World Health Organization

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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	IPCA Laboratories Ltd
Corporate address of manufacturer	International House, 48 Kandivli Industrial Estate, Kandivli (West), Mumbai – 400067, Maharashtra, India
Inspected site	
Name & address of manufacturing site	IPCA Laboratories Ltd Athal Plot No 255/1, Village Athal, Silvassa, Dadra & Nagar Haveli (Union Territory), 396 230, India DUNS: 65-038-7009 GPS: 20°15'27.0" North, 72°57'55.6" East
Manufacturing license number	No NH/34 & NH/35, valid till 31/12/2022
Desk assessment details	
Start and end dates of review	17 – 22 January 2021
Products covered by this desk assessment	**Finished Pharmaceutical Product** Zinc (sulfate) Tablet, Dispersible 20mg Sulfamethoxazole/Trimethoprim Tablet 400mg/80mg Sulfamethoxazole/Trimethoprim Tablet 800mg/160mg Artemether/Lumefantrine Tablet 20mg/120mg Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg Artemether/Lumefantrine Tablet 80mg/480mg Artemether/Lumefantrine Tablet 20mg/120mg
List of documents submitted	1. Government of upper Franconia, Germany inspection report (original). Dates of inspection 3 – 6 September 2019 2. Government of upper Franconia, Germany inspection report (translation to English language). Dates of inspection 3 – 6 September 2019 3. Responses to the Government of upper Franconia, Germany inspection report: i) Initial ii) Update 4. Translators declaration 5. Government of upper Franconia, Germany GMP certificate DE_BY_05_GMP_2020_0010 6. CDSCO (Drugs Control Department & Licensing Authority) inspection report Russia Federation and CAPAs implementation 7. Ministry of Industry and trade of the and CAPAs implementation 8. SMF, annexes and diagrams

	9. Manufacturing authorization No NH/34 & NH/35, valid till 31/12/2022 10. CDSCO GMP certificate No. DMHS/ADC/VVHO-GMP/Ipca/2015/1/752 11. PQRs: i) MA080 Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg ii) MA081 Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg iii) MA082 Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg iv) MA167 Artemether/Lumefantrine Tablet 20mg/120mg dispersible Tablet v) MA167 Artemether/Lumefantrine Tablet 20mg/120mg Tablet 12. Executed BMRs, BPRs and analytical raw data: i) MA080 Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg ii) MA081 Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg iii) MA082 Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg iv) MA167 Artemether/Lumefantrine Tablet 20mg/120mg dispersible Tablet v) MA167 Artemether/Lumefantrine Tablet 20mg/120mg Tablet vi) DI011 Zinc (sulfate) Tablet, Dispersible 20mg 13. Master BMRs and BPRs: i) DI0011 Zinc Sulfate Tablet, Dispersible 20mg (no commercial batches manufactured) ii) HA744/HA745 Sulfamethoxazole/Trimethoprim Tablets 400mg/80mg and 800mg/160mg (no commercial batches manufactured) iii) MA167 Artemether / Lumefantrine Tablet 20mg / 120mg iv) MA167 Artemether / Lumefantrine Tablet dispersible 20mg / 120mg v) MA080 Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg vi) MA081 Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg vii) MA082 Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg 14. List of regulatory inspections 15. List of recalls 16. Declaration - GMP 17. Declaration - warning letter 18. Declaration - notifications of upcoming inspections by competent national regulatory authorities in the next 6 months 19. Declaration – self-inspection 20. Declaration – out of stock 21. Area details of products manufactured
Any documents missing?	None

Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments**	
Government of upper Franconia, Germany inspection report, Germany	Dates of inspection:	3 – 6 September 2019
	Type of inspection:	Routine GMP inspection
	Type of products/Dosage forms covered:	Tablets and capsules • Hydroxychloroquine 200mg tablets • Ramipril 10mg capsules • Cetirizine Hydrochloride Tablets 10mg • Metformin Actavis 1000mg • Amlodipine Tablets 10mg • Loperamide ABECE 2mg Tablets • Risperidone 0.5mg and 1mg film coated tablets • Amitriptyline 25mg film coated tablet • Paracetamol 500mg tablets • Paracetamol 1g tablets • Paracetamol 500mg tablets • Enalapril 20mg tablets
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	The last on-site inspection by WHO PQT was performed 27 - 30 April 2015 Previous desk assessment was performed 21 – 22 August 2019 <u>Outcome of the desk assessment:</u> 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 ***Ipca Laboratories Ltd,*** located at ***Plot No 255/1, Village Athal, Silvassa, Dadra & Nagar Haveli (Union Territory), 396 230, India*** is considered to be operating at an acceptable level of compliance with WHO GMP guidelines. However, due to the nature and extent of the deficiencies raised by Government of Upper Franconia, Germany and Health Canada, this compliance status shall be valid for only a limited period and a WHO on-site inspection may be performed by a WHO PQ Inspections Team within approximately 1 year from the date of this report (27 August 2019).	
Summary of manufacturing activities	Manufacture (production, packaging, quality control and release) of solid dose products – Tablets and hard gelatin capsules	
General information about the company and manufacturing site	IPCA Laboratories Ltd was established in1949 and has its corporate office located at 48 Kandivli Industrial Estate, Kandivli (West), Mumbai, India. The company has facilities at the following locations: • Athal • Kandla • Piparia (Silvassa), • Ratlam	

	• Dehradun • Pithampur • Sikkim • Tarapur • SEZ Indore • Onyx UK, (for formulations) • Ratlam • Indore • Aurangabad • Mahad • Ankaleshwar • Baroda • Nandesari • Boiser • Pisgah Lab USA The production facilities at Athal were established in 1995 on a plot of land 104,000m^2. It was stated to have production capacity of 880 million tablets and 80 million capsules per month. The site manufactures products for human use only and no cytotoxic & hazardous substances or products of β-lactam, cephalosporin, hormones and steroids are manufactured on the site.
Focus of the last desk assessment	• MA062 Artemether/Lumefantrine Tablet 20mg/120mg • MA080 Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg • MA081 Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg • MA082 Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg • MA136 Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg • DI011 Zinc (sulfate) Tablet, Dispersible
Areas covered by desk assessment	• Quality Assurance System • Personnel • Rooms and Equipment • Documentation • Production • Quality Control • Complaints and Product Recalls
Out of scope and restrictions (last desk assessment)	• Self-Inspections • Distribution and Shipping
WHO products covered by the last Desk assessment	• Artemether/Lumefantrine Tablet 20mg/120mg • Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg • Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg • Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg • Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg • Zinc (sulfate) Tablet, Dispersible 20mg
Additional products to be covered by this desk assessment:	None

Abbreviations	Meaning
API	Active pharmaceutical ingredient
BMR	Batch manufacturing record
BPR	Batch production record
CAPA	Corrective and preventive action
CC	Change control
FPP	Finished pharmaceutical product
GMP	Good manufacturing practices
NRA	National regulatory agency
PQR	Product quality review
SMF	Site master file
SOP	Standard operating procedure

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.	Regulatory Authority	Date of Audit
1	Health Canada	20/08/2016 to 25/08/2016
2	TFDA - Tanzania	08/10/2016 to 10/10/2016
3	Government of Refrigers (German Authority)	19/12/2016 to 22/12/2016
4	Eritrea (MOH)	27/01/2017 to 28/01/2017
5	Belarus (MOH)	28/02/2017 to 01/03/2017
6	Health Canada	08/05/2017 to 11/05/2017
7	Russia MOH (**Desk assessment**)	25/07/2017 to 31/07/2017
8	Zimbabwe (MCAZ)	09/10/2017 to 10/10/2017
9	Uganda (NDA)	23/10/2017 to 24/10/2017
10	CDSCO - India	20/08/2018 to 21/08/2018
11	Russia (MOH)	24/09/2018 to 26/09/2018
12	Russia (MOH)	06/08/2019 to 08/08/2019
13	Government of Upper Franconia - Germany	03/09/2019 to 06/09/2019
15	Health Canada	Desk Assessment
16	Uganda (NDA)	Desk Assessment

b) Manufacturing authorization granted by national authorities:
CDSCO manufacturing authorization No NH/34 & NH/35, valid till 31/12/2022
CDSCO GMP certificate No. DMHS/ADC/VVHO-GMP/Ipca/2015/1/752

c) Site master file:
SMF, annexes and diagrams 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:
Total 119 products are manufactured on-site. Therapeutic categories as following:

1. Anti-inflammatory
2. Analgesics
3. Xanthine oxidase inhibitor
4. Anti-depressants
5. Cardiac
6. Anti-malarial
7. Anti-hypertensive
8. Anti-microbial
9. Diuretics
10. Anti-histamine
11. Antacid
12. Cholinesterase inhibitor
13. Anti-diabetic
14. Anti-arthritis
15. Antiepileptic
16. Antirheumatic
17. Antibiotics
18. Antidiarrheal
19. Antiemetic
20. Anticonvulsants
21. Anti-lipemic
22. Antipsychotics
23. Bronchodilators
24. Anti-migraine

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

1. MA080 Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg: 45 batches covered by the PQR
2. MA081 Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg: 84 batches covered by the PQR
3. MA082 Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg:181 batches covered by the PQR
4. MA167 Artemether/Lumefantrine Tablet 20mg/120mg dispersible Tablet:169 batches covered by the PQR
5. MA167 Artemether/Lumefantrine Tablet 20mg/120mg Tablet: batches covered by the PQR

PQRs contained required information and CAPAs.

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

Submitted and checked:

i) Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg
ii) Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg
iii) Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg
iv) Artemether/Lumefantrine Tablet 20mg/120mg dispersible Tablet
v) Artemether/Lumefantrine Tablet 20mg/120mg Tablet
vi) Zinc (sulfate) Tablet, Dispersible 20mg

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

Submitted and checked:

i) Zinc Sulfate Tablet, Dispersible 20mg (no commercial batches manufactured)
ii) Sulfamethaxazole/Trimethoprim Tablets 400mg/80mg and 800mg/160mg (no commercial batches manufactured)
iii) Artemether / Lumefantrine Tablet 20mg / 120mg
iv) Artemether / Lumefantrine Tablet dispersible 20mg / 120mg
v) Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg
vi) Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg
vii) Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg

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

1. Inosert 50 mg and 100 mg Tenocheck tablets, APO-Sertaline 100 mg, batch No. HEA018004, HEA018005, HEA018005, HEA018006, HEA018007, HEA018008, HEA018009, BLQ018002, GFF018001, AZV208005, GOI0118001, GFF018002, EIE018009, AZU238005, AZU178004, GOJ018002. Glass particle observed in ingredient (Calcium Hydrogen Phosphate) on sieve retention batch No GFF8002 (APO – Sertraline 100 mg tablets) - the same lot of Calcium Hydrogen Phosphate used in all above-mentioned batches.
2. Sumatriptan 100mg Tablets, Batch no. EPY028001. Type III Recall due to carton mix-up of lower strength in the batch.
3. Ranitidine 150 mg Tablets, Batch no. GNV015001, GNV016001, GNV017001, GNV025001, GNV025002, GNV026001, GNV026002 and GNV027001. Type II Recall as directed by Swedish regulatory authority.
4. Ramipril 5mg Capsules, Batch no. IKG010001. Type II Recall due to Ramipril 2.5mg capsules found in Ramipril 5mg bottle.

i) 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

j) 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 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:
None

Part 5	Conclusion – Desk assessment outcome

Based on the previous WHO desk assessments 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 ***IPCA Laboratories Ltd*** located at ***Plot No 255/1, Village Athal, Silvassa, Dadra & Nagar Haveli (Union Territory), 396 230, 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. Forty-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 2
   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