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

Part 1	**General information**
Company information	
Name of Manufacturer	Mylan Laboratories Limited, Nashik
Corporate address of manufacturer	Mylan Laboratories Limited, Plot no. 564 / A / 22, Road no. 92, Jubilee Hills, Hyderabad - 500033, India.
Inspected site	
Name & address of manufacturing site	Mylan Laboratories Limited, Nashik F-4, F-12, Malegaon M.I.D.C, Sinnar, Nashik – 422103, Maharashtra state, India
Production Block/Unit	FDF-1, Nashik
Desk assessment details	
Date of review	05 - 09 April 2021
Products covered by this desk assessment	1. HP001 Sofosbuvir Tablet, Film-coated 400mg 2. MA099 Artemether/Lumefantrine Tablet 20mg/120mg 3. MA100 Artemether/Lumefantrine Tablet 40mg/240mg 4. HA426 Lamivudine/Nevirapine/Zidovudine Tablet, Film-coated 150mg/200mg/300mg 5. HA466 Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/300mg/300mg 6. HA467 Ritonavir Tablet, Film-coated 100mg 7. HA392 Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg 8. HA507 Atazanavir (sulfate)/Ritonavir Tablet, Film-coated 300mg/100mg 9. HA403 Efavirenz Tablet, Film-coated 600mg 10. HA410 Tenofovir disoproxil fumarate Tablet, Film-coated 300mg 11. HA417 Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 200mg/300mg 12. HA433 Lamivudine/Nevirapine/Zidovudine Tablet, Dispersible 30mg/50mg/60mg 13. HA444 Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/200mg/300mg 14. HA414 Lamivudine/Tenofovir disoproxil fumarate Tablet, Filmcoated 300mg/300mg 15. TB286 Moxifloxacin (hydrochloride) Tablet, Film-coated 400mg 16. HA635 Abacavir sulfate/Lamivudine Tablets 600 mg/ 300 mg 17. HA621 Ritonavir Tablets 25mg 18. HP026 Sofosbuvir/Velpatasavir Tablet, Film-coated 400mg/100mg

	19. HP025 Daclatasvir (dihydrochloride)/Sofosbuvir Tablet, Filmcoated 60mg/400mg 20. HP019 Ledipasvir/Sofosbuvir Tablet, Film-coated 90mg/400mg 21. HP015 Daclatasvir (dihydrochloride) Tablet, Film-coated 30mg 22. HP016 Daclatasvir (dihydrochloride) Tablet, Film-coated 60mg 23. HA697 Lopinavir/Ritonavir Granules for Oral suspension 40mg/10mg	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last)**	
US FDA, USA	Dates of inspection:	3rd -7th February 2020
	Type of inspection:	Announced pre-approval inspection for an NDA with a follow-up to the previous observations issued to the site.
	Block/Unit:	FDF-1
	Type of products/Dosage forms covered:	Tablets and Hard Gelatin Capsules
EMA (HPMA Ireland and OGYEI, Hungary)	Dates of inspection:	12 to 16 November 2018
	Type of inspection:	Routine inspection
	Block/Unit:	Not described
	Type of products/Dosage forms covered:	- Capsules, hard shells - Tablets
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	6 to 10 November 2017 GMP compliant after CAPAs.	
Brief description of manufacturing activities	Production and quality control of OSDs including Tablets and Hard Gelatin Capsules	
General information about the company and manufacturing site	Mylan Laboratories Limited is the Indian subsidiary of Mylan Laboratories Inc. USA. Mylan Laboratories Limited formally known as Matrix Laboratories Limited has its corporate office located at Hyderabad, India. A total of 1753 employees were at the facility under inspection. A neighboring plot contained a supplementary finished product storage warehouse.	
Focus of the last WHO inspection	The inspection focused on the production and control of anti-HIV, anti-TB and anti-malarial products. The inspection covered all the sections of the WHO GMP text, including premises, equipment, documentation, materials, validation, sanitation and hygiene, production, quality control and utilities	
Areas inspected	• Quality Assurance • Sanitization and hygiene • Qualification and validation • Complaints • Recalls	

	• Self-inspection • Personnel • Training • Personal hygiene • Premises • Equipment • Materials • Documentation • Production • Quality control
Out of scope and restrictions (last WHO inspection)	Products not submitted for prequalification including pilot plant were out of the scope of this inspection. No restrictions.
WHO products covered by the last WHO inspection	Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg (HA392) Nevirapine Tablet 200mg (HA396) Efavirenz Tablet, Film-coated 600mg (HA403) Tenofovir Disoproxil fumarate Tablet, Film-coated 300mg (HA410) Lopinavir/Ritonavir Tablet, Film-coated 200mg/50mg (HA411) Lamivudine/Tenofovir Disoproxil fumarate Tablet, Film-coated 300mg/300mg (HA414) Emtricitabine/Tenofovir Disoproxil fumarate Tablet, Film-coated 200mg/300mg (HA417) Lamivudine/Nevirapine/Zidovudine Tablet, Film-coated 150mg/200mg/300mg (HA426) Lopinavir/Ritonavir Tablet, Film-coated 100mg/25mg (HA429) Lamivudine/Nevirapine/Zidovudine Tablet, Dispersible 30mg/50mg/60mg (HA433) Lamivudine/Zidovudine Tablet, Film-coated 30mg/60mg (HA437) Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/200mg/300mg (HA444) Zidovudine Tablet, Film-coated 100mg (HA464) Efavirenz/Lamivudine/Tenofovir Disoproxil fumarate Tablet, Film-coated 600mg/300mg/300mg (HA466) Ritonavir Tablet, Film-coated 100mg (HA467) Atazanavir (sulfate)/Ritonavir Tablet, Film-coated 300mg/100mg (HA507) Ritonavir Tablet, Film-coated 25mg (HA621) Sofosbuvir Tablet, Film-coated 400mg (HP001) Artemether/Lumefantrine Tablet 20mg/120mg (MA099) Moxifloxacin (hydrochloride) Tablet, Film-coated 400mg (TB286) Total of 11 Products Prequalified (under USFDA ANDA)
Additional products covered by this desk assessment:	1. MA100 Artemether/Lumefantrine Tablet 40mg/240mg 2. HA635 Abacavir sulfate/Lamivudine Tablets 600 mg/ 300 mg 3. HA621 Ritonavir Tablets 25mg 4. HA697 Lopinavir/Ritonavir Granules for Oral suspension

	40mg/10mg 5. HP015 Daclatasvir (dihydrochloride) Tablet, Film-coated 30mg 6. HP016 Daclatasvir (dihydrochloride) Tablet, Film-coated 60mg 7. HP019 Ledipasvir/Sofosbuvir Tablet, Film-coated 90mg/400mg 8. HP026 Sofosbuvir/Velpatasvir Tablet, Film-coated 400mg/100mg 9. HP025 Daclatasvir (dihydrochloride)/Sofosbuvir Tablet, Filmcoated 60mg/400mg
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:

A copy of the following manufacturing licenses issued by Food &Drugs Administration of Maharashtra State was provided.

- *Form 28, Licence No. /NKD/43, Iss Dt: 04/08/2005, Val Dt: 03/08/2025, Ren Dt: 04/08/2020*
- *Form 25, Licence No. /NKD/89, Iss Dt: 04/08/2005, Val Dt: 03/08/2025, Ren Dt: 04/08/2020*,

The copy of GMP certificates No: 6095768 issued by Food &Drugs Administration of Maharashtra State, India on 06/10/2020 was provided, which is valid for five years.

b) Site master file:

The current version of Site Master File was provided and reviewed with no objectional findings. According to the SMF, 1589 people was employed on the site. No toxic or hazardous substances are handled (e.g. with high pharmacological activity and/or with sensitizing properties) at site.

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

Name of Regulatory Authority	Inspection Date	Inspection Scope	Outcome
Food & Drug Administration (FDA), USA	3-7 Feb. 2020	Pre-Approval Inspection	VAI
Food & Drug Administration (FDA), USA	14-18 Jan. 2019	Pre-Approval Inspection	VAI
European Medicines Agency/ Health Products Regulatory Authority (HPRA), Ireland	12-16 Nov. 2018	GMP Inspection	GMP certificate issued.

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

The list of products manufactured at site was provided and reviewed. Oral Solid Dosage forms for human use including Tablets and Hard Gelatin Capsules are manufactured at the site. Veterinary products are not manufactured at Site. The products are manufactured on campaign basis.

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

The following products have been withdrawn since last WHO inspection.

HA396 Nevirapine Tablet 200mg
HA411 Lopinavir/Ritonavir Tablet, Film-coated 200mg/50mg
HA429 Lopinavir/Ritonavir Tablet, Film-coated 100mg/25mg
HA437 Lamivudine/Zidovudine Tablet, Film-coated 30mg/60mg
HA464 Zidovudine Tablet, Film-coated 100mg

The products were prequalified with summary of APQRs provided by the company. The PQRs provided and reviewed with no objectional findings. Some details are to be checked in future on-site inspection. The PQRs as mentioned in the table below are not available currently and need to be followed in next on-site inspection.

Sr. No.	PQ No.	FPP	APR	Remarks
1	HP026	Sofosbuvir/Velpatasvir Tablet, Film-coated 400mg/100mg	NA	Not yet commercialised.
2	HP025	Daclatasvir (dihydrochloride)/Sofosbuvir	NA	Not yet commercialised.
3	HP019	Ledipasvir/Sofosbuvir Tablet, Film-coated 9 0 mg/400mg	NA	Product is commercialised and APR will be prepared first time in this year. Assigned due date in July-21
4	HP015	Daclatasvir (dihydrochloride) Tablet, Film-coated 30mg	NA	Not yet commercialized.
5	HP016	Daclatasvir (dihydrochloride) Tablet, Film-coated 60mg	NA	Product is Commercialized in this year and APR will be prepared in next review period.
6	HA697	Lopinavir/Ritonavir Granules for Oral suspension 40mg/ \	NA	Not yet commercialised.

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

The BMRs/BPRs provided were briefly reviewed with no objectional findings. Some details are to be verified in next on-site inspection. For the products prequalified but not yet commercialised, their BMRs/BPRS are to be followed in next on-site inspection.

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

Master BMRs/BPRs provided were briefly reviewed with no objectional findings. For the products prequalified but not yet commercialised, their Master BMRs/BPRS are to be followed in next on-site inspection.

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

The company provided a recall list since 2018 which was reviewed with no objectional findings.

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 company confirmed that, as per 'Self-inspection program' of Mylan, Nashik site, all the systems, processes and facility are inspected periodically as per predefined frequency for all the products manufactured for different markets including products approved by WHO.

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 declare that, they have not received any Warning Letter or equivalent regulatory action from any regulatory authority during any inspections conducted at Mylan Laboratories Limited, F-4 & F-12, Malegaon MIDC, Sinnar, Nashik, 422 113, Maharashtra, India in last three years.

k) Out-of-stock situations:

The company declared that, there is "No out of stock/potential out stock situation" foreseen. Products are continuously supplied from Mylan where Mylan has been granted tender under WHO Qualification for the Prequalified products.

l) Additional documents submitted:

Nameof Regulatory Authority	Anticipated GMP Inspection Date	Intimation Receipt
Health Products Regulatory Authority (HPRA) on behalf of European Medicines Agency (EMA)	To be confirmed.	27 November 2020 Inspection due year 2021

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, Nashik*** located at ***Mylan Nashik, F-4, F-12, Malegaon M.I.D.C, Sinnar, Nashik – 422103, Maharashtra state, India*** is considered to be operating at an acceptable level of compliance with WHO GMP guidelines.

This WHOPIR will remain valid until **31 December 2022**, 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