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Prequalification Unit Inspection services
WHO INSPECTION REPORT

Desk Assessment of Active Pharmaceutical Ingredient (API) Manufacturer

Part 1	**General information**
Company information	
Name of Manufacturer	Mylan Laboratories Limited, Unit-9
Corporate address of manufacturer	Mylan Laboratories Limited Plot No 564/A/22, Road No 92, Jubilee Hills, Hyderabad-500096 Telangana, India. Tel: + 91-40-30866666/23550543 Fax: + 91-40-30866699 Web: www.mylan.in
Inspected site	
Name & address of manufacturing site	M/s. Mylan Laboratori Es Limited (Unit-9) Plot No: 5, Road No: 12, J.N. Pharma City, Tadi Village Parawada Mandal, Visakhapatnam -531019 Andhra Pradesh, India D-U-N-S: 86-249-9912 GPS coordinates: Longitude: 83.076092° Latitude: 17.670087°
Synthetic Unit/Block/Workshop	MB I, MB II, MB III, MB IV and MB V
Manufacturing license number	Form 25: 07/VP/AP/2009/B/R/CC/R, valid till 31-12-2024, issued by Joint Director & Licensing Authority Drugs Control Administration Government of Andhra Pradesh, Chuttugunta, Guntur.
Desk assessment details	
Start and end dates of review	28 June – 09 July 2021
APIs covered by this desk assessment	Emtricitabine – Prequalified Zidovudine – Prequalified Lumefantrine – Prequalified Dolutegravir Sodium – Prequalified
List of documents submitted	1. Austrian Federal Office for Safety in Health Care inspection report and related CAPAs 2. EU GMP certificate 3. Health Canada inspection report and related CAPAs 4. PMDA Japan inspection report 5. SMF and Annexes 6. Declaration: upcoming inspections 7. Declaration: no out-of-stock situation 8. Declaration: warning letter 9. Declaration: no shared equipment between WHO APIs with sartan API process 10. Declaration: self-inspection

List of documents submitted	11. Declaration: recalls in last 3 years 12. Declaration: recovered solvents 13. List of API manufactured at site 14. Manufacturing authorization, issued by Joint Director & Licensing Authority Drugs Control Administration Government of Andhra Pradesh Chuttugunta, Guntur 15. GMP certificate issued by Office of the Deputy Director Drugs Control Administration Visakhapatnam Region 16. SOP "Annual Product Review / Product Quality Review Process" and 8 Forms 17. PQRs 1. Emtricitabine APQR and Annexures, review period January 2020 – December 2020. 2. Dolutegravir Sodium APQR and Annexures, review period January 2020 – December 2020. 3. Emtricitabine APQR and Annexures, review period January 2020 – December 2020. 4. Lumefantrine APQR Annexures, review period January 2020 – December 2020. 5. Dolutegravir Sodium APQR and Annexures, review period January 2017 – December 2017. 6. Dolutegravir Sodium APQR No APR/U-9/2018/DGS/00, review period January 2018 – December 2018. 7. Lumefantrine APQR and Annexures, review period January 2019 – December 2019. 8. Zidovudine APQR and Annexures, review period January 2019 – December 2019. 9. Zidovudine APQR and Annexures, review period January 2020 – December 2020. 18. Master Batch Production/Packaging Records: 1. Dolutegravir Sodium i. Stage I ii. Stage II iii. Stage III iv. Powder Processing v. Packaging 2. Zidovudine i. Stage I ii. Stage II iii. Powder Processing iv. Packaging 3. Emtricitabine i. Stage ERC-I ii. Packaging 4. Lumefantrine i. Stage I ii. Stage II iii. Stage III

List of documents submitted	iv. Packaging v. Blending 19. Executed BMRs/BPRs/analytical raw data: 1. Dolutegravir Sodium i. Stage I ii. Stage II iii. Stage III iv. Powder processing v. Packaging 2. Zidovudine i. Stage I ii. Stage II iii. Micronisation iv. Packaging 3. Emtricitabine i. Stage I 4. Lumefantrine i. Stage I ii. Stage II iii. Stage III iv. Powder processing v. Packaging	
Any documents missing?	N/A	
Part 2	**Summary of SRA/NRA inspection evidence considered**	
AGES (Austrian Federal Office for Safety in Health Care), Austria	Dates of inspection:	21 – 23 November 2019
	Type of inspection:	GMP inspection
	Block/Unit/Workshop:	Manufacturing blocks • MB-01 • MB-04 (only drying of intermediates), MB-05
	APIs covered:	• Etoricoxib • Levofloxacin Hemihydrate
Health Canada Department of Health Drug GMP Inspection Program, Canada	Dates of inspection:	12 – 15 November 2018
	Type of inspection:	Regular on-site inspection
	Block/Unit/Workshop:	Not specified
	APIs covered:	Not specified
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	Last WHO inspection was conducted from 17 July till 21 July 2017 <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 Laboratories Limited, Unit-9 (manufacturing blocks MB I, MB II, MB III, MB IV, MB V) located at Plot No: 5, Road No: 12, J.N. Pharma City, Tadi Village Parawada Mandal, Visakhapatnam – 531021 Andhra Pradesh, INDIA with WHO good manufacturing practices for active pharmaceutical ingredients will be	

	made after the manufacturer's response to the observations has been assessed. **Final conclusion:** CAPAs were submitted and assessed by the PQT: Inspection Team and the inspection, following the review of the CAPA, was closed 6 October 2017 as compliant with the standards of Good Manufacturing Practices (GMP) for APIs published by the World Health Organization (WHO).
Brief summary of manufacturing activities	The company has a license to manufacture (for sales and distribution) wide range of APIs and intermediates under different therapeutic categories by the Director, Drugs Control Administration, Government of Andhra Pradesh, Visakhapatnam under the drug license in Form-26
General information about the Company and manufacturing site as per SMF	Manufacturing site was established in June 2009 as Vivin Laboratories Pvt. Ltd. (Unit-2) and was acquired by Matrix Laboratories limited, a subsidiary of Mylan Inc. USA in December 2009, renamed as Matrix Laboratories Ltd. Unit-9 in January 2010 and again renamed as Mylan Laboratories Ltd. Unit-9 in October 2011. The facility is engaged in manufacturing of Intermediates and Active Pharmaceutical Ingredients. The site is in Jawaharlal Nehru Pharma city surrounded by Vandana life sciences Pvt. Ltd at east, open area at west & north and Admiron Life Sciences Pvt. Ltd. at south. The facility is designed for the manufacture of Active Pharmaceutical Ingredients and intermediates. The manufacturing process is a chemical synthesis involves unit operations like crystallization, purification, filtration and drying steps. Physical modifications like Blending, Micronization, Compaction, Pulverization and Milling operations have been carried out as per the requirement. The Products are exported to different countries in the world. The facility is designed for the manufacture of various categories of APIs, like Antiretroviral, Antiviral, Antithrombotic, Antimalarial, Anticonvulsant, Antidepressant, Hyperphosphatemia, Hyperlipidemia, Antihypertensive, Anti-inflammatory, Anti-ulcerative, Anti-erectile, Antifibrotic, Antibacterial, Anti-tuberculosis, Anthelmintic agent, Antifibrotic, Antirheumatics, Proton pump inhibitor, Nucleoside analog Reverse Transcriptase Inhibitor, Diagnostic aid (Cardiac stress testing), Erectile Dysfunction, etc. The site has five manufacturing blocks (MB-1, MB-2, MB-3, MB-4 and MB-5)
Focus of the last WHO inspection	• Zidovudine • Lumefantrine • Piperaquine tetraphosphate tetrahydrate • Etravirine
Areas inspected	• Pharmaceutical Quality System • Documentation system • Production System • Facilities and Equipment System • Laboratory Control System

Out of scope and restrictions (last WHO inspection)	Microbiological laboratory APIs not under the scope of prequalification
WHO APIs covered by the last WHO inspection	• Zidovudine • Lumefantrine • Piperaquine tetraphosphate tetrahydrate - withdrawn • Etravirine - withdrawn
Additional products to be covered by this desk assessment:	• Emtricitabine • Dolutegravir Sodium
Abbreviations	**Meaning**
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:
Manufacturing license by Joint Director (FAC) &Licensing Authority Drugs Control Administration Govt. of Andhra Pradesh, Chuttugunta, Guntur Form 25: 07/VP/AP/2009/B/R/CC/R, valid till 31-12-2024

GMP certificate No882/DD/DCA/VSP/2020, issued by Office of the Deputy Director Drugs Control Administration Visakhapatnam Region, valid till 17.08.2021

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

c) List of all the APIs or other products manufactured on-site:
Total number of APIs manufactured at the site: 23

S. No	Name of the Product	Therapeutic Category
Active pharmaceutical Ingredients (APIs)		
1.	Celecoxib	Anti-inflammatory
2.	Chlorthalidone	Antihypertensive
3.	Dipyridamole	Diagnostic aid (Cardiac stress testing)
4.	Dolutegravir sodium	Anti-Retroviral
5.	Emtricitabine	Anti-Retroviral

S. No	Name of the Product	Therapeutic Category
6.	Etoricoxib	Anti-inflammatory, Anti-Rheumatics
7.	Etravirine	Anti-Retroviral
8.	Lamivudine	Anti-Retroviral
9.	Levofloxacin Hemihydrate	Anti-Bacterial
10.	Lumefantrine	Anti-Malarial
11.	Milnacipran Hydrochloride	Anti-Depressant
12.	Mirtazapine Anhydrous	Antidepressant
13.	Mirtazapine Hemihydrate	
14.	Pantoprazole Sodium Sesquihydrate	Proton pump inhibitor
15.	Pirfenidone	Antifibrotic
16.	Pretomanid	Anti-Tuberculosis
17.	Sertraline Hydrochloride (Form-I)	Anti-Depressant
18.	Sertraline Hydrochloride (Form-II)	
19.	Sevelamer Carbonate	Hyperphosphatemia
20.	Sildenafil citrate	Erectile Dysfunction
21.	Tadalafil	Erectile Dysfunction
22.	Zidovudine	Anti-Retroviral
23.	Abacavir Sulfate	Anti-Retroviral

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

S. No	Name of the Regulatory Authority	Inspection Dates	Audit Outcome
1.	Ministry of Food and Drug Safety Korea (MFDS)	15th to 17th May, 2018	Approved
2.	Health Canada	12th to 15th November, 2018	Compliance certificate Issued
3.	AGES - Austria	21st to 23rd November, 2019	GMP Certificate Issued
4.	PMDA-Japan	10th to 13th December, 2019	GMP Certificate Issued
5.	MIT of the Russian Federation	14th to 16th April, 2020	Approved (Desk Assessment)
6.	U.S. Food and Drug Administration	Documents submitted on June 2020 as per FDA Form 4003	Site classified as 'Voluntary Action Indicated', based on AGES inspection report from 2019

e) Most recent product quality reviews (PQRs) of the concerned WHO APIs:

Submitted and reviewed:

- Dolutegravir Sodium APR including 11 Annexures, review period January 2017 to December 2017 and APR including 13 Annexures, review period January 2018 to December 2018
- Lumefantrine APR including 5 Annexures, review period January 2019 to December 2019
- Zidovudine APR including 12 Annexures, review period January 2019 to December 2019 and APR including 14 Annexures, review period January 2020 to December 2020

Note: according to the company declaration.

- Emtricitabine last batch manufactured in 2017

f) Batch manufacturing and packaging records, including the analytical part, for the most recently released batch of relevant APIs:

Submitted and reviewed:

1. Dolutegravir Sodium
   - Stage I & in-process analytical raw data
   - Stage II & in-process analytical raw data
   - Stage III & in-process analytical raw data
   - Powder processing & analytical raw data
   - Packaging
2. Zidovudine
   - Stage I & in-process analytical raw data
   - Stage II & in-process analytical raw data
   - Micronisation & analytical raw data
   - Packaging
3. Emtricitabine
   - Stage I & in-process analytical raw data
   - Packaging
4. Lumefantrine
   - Stage I & in-process analytical raw data
   - Stage II & in-process analytical raw data
   - Stage III & in-process analytical raw data
   - Powder processing & analytical raw data
   - Packaging

g) Master batch manufacturing and packaging records of the APIs of interest:

Submitted and checked:

1. Dolutegravir Sodium
   - Stage I
   - Stage II
   - Stage III
   - Powder Processing
   - Packaging
2. Zidovudine
   - Stage I
   - Stage II
   - Powder Processing
   - Packaging
3. Emtricitabine
   - Stage ERC-I
   - Packaging
4. Lumefantrine
   - Stage I
   - Stage II
   - Stage III
   - Packaging
   - Blending

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

Declaration submitted: no recalls in past 3 years

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

j) Copy of any warning letter, or equivalent regulatory action, issued by any authority for their market, to which the site provides or has applied to provide the API(s):
Declaration submitted: no warning letter, or equivalent regulatory action, issued

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

l) Additional documents submitted:
- Declaration submitted: no shared equipment between WHO APIs with Sartans API process
- Declaration submitted: recovered solvents
- SOP "Annual Product Review / Product Quality Review Process" and 8 Forms

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, Unit-9, manufacturing blocks MB I, MB II, MB III, MB IV, MB V***, located at ***Plot No: 5, Road No: 12, J.N. Pharma City, Tadi Village Parawada Mandal, Visakhapatnam - 531019 Andhra Pradesh, India*** is considered to be operating at an acceptable level of compliance with WHO GMP guidelines for APIs.

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 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 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