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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	Cipla Ltd
Corporate address of manufacturer	Cipla House, Peninsula Business Park, Ganpatrao Kadam, Marg, Lower Parel, Mumbai 400013, India
Inspected site	
Name & address of manufacturing site	Cipla Ltd, Unit I (API) Plot A-33, A37/2/2 & A-2 M.I.D.C, Patalganga, Taluka: Khalapur, District: Raigad Maharashtra state, 410 220, India. D-U-N-S: 916940208 Latitude: 18°, 877177`N Longitude: 73°, 182783`E
Synthetic Unit/Block/Workshop	Unit I
Manufacturing license number	License No (25) 845 & (28) 707 valid until 31.12.2022
Name & address of manufacturing site	Cipla Ltd, Unit II (API) Plot A-42 M.I.D.C., Patalganga, Taluka: Khalapur, District: Raigad Maharashtra state, 410 220 India. D-U-N-S: 916940208 Latitude: 18°, 875662`N Longitude: 73°, 178696`E
Synthetic Unit/Block/Workshop	Unit II
Manufacturing license number	Form 26 - license No (25) KD620 & (28) KD 435 valid until 17.08.2021
Desk assessment details	
Start and end dates of review	26 – 30 October 2020
APIs covered by this desk assessment	Unit I 1. Artesunate 2. Daclatasvir dihydrochloride
APIs covered by this desk assessment	Unit II 1. Lamivudine 2. Artesunate 3. Artemether

	4. Lumefantrine 5. Lamivudine anhydrous
List of documents submitted	1. FDA EIR, dates of inspection 4 – 13 November 2019 and EIR cover letter 2. Compliance report (CAPA) FDA inspection 4 – 13 November 2019 3. USFDA Form 483, dates of inspection 4 – 13 November 2019 4. EDQM inspection report, dates of inspection 7 – 9 March 2018 5. Compliance report (CAPA) EDQM inspection 7 – 9 March 2018 6. EDQM GMP certificate 7. GMP certificates Unit I (issued 19 December 2018 No NEW-WHO-GMP / CERT / KD / 73115 / 2018/ 11/ 26155, valid till 16 December 2021) and Unit II (issued 3 October 2019 No NEW-WHO-GMP / CERT / KD / 83192 / 2019 / 11 / 29628, valid till 26 September 2022. 8. Manufacturing license Unit I issued by Food & Drugs Administration (Maharashtra State) –license No (25) 845 & (28) 707 valid until 31.12.2022 9. Manufacturing license Unit II issued by Food & Drugs Administration (Maharashtra State) Form 26 - license No (25) KD620 & (28) KD 435 valid until 17.08.2021 10. SMF Unit I and Unit II and layouts 11. List of regulatory inspections performed in the last 5 years Unit I and Unit II 12. Lists of products manufactured Unit I and Unit II 13. Recall declarations Unit I and Unit II 14. Confirmation self-inspection Unit I and Unit II 15. Declaration: List of equipment that is shared between WHO APIMFs with Sartan APIs, Unit I and Unit II 16. Declaration: Usage of recovered solvents or reagents in the manufactured of WHO APIMFs, Unit I and Unit II 17. Declaration: Usage of outsourced recovered solvents for WHO APIMFs, Unit I and Unit II 18. Declaration Unit II: Artesunate additional micronization carried out at Unit I 19. Declaration: Lamivudine Anhydrous not manufactured in Unit I 20. Unit I a. Master BMR, BMR, analytical raw data and CoA of Daclatasvir dihydrochloride 21. Unit II a. Master BMR, BMR, analytical raw data and CoA of Artesunate b. Master BMR, BMR, analytical raw data and CoA of Artemether c. Master BMR, BMR, analytical raw data and CoA of Lamivudine d. Declaration regarding Lumefantrine manufacturing at Unit II – last batch manufactured July 2014 22. PQRs Unit I a. Daclatasvir dihydrochloride Mar 2019 – Feb 2020, one batch manufactured 23. PQRs Unit II a. Artesunate Jan 2019 – Dec 2019, 3 batches manufactured b. Artemether Jun 2019 – May 2020, 28 batches manufactured c. Lamivudine Nov 2018 – Oct 2019, no batches manufactured d. Lumefantrine Jun 2019 – May 2020, no batches manufactured
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:	4 – 13 November 2019
	Type of inspection:	Pre-announce surveillance cGMP inspection
	Block/Unit/Workshop:	Unit I FPPs and APIs Unit II FPPs and APIs
	APIs covered:	• Albuterol Sulfate • Cetirizine Dihydrochloride • Danazol • Levalbuterol Hydrochloride • Perindopril Erbumine Monohydrate • Pirfenidone • Praziquantel • Solifenacin Succinate • Levocetirizine Dihydrochloride • Escitalopram Oxalate • Tolterodine Tartrate WHO APIs under PQ were not specifically covered
EDQM	Dates of inspection:	7 – 9 March 2018
	Type of inspection:	GMP inspection in the framework of the CEP dossier
	Block/Unit/Workshop:	Unit I and Unit II
	API covered:	Desloratadine Cetirizine dihydrochloride Finasteride WHO APIs under PQ were not specifically covered
US FDA, USA	Dates of inspection:	27 November – 6 December 2017
	Type of inspection:	Surveillance inspection
	Block/Unit/Workshop:	Unit I and Unit II
	API covered:	• Escitalopram Oxalate • Darifenacin Hydrobromide • Cetirizine Dihydrochloride USP • Danazol USP • Albuterol Sulfate • Valacyclovir Hydrochloride USP • Rivastigmine Tartrate USP • Levocetirizine Dihydrochloride • Artesunate

Part 3	Summary of the last WHO inspection
Date and conclusion of most recent WHO inspection	The site (Unit I and II) was inspected by WHO 15 – 18 January 2018 – routine inspection 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 APIs (Artemether, Artesunate, Lamivudine, Lumefantrine, Moxifloxacin Hydrochloride, Daclatasvir Dihydrochloride) made by Plot A-33 & A-2 MIDC Industrial Area, Patalganga, Raigad District, Maharashtra, 410 220, India and Plot A-42 MIDC Industrial Area, Patalganga, Raigad District, Maharashtra, 410 220, India with WHO GMP for Active Pharmaceutical Ingredients 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 22 June 2018 as compliant with the standards of GMP published by WHO.
Brief summary of manufacturing activities as of January 2018	Manufacturing, quality control and batch release of: • Non-sterile medicinal products: coated/uncoated tablets, • Active Pharmaceutical Ingredients (APIs) and drug intermediates
General information about the company and manufacturing site of January 2018	Cipla Limited is a public limited company established in 1935 by Dr K.A. Hamied and managed by a professional board of directors. It has its own management control & operation and has no parent company. Cipla manufactures products of various ranges including Prescription, Animal Health care, OTC and Active Pharmaceutical Ingredients, which are supplied to over 150 countries located in the various regions including USA, Europe, Australia, South America, Brazil, Middle East Asia and Africa. It also has Research centers located at Vikhroli, Patalganga and Bengaluru.
Focus of the last WHO inspection	APIs under WHO prequalification
Areas inspected	Quality management • Product quality review • APOR Artesunate • APQR Daclatasvir Dihydrochloride • APQR Artemether • APQR Moxifloxacin Hydrochloride • Deviation handling • Management Review • Self- Inspection • Organizational Structure Personnel • Job descriptions • Training Buildings and facility

	• Design and construction • Utilities and Water • Lighting • Sewage and refuse • Sanitation and maintenance Process Equipment • Design and construction • Equipment maintenance and cleaning • Calibration • Computerized systems Documentation and Records • Documentation system and specifications • Equipment cleaning and use record • Master production instructions • Batch production records • Retention period and destruction of documents Materials Management • Vendor Qualification • Quality audits • API warehouse for Unit II Production and In-process controls • Inspected production and in-process control areas for Unit I Packaging and identification labelling of Intermediates and APIs Storage and distribution system Laboratory Controls • Laboratory information management system (LIMS) • Out of specification (OOS) and review of the selected OOS • Analytical incidences • Polymorphism (WHO products) • Stability Validation • Process validation • Stage-I: Manufacturing of DCV Imidazole HCl • Stage-II: Manufacturing of finished Daclatasvir Dihydrochloride • Analytical method validation Change control Rejection and re-use of materials Complaints and recalls Contract manufacturers Self-inspection
Out of scope and restrictions (last WHO inspection)	Products not under WHO PQ

WHO APIs covered by the last WHO inspection	• Artemether • Artesunate • Lamivudine • Lumefantrine • Moxifloxacin Hydrochloride • Daclatasvir Dihydrochloride
Additional products to be covered by this desk assessment:	N/A
Abbreviations	**Meaning**
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
GMP	Good manufacturing practices
PQR	Product quality review
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 authorizations:

- Unit I issued by Food & Drugs Administration (Maharashtra State) –license No (25) 845 & (28) 707 valid until 31.12.2022
- Unit II issued by Food & Drugs Administration (Maharashtra State) Form 26 - license No (25) KD620 & (28) KD 435 valid until 17.08.2021

GMP certificates:

- Unit I (issued 19 December 2018 No NEW-WHO-GMP / CERT / KD / 73115 / 2018/ 11/ 26155, valid till 16 December 2021)
- Unit II (issued 3 October 2019 No NEW-WHO-GMP / CERT / KD / 83192 / 2019 / 11 / 29628, valid till 26 September 2022.

b) Site master file (SMF):

SMF Unit I and Unit II and layouts 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:
Unit I

Sr No	Therapeutic Category	No. of API
1	Anti-Asthmatic	4
2	Anti-Arrthythmic	1
3	Anti-bacterial	1
4	Anti-Convulsant	1
5	Anti-Depressant	3
6	Anti-Emetic	1
7	Antifibrotic & Anti-Inflammatory Agent	1
8	Antifungal	1
9	Anti-Gonadotropin	1
10	Antihelmintic	1
11	Anti-Histaminic	1
12	Anti-Hypertensive	5
13	Anti-Malarial	1
14	Anti-Spasmodic	1
15	Anti-thrombotic	1
16	Anti-viral	3
17	Bronchodilator	1
18	Cardio-vascular	1
19	Glycosylceramide synthase inhibitor	1
20	Nootropic	1
21	Treatment of Benign Prostatic Hypertrophy	2
22	Treatment of Hepatitis C	1
23	Treatment on Urinary Incontinence	2

Unit II

Sr No	Therapeutic Category	No. of API
1	Anti-Material	3
2	Anti – Histaminic	3
3	Anti – Depressant	3
4	Treatment of Benign Prostatic Hypertrophy	1
5	Anti-Retroviral	1
6	Anti-Helminthic	1

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

	Regulatory authority	Dates of inspection	Outcome
1	USFDA Unit I and Unit II	4 – 13 Nov 2019	EIR received
2	Joint Inspection by CDSCO & FDA for WHO GMP certification (Unit II)	6 – 8 May 2019	Approved
3	Ministry of Health, Labour and Welfare Takumi Namato, Japan Unit I and Unit II	Desk top audit March 2019	Accreditation received
4	Joint Inspection by CDSCO & FDA for WHO GMP certification (Unit I)	8 – 10 August 2018	Approved
5	EDQM Unit I and Unit II	7 - 9 March 2018	Approved
6	USFDA Unit I and Unit II	27 Nov - 6 Dec 2017	EIR received
7	TGA Australia	Desk top audit June 2017	Approved
8	Joint Inspection by CDSCO & FDA for WHO GMP certification (Unit II)	19 – 20 September 2016	Approved
9	COFEPRIS, Mexico Unit I and Unit II	16 - 21 February 2015	Approved
10	USFDA Unit I and Unit II	23 - 27 February 2015	EIR received

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

Unit I submitted and reviewed:

1. Daclatasvir dihydrochloride Mar 2019 – Feb 2020

Note:
Declaration submitted: Artesunate and Lamivudine anhydrous – batches not manufactured, PQR not submitted

Unit II
Submitted:

1. Lamivudine Nov 2018 – Oct 2019, no batches manufactured
2. Lumefantrine Jun 2019 – Nay 2020, no batches manufactured

Submitted and reviewed:

1. Artesunate Jan 2019 – Dec 2019
2. Artemether Jun 2019 – May 2020

Note:
Declaration submitted: Lamivudine anhydrous – batches not manufactured, PQR not submitted

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

Unit I submitted and reviewed:

1. Daclatasvir dihydrochloride

Note:
Declaration: Artesunate and Lamivudine anhydrous – batches not manufactured, BMR/BMR and analytical part not submitted

Unit II
Submitted and reviewed:

1. Artesunate
2. Artemether
3. Lamivudine

Note:
Declaration: Lamivudine anhydrous – batches not manufactured, Lumefantrine – last batch manufactured July 2014, BMR/BMR and analytical part not submitted

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

Unit I submitted:

1. Daclatasvir dihydrochloride

Note:
Declaration: Artesunate and Lamivudine anhydrous – batches not manufactured, master BMR/BMR and not submitted

Unit II
Submitted:

1. Artesunate
2. Artemether
3. Lamivudine

Note:
Declaration: Lamivudine anhydrous – batches not manufactured, Lumefantrine – last batch manufactured July 2014, master BMR/BMR not submitted

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

Declaration submitted: no recalls in past three years Unit I and Unit II

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: Unit I and Unit II full self-inspection 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: Unit I and Unit II – no warning letter, or equivalent regulatory action, issued by any authority

k) Out-of-stock situations:
Declaration submitted: Unit I and Unit II: no out-of-stock situations

l) Additional documents submitted:
1. SOP "Evaluation of Nitrosamine impurities"
2. Study protocol & report "Assessment of nitrosamine potential impurities in drug substance
3. PMDS accreditation certificate
4. SOP "Annual product quality review"
5. Amendment to Artemether Jun 2019 – May 2020
6. OOS No XX

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 sites:

- ***Cipla Ltd, Unit I (API)***, located at ***Plot A-33, A37/2/2 & A-2 M.I.D.C, Patalganga, Taluka: Khalapur, District: Raigad-Maharashtra state, 410 220, India*** and
- ***Cipla Ltd, Unit II (API)***, located ***at Plot A-42 M.I.D.C., Patalganga, Taluka: Khalapur, District: Raigad Maharashtra state, 410 220 India***

are 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