World Health Organization

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Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT

Desk Assessment of Finished Product Manufacturer

Part 1	**General information**
Company information	
Name of Manufacturer	**Strides Pharma Science Limited**
Corporate address of manufacturer	Strides Pharma Science Limited Strides House Bilekahalli Bannerghatta Road, Bangalore - 560 076, INDIA Tel: 91-80-67840521
Inspected site	
Name & address of manufacturing site	Strides Pharma Science Limited KRS Gardens', S No. 36/7, Suragajakkanahalli, Indlawadi Cross, Anekal Taluk, Bangalore South - 562 106. INDIA D-U-N-S: 918513263 GPS: Latitude: 12.730050 Longitude: 77.665418
Unit/block	• Tablets and Hard Gelatin Capsules Block • Soft Gelatin Capsules Block • Packaging Block • Warehouse Blocks • QA and QC Block • OLT Block
Manufacturing license number	Form 25 & 28 KTK/25/415/98 & KTK/28/301/98, issued by Government of Karnataka, Drugs Control Department, valid till 31.12.2021
Desk assessment details	
Start and end dates of review	17 – 28 May 2021
Products under prequalification	

Finished Pharmaceutical Product	**Prequalification status**
Lamivudine Tablet 300mg	Prequalified
Lamivudine/Zidovudine + Nevirapine - 150mg/300mg + 200mg	Prequalified
Nevirapine Tablet 200mg	Prequalified
Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg	Prequalified
Efavirenz Tablet, Film-coated 200mg	Prequalified
Efavirenz Tablet, coated 600mg	Prequalified
Abacavir (sulfate) Tablet, Film-coated 300mg	Prequalified
Lamivudine/Nevirapine/Zidovudine Tablet, Film-coated 150mg/200mg/300mg	Prequalified
Tenofovir disoproxil fumarate Tablet, Film-coated 300mg	Prequalified

	Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 200mg/300mg	Prequalified
	Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/200mg/300mg	Prequalified
	Lamivudine/Nevirapine/Zidovudine Tablet, Dispersible 30mg/50mg/60mg	Prequalified
	Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg	Prequalified
	Dolutegravir (Sodium) Tablet, Film-coated 50mg	Under assessment
	Sofosbuvir Tablet, Film-coated 400mg	Under assessment
	Ledipasvir/Sofosbuvir Tablet, Film-coated 90mg/400mg	Prequalified
	Oseltamivir (phosphate) Capsules, hard 75mg	Prequalified
	Artemether/Lumefantrine Tablet 20mg/120mg	Prequalified
	Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg	Prequalified
	Artesunate Capsule, Soft, Rectal 100mg	Prequalified
	Artemether/Lumefantrine Tablet 80mg/480mg	Prequalified
	Albendazole Tablets, Chewable 400mg	Under assessment
Products covered by this desk assessment	Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg	
	Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/200mg/300mg	
	Artemether/Lumefantrine Tablet 20mg/120mg	
	Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg	
	Artesunate Capsule, Soft, Rectal 100mg	
List of documents submitted	1. SMF and 23 Annexures 2. USFDA EIR, dates of inspection 2 – 5 March 2020 and related CAPAs 3. USFDA EIR, dates of inspection 13 – 17 January 2020 and related CAPAs 4. Health and Youth Care Inspectorate - Pharmaceutical Affairs Netherlands, dates of inspection 11 – 14 June 2019 inspection report, related CAPAs and EU GMP certificate No NL/H19/2012262 5. List of GMP certificates 6. List of Regulatory Authorities inspections in the last 5 years 7. Declaration: warning letter 8. Declaration: out-of-stock situation 9. Declaration: self-inspection 10. List of recalls in last 3 years 11. List of all products manufactured on site 12. Forecast modification at the site 13. GMP certificate granted by national Authority 14. Inspection report Medicines Control Authority of Zimbabwe (not reviewed) 15. Inspection report National Drug Authority, Uganda (not reviewed) 16. PQRs: a) Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg July 1, 2019 – July 15, 2020 b) Artemether/Lumefantrine Tablet 20mg/120mg March 1, 2019 – March 14,	

	2020 c) Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/200mg/300mg September 1, 2019 – September 9, 2020 d) Artesunate Capsule, Soft, Rectal 100mg September 1, 2019 – September 2, 2020 e) Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg December 1, 2019 – December 19, 2020 f) Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg June 1, 2018 – June 30, 2019 g) Artemether/Lumefantrine Tablet 20mg/120mg March 1, 2018 – February 28, 2019 h) Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/200mg/300mg September 1, 2018 – August 31, 2019 i) Artesunate Capsule, Soft, Rectal 100mg September 1, 2018 – August 31, 2019 17. Master batch manufacturing records: a) Dolutegravir (Sodium)/ Lamivudine/ Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/ 300mg/ 300mg - Tenofovir disoproxil fumarate and Lamivudine Layer b) Dolutegravir (Sodium)/ Lamivudine/ Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/ 300mg/ 300mg - Dolutegravir (Sodium) Layer c) Dolutegravir (Sodium)/ Lamivudine/ Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/ 300mg/ 300mg d) Efavirenz/ Emtricitabine/ Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/ 200mg/ 300mg e) Artemether/Lumefantrine Tablet 20mg/ 120mg f) Artemether/Lumefantrine Tablet, Dispersible 20mg/ 120mg 18. Artesunate Capsule, Soft, Rectal 100mg 19. Executed BMRs/BPRs/analytical raw data: a) Dolutegravir (Sodium)/ Lamivudine/ Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/ 300mg/ 300mg - Tenofovir disoproxil fumarate and Lamivudine Layer b) Dolutegravir (Sodium)/ Lamivudine/ Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/ 300mg/ 300mg- Dolutegravir (Sodium) Layer c) Dolutegravir (Sodium)/ Lamivudine/ Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/ 300mg/ 300mg d) Efavirenz/ Emtricitabine/ Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/ 200mg/ 300mg e) Artemether/Lumefantrine Tablet 20mg/ 120mg f) Artemether/Lumefantrine Tablet, Dispersible 20mg/ 120mg g) Artesunate Capsule, Soft, Rectal 100mg	
Any documents missing?	N/A	
Part 2	**Summary of SRA/NRA inspection evidence considered and comments**	
USFDA	Dates of inspection:	2 – 5 March 2020
	Type of inspection:	Pre-Approval inspection
	Block/Unit:	Ointment Liquid Topical (OLT) block

	Type of products/Dosage forms covered:	Focused on Ibuprofen Oral Suspension USP, 100 mg/5 mL
US FDA, USA	Dates of inspection:	13 – 17 January 2020
	Type of inspection:	Post-approval inspection focused on Potassium Chloride Extended-Release Tablets USP, 8 mEq (600 mg) and 10 mEq (750 mg).
	Block/Unit:	Tablet and hard gelatin capsule block
	Type of products/Dosage forms covered:	Extended-Release Tablets
Health and Youth Care Inspectorate - Pharmaceutical Affairs, The Netherlands	Dates of inspection:	11-14 June 2019
	Type of inspection:	GMP inspection
	Block/Unit:	Production blocks for soft gelatin capsules, OLT dosage forms, tablet & hard gelatin capsules including the LVMS and SVMS
	Type of products/Dosage forms covered:	Powder for Oral Solution Soft gelatin capsules Hard gelatin capsules Tablets Oral solution
US FDA, USA	Dates of inspection:	16 – 24 May 2019
	Type of inspection:	Routine, comprehensive GMP surveillance and item-specific post approval inspection
	Block/Unit:	Production blocks for soft gelatin capsules, Oral Liquid and Topical, tablet & hard gelatin capsules, including the LVMS and SVMS, Warehouse and QC/QA.
	Type of products/Dosage forms covered:	• Non sterile powders • Prompt release capsules • Soft gelatin capsules • Non sterile liquids • Prompt release tablets • Non sterile ointments and creams
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	Last WHO on-site inspection was carried out from 13-17 June 2016. The site was found to be compliant with the standards of GMP published by WHO. Last WHO desk assessment was performed in August 2019. <u>Conclusion:</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 Strides Pharma Science Limited (formulations 1), located at 36/7, KRS Gardens, Suragajakkanahalli, Indlawadi Cross, Anekal Taluk, Bangalore South-562106, India, is considered to be operations at an acceptable level of compliance with WHO GMP guidelines. This compliance status shall be valid until 14 June 2021 or when another	

	inspection is conducted by WHO or by a stringent regulatory authority. It remains the prerogative of WHO to carry out an inspection any time prior to that.
Summary of manufacturing activities according to the SMF	Manufacture, testing, packaging distribution and sale of Soft gelatine capsules, Tablets, Hard gelatine capsules, Sachets, powders, Semi-solid and Oral solutions dosage forms.
General information about the company and manufacturing site to the SMF	Strides Pharma Science Limited is a global pharmaceutical company with headquarters in Bangalore India. The company is involved in the development, and manufacture of nutritional and pharmaceutical products. The company has eight manufacturing units spread across four continents. The KRSG plant is spread over a total land area of about 23 acres (1.0 million sq. ft. approx.) and commenced production of soft gelatin capsules in 1998, tablets and hard gelatin capsules in 1999. A dedicated block for packaging operation which consist of 13 packaging lines and is made operational in 2006. New dedicated block is commissioned in 2015 to manufacture Oral Liquid & Topical dosage (OLT) form. Large volume manufacturing suite (LVMS) & Small volume manufacturing suites (SVMS) are commissioned in 2016 to manufacture of Tablets/Capsules for commercial and exhibit batch manufacturing respectively. The site has following blocks: • Warehouse block (Raw Materials) • Soft Gelatin Block • Tablet & Hard Gelatin Capsules Block (Including LVMS/SVMS) • Oral Liquid & Topical block • Packaging and Warehouse Block (Including Packing material and Finished goods warehouse) • Quality Assurance and Quality Control Block • New Warehouse (ASRS) All the manufacturing blocks are independent with separate personnel entry and connected to each other for material movement.
Focus of the last desk assessment	**Product** Lamivudine 300mg tablets Lamivudine/zidovudine+Nevirapine-150mg/300mg+200mg tablets Nevirapine 200mg tablets. Lamivudine/Zidovudine 150mg/300mg film coated tablets Efavirenz 200mg film-coated tablets Efavirenz 600mg coated tablets Abacavir sulphate 300mg film-coated tablets Lamivudine/Nevirapine/Zidovudine 150mg/200mg/300mg film coated tablets Tenofovir disoproxil fumarate 300mg film coated tablets Emtricitabine/tenofovir disoproxil fumarate 200mg/300mg film coated tablets Efavirenz/Emtricitabine/tenofovir disoproxil fumarate 600mg/200mg/300mg film coated tablets.

	Lamivudine/Nevirapine/Zidovudine 30mg/50mg/60mg dispersible tablets
	Dolutegravir sodium/lamivudine/tenofovir disoproxil fumarate 50mg/300mg/300mg film-coated tablets.
	Sofosbuvir 400mg film coated tablets
	Ledipasvir/sofosbuvir 90mg/400mg film coated tablets
	Oseltamivir phosphate 75mg hard gelatin capsules
	Artemether/Lumefantrine 20mg/120mg tablets
	Artemether/Lumefantrine 20mg/120mg dispersible tablets
	Artesunate 100mg rectal soft capsule.
	Artemether/Lumefantrine 80mg/480mg tablets.
Additional products to be covered by this desk assessment:	N/A

Abbreviations	**Meaning**
AHU	Air handling unit
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:

Regulatory authority	Dates of inspection	Scope of inspection
TGA, Australia	February 2016	Desktop Approval
Tanzania Food and Drugs Authority (TFDA), Tanzania	05.05.2016	GMP
Democratic Republic of Congo, Congo	24.08.2016 to 25.08.2016	GMP
MOH - Republic of Kazakhstan	13.09.2016 to 14.09.2016	GMP
Ministry of Industry and Trade of the Russian Federation	17.01.2017 to 20.01.2017	GMP
U.S. Food and Drug Administration (FDA), USA	22.05.2017 to 26.05.2017	GMP
TGA, Australia	June 2018	NA
MOH, Yemen	05.03.2019	GMP Compliance
Pharmacy and Poisons Board, Kenya	25.03.2019 to	GMP compliance

Regulatory authority	Dates of inspection	Scope of inspection
	27.03.2019	
National Drug Authority, Uganda	06.05.2019 to 07.05.2019	GMP Compliance
U.S. Food and Drug Administration (FDA), USA	16.05.2019 to 24.05.2019	GMP Compliance
Health and Youth Care Inspectorate (IGJ), The Netherlands	11.06.2019 to 14.06.2019	GMP Compliance
Medicines Control Authority of Zimbabwe	03.10.2019 to 04.10.2019	GMP Compliance
Drugs Control Department, Karnataka, India	06.04.2021	GMP Compliance
Ethiopian Food, Medicine and Health Care Administration and Control	05.05.2021 to 07.05.2021	GMP Compliance

b) Manufacturing authorization granted by national authorities:
Manufacturing licenses: Form 25 & 28 KTK/25/415/98 & KTK/28/301/98, issued by Government of Karnataka, Drugs Control Department, valid till 31.12.2021

GMP certificate: DCD/SPL-1/CR-1347/2020-21, issued by Government of Karnataka, Drugs Control Department, valid till 31.12.2021

c) Site master file:
SMF submitted and reviewed. SMF written according to the WHO TRS No. 961, Annex 14

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

Total No of all FPPs manufactured at site	402
Antimalarial	14
Anti-fungal	21
Anti-retroviral	41
Anti-hypertensive	13
Anti-inflammatory	30
Antihistamine	07
Anti-convulsant	03
Antibiotic	06
Antibacterial	12
Nutraceuticals	10
Supplement	81
Anti-Parkinson's	04
Source of vitamins A and D	06
Anti-anginal	04
Anti-Epileptic	03
Anti-Anxiety	02
Antacid	04
Anesthetic	03

Total No of all FPPs manufactured at site	402
Anti-arrhythmic	01
Anti-depressant	11
Antidiabetic	01
Antidiarrheal	01
Anti-emetic	03
Anti-helminthic	02
Antipsychotic	01
Anti-retroviral	01
Antitussive	01
Antiviral	07
Astringent	01
Calcium channel blocker	06

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

Submitted and reviewed:

a) Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg July 1, 2019 – July 15, 2020
b) Artemether/Lumefantrine Tablet 20mg/120mg March 1, 2019 – March 14, 2020
c) Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/200mg/300mg September 1, 2019 – September 9, 2020
d) Artesunate Capsule, Soft, Rectal 100mg September 1, 2019 – September 2, 2020
e) Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg December 1, 2019 – December 19, 2020
f) Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg June 1, 2018 – June 30 2019
g) Artemether/Lumefantrine Tablet 20mg/120mg March 1, 2018 – February 28, 2019
h) Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/200mg/300mg September 1, 2018 – August 31, 2019
i) Artesunate Capsule, Soft, Rectal 100mg September 1, 2018 – August 31, 2019

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

Submitted and reviewed:

- Dolutegravir (Sodium)/ Lamivudine/ Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/ 300mg/ 300mg- Tenofovir disoproxil fumarate and Lamivudine Layer
- Dolutegravir (Sodium)/ Lamivudine/ Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/ 300mg/ 300mg- Dolutegravir (Sodium) Layer
- Dolutegravir (Sodium)/ Lamivudine/ Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/ 300mg/ 300mg
- Efavirenz/ Emtricitabine/ Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/ 200mg/ 300mg
- Artemether/Lumefantrine Tablet 20mg/ 120mg
- Artemether/Lumefantrine Tablet, Dispersible 20mg/ 120mg
- Artesunate Capsule, Soft, Rectal 100mg

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

Submitted and checked:

- Dolutegravir (Sodium)/ Lamivudine/ Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/ 300mg/ 300mg- Tenofovir disoproxil fumarate and Lamivudine Layer

- Dolutegravir (Sodium)/ Lamivudine/ Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/ 300mg/ 300mg- Dolutegravir (Sodium) Layer
- Dolutegravir (Sodium)/ Lamivudine/ Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/ 300mg/ 300mg
- Efavirenz/ Emtricitabine/ Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/ 200mg/ 300mg Artemether/Lumefantrine Tablet 20mg/ 120mg
- Artemether/Lumefantrine Tablet, Dispersible 20mg/ 120mg
- Artesunate Capsule, Soft, Rectal 100mg

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

2018:
None
2019:
Camvit Plus Capsules
2020:

1. Potassium Chloride ER Tablets 10mEq
2. Ranitidine tablets
3. Potassium chloride ER tablets USP 8 mEq
4. Tacrolimus Capsules USP 1mg

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 ***Strides Pharma Science Limited (KRS Gardens - Bangalore), Formulations 1***, located at ***KRS Gardens', S No. 36/7, Suragajakkanahalli Indlawadi Cross, Anekal Taluk, Bangalore South - 562 106. 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. 1. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eight 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 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

4. 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

5. 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

6. 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/

7. 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/

8. 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

9. 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

10. 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

11. 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

12. 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

13. 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/

14. 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/

15. 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

16. 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

17. 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

18. WHO general guidance on variations to multisource pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties 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

19. 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/

20. 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

21. 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

22. Production of water for injection by means other than distillation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Forth 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

23. Good chromatography practice. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Forth 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

24. 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-Forth 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

25. Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 2. Short name: WHO TRS 1033, Annex 2
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations¨

26. WHO good manufacturing practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 3. Short name: WHO TRS 1033, Annex 3 https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

27. Guideline on data integrity. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 4. Short name: WHO TRS 1033, Annex 4 https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations