers was performed according to the SOP. The qualifications of the supplier included raw materials, excipients and packaging materials. The SOP for supplier audit was in place. The suppliers of critical materials were audited every two years.

The list of critical materials along with the suppliers and the date of the last audit was spot checked.

9. Personnel

There was an adequate number of personnel qualified to perform and supervise the manufacturing and quality control. Steps were taken to prevent unauthorized people from entering production, storage and QC areas.

10. Training

The SOP „General training program" was discussed. Several training modules were in place:

- New staff training
- Post training
- External training

Training effectiveness was evaluated.

The qualification of the operators performing the manual visual inspection of the filled products in ampoules was performed every six months. Eyes checks were performed every 6 months.

11. Personal hygiene

All personnel, prior to and during employment, had to undergo health examinations. Regular health examinations were carried out every year. Personnel conducting visual inspections had to undergo periodic eye examinations every six months. Direct contact between the operator's hands and starting materials, primary packaging materials and intermediate or bulk products were avoided. Smoking, eating, drinking, chewing, and keeping plants, food, drink, smoking material and personal medicines prohibited in production, laboratory and storage areas.

12. Premises

Ancillary areas

Rest and refreshment rooms were separate from manufacturing and control areas.

Storage areas

Storage areas were of sufficient capacity.

Production areas

Exposed surfaces were smooth, impervious and unbroken. Changing rooms were designed as airlocks and used to provide physical separation of the different stages of changing. Changing rooms were flushed with filtered air. Premises were cleaned and disinfected according to written procedures.

Quality control areas

Sufficient space was given to avoid mix ups and cross-contamination. Storage space was provided for samples, reference standards, solvents, reagents and records.

13. Equipment

General

Fixed pipework was labelled to indicate the contents and the direction of flow. Balances and other measuring equipment of an appropriate range and precision were available for production and control operations and were calibrated on a scheduled basis.

14. Materials

Materials were received, sampled and tested according to the written procedures. Acceptable quality level (AQL) was applied for ampoules sampling.

15. Documentation

Documents were available and included SOPs, protocols and records. SOPs were generally followed. Issuing of documents, formats were not always appropriate.

16. Good practices in production

General

In general production operations followed defined procedures. Deviations from procedures were recorded and investigated. Access to production premises was restricted to authorized personnel.

The SOP "Environmental monitoring of clean area Workshop No X" was discussed. Environmental monitoring (EM) was performed by settle plates, contact plates and airborne particle counts. Action and alert levels were specified based on historical data. EM monitoring results for 2015 were discussed. The results of the microbial environmental monitoring for 2015 were almost nil for all the sampled locations.

The SOP "Quality monitoring for process water" was discussed. Action and alert levels were specified based on historical data.

17. Good practices in quality control

General

The QC function was independent from other departments. Adequate resources were available to ensure that all the QC arrangements were carried out. QC personnel had access to production areas for sampling and investigations as appropriate.

Out of specification results (OOS)

The SOP was applicable to investigation results for raw materials and excipients, packaging materials, process water, intermediates, recovered material, APIs and drug products obtained in QC laboratory as well as in stability studies. The sterility test result failure was handled as per the SOP "The investigation procedure of sterility test positive results and necessary action indicated". Register of OOS for 2015 and 2016 were spot checked.

Sampling procedures

The SOP "Sampling procedures of purchased materials" was discussed. For APIs and excipients used for production of finished dosage for exportation to regulated market and first three batches of APIs and excipients provided by new suppliers, each container of the material was sampled for identification. Samples were combined in composite sample for other tests. Sampling rule and procedure for packaging materials was based on AQL principles and was explained in the SOP.

Procedures for sampling of environmental monitoring and for water systems were implemented.

Stability studies

The SOP "Stability studies" was discussed. Yearly at least one batch of each strength of each product was placed for on-going stability studies.

Environmental monitoring of clean area of workshop X

The SOP "Environmental monitoring" was discussed. The risk based approach was adopted for location and frequency of sampling points. Alert and action limits for the results of particulates and microbiological monitoring were and quarterly and yearly trends of environmental monitoring were in place. The appropriate corrective actions after the initiated investigation of trends of environmental monitoring were not prescribed in the operating procedure.

Monitoring for water of workshop X

Sampling plan for city water, PW and WFI were in place. Critical sampling points including return and compounding user points for WFI were sampled and tested daily. Alert and action limits were specified. The results for 2015 for WFI were within established limits, no microbial count had been recorded.

Microbiology laboratory

Laboratory premises were spacious and had separate rooms for positive controls, sterility tests, microorganism identification, media preparation and sterilization and other supportive rooms.

PART 3

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, Qilu Pharmaceutical Co., Ltd., located at No. 317, Xinluo Road, High-Tech Zone, Jinan, Shandong Province, China, 250101 (Building K002, Workshop No. 6) was considered to be operating at an acceptable level of compliance with WHO good manufacturing practices for pharmaceutical products.

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 used for assessing compliance

1. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eight Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2.
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/
   Short name: WHO TRS No. 986, Annex 2

2. 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

3. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2.
Short name: WHO TRS No. 957, Annex 2
http://www.who.int/medicines/publications/44threport/en/

4. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-six 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/

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

6. WHO guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 5
Short name: WHO TRS No. 961, Annex 5
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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

8. WHO Good Practices for Pharmaceutical 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/

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 2
Short name: WHO TRS No. 957, Annex 3
http://www.who.int/medicines/publications/44threport/en/

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 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

21. WHO good manufacturing practices for biological products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 3
Short name: WHO TRS No. 996, Annex 3
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex03.pdf

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

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