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

Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT

Desk Assessment of Finished Product Manufacturer

Part 1	**General information**
Company information	
Name of Manufacturer	Mylan Laboratories Limited, Pithampur
Corporate address of manufacturer	Plot No.564/A/22, Road No.92, Jubilee Hills, Hyderabad-500096, Telangana, India
Inspected Site	
Name & address of manufacturing site	Mylan (Pithampur) Mylan Laboratories Limited, FDF-3, Indore, Plot No. 11,12 & 13, Special Economic Zone, Pharma Zone, Phase-II, Sector-III, Pithampur-454775, Dist.- Dhar, Madhya Pradesh, India. D-U-N-S: 859649433 GPS coordinates: Latitude 22. 63. 3914N Longitude 75. 61.9405E
Production Block/Unit	Block A
Manufacturing license number	Forms 25 & 28, issued by office of the Controller Food and Drugs Administration Madhya Pradesh 25/1/2014 & 28/1/2014, valid till 16.01.2024
Desk assessment details	
Start and end dates of review	21 June – 08 July 2021
Products under prequalification	

Finished Pharmaceutical Product	**Prequalification status**
Dolutegravir (Sodium) Tablet, Film-coated 50mg	Prequalified
Sulfamethoxazole/Trimethoprim Tablet 400mg/80mg	Prequalified
Sulfamethoxazole/Trimethoprim Tablet 800mg/160mg	Prequalified
Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg	Prequalified
Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 400mg/300mg/300mg	Prequalified
Flucytosine Tablet 250mg	Under assessment
Flucytosine Tablet 500mg	Under assessment
Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 400mg/300mg/300mg	Prequalified
Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg	Prequalified
Dolutegravir (Sodium) Tablet, Dispersible 10mg	Prequalified
Linezolid Tablet, Film-coated 600mg	Prequalified
Lamivudine/Nevirapine/Zidovudine Tablet, Dispersible	Prequalified

	30mg/50mg/60mg	
	Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/300mg/300mg	Prequalified
	Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/200mg/300mg	Prequalified
	Lamivudine/Nevirapine/Zidovudine Tablet, Film-coated 150mg/200mg/300mg	Prequalified
	Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg	Prequalified
	Lamivudine/Zidovudine Tablet, Dispersible 30mg/60mg	Prequalified
	Artemether/Lumefantrine Tablet 20mg/120mg	Prequalified
	Artemether/Lumefantrine Tablet 40mg/240mg	Prequalified
	Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 200mg/300mg	Prequalified
	Efavirenz Tablet, Film-coated 600mg	Prequalified
	Abacavir (sulfate)/Lamivudine Tablet, Film-coated 600mg/300mg	Prequalified
	Tenofovir disoproxil fumarate Tablet, Film-coated 300mg	Prequalified
	Ritonavir Tablet, Film-coated 100mg	Prequalified
	Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 300mg/300mg	Prequalified
Products covered by this desk assessment	Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 400mg/300mg/300mg	
	Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg	
	Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg	

List of documents submitted

1. FDA US inspections report, dates of inspections
   a. 21 – 25 October 2019
   b. 20 – 25 May 2019
2. CAPAs related to the FDA US inspection 21 – 25 October 2019
3. OGYEI - National Institute of Pharmacy and Nutrition, Hungary inspection report, dates of inspection 13 – 17 August 2018
4. CAPAs related to the OGYEI - National Institute of Pharmacy and Nutrition, Hungary inspection report, dates of inspection 13 – 17 August 2018
5. National Institute of Pharmacy and Nutrition, Hungary GMP certificate
6. SMF and Annexes
7. List of GMP certificates
8. List of Regulatory Authorities inspections
9. List of products manufactured at site
10. Declaration: self-inspection
11. GMP certificate No V/WHO-GMP/M-2-2018 6780, dated 6-12-18, issued by Licensing Authority Food & Drugs Administration, Idgah Hills, Bhopal (M.P.)
12. List of product recall in the past three years
13. PQRs:
    a. Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg, review period 01/01/18 to 31/07/19 and 01/08/19 to 31/07/20
    b. Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 400mg/300mg/300mg, review period 01/03/19 to 29/02/20 and 01/03/20 to

	28/02/2021 c. Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg, review period 01/01/19 to 31/12/19 and 01/01/2020 to 31/12/2020 14. Master BMRs: a. Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg b. Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg c. Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 400mg/300mg/300mg 15. Master BPRs: a. Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg b. Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg c. Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 400mg/300mg/300mg 16. Executed BMRs/BPRs/analytical raw data: d. Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 400mg/300mg/300mg e. Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg f. Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg 16. Declaration: warning letter 17. Declaration: out-of-stock 18. Details of the inspection of the authorities performed covering the concerned products	
Any documents missing?	N/A	
Part 2	**Summary of SRA/NRA inspection evidence considered and comments**	
US FDA, USA	Dates of inspection:	21 – 25 October 2019
	Type of inspection:	Comprehensive surveillance GMP inspection
	Block/Unit:	Manufacturing Block A – manufacture and packaging of tablets, granules & Hard gelatin capsules
	Type of products/Dosage forms covered:	Prompt and delayed release tablets and capsules
US FDA, USA	Dates of inspection:	20 – 25 May 2019
	Type of inspection:	GMP compliance inspection
	Block/Unit:	Manufacturing Block A Manufacturing Block B
	Type of products/Dosage forms covered:	Fingolimod Hydrochloride capsule Deferasirox Granules Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate film coated tablet 300/300/400 mg
OGYEI National Institute of Pharmacy and Nutrition, Hungary	Dates of inspection:	13 – 17 August 2018
	Type of inspection:	GMP inspection
	Block/Unit:	Block A

	Type of products/Dosage forms covered:	• Efavirenz/Emtricitabine/Tenofovir Disoproxil tablet • Emtricitabine/Tenofovir Disoproxil tablet¨ • Tenofovir Disoproxil tablet • Febuxostat tablet • Prasugrel tablet • Deferasirox tablet
Part 3		
Date and conclusion of most recent WHO inspection	Last WHO inspection was performed 23 – 25 May 2018 <u>Outcome of inspection</u> Initial conclusion: 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, a decision on the compliance of: Mylan, India Plot No 11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase II, Sector III, Pithampur, District Dhar, Madya Pradesh, 454 775, India with WHO GMP guidelines will be made after the manufacturer's response to the observations has been assessed. <u>Final conclusion:</u> CAPAs were submitted and assessed by the PQT: Inspection Team and the inspection, following the review of the CAPA, was closed 27 November 2018 as compliant with the standards of GMP published by WHO.	
Summary of manufacturing activities as per SMF MLLFD3/SMF00 1/ 17	The site manufactured Oral Solid Dosage Formulations (Tablets & Hard Gelatin Capsules)	
General information about the company and manufacturing site as per SMF MLLFD3/SMF00 1/ 17	The Pharmaceutical Manufacturing facility situated at Industrial Area, Indore Special Economic Zone, Phase II of Tehsil Dhar of the Dhar District, Madhya Pradesh, of India was originally owned by Unichem Laboratories Limited. It was constructed in March 2012. This facility has been acquired by Mylan Laboratories Limited in 2013. The facility manufactures Oral Solid Dosage Formulations: Tablets, Granules and Hard Gelatin Capsules. Mylan Laboratories Limited is the Indian Subsidiary of Mylan Laboratories Inc., USA which is a specialty Pharma company. Mylan Laboratories Limited Indian operation has its Corporate Office located at Hyderabad. This site is the third formulation site [FDF-3] for Mylan in India. The company has a Pharmaceutical Formulation Plant located on 117301sq. meter plot area at Pharma Zone Indore SEZ, Pithampur, Dhar, M.P. (India). It is located on National Highway-3 connecting Indore with Ahmedabad and Indore with Mumbai. Nearest airport is Devi Ahilyabai Holkar Airport at Indore which is about 40 Kms, from Pithampur. The nearest railway stations are at Mhow (20 km) and Indore (45 km). The facility includes warehouses for raw materials, packaging materials and finished	

	goods and production sections for the manufacturing and packaging of Tablets/Granules/Capsules dosage forms. There are three separate production areas/facilities, one is for manufacturing of general category Solid Oral Products (Block A), second is for manufacturing of Solid Oral Dosage OEB4 (Occupational Exposure Band 4) products only (Block B) and third is for manufacturing of Solid Oral Dosage OEB4 products and it is dedicated for manufacturing and packaging of Levothyroxine Tablet (Block C). Testing of Raw Material, Packaging Materials, Intermediates and Finished goods samples is done at site in a well-equipped Quality Control Laboratory. A separate Quality Control facility is available for the testing of OEB4 products.
Areas inspected	**Document reviewed including but not limited** • Organization Chart • Job descriptions for key personnel • Personnel training and hygiene • Product Quality Review • Quality Risk Management • Responsibilities of the quality units and production • Complaints and Recalls • Deviation control and change control • CAPA procedure • OOS and investigation • Material release • Self-inspection and vendor qualification • Validation and qualification • Equipment calibration • Data integrity • Sampling and testing of materials • Batch processing records • Materials management system • Purified water system • HVAC system
Out of scope and restrictions (last WHO inspection)	Products not submitted to WHO for Prequalification
WHO products covered by the last WHO inspection	• Protionamide Tablet, Film-coated 250mg • Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg • Efavirenz Tablet, Film-coated 600mg • Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 200mg/300mg • Lamivudine/Nevirapine/Zidovudine Tablet, Film-coated 150mg/200mg/300mg • Lamivudine/Nevirapine/Zidovudine Tablet, Dispersible 30mg/50mg/60mg • Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/200mg/300mg • Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/300mg/300mg • Lamivudine/Zidovudine Tablet, Dispersible 30mg/60mg
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
FPP	Finished pharmaceutical product
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
SMF	Site master file
SOP	Standard operating procedure

Part 4	**Summary of the assessment of supporting documentation**

a) List of all regulatory inspections performed in the last 5 years and their outcomes:

Regulatory Authority	Dates of inspection	Outcome
Central Drugs Standard Control Organization (CDSCO) & Food and Drug Administration (FDA), Madhya Pradesh, India	August 2016	Approved
ANVISA, Brazil	August 2016	Approved
Central Drugs Standard Control Organization (CDSCO), India	September 2016	Approved
National Drug Services Organization (NDSO), Lesotho	October 2016	Closed
ZAZIBONA (Collaboration between National Medicines Regulatory Authorities (NMRAs) in Botswana, Namibia, Zambia, and Zimbabwe)	January 2017	Approved
Pharmacy and Poisons Board (PPB), Kenya	April 2017	Approved
National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria	April 2017	Approved
Food and Drug Authority (FDA), Ghana	May 2017	Approved
Central Drugs Standard Control Organization (CDSCO) & Food and Drug Administration (FDA), Madhya Pradesh, India	January 2018	Approved
National Drug Authority (NDA), Uganda	May 2018	Approved
European Medicines Agency (EMA), EU	August 2018	Approved
Central Drugs Standard Control Organization (CDSCO) & Food and Drug Administration (FDA), Madhya Pradesh, India	September 2018	Approved
Central Drugs Standard Control Organization (CDSCO) & Food and Drug Administration (FDA), Madhya Pradesh, India	January 2019	Approved
United States Food and Drug Administration (USFDA), USA	May 2019	EIR received
Food & Drug Administration (FDA), Madhya Pradesh, India	July 2019	

Regulatory Authority	Dates of inspection	Outcome
Tanzania Medicines and Medical Devices Authority (TMDA), Tanzania	August 2019	Approved
United States Food and Drug Administration (USFDA), USA	October 2019	EIR received
State Food and Drug Administration (FDA), MP State, India	June 2020	Approved
Central Drugs Standard Control Organization (CDSCO) & Food and Drug Administration (FDA), Madhya Pradesh, India	September 2020	Approved
Food and Drug Administration (FDA), Madhya Pradesh, India	October 2020	Approved

b) Manufacturing authorization granted by national authorities:
Forms 25 & 28, issued by office of the Controller Food and Drugs Administration Madhya Pradesh 25/1/2014 & 28/1/2014, valid till 16.01.2024

GMP certificate No V/WHO-GMP/M-2-2018 6780, dated 6-12-18, issued by Licensing Authority Food & Drugs Administration, Idgah Hills, Bhopal (M.P.)

c) Site master file:
SMF submitted and reviewed. SMF written according to the WHO TRS No. 961, Annex 14

d) List of all the products and dosage forms manufactured on-site:
Total number of products 84

Sr. No.	Therapeutic Group	Numbers of Product
1.	Antivirals and Antiretroviral Drugs [ARVs]	40
2.	Antidepressants	01
3.	Antiasthmatic	01
4.	Anti Malarials	06
5.	Antipsychotic Drug	02
6.	Antiplatelet	02
7.	Muscle relaxant	01
8.	Antitubercular	02
9.	Antihypertensive	06
10.	Anti-Gout	02
11.	Anti-hyperlipidemic	01
12.	Non-beta lactam antibiotics / antibacterial / anti-fungal	03
13.	Anti-coagulant	02
14.	Iron chelator	02
15.	Immunomodulator/ Antineoplastic/ Fumaric Acid Ester	07
16.	Antiemetic / gastrointestinal	02
17.	Synthetic hormone	01
18.	Nonsteroidal anti- inflammatory drugs	01
19.	Bisphosphonates / Bone Modulator	01
20.	Mucolytic	01

e) Most recent product quality reviews (PQR)s of the concerned WHO products:
Submitted and reviewed:
- Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg, review period 01/01/18 to 31/07/19 and 01/08/19 to 31/07/20
- Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 400mg/300mg/300mg, review period 01/03/19 to 29/02/20 and 01/03/20 to 28/02/21
- Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg, review period 01/01/19 to 31/12/19 and 01/01/2020 to 31/12/2020

f) Batch manufacturing and packaging records, including the analytical part, for the most recently released batch of relevant products:
Submitted and checked:
- Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 400mg/300mg/300mg
- Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg
- Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg

g) Master batch manufacturing and packaging records of the products of interest:
Submitted and checked:
BMRs:
- Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg
- Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg
- Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 400mg/300mg/300mg

BPRs
- Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg
- Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg
- Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 400mg/300mg/300mg

i) Recalls in the past three years related to products with quality defects:
Tenofovir Disoproxil Maleate / Emtricitabine 300 mg /200 mg Tablets
Batch Numbers:
3102833, 3102835, 3105048, 3108440, 3108441 & 3108442

j) Confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the products has been performed and all matters dealt with:
Declaration submitted: that a full self-inspection or external audit dedicated to the products has been performed and all matters dealt with

k) 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:
Declaration submitted: no warning letter, or equivalent regulatory action, issued by any authority

k) Out-of-stock situations:
Declaration submitted: no out-of-stock situation

l) Additional documents submitted:
N/A

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 ***Mylan Laboratories Limited, FDF-3, Indore, Block A***, located at ***Plot No. 11,12 & 13, Special Economic Zone, Pharma Zone, Phase-II, Sector-III, Pithampur-454775, Dist.- Dhar, Madhya Pradesh, India*** is considered to be 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 TRS No. 986, Annex 2**
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

2. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. **Short name: WHO TRS No. 957, Annex 2**
http://www.who.int/medicines/publications/44threport/en/

3. WHO 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

4. 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

5. 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

6. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1. **Short name: WHO TRS No. 957, Annex 1**
http://www.who.int/medicines/publications/44threport/en/

7. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 3. **Short name: WHO TRS No. 957, Annex 3**
http://www.who.int/medicines/publications/44threport/en/

8. 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

9. 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

10. 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

11. 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

12. 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

13. 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/

14. 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/

15. 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

16. 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

17. 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

18. WHO general guidance on variations to multisource pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10. **Short name: WHO Multisource guidance** or **WHO TRS No. 996, Annex 10**
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

19. 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/

20. 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

21. 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

22. Production of water for injection by means other than distillation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 3. **Short name: WHO TRS No. 1025, Annex 3**
https://www.who.int/publications-detail/978-92-4-000182-4

23. Good chromatography practice. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 4. **Short name: WHO TRS No. 1025, Annex 4**
https://www.who.int/publications-detail/978-92-4-000182-4

24. Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 6. **Short name: WHO TRS No. 1025, Annex 6**
https://www.who.int/publications-detail/978-92-4-000182-4

25. Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 2. **Short name: WHO TRS 1033, Annex 2**
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations¨

26. WHO good manufacturing practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 3. **Short name: WHO TRS 1033, Annex 3**
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

27. Guideline on data integrity. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 4. **Short name: WHO TRS 1033, Annex 4**
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations