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Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT

Desk Assessment of Active Pharmaceutical Ingredient (API) Manufacturer

Part 1	**General information**
Company information	
Name of Manufacturer	Anuh Pharma Limited
Corporate address of manufacturer	Anuh Pharma Ltd 3-A Shivsagar Estate, Dr. Annie Besant road, Worli, Mumbai-400018, India Tel. No. :91-22-6622 7575
Inspected site	
Name & address of manufacturing site	Anuh Pharma Limited E17/3, 17/4 & E-18, MIDC, Boisar, Tarapur, Palghar District, Maharashtra, 401 506, India. D-U-N-S: 915041156 GPS coordinates Latitude: 19°48'6". N Longitude: 72°44'3".E
Synthetic Unit/Block/Workshop	Buildings: E-17/3, E-17/4, APL – 1 & APL – 2 & E - 18 Blocks: NP – 1, AB – 3, AJM – 01, AJM – 02, INT - 2A
Manufacturing license number	Forms 25 & 28, issued by Food & Drugs Administration (Maharashtra) state 25-KD/1194 & 28-KD/990, valid till 31/12/2022
Desk assessment details	
Start and end dates of review	14-18 June 2021
APIs covered by this desk assessment	**Active Pharmaceutical Ingredient** / **Prequalification status** Pyrazinamide / Prequalified Sulfadoxine / Prequalified Pyrimethamine / Prequalified Isoniazid / Under Assessment
List of documents submitted	1. SMF and Annexures 2. US FDA inspection report 3. List of regulatory authorities' inspections in last 5 years 4. Manufacturing license Forms 25 & 28, issued by Food & Drugs Administration (Maharashtra) state 25-KD/1194 & 28-KD/990, valid till 31/12/2022 5. GMP certificate, issued by Food & Drugs Administration (Maharashtra) state, valid till 07/08/2021 6. List of all products manufactured at the site 7. Declaration: recalls 8. Declaration: self-inspection 9. Declaration: shared equipment 10. Declaration: recovered solvents 11. Declaration: warning letter

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	12. Declaration: out-of-stock 13. Declaration: upcoming inspections 14. Manufacturing process for the concerned product covered by the inspection of SRA 15. PQRs: a. Declaration of CpK & Graphical Representation b. Isoniazid and Annexes April 2020 – March 2021 c. Pyrazinamide and Annexes April 2020 – March 2021 d. Pyrimethamine and Annexes April 2020 – March 2021¨ e. Sulfadoxine and Annexes April 2020 – March 2021 16. BMR&BPR& analytical raw data: a. Isoniazid manufacturing/blending/packaging, analytical raw data b. Sulfadoxine intermediate manufacturing/blending/packaging/analytical raw data c. Sulfadoxine manufacturing/blending/packaging, analytical raw data d. Pyrazinamide manufacturing/blending/packaging, analytical raw data e. Pyrimethamine manufacturing/blending/packaging, analytical raw data 17. Master Production Control records: a. Isoniazid b. Sulfadoxine intermediate c. Sulfadoxine d. Pyrimethamine e. Pyrazinamide	
Any documents missing?	N/A	
Part 2	**Summary of SRA/NRA inspection evidence considered and comments**	
FDA US	Dates of inspection:	16 – 20 September 2019
	Type of inspection:	Initial GMP inspection
	Block/Unit/Workshop:	NP-2/NP-3NP-2/NP-4, AB-4
	APIs covered:	Erythromycin USP Erythromycin Ethyl Succinate USP Azithromycin USP (Dihydrate) Chloramphenicol Palmitate USP
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	Last joint WHO & EDQM inspection was carried out 26 – 28 November 2018. CAPAs were submitted and assessed by the PQT: Inspection Team and EDQM and the inspection, following the review of the CAPA, was closed 2 August 2019 as compliant with the standards of GMP published by WHO.	
Brief summary of manufacturing activities	Manufacture and distribution of the APIs	
General information about the company	Anuh Pharma Limited is a manufacturer of Active Pharmaceutical Ingredients since 1989. Anuh Pharma Ltd is Public limited company listed in Mumbai Stock Exchange. It is a part of SK Group, which is serving since 1932.	

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and manufacturing site as per SMF-001-26	The manufacturing site is developed on a plot provided by Maharashtra Industrial Development Corporation (MIDC) and is situated in Tarapur Industrial Area, Boisar, there are several small to medium scale chemical, pharmaceutical, engineering & textile companies in the industrial area. The manufacturing plant is situated at Plot No. E-17/3, 17/4 & E-18 Tarapur Industrial Area, M.1.0.C., Boisar, Palghar 401 506, Maharashtra, India. The Plot area of E17/3, 17/4 3600 Sq. Meter and for E18 7800 Sq. Meter. It is about 125 km from Mumbai. The site is easily accessible by road and rail. The site consists of 2 plots: 1. E-17/3 and E-17/4 2. E-18 E-17/3 and E-17/4 consists of 2 buildings: 1. APL – 1 2. APL – 2 APL – 1 building consists of: • AB – 3 Mfg. Block • AB – 4 Mfg. Block • AJM – 1 Block • AJM – 2 Block • Blending and Packing Room • Quality Control Lab • Microbiology Lab APL – 2 building consists of following: • NP – 1 Mfg. Block • NP – 2 Mfg. Block • NP – 3 Mfg. Block • NP – 4 Mfg. Block E-18 building consists of • API-I • API-II • Intermediate (INT - 2A) Each of the above mfg. blocks have independent Air Handling Units, Synthesis Area, Powder Processing Area and Packing Area. Administration Building Intermediate Warehouse Finished Product Warehouse Effluent Treatment Plant Boiler House The site carries out their activities under a license of the FDA if Maharashtra State (India), manufacturing license, it also holds a written confirmation issued by CDSCO

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	for several APIs exported to EU.
Focus of the last WHO&EDQM inspection	• Erythromycin Ethylsuccinate • Erythromycin (base) • Pyrazinamide • Ambroxol HCl Products under WHO prequalification: • Sulfadoxine • Pyrimethamine • Pyrazinamide
Areas inspected	• Main aspects of Quality Assurance • Personnel • Manufacturing areas ✓ APL-1 block ✓ APL-2 block • Storage facilities • Utilities • Quality Control Laboratories • Validation • Qualification • CEP dossier verification • WHO PQ Dossier verification • Supplier qualification • Out-sourced activities • GDP activities
Out of scope and restrictions (last WHO&EDQM inspection)	APL-1 block: • Workshop AB-4 APL-2 block: • Workshops NP-3, NP-4 R&D activities Availability of Chemical Reference Standards for APIs & related substances Availability of current version of European Pharmacopoeia
WHO APIs covered by the last WHO inspection	• Sulfadoxine • Pyrimethamine • Pyrazinamide
Additional products to be covered by this desk assessment:	• Isoniazid
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

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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 Forms 25 & 28, issued by Food & Drugs Administration (Maharashtra) state 25-KD/1194 & 28-KD/990, valid till 31/12/2022
GMP certificate 6094875, issued by Food & Drugs Administration (Maharashtra) state, valid till 07/08/2021

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 (intermediates, dosage forms) manufactured on-site:

API	Type
Erythromycin	Antibacterial
Erythromycin Stearate	
Erythromycin Estolate	
Erythromycin Ethyl Succinate	
Erythromycin Propionate	
Erythromycin 11, 12 carbonate	
Erythromycin Phosphate	
Azithromycin	
Chloramphenicol	
Chloramphenicol Palmitate	
Ofloxacin	
Moxifloxacin Hydrochloride	
Pyrazinamide	Anti-tuberculosis
Isoniazid	
Sulfadoxine	Antimalarial
Pyrimethamine	
Losartan Potassium	Anti-hypertensive
Telmisartan	
Ambroxol Hydrochloride	Mucolytic agent
Atorvastatin calcium	Anti-hyperlipidemic
Gliclazide	Antidiabetic
Fexofenadine Hydrochloride	Anti-histamine
Aripiprazole	Atypical Antipsychotic
Favipiravir	Anti-viral

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

Regulatory Authority	Dates of inspection	Inspected APIs/ buildings
EDQM/ANSM	10th to 12thFebruary 2016	Erythromycin Ethyl succinate NP – 2
EDQM/ANSM/ WHO PQ	14th to 16thSeptember 2016	Erythromyicn Erythromyicn Ethyl succinate Pyrazinamide Sulphadoxine NP – 2 NP – 1 NP- 1 AB – 3
CDSCO India	22nd to 23rd December 2016	Erythromycin Stearate Erythromycin Estolate Sulfadoxine Chloramphenicol Palmitate Azithromycin Erythromycin Propionate Pyrazinamide Erythromycin Erythromycin Ethyl Succinate Chloramphenicol All Workshops
CDSCO India	28th Aug. to 29thAug. 2017	Chloramphenicol Palmitate Ambroxol Hydrochloride BP/EP Sulfadoxine Pyrazinamide Erythromycin Stearate Erythromycin Estolate Erythromycin Ethyl Succinate All Workshops
FDA (Thane- MH)	14th November2018	All Workshops
EDQM & WHO Joint inspection	26th to 28th November 2018	Erythromycin Erythromycin Ethyl Succinate Pyrazinamide Pyrimethamine Ambroxol HCL NP-2 NP-1 AB-3
Maharashtra FDA India	18th July 2019	All APIS/Workshops
USFDA, USA	16th to 20th September 2019	Erythromycin Erythromycin Ethyl succinate Chloramphenicol Palmitate USP Azithromycin NP-2/NP-3NP-2/NP-4 AB-4 NP-4
CDSCO India	23rd to 24th January 2020	Erythromyicn Stéarate Erythromyicn Estolate

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Regulatory Authority	Dates of inspection	Inspected APIs/ buildings
		Sulfadoxine Chloramphénicol Palmitate Chloramphenicol Azithromyicn Erythromycin Propionate Pyrazinamide Eythromycin Erythromycin Ethyl succinate Ambroxol Hydrochloride All workshops
CDSCO & FDA India	09th to 10th December 2020	Erythromyicn Stéarate BP/EP/USP Erythromyicn Estolate BP/EP/USP Sulfadoxine BP Chloramphénicol PalmitateBP/EP/USP Chloramphenicol BP/EP/USP Azithromyicn BP/EP/USP Erythromycin Propionate FP Pyrazinamide BP/EP/USP Eythromycin BP/EP/USP Erythromycin Ethyl succinate BP/EP/USP Ambroxol Hydrochloride BP/EP

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

Submitted and checked:

a) Isoniazid and Annexes April 2020 – March 2021 batch manufactured

Submitted and reviewed:

a. Pyrazinamide and Annexes April 2020 – March 2021
b. Pyrimethamine and Annexes April 2020 – March 2021
c. Sulfadoxine and Annexes April 2020 – March 2021

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

Submitted and reviewed:

a. Isoniazid manufacturing/blending/packaging, analytical raw data
b. Sulfadoxine intermediate manufacturing/blending/packaging/analytical raw data
c. Sulfadoxine manufacturing/blending/packaging, analytical raw data
d. Pyrazinamide manufacturing/blending/packaging, analytical raw data
e. Pyrimethamine manufacturing/blending/packaging, analytical raw data

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

Submitted and checked:

a. Isoniazid
b. Sulfadoxine intermediate

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c. Sulfadoxine
d. Pyrimethamine
e. Pyrazinamide

h) Recalls in the past three years related to APIs with quality defects:
Declaration submitted: no recalls in the past three years related to APIs with quality defects

i) Confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the APIs has been performed and all matters dealt with:
Declaration submitted: a full self-inspection or external audit dedicated to the APIs 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 APIs:
Declaration submitted: 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:
a. Declaration: shared equipment
b. Declaration: recovered solvents
c. Declaration: upcoming inspections
d. Manufacturing process for the concerned product covered by the inspection of SRA

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 ***Anuh Pharma Limited***

- ***Buildings: E-17/3, E-17/4, APL–1 & APL–2 & E-18.***
- ***Blocks: NP–1, AB–3, AJM–01, AJM–02, INT- 2A.***

located at ***E17/3, 17/4, E-18, MIDC, Boisar, Tarapur, Palghar District, Maharashtra, 401 506, India*** is considered to be operating at an acceptable level of compliance with WHO GMP guidelines for APIs.

This 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-eight 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/

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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

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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. Fifties 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,

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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-Forth 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-Forth 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-Forth 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

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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

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