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Prequalification Unit Inspection services
WHO PUBLICK INSPECTION REPORT

Desk Assessment of Finished Product Manufacturer

Part 1	**General information**
Company information	
Name of Manufacturer	Ajanta Pharma Limited
Corporate address of manufacturer	Ajanta House, Charkop, Kandivli (W), Mumbai, 400 067, India Telephone Number: +91-22-66061,000 Fax: +91-22-66061200/66061300
Inspected site	
Name & address of manufacturing site	Ajanta Pharma Ltd B-4/5/6 MIDC Industrial Area, Aurangabad, Paithan District, Maharashtra, 431 148, India GPS details: Latitude - 19.48'N Longitude - 75.38'E D-U-N-S Number: 91-859-48-59
Desk assessment details	
Start and end dates of review	09 November – 11 November and 16 – 18 November 2020
Products covered by this desk assessment	MA092 – Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg MA095 – Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg MA096 – Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg MA097 – Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg MA111 – Artemether/Lumefantrine Tablet 20mg/120mg MA128 – Artemether/Lumefantrine Tablet 40mg/240mg MA129 – Artemether/Lumefantrine Tablet 60mg/360mg MA130 – Artemether/Lumefantrine Tablet 80mg/480mg
List of documents submitted	1. CDSCO India inspection report 2018 and CAPAs to the report 2. FDA Maharashtra, India inspection report 2018 and CAPAs to the report 3. FDA Ghana inspection report 2019 and CAPAs to the report 4. MCAZ Zimbabwe inspection report 2017 and CAPAs to the report 5. PPB Kenya inspection exit report 2019 and CAPAs to the report 6. CAPAs to Yemen inspection report 2017 7. ZAMRA Zambia inspection report 2019 and CAPAs to the report 8. US FDA EIR, dated 07/30/2019 9. US FDA Form 483, dates of inspection 6/24/2019 - 6/28/2019 and CAPAs 10. Manufacturing license No 25-AD/018, valid up to 31/12/2022 and No 28-AD/024, valid up to 31/12/2022 11. SMF, AHU and Purified water drawings 12. List of regulatory inspections, last 5 years 13. List of products manufactured at the site 14. Recall statement 15. Declaration self-inspection 16. Declaration warning letters or equivalency regulatory actions

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	17. Declaration out-of-stock situations 18. Declaration upcoming inspections 19. Manufacturing process for concerned products - covered by inspection 20. Executed BMR/BPR and analytical raw data: 1. BMR common blend batch i. Artemether/Lumefantrine Tablet 40mg/240mg ii. Artemether/Lumefantrine Tablet 60mg/360mg iii. Artemether/Lumefantrine Tablet 80mg/480mg 2. Artemether/Lumefantrine Tablet 20mg/120mg batch 3. Artemether/Lumefantrine Tablet 40mg/240mg batch 4. Artemether/Lumefantrine Tablet 60mg/360mg batch 5. Artemether/Lumefantrine Tablet 80mg/480mg batch 6. Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg batch 7. Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg batch 8. Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg batch 9. Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg batch 21. Master MBR and MPR 1. Artemether/Lumefantrine Tablet 20mg/120mg 2. Artemether/Lumefantrine Tablet 40mg/240mg 3. Artemether/Lumefantrine Tablet 60mg/360mg 4. Artemether/Lumefantrine Tablet 80mg/480mg 5. Common blend batch i. Artemether/Lumefantrine Tablet 40mg/240mg ii. Artemether/Lumefantrine Tablet 60mg/360mg iii. Artemether/Lumefantrine Tablet 80mg/480mg 6. Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg 7. Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg 8. Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg 9. Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg 22. PQRs: 1. Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg 2. Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg 3. Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg 4. Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg 5. Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg 6. Artemether/Lumefantrine Tablet 40mg/240mg 7. Artemether/Lumefantrine Tablet 60mg/360mg 8. Artemether/Lumefantrine Tablet 80mg/480mg	
Any documents missing?	N/A	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments**	
USFDA, USA	Dates of inspection:	24 – 28 June 2019
	Type of inspection:	cGMP and post approval inspection
	Type of products/Dosage forms covered:	1. Lansoprazole Delayed Release Capsules USP 30 mg 2. Lansoprazole Delayed Release Capsules USP 15 mg

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		3. Duloxetine Delayed Release Capsules 30 mg 4. Montelukast Sodium Tablets USP 10 mg 5. Memantine Hydrochloride Tablets 10 mg 6. Voriconazole Tablets 200 mg 7. Amlodipine and Olmesartan Medoxomil Tablets USP 5 mg I 40 mg 8. Tadalafil Tablets 5 mg 9. Clonidine Hydrochloride Extended Release Tablets 0.1 mg 10. Etoricoxib Tablets 120 mg WHO products under PQ were not specifically covered
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	Desk assessment of the site was performed, 21 – 29 May 2019 and the following inspection report was reviewed: • US FDA, dates of inspection 30.01.2017-3.02.2017 and 6-02-2017-7.02.2017 Outcome of desk assessment: 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 M/s Ajanta Pharma Limited located at B-4/5/6 MIDC Industrial Area, Aurangabad, Paithan District, Maharashtra, 431148, India is operating at an acceptable level of compliance with WHO GMP guidelines. This compliance status shall be valid until 07.02.2020 or when another inspection is conducted by WHO or by a stringent regulatory authority. An onsite inspection may be scheduled before this date at the discretion of WHO. Last WHO on-site inspection was performed April 25 - 28, 2016 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 M/s Ajanta Pharma Limited, located at Ajanta Pharma Ltd, B-4/5/6 MIDC Industrial Area, Aurangabad, Paithan District, Maharashtra, 431 148, India with WHO GMP guidelines will be made after the manufacturer's response to the observations has been assessed CAPAs were submitted and assessed by the PQT: Inspection Team and the inspection, following the review of the CAPA, was closed 6 July 2016 as compliant with the standards of GMP published by WHO	
Summary of manufacturing activities as of April 2016	Manufacturing, packaging, quality control, stability testing, storage and distribution of: • Tablets (coated and un-coated) • Capsules • Oral powders	
General information about the company and manufacturing	Ajanta Pharma Limited (here after referred as “Ajanta”) was incorporated in 1973. Ajanta is involved in manufacturing and marketing of the pharmaceutical products in India and overseas. Ajanta’s global head quarter and corporate office is located at Kandivli, Mumbai. Ajanta employs over 6,900 personnel worldwide (including India) including sales, marketing, Research and Development (R&D), manufacturing, quality, regulatory, human resources, accounts, finance, secretarial, legal, administration and	

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site as of April 2016	various other functions. In India, Ajanta has several branded generic products with therapeutic focus on cardiology, ophthalmology, dermatology, musculoskeletal and Over-the-counter (OTC) segments. Ajanta's products are developed at the Research and Development (R&D) center located at Kandivli, Mumbai, India. Globally, Ajanta has eight manufacturing facilities, seven in India {Six formulation facilities and one Active Pharmaceutical Ingredient (API) facility} and one in Mauritius. Toxic or hazardous products, β-Lactams, cytotoxic drugs, hormones and steroids were not being manufactured at the site.
Focus of the last WHO inspection	The inspection covered sections of the WHO GMP for oral solid dosage products text, including quality assurance, premises, equipment, documentation, validation, production, and manufacture
Areas inspected	• Quality Assurance • Qualification and validation • Complaints • Recalls • Contracts • Premises • Equipment • Documentation • Production • Quality control
Out of scope and restrictions (last WHO inspection)	Products out of WHO PQ
WHO products covered by the last WHO inspection	MA092 – Artemether / Lumefantrine Tablet, Dispersible 20mg/120mg MA095 – Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg MA096 – Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg MA097 – Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg MA111 – Artemether/Lumefantrine Tablet 20mg/120mg
Additional products to be covered by this desk assessment:	MA128 – Artemether/Lumefantrine Tablet 40mg/240mg MA129 – Artemether/Lumefantrine Tablet 60mg/360mg MA130 – Artemether/Lumefantrine Tablet 80mg/480mg

Abbreviations	**Meaning**
AHU	Air handling unit
API	Active pharmaceutical ingredient
BMR	Batch manufacturing record
BPR	Batch packaging record
CAPA	Corrective and preventive action
CC	Change control
GMP	Good manufacturing practices
PQR	Product quality review
SMF	Site master file
SOP	Standard operating procedure

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Part 4	Summary of the assessment of supporting documentation

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

Sr. No.	Inspection Date	Regulatory Authority/Agency	Report/ Certificate Date
1	18th to 20th Jan 2016	East African Community (EAC)	3rd Nov, 2016
2	13th Mar 2016	Food and Drug Administration, Maharashtra, India	13th Mar, 2016
3	21st to 25th Mar 2016	Agencia Nacional De Vigilancia Sanitaria (ANVISA), Brazil	4th Oct, 2017
4	25th to 28th Apr 2016	WHO - Prequalification, Geneva	24th May, 2016
5	21st to 22nd Jun 2016	Central Drug Standards Control Organization (CDSCO), India	6th Sep, 2016
6	30th Jan to 7th Feb 2017	United States Food and Drug Administration (USFDA), USA	16th Jun, 2017
7	1st Mar 2017	Pharmacy Board, Sierra Leone	Report awaited
8	17th May 2017	National Agency for Food and Drug Administration and Control (NAFDAC), Uganda	Report awaited
9	3rd to 5th Oct 2017	Federal Ministry of Health, National Medicines & Poison Board, Sudan	4th Sep, 2018
10	13th Oct 2017	Iraqi Ministry of Health, Iraq.	Report awaited
11	28th to 29th Oct 2017	Ministry of health and population Republic of Yemen	CAPA submitted at the end of inspection, verbally accepted by inspector.
12	11th to 12th Dec 2017	Medicines Control authority of Zimbabwe (MCAZ), Zimbabwe	4th Jul, 2018
13	20th & 29th Mar 2018	Food and Drug Administration, Maharashtra, India	25th May, 2018
14	30th Jul to 1st Aug 2018	Central Drug Standards Control Organization (CDSCO), India	14th Sep, 2018
15	21st to 29th May 2019	WHO (Desk Assessment)	4th Jun 2019
16	24th to 28th Jun 2019	United State Food and Drug Administration (USFDA), USA	5th Aug 2019
17	16th to 18th Sep 2019	Zambia Medicines and Regulatory Authority (ZAMRA), Zambia	6th Feb 2020

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Sr. No.	Inspection Date	Regulatory Authority/Agency	Report/ Certificate Date
18	13th to 14th Nov 2019	Pharmacy and Poison Board (PPB, Kenya), Kenya	14th Nov 2019
19	20th to 21st Nov 2019	Food and Drug Administration (FDA), Ghana	26th Feb 2020

b) Manufacturing authorization granted by national authorities:

1. License No 25-AD/018 issued on the 24/01/2018 by the Food and Drugs Administration (Maharashtra State) valid till 31/12/2022
2. License number No 28-AD/024 issued on the 24/01/2018 by the Food and Drugs Administration (Maharashtra State) valid up to 31/12/2022

c) Site master file:

SMF, AHU and Purified water drawings submitted and reviewed. SMF written according to the WHO TRS No. 961, Annex 14

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

Total 240 products of Tablets, Capsules and Oral Powder dosage forms manufactured at site with different therapeutic groups such as Antibacterial, Antibiotic, Anti-Diabetic, Antiepileptic, Anti-Fungal, Anti-Histaminic, Anti-Nicotinic, Anti-Malarial, Antispasmodics, Cardiology, Gastroenterology, General Health, Gynaecology, Male Erectile Dysfunction, Nephrology, Neurology, NSAID, Nutraceuticals / Multivitamins, Pain management arthritis disorder, Psychiatric and Respiratory.

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

Submitted and reviewed:

- Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg
- Artemether/Lumefantrine Tablet 20mg/120mg
- Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg

Submitted and checked

- Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg
- Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg
- Artemether/Lumefantrine Tablet 40mg/240mg
- Artemether/Lumefantrine Tablet 60mg/360mg
- Artemether/Lumefantrine Tablet 80mg/480mg

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

Submitted and reviewed:

1. BMR common blend batch
   i. Artemether/Lumefantrine Tablet 40mg/240mg
   ii. Artemether/Lumefantrine Tablet 60mg/360mg
   iii. Artemether/Lumefantrine Tablet 80mg/480mg
2. Artemether/Lumefantrine Tablet 20mg/120mg
3. Artemether/Lumefantrine Tablet 40mg/240mg

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4. Artemether/Lumefantrine Tablet 60mg/360mg
5. Artemether/Lumefantrine Tablet 80mg/480mg
6. Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg
7. Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg
8. Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg
9. Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg

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

1. Artemether/Lumefantrine Tablet 20mg/120mg
2. Artemether/Lumefantrine Tablet 40mg/240mg
3. Artemether/Lumefantrine Tablet 60mg/360mg
4. Artemether/Lumefantrine Tablet 80mg/480mg
5. Common blend batch
    i. Artemether/Lumefantrine Tablet 40mg/240mg
    ii. Artemether/Lumefantrine Tablet 60mg/360mg
    iii. Artemether/Lumefantrine Tablet 80mg/480mg
6. Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg
7. Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg
8. Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg
9. Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg

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:
Statement submitted: one product recall in the past 3 years:
Ranitidine Hydrochloride capsules 150 mg and 300 mg. Class II (retail level).

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: a full self-inspection or external audit dedicated to the products 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: no NOC, warning letters or equivalency regulatory actions issued

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

l) Additional documents submitted:
Declaration upcoming inspections – MCAZ Zimbabwe, planned inspection dates 14 – 18 December 2020

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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 ***Ajanta Pharma Ltd,*** located ***at B-4/5/6 MIDC Industrial Area, Aurangabad, Paithan District, Maharashtra, 431 148, 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 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. 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

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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