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Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT

Desk Assessment of Finished Product Manufacturer

Part 1	**General information**
Company information	
Name of Manufacturer	Panacea Biotec Pharma Limited
Corporate address of manufacturer	Panacea Biotec Pharma Limited B-1 Extension / A – 27, Mohan Co-operative, Industrial Estate, Mathura Read, New Delhi, South Delhi, Delhi, India 110044 +911141578000 www.panaceabiotec.com
Inspected site	
Name & address of manufacturing site	Panacea Biotec Pharma Limited (Unit I) Malpur, Baddi, Tehsil Nalagarh, Solan District, Himanchal Pradesh, 173 205, India GPS: 30° 5641.50" N76° 4701. 60" E
Production Block/Unit	Rifampicin block Unit I
Manufacturing license number	1. License: No L/15/1615/MB on form 28-A, issued by Health and Family Welfare Department Himachal Pradesh 2. License: No L/14/1418/MNB on Form 25-A, issued by Health and Family Welfare Department Himachal Pradesh
Desk assessment details	
Start and end dates of review	14 – 18 September 2020
Inspection record number	INSP-2019-0195
Inspector	Iveta Streipa
Products covered by this desk assessment	1. Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin Tablet, Film-coated 275mg/75mg/400mg/150mg 2. Isoniazid/Rifampicin Tablet, coated 75mg/150mg
List of documents submitted	1. List of regulatory inspections performed in last 5 years 2. List of all products manufactured at site 3. Austrian Federal Office for Safety in Health Care (BASG) draft inspection report 26 – 28 February 2019 4. Austrian Federal Office for Safety in Health Care (BASG) final inspection report 26 – 28 February 2019 5. CAPAs to Austrian Federal Office for Safety in Health Care (BASG) inspection 26 – 28 February 2019 6. BASG GMP certificated, dated 26.02.2019 (valid for 3 years) 7. Organogram-production 8. US FDA Letter to Panacea Biotec, dated 20 June 2019 9. US FDA EIR, dates of inspection 22 – 30 April 2019 10. US FDA EIR, dates of inspection 5 – 9 August 2019

	11. US FDA Form 483 – dates of inspection 10 – 20 February 2020 12. CAPAs - responses to the US FDA Form 483 – dates of inspection 10 – 20 February 2020 13. CAPAs - responses to the US FDA Form 483 – dates of inspection 5 – 9 August 2019 14. License: No L/15/1615/MB on form 28-A, issued by Health and Family Welfare Department Himachal Pradesh 15. License: No L/14/1418/MNB on Form 25-A, issued by Health and Family Welfare Department Himachal Pradesh, valid until 25-09-2024 16. GMP certificate No: HFW-H 1049/14, issued by Health and Family Welfare Department Himachal Pradesh 17. Letter: change of company name 18. SMF with annexes 19. APQR Isoniazid/Rifampicin Tablet, coated 75mg/150mg 20. APQR Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin Tablet, Film-coated 275mg/75mg/400mg/150mg 21. CoAs: Rifampicin API Isoniazid API 22. BMR Isoniazid/Rifampicin Tablet, coated 75mg/150mg 23. Batch summary record (including primary and secondary packaging) Isoniazid/Rifampicin Tablet, coated 75mg/150mg 24. Electronic printouts of different stages Isoniazid/Rifampicin Tablet, coated 75mg/150mg 25. Status labels (containers) Isoniazid/Rifampicin Tablet, coated 75mg/150mg 26. Overprinting specimens primary and secondary packaging materials Isoniazid/Rifampicin Tablet, coated 75mg/150mg 27. Analytical raw data Isoniazid/Rifampicin Tablet, coated 75mg/150mg 28. Master batch records manufacturing and packaging Isoniazid/Rifampicin Tablet, coated 75mg/150mg 29. COAs: Rifampicin, Isoniazid, Pyrazinamide, Ethambutol hydrochloride APIs 30. BMR Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin Tablet, Film-coated 275mg/75mg/400mg/150mg 31. Electronic printouts of different stages Rifampicin, Isoniazid, Pyrazinamide, Ethambutol hydrochloride 32. BMR Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin Tablet, Film-coated 275mg/75mg/400mg/150mg 33. Status labels Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin Tablet, Film-coated 275mg/75mg/400mg/150mg 34. Overprinting specimens primary and secondary packaging materials Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin Tablet, Film-coated 275mg/75mg/400mg/150mg 35. Analytical raw data Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin Tablet, Film-coated 275mg/75mg/400mg/150mg 36. Master batch records manufacturing and packaging Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin Tablet 37. Declaration: Out of stock situations 38. Declaration: list of recalled products in last 3 years 39. Parts of manufacturing process covered by SRA 40. Response CpK value

	41. SOP "Annual product quality review"	
Any documents missing?	N/A	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments**	
US FDA, USA	Dates of inspection:	10 – 20 February 2020
	Type of inspection:	GMP compliance inspection
	Block/Unit:	Oncology Product Block Unit I
	Type of products/Dosage forms covered:	Azacitidine for Injection 100 mg/vial WHO products under PQ were not covered. Inspection was focused on sterile aseptically processed injections
US FDA, USA	Dates of inspection:	05 – 09 August 19
	Type of inspection:	GMP compliance inspection
	Block/Unit:	OSD Product Block Unit I
	Type of products/Dosage forms covered:	Cyclosporine capsule 25 mg and Cyclosporine capsule 100 mg WHO products under PQ were not covered. Inspection was focused on oral solid dosage form facility for the products (Cyclosporine capsule 25 mg and Cyclosporine capsule 100 mg)
US FDA, USA	Dates of inspection:	22 – 30 April 2019
	Type of inspection:	Pre-approval inspection and to cover field alert reports. Also, to verify implemented CAPAs to previous FDA inspection FDA-483
	Block/Unit:	Oncology Product Block Unit I
	Type of products/Dosage forms covered:	Azacitidine for Injection 100 mg/vial WHO products under PQ were not covered. Inspection was focused on sterile aseptically processed injection
Austrian Federal Office for Safety in Health Care (BASG), Austria	Dates of inspection:	26 – 28 February 2019
	Type of inspection:	GMP compliance inspection
	Block/Unit:	Rifampicin block Unit I
	Type of products/Dosage forms covered:	1) Rimactazid 150 mg/ 75 mg film coated tablets (Rifampicin 150 mg Isoniazid 75 mg tablets) 2) Rimstar film coated tablets (Rifampicin 150 mg Isoniazid 75 mg / Pyrazinamide 400 mg / Ethambutol Hydrochloride 275 mg tablets)

Part 3	**Summary of the last WHO inspection**
Date and conclusion of most recent WHO inspection	The site was twice inspected by the WHO in 2010 and was considered to be operating at an unacceptable level of compliance with WHO GMP guidelines. Conclusion of the routine inspection September 13 - 16, 2010 "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 Panacea Biotec Ltd, Baddi, India considered to be operating at an unacceptable level of compliance with WHO GMP guidelines".
Abbreviations	**Meaning**
BMR	Batch manufacturing record
BPR	Batch production record
CAPA	Corrective and preventive action
CC	Change control
CoA	Certificate of analysis
FMECA	Failure mode effects and criticality analysis
FPP	Finished pharmaceutical product
GMP	Good manufacturing practices
HVAC	Heating ventilation and air conditioning system
APQR	Annual Product quality review
RA	Risk assessment
SMF	Site master file
SOP	Standard operating procedure
SRA	Stringent regulatory agency

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

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

S.N.	Authority	Dates of inspection	Purpose of inspection	Outcome
1	National Drug Authority Uganda	11,12,15,16 Jun. 2015	GMP inspection	Approval received
2	HP State FDA	29 Jul. 2015	GMP inspection (For renewal of Mfg. License)	Approval received
3	QP (Phast-Germany)	01, 02 Sep. 2015	GMP inspection	Approval received
4	CDSCO India	26,27 Oct. 2015	GMP inspection	Approval received
5	USFDA	30 Nov to 11 Dec.2015	GMP inspection	EIR Received
6	Saarland (Germany)	02 Dec to 8 Dec. 2015	GMP inspection	Approval received
7	Turkey	12 to 15 Dec. 2016	GMP inspection	Approval received
*8	Austria	31 Jan. to 02 Feb. 2017	GMP inspection	Approval received
9	MCC South Africa	27 to 29 Mar. 2017	GMP inspection	Approval received
10	Russia	17, 18 Apr. 2017	GMP inspection	Approval received
11	Ukraine	19 to 25 Jun. 2017	GMP inspection	Approval received
12	Anvisa Brazil	03 to 07 Jul. 2017	GMP inspection	Approval received

S.N.	Authority	Dates of inspection	Purpose of inspection	Outcome
13	CDSCO & State FDA	29, 30 Aug. 2017	GMP inspection	Approval received
14	Sandoz	04, 05 Oct. 2017	GMP inspection	Approval received
15	USFDA	04 to 12 Dec. 2017	GMP inspection	EIR Received
16	CDSCO	02 Feb. 2018	GMP inspection	Approval received
17	Kenya GMP	24 to 26 May 2018	GMP inspection	Approval received
18	Ghana FDA	12, 13 Jun. 2018	GMP inspection	Approval received
*19	Austria (AGES)	26 to 28 Feb. 2019	GMP inspection	Approval received
20	Croatia (Halmed)	26 to 29 Mar. 2019	GMP inspection	Approval received
21	Croatia QP	26 to 29 Mar. 2019	GMP inspection	Approval received
22	USFDA	22 to 30 Apr. 2019	GMP inspection	EIR Received
23	USFDA	05 to 09 Aug. 2019	GMP inspection	EIR Received
24	Uganda	11,13 Sep. 2019	GMP inspection	Approval awaited
20	Croatia (Halmed)	26 to 29 Mar. 2019	GMP inspection	Approval received
25	Tanzania	15 to 16 Oct. 2019	GMP inspection	Approval received
26	HP State FDA	17 Oct. 2019	GMP inspection for GMP Renewal	Approval received
27	Joint inspection of CDSCO & State FDA	27, 28 Jan. 2020	GMP inspection	Approval received
28	USFDA	10 to 20 Feb. 2020	GMP inspection	EIR awaited

*This audit was conducted specifically pertaining to Products:

- Rifampicin 150mg/ Isoniazid 75mg Film Coated Tablets
- Rifampicin 150mg/Isoniazid 75mg/Pyrazinamide 400mg/ Ethambutol Hydrochloride 275mg Film Coated Tablets.

b) Manufacturing authorization granted by national authorities:

3. License: No L/15/1615/MB on form 28-A, issued by Health and Family Welfare Department Himachal Pradesh
4. License: No L/14/1418/MNB on Form 25-A, issued by Health and Family Welfare Department Himachal Pradesh,
5. GMP certificate No: HFW-H 1049/14, issued by Health and Family Welfare Department Himachal Pradesh

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:

Rifampicin block:

- Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin Tablet, Film-coated 275mg/75mg/400mg/150mg
- Isoniazid/Rifampicin Tablet, coated 75mg/150mg

In other blocks a total of 107 products are manufactured with following therapeutic groups:

- Renal transplantation
- Anti-Osteoporosis
- Anti-Diabetic
- Anti-Hypertensive
- Anti-Pyretics
- Immunosuppressant
- Anti Gastroentitis & Anti Colonitis
- Peptic ulcers
- Cardiac emergencies
- Migraine
- Laxatives

e) Most recent product quality reviews (APQR) of the concerned WHO products:
Submitted and reviewed:

- APQR Isoniazid/Rifampicin Tablet, coated 75mg/150mg
- APQR Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin Tablet, Film-coated 275mg/75mg/400mg/150mg

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

- BMR Isoniazid/Rifampicin Tablet, coated 75mg/150mg
- Batch summary record (including primary and secondary packaging) Isoniazid/Rifampicin Tablet, coated 75mg/150mg
- Electronic printouts of different stages Isoniazid/Rifampicin Tablet, coated 75mg/150mg
- Status labels (containers) Isoniazid/Rifampicin Tablet, coated 75mg/150mg
- Overprinting specimens primary and secondary packaging materials Isoniazid/Rifampicin Tablet, coated 75mg/150mg
- Analytical raw data Isoniazid/Rifampicin Tablet, coated 75mg/150mg

g) Master batch manufacturing and packaging record of the products of interest:
Submitted and reviewed

- Master batch records manufacturing and packaging Isoniazid/Rifampicin Tablet, coated 75mg/150mg
- Master batch records manufacturing and packaging Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin Tablet

h) If any of the products are sterile, the completed batch records for the most recent media fill validation that is relevant to the products of interest and report on its outcome:
N/A

i) Recalls in the past three years related to products with quality defects:
Declaration submitted: no product recall with respect to products 2FDC and 4FDC in last three years

Product	Batch number/ market	Reason for recall	Remark – explanation by the company
Alphadol (Alfacalcidol Capsules 0.25 mcg)	30136521 India	Show cause notice reported for the product, as 1 batch of the product did not comply with the specification in terms of assay limit, when tested by the government laboratory	Detailed investigation performed at plant and assay was found satisfactory. However, in consideration of potential safety concern for the patients, batch was recalled (initiated on Jun 16, 2018) from market
Alben Suspension (Albendazole Suspension 200 mg/5 ml)	54517008 Kenya	As a result of a post market surveillance by the Ministry of Health, the local regulatory agency PPB Kenya picked sample of a batch of Alben suspension, analysis was performed, and assay was found to be out of specification limits	Detailed investigation performed at plant and assay results were found satisfactory. However, a recall process was initiated (on Dec. 13, 2018) in consideration of potential safety concern for patient. Meanwhile, re-analysis was performed by PPB Kenya and assay results were found satisfactory. As a result, Kenya authority withdrew the suspension letter for sale and distribution of the batch and initiated recall process was invalidated, hence, there was no actual physical recall of this batch.

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 product(s) 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: September 25, 2020, the site received a WL from FDA for the referenced Feb 2020 inspection of Panacea's sterile oncology products' manufacturing facility

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

l) Additional documents submitted:
SOP "Annual product quality review"

Part 5	Conclusion – Desk assessment outcome

Based on the information available and the GMP evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site ***Panacea Biotec Pharma Ltd*****,** located at ***Malpur, Baddi, Tehsil Nalagarh, Solan District, Himanchal Pradesh, 173 205, 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 good manufacturing practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-sixth Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2.
   Short name: WHO TRS No. 970, Annex 2
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/

4. 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

5. 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/

6. 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

7. 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/

8. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2.
Short name: WHO TRS No. 957, Annex 3
http://www.who.int/medicines/publications/44threport/en/

9. 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

10. 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

11. 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

12. 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

13. 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

14. 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/

15. 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/

16. 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

17. 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

18. 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

19. 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

20. Guidance on good data and record management practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 5.
Short name: WHO GDRMP guidance or **WHO TRS No. 996, Annex 5**
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf

21. 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

22. 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

23. 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

24. 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

25. 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

26. 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