World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

**Prequalification Team Inspection services**
**WHO PUBLIC INSPECTION REPORT**
**(WHOPIR)**
**Finished Product Manufacturer**

| **Part 1** | **General information** |
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| **Manufacturers details** | |
| Name of manufacturer | Incepta Pharmaceuticals Ltd |
| Corporate address of manufacturer | 40, Shahid Tajuddin Ahmed Sarani, Tejgaon I/A, Dhaka-1208, Bangladesh |
| **Inspected site** | |
| Name & address of inspected manufacturing site if different from that given above | Incepta Pharmaceuticals Ltd<br>Krishnapura, Sahabelishor, Dhamrai, Dhaka, Bangladesh. |
| Unit/block/ workshop number | Injectable Potent Drug Facility (IPD, Unit-1) |
| **Inspection details** | |
| Dates of inspection | 15 -16 March 2020 |
| Type of inspection | Routine inspection |
| **Introduction** | |
| Brief description of the manufacturing activities | Manufacturing and quality control of Finished pharmaceutical products. including OSD and IPD at Unit-1. |
| General information about the company and site | Incepta Pharmaceuticals Ltd was established in 1999 and started operations January 2000. Incepta Pharmaceuticals Ltd is structured with two manufacturing sites. Among the two sites, Dhamrai Facility in the inspection scope is a new campus, with ongoing extensions being constructed to expand the manufacturing facilities. The site employed 594 employees at the time of inspection. |
| History | The current inspection was the first routine inspection after the product dossier submission being accepted by WHO medicines PQ programme.<br><br>A WHO pre-inspection was held 24 to 28 July 2017 to support a rolling submission for the DMPA Injection. The product was qualified by WHO PQ programme in February 2020.<br><br>The sterile DMPA injection manufactured in Unit-1 has not been inspected by any international inspectorate. However, the site had previously been inspected by the German Authority (Sachsen) in March 2018 for OSD with positive outcome. The site was inspected by the Bangladesh Authority, |

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| | Directorate of Drug Administration Bangladesh (IPL) in May 2018 and February 2020. |
| **Brief report of inspection activities undertaken – Scope and limitations** | |
| Areas inspected | • Quality management system<br>• Injectable Potent Drug Facility (IPD, Unit-1)<br>• Quality control laboratory |
| Restrictions | The inspection was restricted to the production of the product listed in the inspection scope.<br>This inspection was planned to be conducted from 15 to 19 March 2020, however it was closed earlier due to the COVID-19 pandemic. Several sections as mentioned in the report were not covered during this inspection due to inspection being shortened and the requirement for the inspection team to return immediately due to the various travel restrictions being announced following the declaration of a global pandemic on 6 March 2020. |
| Out of scope | All other products and production facility on the site were outside of the inspection scope and were not visited. |
| WHO products covered by the inspection | RH084 Medroxy progesterone Intramuscular Injection 150 mg/ml (suspension) DMPA Injection |
| **Abbreviations** | **Meaning** |
| AHU | Air handling unit |
| ALCOA | Attributable, legible, contemporaneous, original and accurate |
| API | Active pharmaceutical ingredient |
| APR | Annual product review |
| APS | Aseptic process simulation |
| BMR | Batch manufacturing record |
| BPR | Batch production record |
| CC | Change control |
| 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 |

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| | chromatography equipment) |
| HVAC | Heating, ventilation and air conditioning |
| IQ | Installation qualification |
| LAF | Laminar air flow |
| LIMS | Laboratory information management system |
| MB | Microbiology |
| MBL | Microbiology laboratory |
| MF | Master formulae |
| MFT | Media fill Test |
| MR | Management review |
| NC | Non conformity |
| NRA | National regulatory agency |
| OQ | Operational qualification |
| PHA | Process hazard analysis |
| PLC | Programmable logic controller |
| PM | Preventive maintenance |
| PQ | Performance qualification |
| PQR | Product quality review |
| PQS | Pharmaceutical quality system |
| PW | Purified water |
| QA | Quality assurance |
| QC | Quality control |
| QCL | Quality control laboratory |
| QMS | Quality management system |
| QRM | Quality risk management |
| RA | Risk assessment |
| RCA | Root cause analysis |
| RO | Reverse osmosis |
| 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 |
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## 1. Pharmaceutical quality system

A documented system for quality assurance was established, with procedures covering key quality elements in place. Operations were specified in written form and critical GMP requirements were essentially being met. The procedures reviewed and discussed during the inspection were generally of an acceptable standard.

The Quality Department was divided into QA and QC and these units are separate from the Production department. Although there were elements of QA oversight and approval over the overall process, the detailed dossier audit procedures were not fully developed and formally documented to manage the assembly and review of regulatory dossiers prior to be submission for completeness and accuracy. These were addressed by the manufacturer in the subsequent CAPA to an acceptable level.

**Annual Product Quality Review**
The company had in place an SOP for performing product quality reviews. The following PQRs were reviewed during the inspection.

*DMPA injection (WHO grade)*
A PQR for Medroxy progesterone 150 mg/ml vials (WHO grade) was approved in November 2017. The quality review of the API and FPP were covered. It listed the following: Deviations 0, OOS 0 and some change controls were reported. The stability study data of the injection product was reviewed. Non-compliances observed during the inspection that was listed in the full report regarding PQR were addressed by the manufacturer to a satisfactory level.

**Quality Risk Management**
Quality risk management was not reviewed in detail due to time constraint. Some potential risk was noted during the review of manufacturing process e.g. sterilization by filtration. It has been assessed by the company subsequently in the relevant SOP at an acceptable level.

**Deviations, OOS and Non-Compliance Management**
The company had procedures for management of Deviations, OOS and non-compliance established and recorded in the appropriate register for IPD products. The observations regarding the OOS procedure listed in the full report have been addressed by the manufacturer to a satisfactory level.

**CAPAs**
The company stated that the CAPAs for the major deficiencies observed in the previous inspection have been closed in the opening meeting. The CAPA Register and CAPAs for Unit-1 block for 2019 was reviewed and discussed.

**Change Control (CC)**
A change control procedure was in place. Major changes made since the previous inspections were documented. All CCs for 2017 and 2018 had been closed. Most of the CC for 2019 has been closed.

At the time of inspection, several changes proposed for dossier variation submission to WHO regarding RH084 Medroxyprogesterone acetate suspension for injection 150mg/ml listed in the full report were ongoing and need to be checked in future inspection.

The inadequacy in a CC of introduction of new Glove system in vial filling and stoppering machine observed during the inspection listed in the full report has been addressed by the manufacturer in the subsequent CAPAs.

**Product Release**
Product release was managed according to an SOP. A check list used for review was documented. The procedure was acceptable in general.

The commercial batches of WHO Prequalified product within the scope of the inspection had not yet been supplied to markets by the site at the time of the inspection

## 2. Good manufacturing practices for pharmaceutical products

Good manufacturing practices were generally implemented. Necessary human and physical resources with adequate premises, equipment and utilities were provided for the current operational level of DMPA injection manufacturing activities. The manufacturing processes followed procedures as defined and documented in the BMRs. The personnel are appropriately qualified. The manufacturing facility where DMPA injection is produced is a dedicated facility.

## 3. Sanitation and hygiene

Sanitation of clean areas is performed frequently in accordance with the SOP. Disinfectants were sterilized before used in Grade A & B areas. The facilities for sanitation and hygiene established on the site appeared acceptable. The disinfectant programme and monitoring were not checked in detail due to time constraints.

## 4. Qualification and validation

Validations and qualifications were performed according to the site policy and documented procedures. Necessary resources in production were provided, including qualified and trained personnel, adequate premises, equipment and services, appropriate materials, approved procedures and instructions, laboratories and equipment for in-process and other controls.

Equipment and process validation had been identified what required qualification and validation activities. Revalidation was required to be performed as trigged by changes. Media fill for the production line in Unit I was performed according to documented procedures. The key elements of a qualification and validation programme were defined.

Equipment was qualified according to the in-house procedure. Critical equipment was requalified at specified time intervals. The recent annual requalification of the autoclave used for parts sterilisation and the tunnel hot air steriliser was reviewed and found to be satisfactory.

During the inspection procedures and validations were reviewed for

- Validation of aseptic processes SOP
- Media simulations report and batch record performed in 2019 and 2020.
- A smoke test of filling LAF validation and documentation.
- An autoclave qualification protocol and report
- An operation and cleaning of autoclave SOP
- A process validation protocol and report
- Tunnel qualification was spot checked.

The validation and qualification activities reviewed were found acceptable in general, however the deficiencies noted and listed in the full report have been addressed by the manufacturer to an acceptable level.

The production line was dedicated to DMPA injections and included different quality specifications for the different API sources. The cleaning validation of the DMPA production line was not reviewed by this inspection due to time constraints.

Computerized systems were used in the warehouse for material management and logistic administration, as well as in the QC laboratory for material and product testing and data management. The company had procedures in place for back up and archiving of data.

Computerised system validation and qualification were not reviewed in detail due to time constraints.

## 5. Complaints

Complaints was not inspected due to time constraints.

## 6. Product recalls

Product recall was not inspected due to time constraints.

## 7. Contract production, analysis and other activities

There is currently no contract production outsourced or for other licence holders in the high potency injectable suite.

Some testing of the API impurities was contracted to external QC testing laboratories.

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

The company has a qualification procedure for approving suppliers in place. The responsibility for final approval and signature was QA head. The flow diagram of the procedure was included and showed that commercial batches were tested for quality and additionally with a site audit conducted for API manufacturers. Agreements has been finalised after quality approval has completed.

Self-inspection was not covered in this inspection due to time constraints.

## 9. Personnel

The manufacturer had defined and documented the organization and management structure. The responsibility, authority and interrelationship of the personnel was specified in the organization chart.

The personnel met during the inspection appeared to have adequate awareness of the principles of GMP and showed that they received initial and continuing training, including hygiene instructions, relevant to their responsibilities in the production process. The total number of employees at the Dahmrai site in the Company was 594 at the time of the inspection. Steps were taken to prevent unauthorized people from entering production and QC areas and appeared to be effective.

## 10. Training

The training was briefly discussed and indicates that the company has procedures in place to allow, for newly appointed personnel to be trained on principle and job specific training and re-training in the event of personnel errors, resulting in a CAPA event. The QA department is responsible for training.

## 11. Personal hygiene

Changing and washing before entry to production areas followed written procedures. Direct contact was avoided between the operator's hands and starting materials, primary packaging materials and intermediate or bulk product. The protective clothing, washing and sterilization operations followed standard operating procedures.

## 12. Premises

Exposed surfaces of production areas were generally smooth, impervious and unbroken to minimize the shedding or accumulation of particles or microorganisms.

The injection production line dedicated to DMPA injection was located on one side of Unit-1 block. An OSD facility was on another side. These two production areas were separated.

Changing rooms were designed with airlocks to provide physical separation of the different stages of changing. Changing rooms were flushed with filtered air. The final stage of the changing room was in the at-rest state, the same grade as the area into which it leads. Changing rooms were equipped with mirrors.

QC laboratories were separated from production areas. Entering QC was access controlled. The QC laboratory was well designed and with adequate space for the various activities. The dedicated secondary controlled area for the handling of DMPA requires entering through changing room with gowning procedure, with appropriate pictorials.

Finished Goods warehouse in Unit-1 was briefly visited. The products were managed by the SAP system. The product status was spot checked and found acceptable.

## 13. Equipment

The production equipment installed in Unit-1 dedicated to DMPA injections was of an acceptable standard and appeared to be adequately maintained. Manufacturing was performed in vessels with automatic CIP and SIP process or autoclaved. The equipment, batch size and manufacturing process was spot checked during the inspection. The product filling line was equipped with RABS as a barrier for human interventions during the aseptic filling. Gloves had been installed on the RABS as CAPAs to the deficiencies of last inspection.

## 14. Materials

Incoming materials were purchased from approved suppliers, sampled and tested according to specifications and testing procedure. Finished products were kept in quarantine until final release.

## 15. Documentation

The company has an adequate document system in place. The documentation was in general well structure, prepared, number and duly signed by QA and other signatories.

Master BMRs for WHO grade DMPA injections, SOPs and logbooks in production were reviewed and found acceptable in general.

## 16. Good practices in production

It was noted that WHO grade DMPA injection 150mg/ml have been qualified, and commercial batches have not been supplied to market.

The Unit-1 production area was visited. The general design of the facilities was adequate. The sterile API dispensing, and charging operation were observed. The production area was briefly inspected. The filling line was not in operation which was scheduled for the next day. The filling line was however not inspected due to the closing of the inspection earlier than planned.

Clean areas for the manufacture of sterile products were classified according to the environment requirement for aseptic production process.

The product label, leaflet and secondary packaging for WHO DMPA product have not been finalised at the time of inspection. The secondary packaging for domestic DMPA product was performed manually at the time of the inspection. The line clearance in the secondary packaging area was checked.

The following documentation was reviewed during the inspection:

- A filter integrity test SOP;
- An incoming rubber stopper testing specification and endotoxin control SOP;
- A material flow of injectable potent drug facility SOP;
- A leak test procedure of filled vials SOP;

The company provided Video material to assist review of aseptic operations in a biosafety unit

The process control reviewed appeared acceptable, however some deficiencies noted and listed in the full report has been addressed by the manufacturer to a satisfactory level.

## 17. Good practices in quality control

The QC laboratory was divided into two main sections and was generally well designed, spacious and with the required equipment available. The one area focusses on general QC analyses and whereas the other area is dedicated for the handling of DMPA. The area for IR analyses was a separate room. Appropriate control access and gowning procedures were in place with adequate pictorials present to guide those upon entering the DMPA area. List of authorized persons to the DMPA area was available. The final finished product CoA is generated from the electronic blank copy by QC residing in QA. The safe handling of DMPA was in place.

The Microbiological laboratory was not inspected due to time constraints.

**Weighing**
A balance was housed in a biosafety cabinet. The utilization of the biosafety cabinet was discussed. A corresponding SOP was in place. A filter leak test of the unit was in place.

**Computerized Systems**
QC laboratory function for primary HPLCs, IR were equipped with Lab Solutions CS software that was requalified in 2019. HPLC and IR was spot-checked for log-in and audit trail procedures. Several standalone equipment is still in use, included pH meter, balances, Karl Fisher. Access to computers was password controlled. The log-in trails and activities were adequately retrievable.

**Sample Management**
The company has a system for sample management as guided by an SOP. A sample logbook showed details of the samples received for testing. No medroxy progesterone samples were being tested during the inspection. A monthly stability program list was available to ensure timely testing stability samples.

**Reference Samples**
A fridge used for storing reference samples was secure and locked. The deficiencies noted and listed in the full report, for logging of the reference standards, have been addressed by the manufacturer to an acceptable level.

**Working Standards**
Several procedures to prepare, qualify and to control working standards are in place and found acceptable. The qualification of the working standards was signed by QC and QA.

**Retention Samples**
The retention samples were well secured with access control and register list for authorised personnel. The environmental conditions of the retention room were in line with storage requirements. Procedures to manage retention samples were in place and found acceptable.

**Equipment**
The QC laboratory was adequately equipped for IPD quality control testing and access of instrumentation was secured though password control procedure for LabSolutions login. Calibration status and re-calibration dates were found acceptable. The records and logs were adequately maintained. Procedures were place for equipment use during analyses and acceptable weighing practises were followed.

**Stability studies:**
Stability study chambers were placed and functional to conduct the stability studies under for appropriate conditions. The stability study registers for samples stored at 30°C and 75% RH and at accelerated stability conditions at 40°C and 75% were reviewed and found acceptable. The ongoing stability programme for DMPA, stored at 30°C and 75% RH, was spot checked, for WHO batches and to be followed at next inspection. The stability data to date was discussed and found acceptable.

| Part 3 | Conclusion – Inspection outcome |
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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, ***Incepta Pharmaceuticals Ltd***, located at ***Krishnapura, Sahabelishor, Dhamrai, Dhaka, Bangladesh*** 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 |
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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. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 10.
***Short name: WHO TRS No. 1010, Annex 10***
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf