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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Desk Assessment of Finished Pharmaceutical Product (FPP) Manufacturer

Part 1	**General information**	
Company information		
Name of Manufacturer	**Cipla Ltd**	
Corporate address of manufacturer	Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai – 400 013, India. Phone: + 91 22 24826000 Fax: +91 22 24826120	
Inspected site		
Name & address of manufacturing site	Cipla Ltd Plot No. 9, 10 Indore Special Economic Zone, Phase II Pithampur, District Dhar, 454775 Madhya Pradesh, India	
Production Block/Unit	Unit-I and IV	
Desk assessment details		
Date of review	15 June 2020	
Products covered by this desk assessment	1. HA365 (Lamivudine/Nevirapine/Zidovudine Tablets, 150/200/300mg) 2. MA064 (Artemether/Lumefantrine Tablets, 20/120mg) 3. HA060 (Lamivudine/Zidovudine Tablets, 150/300mg) 4. TB321 (Linezolid Tablets, 600mg) 5. MA115 (Artemether/Lumefantrine Dispersible Tablets, 20/120mg) 6. HA053 (Lamivudine Oral Solution, 50mg/5ml) 7. HA200 (Nevirapine Oral Solution, 50mg/5ml) 8. HA382 (Abacavir Oral Solution, 20mg/ml) 9. HA054 (Zidovudine Oral Solution, 50mg/ml) 10. HA680 (Dolutegravir Tablets, 50mg)	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last)**	
UKMHRA	Dates of inspection:	4-7 June 2019
	Type of inspection:	Routine re-inspection
	Block/Unit:	Unit- I, II, III, IV
	Type of products/Dosage forms covered:	Nonsterile finished products
USFDA	Dates of inspection:	2-13 April 2018
	Type of inspection:	Routine inspection
	Block/Unit:	Plot No 9 & 10

	Type of products/Dosage forms covered:	Sterile and non-sterile drug products
USFDA	Dates of inspection:	13-17 May 2019
	Type of inspection:	Post approval inspection
	Block/Unit:	Plot No 9 and 10 (Unit I, IV)
	Type of products/Dosage forms covered:	Oral suspension and tablets
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	3-6 October 2017, Compliant	
Brief description of manufacturing activities	Cipla Ltd, Indore is situated within the Indore Special Economic Zone (SEZ) at Pithampur, Dist. Dhar, (Madhya Pradesh). It is about 40 Kilometers away from Indore city. The operations commenced in Year 2010. The total area of site (Plot no 9 & 10) is approximately 153,100 sq. m. <u>Plot No. 9 consists of following Units:</u> - Unit-I: form fill seal and liquid oral - Unit-II metered dose inhalers - Unit-III nasal sprays, eye drops and pre-filled syringes <u>Plot No. 10</u> consists of - Unit-IV (tablets, capsules, pellets, sachets and multi-inhalers)	
General information about the company and manufacturing site	Cipla Limited is a public limited company established in 1935 by Dr. K.A. Hamied and managed by a professional board of directors. It has its own management control & operation and has no parent company. Cipla manufactures products of various range including prescription, animal health care, over the counter (OTC) and active pharmaceutical ingredients, which are supplied to over 150 countries located in the various regions including USA, Europe, Australia, South America, Brazil, Middle East Asia and Africa. The corporate headquarters including the corporate quality assurance is located in Mumbai. Senior personnel are available in Mumbai for providing support to the manufacturing units in the area of technology, R&D, manufacturing, quality assurance, quality control and regulatory affairs. Import, export and distribution activities are monitored from the corporate office. Research centers are located at Vikhroli, Patalganga, Kurkumbh and Bengaluru. Cipla has eight manufacturing facilities in India: - Active Pharmaceutical Ingredients are manufactured at Bengaluru, Bommasandra, Patalganga and Kurkumbh. - Pharmaceutical formulations are manufactured at Goa, Patalganga,	

	Kurkumbh, Baddi, Sikkim, Bengaluru and Indore
Focus of the last WHO inspection	Routine GMP inspection covering Prequalified and products under assessment
Areas inspected	**Document reviewed including but not limited to** - Organization Chart - Job descriptions for key personnel - Product Quality Review - Quality Risk Management - Management Review - Responsibilities of the quality units and production - Complaints and Recalls - Deviation control and change control - OOS and investigation - CAPA procedure - Material release - Validation and qualification - Data integrity - Product release - Sampling and testing of materials - Batch processing records - Materials management system - Purified water system **Site visited:** - Unit-I and Unit-IV. - Stability study QC laboratory and control system - Starting material and finished Goods warehouse
Out of scope and restrictions (last WHO inspection)	None
WHO products covered by the last WHO inspection	HA365 (Lamivudine/Nevirapine/Zidovudine Tablets, 150/200/300mg) MA064 (Artemether/Lumefantrine Tablets, 20/120mg) HA060 (Lamivudine/Zidovudine Tablets, 150/300mg) TB321 (Linezolid Tablets, 600mg) MA115 (Artemether/Lumefantrine Dispersible Tablets, 20/120mg) HA053 (Lamivudine Oral Solution, 50mg/5ml) HA200 (Nevirapine Oral Solution, 50mg/5ml) HA382 (Abacavir Oral Solution, 20mg/ml) HA054 (Zidovudine Oral Solution, 50mg/ml) HA680 (Dolutegravir Tablets, 50mg)
Additional products covered by this desk assessment:	None

Abbreviations	Meaning
AHU	Air handling unit
API	Active pharmaceutical ingredient
BMR	Batch manufacturing record
BPR	Batch production record
CAPA	Corrective and preventive action
CC	Change control
GMP	Good manufacturing practices
NC	Non conformity
NRA	National regulatory agency
PQR	Product quality review
PQS	Pharmaceutical quality system
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
SOP	Standard operating procedure

Part 4	Summary of the assessment of supporting documentation

a) Manufacturing authorization and GMP certificate granted by the local authority:

The State Food and Drug Administration, Madhya Pradesh, India had issued a Manufacture Licenses 25/2/2010 (Form 25) and 28/2/2010 (Form 28). The licenses were valid until 25-02-2020. It was noted that the company have applied for a retention of the licence. The retention certificate from the office of the controller food and drug administration Madhya Pradesh states "Drugs Manufacturing Licences No. 25/2/2010 in Form 25 and 28/2/2010 in Form 28 which are valid up to 25-02-2020. The firm has deposited requisite online fee for retention of licence (s) for further period of 26-02-2020 to 25-02-2025. In view of above as per GSR 1337(E) dated 27-10-2017, the above-mentioned licences are deemed to be valid for a period of 5 years i.e. up to 25-02-2025."

The Food and Drug Administration, Bhopal, Madhya Pradesh, India has issued a certificate of GMP (Certificate No. 03/2010) based on the inspection carried out on 3rd and 4th of June 2019. The certificate is valid until 18 June 2022.

b) Site master file (SMF):

The manufacturer has submitted the site master file (SMF) (SMF/CIP/IND/F Version No 17 effective date 6 May 2020) of their Pithampur manufacturing site. The SMF provided a high-level overview of the manufacturing activities carried out on the site. The SMF was supported with 11 annexures. In general, the SMF appeared to be adequate.

c) List of regulatory inspections performed in the last 3 years and their outcome:

S. No.	Authority	Dates of Inspection	Outcome
1.	Medicine & Healthcare Product Regulatory Agency, UK	04th-07th June 2019	Approved
2.	Medicine & Healthcare Product Regulatory Agency, UK	20th – 25th Feb 2017	Approved.
3.	United States Food & Drug Administration, (USFDA)	13th -17th May 2019	EIR received
4.	United States Food & Drug Administration (USFDA)	02nd -13th Apr 2018	EIR Received
5.	United States Food & Drug Administration (USFDA)	19th – 23rd Jun 2017	EIR received
6.	United States Food & Drug Administration (USFDA)	23rd - 27th Jan 2017	EIR received
7.	National Drug Authority (NDA), Uganda	05th - 10th Oct 2017	Approved
8.	Therapeutic Goods Administration (TGA), Australia	17th - 25th Feb 2016	Approved
9.	Medicines Control Authority, Zimbabwe (MCAZ)	10th -15th Dec 2015	Approved
10.	Kingdom of Saudi Arabia, Saudi Food and Drug Authority	4th-5th Feb 2020	Approval
11.	WHO, Geneva	3rd-6th Oct 2017	Approved
12.	National Agency for Food and Drug Administration and control (NAFDAC), Nigeria	21st – 22nd Mar 2017	Approved
13.	Belarus	6th -7th Apr 2016	Approved
14.	PMPB Malawi	15th Mar 2016	Approved
15.	Regierungspräsidium Darmstadt, Germany	14th-17th Mar 2016	Approved
16.	CDSCO Joint Inspection, India	3rd-4th Jun 2019	Approved
17.	WHO GMP Renewal inspection, India	5th- 6th Jan 2017	Approved
18.	CDSCO Mumbai-FDA Bhopal Joint Inspection, India	15th July 2016	Approved

d) List of all the products and dosage forms manufactured on-site:

The manufacturer has provided a list of products manufactured at all four Units. Unit-I has two dosage forms (form fill seal and liquid orals) whereas Unit-IV primarily produces capsules, powder/granules and tablets. Both Unit-I and IV produces product of different therapeutic areas.

e) Most recent product quality review(s) (PQR)(s) of the concerned WHO product(s):

Sr. No.	PQT Number	Product Name	Exhibit Details
1	HA365	Lamivudine/Nevirapine/Zidovudine Tablets, 150/200/300mg	***Exhibit no. 6***
2	MA064	Artemether/Lumefantrine Tablets, 20/120mg	***Exhibit no. 7***
3	HA060	Lamivudine/Zidovudine Tablets, 150/300mg	***Exhibit no. 8***
4	TB321	Linezolid Tablets, 600mg	***Exhibit no. 9***
5	MA115	Artemether/Lumefantrine Dispersible Tablets, 20/120mg	***Exhibit no. 10***
6	HA052	Zidovudine Capsules, 100mg	***Exhibit no. 11*** (Withdrawn)
7	HA680	Dolutegravir Tablets, 50mg	***Exhibit no. 12***
8	HA053	Lamivudine 50mg/5ml Oral solution	***Exhibit no. 13***
9	HA200	Nevirapine Oral Suspension 50 mg/5ml	***Exhibit no. 14***
10	HA382	Abacavir Oral Solution, 20mg/ml	***Exhibit no. 15*** (Withdrawn)
11	HA054	Zidovudine Oral Solution, 50mg/ml	***Exhibit no. 16***

The APQRs of the above-mentioned products were provided. Some of the listed products have been either withdrawn or no batch produced by Cipla hence no APQR submitted.

The APQR for product "Lamivudine/Nevirapine/Zidovudine Tablets, 150/200/300mg" (HA365) for the review period May 2018 – Apr 2019 was reviewed. There was no batch produced, released, rejected during the review period.

The APQR of Artemether 20mg and Lumefantrine 120mg tablets (MA064) for the review period Aug 2018 to July 2019 was reviewed. The APQR documentation was in detail covering aspects of starting materials, intermediates and finished products. The APQR was supported with graphical presentation and statistical analysis. In general, it appeared to be adequate.

The APQR of Lamivudine/Zidovudine Tablets, 150/300mg (HA060) for the review period December 2018 to November 2019 was reviewed. It was noted that there was no batch produced, released, rejected during the review period.

The APQR of Linezolid Tablets, 600mg (TB321) for the review of period January 2019 to December 2019 was reviewed. During this reporting period, one batch was produced and released. The graphical presentation including statistical evaluation was not part of the APQR as at least (ten) 10 to fifteen (15) batches are required for such analysis. In general, the APQR appeared to be adequate.

The APQR of Artemether/Lumefantrine Dispersible Tablets, 20/120mg (MA115) for the reporting period January 2019 to December 2019 was reviewed. During the reporting period, a total of 64 batches produced and 108 batches were packed and released. In general, the information provided appeared to be adequate.

The APQR of Dolutegravir Tablets, 50mg (HA680) for the reporting period January 2019 to December 2019 was reviewed. During the reporting period, a total of four (4) batches produced and 17 batches packed and released.

The APQR of Lamivudine 50mg/5ml Oral solution (HA053) for the reporting period June 2017 to May 2018 was provided. Thirteen (13) batches were manufactured during 2018-19 period.

The APQR of Nevirapine Oral Suspension 50 mg/5ml (HA200) for the reporting period October 2017 to September 2018 was reviewed. Eight (8) batches were produced and released. Ten (10) batches were manufactured in 2018-19.

The APQR of Zidovudine Oral Solution, 50mg/ml (HA054) for the reporting period February 2018 to January 2019 was reviewed. During the review period, no batch was produced, packed and released.

f) Batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant product(s):

Sr. No.	PQT Number	Product Name	BMR	BPR	FP COA	Exhibit Details
1	HA365	Lamivudine/Nevirapine /Zidovudine Tablets, 150/200/300mg	Not applicable	Not applicable	Not applicable	Not commercialized yet
2	MA064	Artemether/Lumefantri ne Tablets, 20/120mg	***ID00477***	***ID00562***	***ID00562***	***Exhibit no. 7***
3	HA060	Lamivudine/Zidovudin e Tablets, 150/300mg	Not applicable	Not applicable	Not applicable	Not commercialized yet

Sr. No.	PQT Number	Product Name	BMR	BPR	FP COA	Exhibit Details
4	TB321	Linezolid Tablets, 600mg	***ID92585***	***ID92598***	***ID92598***	***Exhibit no. 9***
5	MA115	Artemether/Lumefantrine Dispersible Tablets, 20/120mg	***ID00074***	***ID00492***	***ID00492***	***Exhibit no. 10***
6	HA052	Zidovudine Capsules, 100mg	Not applicable	Not applicable	Not applicable	***Exhibit no. 11*** (Withdrawn)
7	HA680	Dolutegravir Tablets, 50mg	***ID93102***	***ID00198***	***ID00198***	***Exhibit no. 12***
8	HA053	Lamivudine 50mg/5ml Oral solution	***IA90640***	***IA90648***	***IA90648***	***Exhibit no. 13***
9	HA200	Nevirapine Oral Suspension 50 mg/5ml	***IA90680***	***IA90682***	***IA90682***	***Exhibit no. 14***
10	HA382	Abacavir Oral Solution, 20mg/ml	Not applicable	Not applicable	Not applicable	***Exhibit no. 15*** (Withdrawn)
11	HA054	Zidovudine Oral Solution, 50mg/ml	Not applicable	Not applicable	Not applicable	Not commercialized yet

The BMR, BPR and analytical records of the above-mentioned products have been provided and appeared to be adequate. It was also noted that several products had been withdrawn as well as some of the products have not been commercialized yet.

g) Master batch manufacturing and packaging record(s) of the product(s) of interest:

Sr. No.	PQT Number	Product Name	BFG CODE	Exhibit Details for Master BMR & BPR
1	HA365	Lamivudine/Nevirapine/Zidovudine Tablets, 150/200/300mg	Not applicable	Not commercialized yet ***Refer Exhibit no. 6 for Agency communication***
2	MA064	Artemether/Lumefantrine Tablets, 20/120mg	31000137	***Exhibit no. 7***
3	HA060	Lamivudine/Zidovudine Tablets, 150/300mg	Not applicable	Not commercialized yet ***Exhibit no. 8***
4	TB321	Linezolid Tablets, 600mg	31004738	***Exhibit no. 9***

Sr. No.	PQT Number	Product Name	BFG CODE	Exhibit Details for Master BMR & BPR
5	MA115	Artemether/Lumefantrine Dispersible Tablets, 20/120mg	31000471	***Exhibit no. 10***
6	HA052	Zidovudine Capsules, 100mg	Not applicable	***Exhibit no. 11*** (Withdrawn)
7	HA680	Dolutegravir Tablets, 50mg	31006891	***Exhibit no. 12***
8	HA053	Lamivudine 50mg/5ml Oral solution	31005063	***Exhibit no. 13***
9	HA200	Nevirapine Oral Suspension 50 mg/5ml	31002735	***Exhibit no. 14***
10	HA382	Abacavir Oral Solution, 20mg/ml	31000075	***Exhibit no. 15*** (Withdrawn)
11	HA054	Zidovudine Oral Solution, 50mg/ml	31004111	***Exhibit no. 16***

The master batch manufacturing and packaging records for the above-mentioned products appeared to be adequate. It was also noted that several products had been withdrawn and some products have not been commercialized yet.

h) Recalls in the past three years related to products with quality defects:

The manufacturer has provided a list of recalls initiated on voluntary basis for various products. The list did not include any WHO Prequalified products.

i) Confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the product(s) has been performed and all matters dealt with:

The manufacturer confirmed that an internal audit program is being carried out at a defined frequency for all units at the Indore site. The internal audits covered all six systems of GMP.

j) copy of any warning letter, or equivalent regulatory action, issued by any authority to which the site provides or has applied to provide the product:

The company confirmed that there was no warning letter, or equivalent regulatory action, issued by any authority to Cipla Limited, Indore SEZ.

k) Out-of-stock situations:

The manufacturer confirmed that there was no out-of-stock situation occurred in past 3 years and same is not expected in future years as well as plant is having enough production capacity.

l) Additional documents submitted:

The manufacturer confirmed that there is no upcoming Inspection notification received to Cipla Ltd Indore. In case we receive any communication from Regulatory agency during the WHO desk assessment, we will notify to agency.

The manufacturer has also provided manufacturing process details confirming that the WHO Prequalified products are inspected by the SRAs.

Part 5	**Conclusion – Desk assessment outcome**

Based on the previous WHO inspections and on the GMP evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site ***Cipla Ltd*** located at ***Plot No. 9, 10 and 15, Unit-I & IV, Indore Special Economic Zone, Phase II Pithampur, District Dhar, Madhya Pradesh, India*** is operating at an acceptable level of compliance with WHO GMP guidelines.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 6	**List of guidelines referenced in this 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 GMP Guidelines*** or ***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 ***WHO TRS No. 957, Annex 2***
   http://apps.who.int/medicinedocs/documents/s20119en/s20119en.pdf

3. WHO guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report. Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 9. ***Short name: WHO TRS 1010, Annex 9***
   https://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS1010annex9.pdf?ua=1

4. 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/

5. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
Short name: WHO TRS No. 929, Annex 4
http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

6. 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 HVAC Guidelines*** *or* ***WHO TRS No. 1010, Annex 8***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en/

7. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4.
Short name: WHO TRS No. 937, Annex 4
http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

8. WHO Good Practices for Pharmaceutical 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** ***WHO TRS No. 957), Annex 1***
http://www.who.int/medicines/publications/44threport/en/

9. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2.
Short name: WHO TRS No. 957, Annex 2
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 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

19. 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

20. 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

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 guidelines 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