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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
of the Active Pharmaceutical Ingredient (API) Manufacturer

Part 1	**General information**
Manufacturers Details	
Company information	
Name of manufacturer and address	**Zhejiang Jiangbei Pharmaceutical Co., Ltd.** Dongdai Zhang'an Street, Jiaojiang District, Taizhou City, 318017, Zhejiang Province, The People's Republic of China *North latitude:* N 28°42′20.0″, *East longitude:* E 121°22′03.2″ *D-U-N-S:* 420631715
Corporate address of manufacturer	As above
Inspected site	
Address of inspected manufacturing site if different from that given above	As above
Manufacturing buildings	Darunavir: Workshop 02 building 11 (B); Workshop 03 buildings 07, 08; building 09. Efavirenz: Workshop 02 building 11 (A); Workshop 06; building 09; building 25.
Manufacturing license number	No: Zhe 20060462 for manufacture API (Simvastatin, Levetiracetam, Clopidogrel hydrogen sulphate, Efavirenz, Atorvastatin calcium, Linezolid, Esomeprazole sodium, Darunavir)
Inspection details	
Dates of inspection	13 – 16 August 2018
Type of inspection	Routine
Introduction	
Brief summary of the manufacturing activities	Production, quality control, packaging, storage and distribution of intermediates and APIs and finished dosage form products - tablets (*to note*: finished dosage forms not yet commercialized at the time of the inspection)
General information about the company and site	Zhejiang Jiangbei Pharmaceutical Co., Ltd. is a privately owned company founded in 1993 as Jiangbei Chemical Factory. In 2004 it was renamed as Zhejiang Jiangbei Pharmaceutical Co., Ltd. The site covers an area of 80,000 m2. The main APIs produced at the site are anti-hyperlipidemics: Simvastatin, Atorvastatin

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<table>
<tr><td></td><td>with other APIs including Calcium; anti-epileptic: Levetiracetam, and anti-virals: Efavirenz, Sofosbuvir.
Starting material (E02) and Intermediate (E05) used in the manufacture of Efavirenz are also produced on the site. E05 is also supplied to external customers. There are no toxic or hazardous substances such as antibiotics, hormones or cytostatic manufactured at this site.

The company had recently completed a new workshop for manufacture of finished pharmaceutical products. It was stated that production will include Efavirenz tablets.</td></tr>
<tr><td>History</td><td>The site was inspected by WHO:
• May 2016
The site was also inspected by the following authorities:
<table>
<tr><th>Authority</th><th>Date/s of inspection</th><th>Scope of inspection</th></tr>
<tr><td>Pharmaceuticals and Medical Devices Agency of Japanese</td><td>August 26th to 28th, 2013</td><td>Ipriflavone</td></tr>
<tr><td>United States Food and Drug Administration(USFDA)</td><td>March 31st to April 3rd, 2014</td><td>Simvastatin Ammonium Salt</td></tr>
<tr><td>China Food and Drug Administration (CFDA)</td><td>January 14th to 16th , 2015</td><td>Simvastatin</td></tr>
<tr><td>German Health Authority Landesant fur Gesundheit und Soziales</td><td>July 21st to 23rd, 2015</td><td>Simvastatin</td></tr>
<tr><td>United States Food and Drug Administration(USFDA)</td><td>May 02nd to 06th, 2016</td><td>Simvastatin Ammonium Salt</td></tr>
<tr><td>China Food and Drug Administration (CFDA)</td><td>Nov. 27th to 29th, 2017</td><td>Efavirenz</td></tr>
<tr><td>Ministry for Industry and Trade of the Russian Federation (Minpromtorg of Russia)</td><td>March 21st to 23rd, 2018</td><td>Simvastatin, Efavirenz, Darunavir, Clopidogrel, Levetiracetam Rosuvastatin, Atorvastatin</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>• Pharmaceutical Quality System
• Documentation system
• Production System
• Packaging system
• Facilities and Equipment System
• Laboratory Control System</td></tr>
<tr><td>Restrictions</td><td>During the site inspection attention was paid only to Darunavir production process starting from the first step.</td></tr>
<tr><td>WHO product</td><td>API and intermediates used for manufacture HIV medicines</td></tr>
</table>

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covered by the inspection

Abbreviations

AHU	air handling unit
ALCOA	attributable, legible, contemporaneous, original and accurate
AQL	Acceptance quality limit
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
MACO	maximum allowable carry over
MB	Microbiology
MBL	microbiology laboratory
MF	master formulae
MR	management review
NIR	near-infrared spectroscopy

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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
TOC	Total organic carbon
URS	user requirements specifications
UV	ultraviolet-visible spectrophotometer
VMP	Validation Master Plan
WFI	water for injection
WS	working standard

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Part 2	Brief summary of the findings and comments

1. Pharmaceutical quality system

The quality management system was generally established and documented; the system encompassed organizational structure, procedures and processes. QA and QC departments were independent of production. In general, deviations from established procedures were documented and explained. A procedure was in place for notifying the responsible management of regulatory inspections, serious GMP deficiencies, product defects and related actions.

Data integrity policy

The SOP "Data integrity policy" was briefly discussed. The SOP was general and gave references to related SOPs. According to the SOP, QA should review once per months at least 3 batches on each instrument, each product audit trails. The following related documents were briefly discussed:

- SOP "Test record management", applicable to paper and electronic data generated in the QC lab.
- SOP "QC electronic data management"
- SOP "QC computer management" back-up of Empower 3 data:
  - ✓ Qualification report of QC data back-up/restoration
  - ✓ Qualification protocol for QC data back-up
- SOP "QC chromatogram management"
- SOP "Management of Empower 3 chromatography workstations": all delete functions were deactivated for all user groups; 5 access levels were specified
- SOP "Quality review and release procedure of finished product"

Inspectors requested the Company to export to Excel sheets Empover 3 system and project audit trails for WHO products starting from the previous WHO inspection. The submitted files were reviewed and no data integrity issues noted. Selected actions were cross checked. Laboratory incidents and deviations were recorded and were traceable and legible.

Qualification reports on Empower 3 were available, IQ and OQ had been performed by supplier - Waters, PQ had been performed in-house; challenges of access rights and audit trails were part of the PQ.

Management review (MR)

The SOP "Management procedure of quality system assessment" and latest MR minutes were briefly discussed. According to the procedure MR should be performed once per year. Spot checks confirmed that generally the standard agenda specified in the SOP had been followed. MR minutes were signed by all participants, corrective actions were specified.

Product Quality Review (PQR)

The SOP "Annual product quality review" and z APQR for 2017 for specific product were briefly discussed.

The SOP "Operation procedure of Minitab" was briefly discussed. The Cp criterion was taken from PDA TR No 59 "Utilization of statistical methods for production monitoring".

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Deviations, incidents

The SOP "Deviation management" was briefly discussed. Deviations were trended annually. Trends were found to be detailed and explanatory. Deviation trends for 2017 were briefly discussed. Ishikawa diagram was used for root cause analysis. According to the SOP critical and moderate deviation investigations should be extended to other batches relevant to the batch involved.

The SOP "QC lab deviation management procedure" was briefly discussed. The procedure was applicable but not limited to the following laboratory incidents: system suitability failure, instrument failure, analyst error, transcription error. Laboratory deviations were trended; trends for 2017 were briefly discussed.

Change control (CC)

The SOP "Change control management" and trends for 2017 were briefly discussed.

Complaints/ returns/recalls

The following SOPs and respective registers were briefly discussed:

- SOP "Customer complaint management",
- SOP "Disposal of product return" and SOP "Product return receive form"
- SOP "Operating product recall". Recalls were classified as:
  - ✓ Primary, customers should be informed within 24 hours
  - ✓ Secondary, customers should be informed within 48 hours
  - ✓ Tertiary, customers should be informed within 72 hours.

Self-inspection

The SOP "GMP self-inspection procedure" was briefly discussed. According to the SOP self-inspection should be conducted at least once per year for the entire site. Self-inspection schedule for 2018 July – September was presented to inspectors.

Supplier qualification

The SOP "Supplier management" was briefly discussed. According to the SOP, on-site audits of suppliers of key starting materials and primary packaging materials were conducted every three years. Audit schedule for 2017 and 2018 (key starting materials) and approved suppliers list were presented to inspectors. Spot checks confirmed that audit schedules were followed.

Personnel

Training

The SOP "Personnel training management" and training plan for 2018 were briefly discussed. The SOP was applicable also for training and qualification of analysts. True/false, multiple choice questions and open questions were used for training evaluation.

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2. Documentation system

Documentation system was generally established. Documents related to the manufacture of intermediates and APIs were prepared, reviewed, approved and distributed according to written procedures. The issuance, revision, superseding and withdrawal of documents were controlled with maintenance of revision histories. Specifications were established for raw materials, intermediates and APIs.

3. Production system

In general, production operations followed defined procedures. Process flows (with IPCs) and routes of synthesis were available. Deviations from procedures were recorded; major deviations were investigated.

The SOP01-SC009 "Workshop material management" was briefly discussed. The procedure explained material transportation within the site between different buildings. The Company stated that only solid materials were transported between buildings.

Reprocessing and Reworking

The SOP "Reprocess and rework" and reprocessed products register for 2018 were briefly discussed. According to the SOP reworking of intermediates and finished APIs was not allowed.

Blending

The SOP "Operation procedure for blending of XXX" and SOP "Management of batch number, manufacture date and retest date" were briefly discussed. The SOP was applicable to intermediates and finished API. .

Cleaning

Cleaning procedures appeared to be sufficiently detailed and adapted to the specific properties of materials/products. Detergents were not used. Dirty equipment hold time was established. Verification of cleaning was conducted. UV was mainly used. The Company was aware of the PDE concept. 10 ppm cleaning limit appeared to be adequate for APIs processed at the site.

Cleaning of process pipelines was briefly discussed. The general approach of the Company was that process hoses which were disassembled were dedicated. .

The SOP "Cleaning validation operation procedure" was briefly discussed. Cleaning procedures and records for some equipment were checked. The latter were specific for product/material and stage of synthesis.

Recovery of solvents

The following documents were briefly discussed:

- SOP "Procedure of batch number management of recovered solvent"
- SOP "Cross-contamination prevent and risk control management" section stated that recovered solvents could be used in the same product the same or earlier step.

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4. Facilities and equipment system

Facilities were designed to minimize potential contamination. Adequate space was provided for orderly placement of equipment and materials to prevent mix-ups and contamination. Buildings were constructed of materials appropriate to the activities carried out. Production premises inspected were well maintained and clean.

The site tour included:

- Workshop 02 Building 11 (B)
- Workshop 03 Building 07, 08
- Building 09
- PW system, building 12
- Intermediates and finished products storage room, building 24
- Cold storage 2 – 8 °C room, building 24
- Warehouse B2 storage of solvents in drums
- Workshop 03 Building 07 Clean rooms

Cold storage room

Temperature (T) in the in-built and isolated cold storage room was continuously recorded every 30 minutes using two sensors and checked manually twice per day. An alarm system was connected to mobile phones and was challenged once a year. Alarms were registered in the maintenance log book. Alarm system challenge records were briefly discussed. Cold room T mapping studies were briefly discussed.

Finished products warehouse

IQ and PQ protocol and report "Temperature mapping for finished product warehouse was briefly discussed.

Production equipment

Generally equipment used in the manufacture of intermediates and APIs was of appropriate design, adequate size, and suitably located for its intended use. Glass line reactors were used in the first steps of synthesis, stainless steel 316L "clean room" equipment was used in final steps of production. Centrifuge bags were stated to be product dedicated. Major equipment and permanently installed processing lines were identified. Food grade oil was used for lubrication when equipment was in contact with product. Food grade oil CoA was available for review.

The SOP "Operation and maintenance of square vacuum drier" was briefly discussed.

Laboratory instruments

HPLCs in-house calibration was performed once in 6 months. HPLC XX in-house calibration was performed YY. Calibration records were briefly discussed.

Balances of appropriate range and precision were available for quality control operations and were calibrated. Daily check was performed using minimum weight (10mg), maximum weight and most frequently used weight. Self-calibration was run before each weighing. Monthly calibration was performed following USP chapter 41 and 6 monthly following USP chapter 1251. Balances were connected to printers, time and date functions were blocked.

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Utilities

Site tour included inspection of purified water (PW) system located in building 12, supplying buildings 07 and 08, and HVAC system, supplying air to building 07 clean rooms.

PW system appeared to be constructed of suitable materials and was well maintained. Conductivity was continuously monitored on line at three points: before RO, after RO and at the return loop. Flow meter was installed at the return loop. Heat sanitisation (80 °C) was performed twice per month from June to September and once per month during other periods. Chemical sanitisation was also applied. The SOP "Cleaning and sanitisation of PW system" and SOP "Operation and maintenance of PW system" were briefly discussed.

Building 07 had one AHU XX serving all clean rooms, including corridors and changing rooms. HEPA filters were installed in grade D (ISO 8) rooms. 70 % fresh air was used. AHU XX was inspected.
The SOP "Operation and maintenance of XX air conditioning system" was briefly discussed. In clean rooms, T&RH and Δp were recorded twice per day. Δp minimum limits in clean rooms were established as 5 Pa and 10 Pa

Laboratory premises

Laboratory areas and operations were separated from production areas. IPC laboratory for the whole site was located in a separate building at production compound. QC laboratories were designed to suit the operations to be carried out in them. Sufficient space was given to avoid mix ups and cross-contamination. Microbiological laboratory premises were separated from the QC laboratory.

5. Laboratory control system

Sampling procedure

The SOP "Sampling management" was briefly discussed. The SOP was applicable to raw materials, packaging materials, intermediate and finished products sampling, including blended batches. AQL inspection level II was applied for sampling of primary packaging materials. AQL 0.10 was applied for all defect classes.

Reference standards

Primary reference standards were used to qualify working standards. Qualified working standards were dispensed into single use amber vials. A 1 year expiry was assigned to working standards. Standards were stored in a dedicated fridge at T 2 – 8 °C. T were recorded on-line every 30 minutes and checked daily. The fridge was equipped with an alarm system.

Stability studies

Stability studies had been completed for intermediates XX. Dry intermediates were also supplied to customers. Study report on YY was checked. Annually one batch was put on stability verification.

SOP 01 "Product stability study system" was briefly discussed; the SOP was applicable to finished APIs and "commercial" intermediates.

OOS OOT

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The procedure SOP "OOS / OOT investigation" followed the MHRA guidance. Logbooks were maintained and were spot checked; case reports were available for the requested OOS/OOT. Logbooks indicated actions/CAPA in QC or related to production.

6. Packaging and labelling system

Packaging of the final API was performed in cleanrooms. No packaging operations were carried out during the inspection. According to the procedures APIs were packed in double PE bags which were placed in hermetically sealed aluminium foil bags. Inner label was applied to the aluminium foil bags which were placed in carton drums. Inner and outer labels were printed in the QA department.

Part 3

Conclusion – inspection outcome

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report ***Zhejiang Jiangbei Pharmaceutical Co., Ltd. Dongdai Zhang'an Street, Jiaojiang District, Taizhou City, 318017, Zhejiang Province, The People's Republic of China*** was considered to be operating at an acceptable level of compliance with WHO good manufacturing practices for active pharmaceutical ingredients 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.

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PART 4

List of GMP guidelines referenced in the inspection report

1. 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/

2. 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/

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 TRS No. 961, 957), Annex 1
   http://www.who.int/medicines/publications/44threport/en/

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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/

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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 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

18. 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

19. 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 TRS No. 996, Annex 5
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf

20. 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

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