World Health Organization

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

Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR
Desk Assessment of Active Pharmaceutical Ingredient (API) Manufacturer

Part 1	**General information**
Company information	
Name of Manufacturer	Macleods Sarigam (Corporate name: Macleods Pharmaceuticals Ltd)
Corporate address of manufacturer	Macleods Pharmaceuticals Ltd, 304 Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, 400 059, India
Inspected site	
Name & address of manufacturing site	Macleods Pharmaceuticals Ltd, (Unit V), Plot No 2209 GIDC Industrial Area, At and Post Sarigam, Taluka: Umbergaon, Valsad District, Gujarat, 396 155, India
Synthetic Unit/Block/Work shop	Blocks A, B, C, D, E, G (Unit 5)
Manufacturing license number	Form 25 No: G/25/1759, valid up to 28/02/2022
Desk assessment details	
Start and end dates of review	20 – 24 July 2020 10 – 14 and 24 – 27 August 2020
APIs covered by this desk assessment	• Dolutegravir sodium • Atazanavir monosulphate • Linezolid • Sulfadoxine • Pyrimethamine • Rifapentine • Lumefantrine • Praziquantel • Clofazimine • Ethionamide • Tenofovir disoproxil fumarate • Emtricitabine • Cycloserine • Oseltamivir monophosphate • Terizidone • Para-aminosalicylate monosodium dihydrate • Levofloxacin hemihydrate • Pyrazinamide • Moxifloxacin Hydrochloride • Artemether
List of documents submitted	1. USFDA EIR, date of inspection 6 – 10 January 2020 2. USFDA letter 3. USFDA form 483

	4. Horizontal analysis of FDA483 for WHO products 5. EIR copies of 2014, 2017 and 2018 6. EDQM inspection report 7. MHRA inspection report. Inspection was focused on manufacture and control of tablets, therefore was not assessed 8. Macleods response to MHRA inspection report 9. MHRA GMP certificate 10. FSI SID & GP (Russia) inspection report 11. CAPAs to FSI SID & GP (Russia) inspection report 12. Manufacturing license 13. SMF 14. Layouts of PW and HVAC systems 15. List of APIs manufactured on sites 16. Declaration self-inspection 17. Declaration warning letters 18. Declaration out of stock situation 19. SOP Product Quality Review 20. PQRs: 1) Tenofovir disoproxil fumarate 2) Levofloxacin hemihydrate 3) Pyrazinamide 4) Cycloserine 5) Clofazimine 6) Oseltamivir monophosphate 7) Ethionamide 8) Emtricitabine 9) Terizidone 10) Para-aminosalicylate monosodium dihydrate 11) Moxifloxacin Hydrocloride 12) Linezolid 13) Ethionamide 14) Atazanavir monosulphate 15) Dolutegravir sodium 16) Lumefantrine 17) Sulfadoxine 18) Pyrimethamine 19) Artemether 20) Rifapentine 21. List of SRA inspections 22. Batch production and control records, batch packaging records, analytical raw data sheets and Master production and control records for the following APIs 1) Tenofovir disoproxil fumarate 2) Levofloxacin hemihydrate 3) Pyrazinamide 4) Cycloserine 5) Clofazimine 6) Oseltamivir monophosphate 7) Ethionamide 8) Emtricitabine

	9) Terizidone 10) Moxifloxacin Hydrocloride 11) Linezolid 12) Dolutegravir sodium 13) Rifapentine 14) Para-aminosalicylate monosodium dihydrate 15) Ethionamide 16) Atazanavir monosulphate 17) Lumefantrine 18) Sulfadoxine 19) Pyrimethamine 20) Artemether 23. Recalls history 24. List of changes implemented for Cycloserine 125 and 250 mg capsules from 2015 25. Review report for Cycloserine API 26. Risk assessments: 1) Candesartan Cilexetil 2) Irbesartan 3) Losartan Potassium 4) Valsartan	
Any documents missing?	Not applicable	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments**	
USFDA, USA	Dates of inspection:	January 6-10, 2020
	Type of inspection:	Pre-approval GMP inspection
	Block/Unit/Workshop:	Block A and C
	APIs covered:	• Losartan Potassium • Sacubitril Valsartan Trisodium API (FDA selected them because they were viewed as high risk products.) WHO APIs were not specifically covered
USFDA, USA	Dates of inspection:	August 6-10, 2018
	Type of inspection:	Pre-approval inspection and good manufacturing practice surveillance inspection
	Block/Unit/Workshop:	Blocks B, C, D, E, G and H
	APIs covered:	• Levothyroxine sodium API • Levothyroxine sodium tablets WHO APIs were not specifically covered
USFDA, USA	Dates of inspection:	4 – 8 September 2017
	Type of inspection:	Pre-Approval and Post Approval Inspection The objective of this inspection was the readiness for commercial manufacturing, conformance to the application and data integrity audit forthe AN DA 210377 Dimethyl Fumarates and post

		approval coverage for Pramipexole dihydrochloride Monohydrate and Zolmitriptan.
	Block/Unit/Workshop:	Blocks: A, B, C, D, F, G and H
	APIs covered:	• Dimethyl Fumarate • Pramipexole Dihydrochloride Monohydrate • Zolmitriptan WHO APIs were not specifically covered
EDQM	Dates of inspection:	11 -13 September 2017
	Type of inspection:	Inspection focused on the compliance with the information provided in the application for a certificate of suitability as well as implementation of a suitable Quality Management system bases on the GMP
	Block/Unit/Workshop:	Blocks A, C, D and G
	APIs covered:	Donepezil Hydrochloride Sildenafil citrate WHO APIs were not specifically covered
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	The last onsite inspection by the WHO was performed 8-12 August 2016. There were 0 critical, 4 major and 11 "other" deficiencies reported. Conclusion of the inspection: "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 Macleods Pharmaceuticals Limited located at Plot No.: 2209, GIDC, Sarigam-396155, Dist Valsad, Gujarat State, India with WHO GMP guidelines will be made after the manufacturer's response to the observations has been assessed" Final conclusion after evaluation of CAPAs, dated 9 March 2017: "In general, CAPAs are considered to be acceptable. Therefore, taking into account these responses, as well as the findings of the inspection, the Prequalification Inspection Group has recommended that the site can be considered to be compliant with the standards of Good Manufacturing Practices (GMP) for Active Pharmaceutical Ingredients (APIs) published by the World Health Organization (WHO), for the scope of activities listed below: • manufacture of following active pharmaceutical ingredients by chemical synthesis and packaging for: 1. Tenofovir Disoproxil Fumarate 2. Emtricitabine 3. Cycloserine 4. Oseltamivir Monophosphate 5. Terizidone 6. Aminosalicylate Sodium 7. Levofloxacin Hemihydrate 8. Pyrazinamide	

	9. Atazanavir Sulfate 10. Linezolid 11. Ethionamide
Brief summary of manufacturing activities as of August 2016	The Unit -V was specifically designed for manufacturing of Active Pharmaceuticals ingredients (APIs) and its intermediates. The site was established in year 2007. The manufacturing blocks are multi-product except a dedicated facility for manufacturing of Levothyroxine Sodium.
General information about the company and manufacturing site as of August 2016	The Macleods Pharmaceuticals Limited was established in year 1989 for production of pharmaceuticals products. There are approximately 10000 employees associated with the company in various departments. The corporate office with the R&D center is located in Andheri Mumbai. Finished dosage forms and active pharmaceutical ingredients are manufactured in 7 units: • Unit-I), Palghar (District Thane) Pharmaceuticals Formulation • Unit-Il), Daman (Union Territory) Pharmaceuticals Formulation • Unit-III), Daman (Union Territory) Pharmaceuticals Formulation • • Unit-V), Sarigam (Gujarat) Active Pharmaceutical Ingredient • Unit-VI, Nalagarh (Himachal Pradesh) Pharmaceuticals Formulation • Unit-VII, Daman (Union Territory) Pharmaceuticals Formulation • Unit-IX, Sikkim Pharmaceuticals Formulation
Focus of the last WHO inspection	The APIs in the scope of the inspection were: • Tenofovir Disoproxil Fumarate • Emtricitabine • Cycloserine • Oseltamivir Monophosphate • Terizidone • Aminosalicylate Sodium • Levofloxacin Hemihydrate • Pyrazinamide • Atazanavir Sulfate • Linezolid • Ethionamide
Areas inspected	• Quality management • Personnel • Buildings and facilities • Process equipment • Documentation and records • Materials management • Production and in-process controls • Packaging and identification labelling of APIs and intermediates • Storage and distribution • Laboratory controls • Validation • Change control • Rejection and reuse of materials • Complaints and recalls • Contract manufacturers (including laboratories)

	Site visit: • Block G • Warehouse 1 and 2 • Quality Control Labs • Stability chambers • Purified Water plant
Out of scope and restrictions (last WHO inspection)	APIs out of WHO PQ
WHO APIs covered by the last WHO inspection	The APIs in the scope of the inspection were: • Ethionamide • Tenofovir Disoproxil Fumarate • Emtricitabine • Cycloserine • Oseltamivir Monophosphate • Terizidone • Aminosalicylate Sodium • Levofloxacin Hemihydrate • Pyrazinamide • Atazanavir Sulfate • Linezolid • Ethionamide
Abbreviations	**Meaning**
BMCR	Batch manufacturing and control record
CAPA	Corrective and preventive action
CC	Change control
EDQM	European Directorate for the Quality of Medicines
GMP	Good manufacturing practices
PQR	Product quality review
SMF	Site master file
PW	Purified water
HVAC	Heating ventilation and air conditioning

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

a) Manufacturing authorization and GMP certificate granted by the local authority:
Form 25 No: G/25/1759, valid up to 28/02/2022
GMP certificate No: GMP/S-GMP/19081536/85816

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:

The site manufactures 127 APIs and following therapeutic groups:

- Antiviral
- Antibacterial
- Antituberculosis
- Antibacterial (Tuberculostatic)
- Antimycobacterial agents, Treatment of tuberculosis
- Antileprosy
- Antibiotic
- Antimalarial

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

Name of regulatory authority	Dates of inspection	Outcome
EDQM	11 – 13 September 2017	GMP compliance
USFDA	4 - 8 September 2017	No actions indicated (NAI)
MHRA UK	26 – 28 June 2018 (only inspection of tablets production and control	GMP compliance
USFDA	6-10 August 2018	No actions indicated (NAI)
FSI SID & GP Russia	12 – 14 December 2018	GMP compliance
USFDA	6 – 10 January 2020	GMP compliance

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

Submitted and checked:

1) Levofloxacin hemihydrate
2) Pyrazinamide
3) Clofazimine
4) Oseltamivir monophosphate
5) Emtricitabine
6) Terizidone
7) Para-aminosalicylate monosodium dihydrate
8) Linezolid
9) Ethionamide
10) Lumefantrine
11) Sulfadoxine
12) Pyrimethamine
13) Artemether
14) Rifapentine

Submitted and reviewed:

1) Atazanavir monosulphate
2) Moxifloxacin Hydrocloride
3) Dolutegravir sodium
4) Tenofovir disoproxil fumarate
5) Cycloserine

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

Submitted and checked batch manufacturing and packaging records:

1) Tenofovir disoproxil fumarate
2) Levofloxacin hemihydrate
3) Pyrazinamide
4) Clofazimine
5) Oseltamivir monophospate
6) Emtricitabine
7) Para-aminosalicylate monosodium dihydrate
8) Ethionamide
9) Lumefantrine Sulfadoxine
10) Pyrimethamine
11) Artemether

Submitted and reviewed batch manufacturing and packaging records and analytical raw data:

1) Linezolid
   a. Stage I
   b. Stage II
   c. Stage III
   d. Stage IV
   e. Stage Pharma
2) Moxifloxacin Hydrocloride
   a. Stage I
   b. Stage Pharma
3) Terizidone
   a. Stage I
   b. Stage Pharma
4) Ethionamide
   a. Stage I
   b. Stage II
   c. Stage III
   d. Stage Pharma
5) Cycloserine
   a. Stage I batch XX
   b. Stage I batch YY
   c. Stage Pharma batch XX
   d. Stage Pharma batch YY
6) Atazanavir monosulphate:
   a. Stage I
   b. Stage II
   c. Stage Pharma
7) Dolutegravir sodium
   a. Stage I
   b. Stage II
   c. Stage III
   d. Stage Pharma

8) Rifapentine
   a. Stage I
   b. Stage Pharma

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

1) Tenofovir disoproxil fumarate
2) Levofloxacin hemihydrate
3) Pyrazinamide
4) Cycloserine
5) Clofazimine
6) Oseltamivir monophosphate
7) Ethionamide
8) Emtricitabine
9) Terizidone
10) Para-aminosalicylate monosodium dihydrate
11) Moxifloxacin Hydrocloride
12) Linezolid
13) Ethionamide
14) Atazanavir monosulphate
15) Dolutegravir sodium
16) Lumefantrine
17) Sulfadoxine
18) Pyrimethamine
19) Artemether
20) Rifapentine

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

Date	Product Name	Batch Number
24-Aug-2017	Chlorthalidone	E/1143/D17001T
3-0ct-2018	Oseltamivir Phosphate	E/9989/A18015
09-Jan-2019	Ziprasidone Hydrochloride	E/1305/Al8001 E/1305/A18002 E/1305/A18003 E/1305/A18004

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 that 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 API(s):
Declaration submitted no warning letter, or equivalent regulatory action, issued by any authority

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

l) Additional documents submitted:
SOP Product Quality Review

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 ***Macleods Pharmaceuticals Ltd, Unit V (manufacturing blocks: A, B, C, D, E, G)***, located at ***Plot no 2209, GIDC Industrial area, At and Post Sarigam, Taluka: Umbergaon, Valsad district, Gujarat 396155 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 GMP for APIs or WHO TRS No. 957, Annex 2***
   http://apps.who.int/medicinedocs/documents/s20119en/s20119en.pdf

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 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. 961, 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 3.
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. WHO Recommendations for quality requirements when plant – derived artemisin is used as a starting material in the production of antimalarial active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 6
Short name: WHO TRS No. 992, Annex 6
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

21. 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

22. 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

23. 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

24. 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. 1015), Annex 3.
Short name: WHO TRS No. 1025, Annex 3
https://www.who.int/publications-detail/978-92-4-000182-4

25. 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

26. 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

27. 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