World Health Organization

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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
Finished Product Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**Suheung Co., Ltd.** 61, Osongsaengmyeong-Ro, Osong-Eup, Heungdeok-Gu, Cheongju-Si, Chungcheongbuk-Do, 28161 South KOREA North latitude: 36° East longitude: 127° D-U-N-S: 687943324
Corporate address of manufacturer	As above TEL:82-43-249-4300 FAX:82-43-249-4399
Inspected site	
Name & address of inspected manufacturing site if different from that given above	As above
Unit	Osong Plant
Building	Building B (Food and Pharmaceuticals Building)
Inspection details	
Dates of inspection	8 – 12 April 2019
Introduction	
Brief description of the manufacturing activities	Pharmaceutical activities were limited to the manufacturing of soft gel capsules in building B, pharmaceutical area. In addition, solid dosage forms of food nutraceuticals were produced in a separated part of the same building. The second production building (Building A) was used for manufacturing products of hard empty capsules. • Tablets • Hard capsules • Powders for oral use
General information about the company and site	The company Suheung was founded in 1973 specialized on the production of capsules. The new plant in Osong is located in a Life Science Park and was completed in March 2012. Suheung produces hard empty capsules and a variety of capsule products including hard and soft gelatin capsules; HPMC (vegetarian) capsules; and fish-based gelatin capsules. The company's main profile is contract manufacturing up to bulk capsules without final product testing and release. Amongst more than 100 active substances in the product list (including food supplement "actives") only 12 products are considered as "own".

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History	The site had been inspected by the following authorities:

Authority	Date/s of inspection	Scope of inspection
KGMP	2017 February	Block B
FIMEA	2019 March	Block B, soft gelatin capsules

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	Clofazimine soft Capsules, 100mg (bulk)

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

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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

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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 of 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 "Good documentation and data integrity practices" was briefly discussed. Document explained ALCOA principles, back up of electronic data and data restoration.

Management review (MR)

MR was explained in Quality Manual which was based on ISO 9000:2015.

Section "Management review" specified that MR should be performed in July and December.

SOP "GMP Committee Management" was briefly discussed. According to the SOP periodic committee meetings should be carried out quarterly or on demand. Participants should be from all departments.

Currently meetings were carried out monthly. Committee meeting minutes from March 2019 were briefly discussed.

Separate GMP meetings were carried out monthly. Presentation from the meeting in March 2019 was presented to inspectors.

Quality Risk Management

SOP "Risk assessment (RA)" was briefly discussed. Performed risk assessment register was presented to the inspectors. Company stated that in major cases FMEA was used.

RA HVAC-XX "Set up of HVAC system re-qualification frequency" was briefly discussed.

Product Quality Review (PQR)

SOP "Annual product review" was briefly discussed.

The PQR of a product XX representing the production facility, equipment and production process of the Clofazimine Capsules was briefly discussed.

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Deviations/corrective actions and preventive actions (CAPA)
SOP "Deviations" was briefly discussed together with the investigation DEV XX.

There were XX CAPA cases reported in 2018 and YY in 2019. The recorded CAPAs were triggered by customer audits, internal audits and complaints. The CAPA xx was briefly discussed.

Change control (CC)
SOP "Change control" was briefly discussed. Change control registers were presented to the inspectors.

A number of CC investigations were discussed.

Complaints
SOP "Complaints", its flow chart and registers for 2018 and 2019 were presented to the inspectors. Complaints were classified as:

- Critical
- Major
- Other

According to the SOP complaint investigation should be finished within 7 days and closed within 14 days. Trending of complaints was performed regularly during GMP committee meetings.

A number of complaint investigation records were briefly discussed.

Recalls
SOP "Product recall" was briefly discussed. Dong-A as marketing authorization holder was responsible for the recall.

Reprocessing & reworking
SOP "Reprocessing & reworking procedure" was briefly discussed. According to the company statement no products were reprocessed & reworked and reprocessing & reworking.

Self-inspection
SOP "Self-inspection". Full scale self-inspection covering all item was carried out annually using department wise check lists provided by Ministry of Food and Drugs Safety. Major GMP standards inspection was carried out every month.

Supplier management
SOP "Supplier qualification" and suppliers audit schedule were briefly discussed.
Paper based supplier audit report for gelatin manufacturer XX and glycerin manufacturer YY was briefly discussed. Approved suppliers' list was presented to the inspectors.

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Contract manufacturing

Suheung Co., Ltd. was the contract manufacturer of Clofazimine soft Capsules, 100mg with Dong-A ST as marketing authorization holder – and applicant. The "First amendment to manufacturing consignment agreement "between both partied was briefly discussed.

Documentation

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.

SOP "Document control" was briefly discussed. According to the SOP documents should be reviewed every three years.

Documentation was a 4-level system:

- Level I: Quality Manual
- Level II: Regulations (master formula, production control and quality control documents, etc)
- Level III: SOPs
- Level IV: Protocols/records

The batch manufacturing record of Clofazimine soft Capsules, 100mg (bulk) batch XX was discussed.

Personnel

Training

The following SOPs were briefly discussed:

- "Education and training control" – SOP explained
    - Orientation training
    - On-job training
    - Periodic training

  Training effectiveness was evaluated by oral test or written test specified in annual training schedule. Annual training schedule was presented to the inspectors.
- "Qualification guide of test operator". Theoretical training evaluation was carried out by written test - open questions. New analyst's practical evaluation was performed by comparing his/her tests results by qualified analyst test results. Re-qualification was not performed.
- "Management of internal auditors and training instructor qualification", training effectiveness was evaluated by written test, containing 16 questions with pre-given answers, 3 questions with given text and open space for explanation and 1 question – calculation should be done by trainee and 1 question regarding pressure differentials. Internal and external training was provided.

The training record of the sorting machine operator (involved in the equipment cleaning before the manufacturing of validation batch Clofazimin capsules) on the topic "operating and cleaning of sorting machine" was available and presented to the inspectors.

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The following SOPs were briefly discussed:

- "Workers clothing management"
- "Personnel hygiene control"
- "Entrance regulations" (implementation date 2019.04.01)
- "Potent materials control".

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.

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Clofazimine Capsules, soft 100mg were not manufactured during the inspection. Inspectors visited the production premises and observed other pharmaceutical products manufacturing processes.

Weighing of APIs and excipients was carried out in dispensing rooms under LAF. Operators, balances and containers locations were clearly specified and established during LAF qualification.

Dispensing tools were cleaned in dedicated area and stored in UV storage.

Requirements for pressure differentials between rooms was NLT 5 Pa.

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. In general production premises were seen to be maintained in good order, however some cleaning issues were noted and listed in Part 3 Deficiencies.

A number of balances were available in the weighing rooms. Balances were verified daily and monthly. Standard weighs were calibrated every three years by government accredited third party. SOP "Balance control method" was briefly discussed. SOP was applicable for all types of balances including analytical balances.

The encapsulation machine XX and the belonging tumbler dryer was used for Clofazimin capsules production and the same was reflected in the batch manufacturing record and the validation protocol.

The manufacturing equipment has operating manuals including disassembling and assembling procedure after production and cleaning.

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SOP "Facility and equipment maintenance policy" was briefly discussed. The maintenance program and the corresponding documents of XX encapsulation machine were briefly discussed.

The re-qualification of the encapsulation machines was due in every 5 years. The re-qualification protocols and records of the XX were briefly discussed.

The measuring devices belonging to the production equipment were calibrated regularly. The calibration records of the temperature sensor XX, model YY for segment temperature checking were briefly discussed.

The cleaning protocols and the corresponding cleaning validation of the XX homogenizer encapsulation machine YY and the sorting machine were briefly discussed.

The cleaning of the equipment was performed by the manufacturing operators.

Validation Master Plan (VMP)

SOP "Validation Master Plan" was briefly discussed. VMP was applicable for all facilities, equipment, automated systems, manufacturing processes, utilities, analytical methods and cleaning validation.

There were two Clofazimine soft Capsules, 100mg (bulk) validation batches manufactured in 2018.

Validation protocol and report were briefly discussed.

The validation covered hold time study for final blend and bulk capsules. All the testing and sampling was done by Dong-A. The raw data were available, but the document was still under finalization.

Utilities HVAC

There were XX AHUs supplying the pharma processing area. The pre-filters were regularly checked and changed.

The qualification and environment control of facilities supplied by AHU XX and in particular room YY were briefly discussed.

IQ, OQ and PQ studies has been performed following to the reconstruction of the air handling systems. HEPA filters leak tests were carried out annually and filters were replaced every 3 years based on SOP "Filter management of the workshop" and the supporting risk assessment.

The monthly environmental monitoring of the AHUs was defined. Sampling locations were defined risk based considering the qualification results.

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Utilities purified water (PW)
Inspectors visited PW generation system. PW system was seen to be well maintained. PW was generated by RO. Velocity at the return loop was NLT 1.5 m/s, loop was maintained at T NLT 65 ℃. Sanitization of the loop was carried out weekly at T NLT 80 ℃. PW system was made from 316L stainless steel.

PW system was operated according to the SOP "Purified system control".

The specification of the water (including purified water) was defined in SOP "Water control". The monitoring results of the loop X, user point Y (room Z) were briefly discussed.

Compressed air
Inspectors visited the compressed air generation system. Compressed air system was seen to be well maintained. Compressed air was used in direct contact with product. Oil free compressors were used.

Laboratory premises
Laboratory facilities were of a suitable size, construction and location and were designed to suit the functions and operations to be conducted. Chemical/physical/ instrumental laboratories were separated from microbiological laboratory. Laboratories were seen to be clean and well maintained.

Laboratory equipment
Laboratories were equipped with necessary instruments and equipment. All laboratory instruments were stand alone.

SOP "Autoclave" and autoclave XX re-qualification report (microbiological laboratory) were briefly discussed. Re-qualification was carried out annually. Qualified sterilisation T and time was 15 minutes/121 ℃.

Disintegration tester XX re-qualification protocol/report No YY was briefly discussed.

4. Laboratory control system
During laboratory tour inspector cross-checked Glycerin LOT No XX some analytical raw data with equipment ID numbers and usage logs, reference standard usage log, no discrepancies were noted.

The following SOPs were briefly discussed:

- "Preparation & batch control of microbiological media & Reagents". According to the microbiological media preparation log book all medias sterilization conditions were T – 121 ℃ and 20 minutes.
- "Environmental control". Settle plates were exposed for 4 hours. Not validated that after 4 hours there is growth.
- "How to write raw data of quality records".
- "Review of test results".
- "Deviation control" was also focusing on the OOS, quality defect and reject related issues. Laboratory deviations (incidents) for example but not limited: system suitability failure, retention

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time error, recognized was analyst error before performing tests etc. Register of laboratory deviations was presented to the inspectors.

- "XX GC". In case manual integration was required request for manual integration should be sent to laboratory manager and approved by manager. Written approval was recorded to laboratory deviation from.
- "Control of OOS results". SOP was applicable to chemical/physical and microbiological analysis.

Sampling of starting materials

Selected raw materials purchased and supplied by the contract giver (in case Clofazimin capsules: Dong-A) were sampled 100% and tested for identity.

The rest of the raw materials were sampled based on a sampling plan "√n+1" for quality testing and 100% for identity. Retention samples were drawn from every raw material batch.

5. Materials system

Inspectors visited the raw materials, packaging materials and finished good warehouses. Materials in the warehouses visited were stored under appropriate conditions and in orderly fashion to permit batch segregation and stock rotation. Warehouses seen were clean and in good order. Separate locked rooms were provided for storage of rejected and returned materials. T and RH limits were set up and registered by a chart recorder.

T&RH mapping of warehouses was carried out for summer and winter season. T&RH mapping studies for raw materials warehouse, summer and winter season reports were available for inspection but not discussed.

T&RH mapping report XX for half-finished product room was briefly discussed. Study was performed according to the WHO guideline.

Sampling of the raw materials was carried out in one sampling room under LAF. According to the contract with Dong-A for Clofazimine Capsules only some excipients and agents were sampled and dispensed at Suheung. API and some other materials were sampled and dispensed at Dong-A site. At Suheung site only gross weight was checked before production.

Raw material management was described in SOPs Raw material Control", "Customer Supplies Control" and "Sampling and storage".

Sampling of primary packaging was done in finished products warehouse under movable LAF.

Material management/reconciliation was handled manually on stock cards and using SAP system.

NIR was used for 100% identity checks (ID). ID was performed during dispensing of raw materials.

The batch release was the responsibility of the QA manager.

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6. Packaging and labelling system

Every container/package of the materials (including raw materials, intermediates, bulk materials and finished products) were labelled. The relevant procedures were captured in the corresponding raw and finished material handling SOPs. During inspection Clofazimine Capsules, soft 100mg packaging was not carried out. Suheung performed only sorting, visual inspection and bulk packaging of Clofazimine Capsules, soft 100mg. Primary and secondary packaging was carried out by Dong-A. Inspectors observed other products sorting, visual inspection and bulk packaging.

Part 3	Initial conclusion – Inspection outcome

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, ***Suheung Co., Ltd.,*** located at ***61, Osongsaengmyeong-Ro, Osong-Eup, Heungdeok-Gu, Cheongju-Si, Chungcheongbuk-Do, 28161 South KOREA*** 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

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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