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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
Finished Product Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**Cipla Quality Chemical Industries Ltd** Plot 1-7, 1st Ring road, Luzira Industrial Park, P.O. Box 34871, Kampala Uganda North latitude: 0°18'17.0"N, Latitude:0.304723 East longitude: 32°38'22.0"E, Longitude:32.639436 D-U-N-S: 850499499
Corporate address of manufacturer	Cipla Ltd, Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai: 400013, India Cipla QCIL: Plot 1-7, 1st ring road, Luzira Industrial Park, P.O. Box 34871, Kampala Uganda
Inspected site	
Name & address of inspected manufacturing site if different from that given above	As above
Unit / block / workshop number	Main building
Manufacturing license number	• Certificate of suitability of premises: NDA/PRE/PMC/1847 • Certificate of compliance with good manufacturing practice guidelines: 123/GMP/2017 • License to operate pharmaceutical manufacture "C"
Dates of inspection	12 – 14 and 17-18 June 2019
Type of inspection	Routine
Introduction	
Brief description of the manufacturing activities	Cipla Quality Chemical Industries Limited manufactures non-sterile oral solid dosage forms, uncoated and coated tablets for human consumption.
General information company and site	Cipla Quality Chemical Industries Limited (Cipla QCIL) is a public listed pharmaceutical manufacturing plant located in Kampala, founded in June 2005. Cipla QCIL began as a joint venture between Quality Chemicals Ltd. (QCL) - a importer and distributor of pharmaceutical products in Uganda and Cipla Ltd., manufacturer of generic medicines with its head office in India. With Cipla currently the majority shareholder, the company manufactures a wide range of pharmaceutical formulations.

<table>
<tr><td></td><td>The pharmaceutical manufacturing facility constructed at Luzira Industrial Park is licensed by the National Drug Authority of Uganda and is covered by manufacturing licenses. These licenses are renewed annually.

Cipla QCIL has one manufacturing unit with additional warehouses for storage of raw-, packing materials and finished product located at several sites in Kampala.

Details of the additional warehousing facility are:
1. Cipla QCIL warehouse: Plot 13-15 and plot 17-23 1st ring road, P.O. Box 34871, Kampala
2. Zenith Investment Ltd: Plot No. 47/40, Port Bell Road P.O Box 3099, Kampala (GPS 0.297613, 32.649883): secondary and tertiary packaging materials only.
3. Kazi Foods Logistics: Plot No. 11502, Kyambogo Road P.O Box 4903, Kampala (GPS 0.339674, 32.625593)
4. Beyond Logistics Ltd: Plot 1661, Link Road, Bweyogerere Kampala, Uganda P.O. Box 23687 (GPS 0.364779, 32.662281)</td></tr>
<tr><td>History</td><td>The site was previously inspected by WHO 3 - 6 December 2015.
The site had since been inspected by the following authorities:
<table>
<tr><th>Authority</th><th>Date/s of inspection</th><th>Scope of inspection</th><th>Facility/block/unit covered by inspection</th></tr>
<tr><td>Uganda National Drug Authority</td><td>21st – 22nd January 2016</td><td>Annual Inspection</td><td>General GMP inspection</td></tr>
<tr><td>Ghana Food and Drug Authority</td><td>25-26 May 2016</td><td>Product approval / GMP inspection</td><td>General GMP inspection</td></tr>
<tr><td>National Drug Authority</td><td>22nd – 24th February 2017</td><td>Annual Inspection</td><td>General GMP inspection</td></tr>
<tr><td>National Drug Authority</td><td>4th – 6th December 2017</td><td>Annual Inspection</td><td>General GMP inspection</td></tr>
<tr><td>Medicines Control Authority of Zimbabwe</td><td>12th – 13th December 2017</td><td>Product approval</td><td>General GMP inspection</td></tr>
<tr><td>National Drug Authority</td><td>20th – 21th November 2018</td><td>Annual Inspection</td><td>General GMP inspection</td></tr>
<tr><td>East African Community</td><td>24th to 26th April 2019</td><td>Product approval</td><td>General GMP inspection</td></tr>
<tr><td>ZAZIBONA</td><td>6th to 8th</td><td>Product</td><td>General GMP inspection</td></tr>
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	GMP Inspection (Southern Africa)	May 2019	approval		

Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	See Part 2 below
Restrictions	N/A
Out of scope	Products out of scope of WHO PQ
WHO products numbers covered by the inspection	• Nevirapine 200 mg tablets • Lamivudine/Zidovudine 150/300 mg tablets • Artemether/Lumefantrine 20/120 mg tablets • Efavirenz 600 mg tablets • Lamivudine/Zidovudine/Nevirapine 150/300/200 mg tablets • Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/300mg/300mg

Abbreviations	**Meaning**
ADE	Acceptable daily exposure
ADR	Adverse drug reaction
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
APQR	Annual product quality review
APS	Aseptic process simulation
AQL	Acceptance quality limit
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
CCEA	Complete, consistent, enduring, available
CFU	Colony-forming unit
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
GPT	Growth promotion test
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

LAF	Laminar air flow
LIMS	Laboratory information management system
LoD	Loss in drying
MB	Microbiology
MBL	Microbiology laboratory
MF	Master formulae
MFT	Media fill Test
MR	Management review
NC	Non-conformity
NCA	National control authority
NCL	National control laboratory
NRA	National regulatory agency
OQ	Operational qualification
PDE	Permitted daily exposure
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
SIP	Sterilization in place
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 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 for batch release. Regular monitoring and reviews of the quality of pharmaceutical products were being conducted according to documented schedules and procedures.

Data integrity policy

SOP "Handling of data integrity incidents" was checked. SOP was applicable to all GxP data generated by electronic and paper-based systems at Cipla and its associated sites.

Product Quality Review (PQR)

SOP "Annual product quality review" and APQR schedule for 2018 – 2019 were checked. APQRs were prepared according to a monthly sliding schedule. CpK by manual calculation using Excel was used for process capability critical process parameters.

PQRs Artemether/Lumefantrine 20/120 mg tablets (WHO and non-WHO market) March 2018 – February 2019 and Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/300mg/300mg April 2018 – March (WHO) 2019 were checked.

Management review (MR)

SOP "Quality management review and escalation procedure". According to the SOP MR should be performed every 3 months. Last MR from 12 April 2019 minutes were presented to the inspectors. The SOP "Quality metrics (QM)" (corporate) and QM report for April 2019 were checked.

Complaints

SOP "Handling of product complaints" (corporate) and its flow chart were checked. When complaints were received those were sent to Cipla corporate where complaints were logged and acknowledged. Classification to critical/non-critical was also done by Cipla corporate. Investigation was carried out by Cipla QCIL. Medical complaints were investigated by Cipla drug safety department, located in India. According to the register only one complaint was recorded in 2016 and 2017. No complaints were recorded in 2018 and 2019.

Recalls

SOP "Recall procedure" and its flow chart were checked. According to the company explanation there were no recalls in company history. Mock recall was performed every two years for domestic and international markets.

Batch release

SOP "Batch release system of formulations" and its flow chart were checked.

Personnel
Contract workers were tasked with cleaning of sampling and dispensing rooms. Contract workers were also present and involved in production activities as for example loading and offloading products, dispensing, cleaning of production rooms.

Training SOP was checked. Competency and training matrices were maintained by QA on a yearly basis. These listed both permanent staff as well as contract workers.

Change control
The management of change requests is a paper-based system. Examples of change requests were seen and found generally acceptable. From logbooks the change forms were well accessible.

Deviation management
Corporate SOP was verified. Deviations were recorded in the system Trackwise since September 2018. The company was advised that planned deviations should be treated as change controls.

Corrective and preventive actions (CAPAs)
CAPAs were managed in Trackwise. Their corresponding deviations could easily be found. CAPAs could remain open for a long time.

Documentation
Generally, documents related to the manufacture of intermediates and FPPs were prepared, reviewed, approved and distributed according to written procedures. The SOPs were also displayed at appropriate points. The issuance, revision, superseding and withdrawal of documents were controlled with maintenance of revision histories. However un-controlled documents copies were found in production premises.

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. Production rooms appeared to be well maintained and clean. Stainless steel bins and containers were used for production and storage of in process products. Metal detectors were challenged before and after the batch and every 2 hours during production. Punches/dies rotation was ensured, dimensions checks were performed. Dedicated finger bags were used for different products. Integrity checks on finger bags and screens were carried out.

The following documents were checked:
- SOP “Handling of returned/rejected goods”. There was no register. According to the SOP returned goods could be destructed or redressed
- SOP “Re-dressing of products in packing”
- SOP “Handling of excess materials and finished goods”
- SOP “Reprocessing, reworking and utilization of recoverable”

During inspection inspectors visited production facilities and observed some activities from the windows from ISO 8 corridor:

- DC granulation - Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/300mg/300mg (TLE),
- Efavirenz layer granulation
- Artemether/Lumefantrine 20/120 mg tablets (AL) blending
- TLE - compression of TLE tablets was fully automated.
- TLE batch coating
- Blend storage room
- IPC laboratory.

During inspection it was learned that hold times were assigned for blend and compressed tablets.

Efavirenz/Lamivudine/Tenofovir disoproxil fumarate (TLE) Tablet, Film-coated 600mg/300mg/300mg process validation protocol/report was checked.

3. Facilities and equipment system

Production premises were located, designed, constructed, adapted and maintained to suit the operations to be carried out. Premises were cleaned and disinfected according to detailed written procedures, records were maintained. Throughout the facility a lack of space could be seen. Storage areas were very full, e.g. blend store, bulk store.

Utilities – HVAC

There were XX AHUs supplying air to production clean rooms.
The SOP "Operation of AHU and forced air ventilation system" and AHU XX were checked. Filter cascade was following G4 →F7→ F9→ terminal HEPA H13.
HVAC system re-qualification, including HEPA filters integrity test was carried out annually, smoke test was carried out bi-annually. FMEA criticality analysis for switching off AHU was checked. AHU supplying air to the in-process storage areas, materials store and main production corridor were kept running.

Laboratory premises

Laboratories were well equipped with instruments and software tools for managing analyses. HPLCs and GCs were networked. The laboratory appeared overcrowded with instruments and personnel performing analysis which increase the risk of mix-ups and contamination. The company announced that end of 2019 the lab would move to new, larger rooms in the main building. Balances at the lab had printers attached which printed date and time. A small microbiology lab was accessible from the main lab only. This lab was not visited during this inspection.

Stability chambers were equipped to present 25ºC/60%RH, 30ºC/65%RH, 30ºC/75%RH and 40ºC/75%RH. These were all fitted with alarms.

Computerized systems
A list of computerized systems was verified. The upgraded Anatech temperature/RH sensor system was currently under validation. Qualification of TQC module Labicon was ongoing. This system was installed to replace stand-alone analytical balances with unvalidated calculation software.

Validation documentation for Chromeleon v6.8 was checked.

The inventory of reference standards was kept with the system TQC. This was validated in 2014 according to the list of computerized systems.

4. Laboratory control system
The following SOPs were checked:

- "Sampling" and its flow charts. SOP was applicable for raw materials and packaging materials sampling. Identity tests of each container of APIs were done. Sampling of packaging materials was carried out following AQL, inspection level II.
- "Sampling and analysis of API and excipients (for WHO)"
- Validation report "Justification for reduced sampling and testing" for Magnesium stearate was checked.
- "Quality control of API and excipients".
- "Receipt, registration and testing of sample".
- "Software Chromeleon". The system had 10 access levels:
- "Backup and restoration of electronic data in server". Full daily and weekly backups were done automatically through system NetBackup. Restoration of data was done annually.
- Validation of electronic data backup and restoration procedure protocol.
- "Audit trail in Chromeleon software
- "Good chromatographic practice"
- "Integration of chromatographic data"
- "Data organization procedure for chromeleon software
- "Laboratory non-conformance investigation procedure", its flow chart and registers (separate OOS, OOT and laboratory incidents) were checked. SOP was applicable to OOS/OOT and laboratory incidents that occur during execution of testing. SOP was based on MHRA OOS guidelines.

OOS investigation records:
A number of OOS investigation reports were checked.

5. Materials system
Materials were stored at a number of locations. In the production building stocks were stored of raw materials, primary and secondary packaging materials, and finished products. For Artemether API two 2-8^{o}C rooms were installed. On the same site a new warehouse had been built. The warehouse looked spacious and clean. A new sampling suite was under qualification.

All warehouse areas were temperature controlled. Monitoring was done by data loggers which were read once a week. A computerized system Anatech to get real time data from sensors was under validation.

The following documents were checked:

- SOP "Receipt, storage and handling of materials and maintenance of external warehouse". Left over amounts of packaging materials could be returned to the warehouse.
- SOP "Handling of Damaged containers/packs and spillage material in stores"
- SOP Temperature/relative humidity distribution study of an area", effective date 2 January 2015, no reference to WHO guidelines.
- Validation report "Temperature/relative humidity distribution study in critical and non-critical areas".
- "Electronic signature in chromeleon software"
- "Organization of analytical instrument electronic data

6. Packaging and labelling system

In primary and secondary packaging areas equipment was used that had camera checks for missing or deformed tablets and for quality of printing. Checkweighers were used and also visual checks for readability of embossing.

Products were packaged in PVC/Alu foil and cartons or in PDE bottles. To protect the tablets cotton or rayon inserts were used.

Part 3	**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 ***Cipla Quality Chemical Industries Ltd, located at Plot 1-7, 1st Ring road, Luzira Industrial Park, P.O. Box 34871, Kampala Uganda*** 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 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 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. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Third Report Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 2. **Short name: WHO TRS No. 1019, Annex 2**
   https://apps.who.int/iris/bitstream/handle/10665/312316/9789241210287-eng.pdf?ua=1

7. 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://apps.who.int/iris/bitstream/handle/10665/312316/9789241210287-eng.pdf?ua=1

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

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

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

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

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

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

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**
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

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**
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

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. 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. 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