World Health Organization

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Prequalification Unit Inspection services
WHO INSPECTION REPORT

Desk Assessment of Finished Product Manufacturer

Part 1	General information
Company information	
Name of Manufacturer	Hetero Labs Ltd, Unit 5
Corporate address of manufacturer	Hetero Labs Ltd. Hetero Corporate, 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad – 500 018, Telangana, India
Inspected site	
Name & address of manufacturing site	Hetero Labs Ltd, Unit 5 Survey No 439, 440, 441 & 458 TSIIC Formulation SEZ, Polepally Village, Jadcherla (M), Mahaboob Nagar District, Telangana, 509 301, India DUNS number: 65-045-2530
Production Block/Unit	Blocks: V, VA and VB
Manufacturing license number	No 50/MN/AP/2009/F/R, Form 25, valid up to 18/12/2024
Desk assessment details	
Start and end dates of review	17 - 27 August 2020 and 01 – 05 September 2020
Products covered by this desk assessment	1. Lamivudine/Nevirapine/Zidovudine Tablet, Film-coated 150mg/200mg/300mg 2. Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/200mg/300mg 3. Valganciclovir (hydrochloride) Tablet, Film-coated 450mg 4. Abacavir (sulfate)/Lamivudine Tablet, Film-coated 600mg/300mg 5. Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 400mg/300mg/300mg 6. Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg 7. Lamivudine/Tenofovir disoproxil fumarate Tablet 300mg/300mg 8. Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/300mg/300mg 9. Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg 10. Dolutegravir (Sodium) Tablet, Film-coated 50mg 11. Sofosbuvir Tablet, Film-coated 400mg 12. Entecavir Tablet, Film-coated 0.5mg 13. Entecavir Tablet, Film-coated 1mg 14. Daclatasvir (dihydrochloride) Tablet, Film-coated 30mg 15. Declatasvir (dihydrochloride) Tablet, Film-coated 60mg 16. Artemether/Lumefantrine 20mg/120mg 17. Linezolid Tablet, Film-coated 600mg 18. Moxifloxacin (hydrochloride) 400 mg

	19. Abacavir (sulfate)/Lamivudine Tablet 60mg/30mg
List of documents submitted	1) Infarmed inspection (21 – 24 January 2020) preliminary report 2) Hetero initial response, dated 21st February 2020 3) Hetero response to the preliminary report, dated 5th May 2020 4) Infarmed inspection (21 – 24 January 2020) final report 5) Documents submitted after final report 6) EurdaGMP certificate No FISMF006/001/2020, dated 12th May 2020 7) Infarmed inspection (21 – 25 January 2019) report 8) Hetero initial response to inspector Mr. Antonio Azevedo 9) Hetero initial response to inspector Dr Judit Geher 10) Hetero initial response to inspector Mr. Pedro Marques 11) Hetero initial response to inspector to Infarmed inspection report 12) EurdaGMP certificate No FI006/001/2019, dated 1st April 2019 13) USFDA establishment inspection report, dates of inspection 18 – 19 April 2019, 22 – 26 April 2019 14) USFDA establishment inspection report letter, dated 16 January 2020 15) USFDA Form 483 16) CAPAs to USFDA establishment inspection report 17) Minutes of meeting on the Teleconference between FDA and Hetero, date of meeting 18th September 2019 18) Health Canada (HC), dates of inspection 19) HC inspection exit notice (deficiencies) and cover letter 20) CAPAs to HC inspection report 21) HC clarification letter 22) Hetero response to HC clarification letter 23) HC inspection closure letter 24) List of SRA inspection in last 5 years 25) Declaration – self inspection 26) Declaration – out of stock situation 27) Declaration – no schedules upcoming inspections 28) GMP certificate L.Dis.No.33261/TS/2020. Dated 6-3-2020 29) SOP CQA010-02 “Product Quality Review” 30) SOP CQA029-01 “Data trending” 31) License retention certificate, license No 50/MN/AP/2009/F/R, Form 25, valid up to 18/12/2024 32) FDA warning letter, dated 15 August 2017, related to the inspection 7 – 16 December 2016 33) SMF-FV-01-24 34) List of products manufactured at Blocks V, VA and VC 35) BMR/BPR/master batch records/analytical raw data and PQRs: a) Sofosbuvir Tablet 400mg b) Dolutegravir Tablet 30mg c) Linezolid Tablet 600mg d) Efavirenz / Emtricitabine / Tenofovir Disoproxil Fumarate Tablet 600mg/200mg/300mg: BMR blend e) Efavirenz / Lamivudine / Tenofovir Disoproxil Fumarate Tablet 600mg/300mg/300mg f) Dolutegravir, Lamivudine, Tenofovir Tablet 50mg/300mg/300mg

	g) Lamivudine, Tenofovir Tablet 300mg/300mg h) Daclatasvir Tablet 60mg i) Moxifloxacin Tablet 400mg j) Lamivudine, Zidovudine Tablet 150mg/300mg k) Valganciclovir Tablet 450mg l) Abacavir sulfate, Lamivudine tablet 60 mg /300mg m) Entecavir Tablet 500 mg n) Entecavir Tablet 100 mg o) Abacavir, Lamivudine tablet 60mg, 30mg p) Artemether, Lumefantrine 20mg, 120mg q) Dolutegravir Tablet 50mg r) Efavirenz, Lamivudine, Tenofovir Tablet 400mg, 300mg, 300mg s) Lamivudine, Zidovudine, Nevirapine Tablets 150mg, 300mg, 200mg	
Any documents missing?	N/A	
Part 2	Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments	
INFARMED (National Authority of Medicines and Health Products, Portugal), Portugal	Dates of inspection:	21 – 24 January 2020
	Type of inspection:	Follow-up and GMP certificate renewal inspection
	Block/Unit:	Block V and Block V-A of Unit V Block V-B
	Type of products/Dosage forms covered:	Entecavir Accord, 0.5 mg and 1 mg, film-coated tablets WHO products under PQ were not specifically covered
USFDA, USA	Dates of inspection:	18 – 19 April 2019, 22 – 26 April 2019
	Type of inspection:	GMP surveillance inspection
	Block/Unit:	Block V, V-A and V-B
	Type of products/Dosage forms covered:	• Pantoprazole Sodium Delayed Release Tablets USP 20mg • Pantoprazole Sodium Delayed Release Tablets USP 40 mg • Rosuvastatin Calcium Tablets 5 mg • Rosuvastatin Calcium Tablets l 0 mg • Rosuvastatin Calcium Tablets 20 mg • Rosuvastatin Calcium Tablets 40 mg • Levofloxacin Tablets USP 250 mg • Levofloxacin Tablets USP 500 mg • Levofloxacin Tablets USP 750 mg • Aripiprazole Tablets 5 mg • Aripiprazole Tablets 10 mg • Valsartan Tablets 40 mg • Valsartan Tablets 80 mg • Valsartan Tablets 160 mg

		• Valsartan Tablets 320 mg • Valacyclovir Tablets 100 mg • Valacyclovir Tablets 500 mg • Telmisartan Tablets USP 20 mg • Telmisartan Tablets USP 40 mg • Telmisartan Tablets USP 60 mg WHO FPPs were not specifically covered
INFARMED (National Authority of Medicines and Health Products, Portugal), Portugal	Dates of inspection:	21 – 25 January 2019
	Type of inspection:	GMP inspection
	Block/Unit:	Block V and Block V-A of Unit V Block V-B
	Type of products/Dosage forms covered:	Entecavir 0.5 mg and 1 mg, film-coated tablets
Health Canada, Canada	Dates of inspection:	3rd to 6th December 2018
	Type of inspection:	Re-inspection
	Block/Unit/Workshop:	Blocks V, VA and VB
	FPPs covered:	1. Sildenafil Citrate Tablets 25 mg, 50 mg & 100 mg 2. Clopidogrel tablets 75 mg & 300 mg 3. Pioglitazone Tablets 15 mg, 30 mg & 45 mg 4. Montelukast sodium 10 mg tablets 5. Montelukast sodium Chewable Tablets 4 mg & 5 mg 6. Olanzapine tablets 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg & 20 mg 7. Donepezil Tablets 5 mg & 10 mg 8. Escitalopram tablets 10 mg, 15 mg & 20 mg 9. Tolterodine IR tablets 1 mg & 2 mg 10. Irbesartan Tablets 75 mg, 150 mg & 300 mg 11. Quetiapine Fumarate IR tablets 25 mg, 100 mg, 150 mg, 200 mg & 300 mg 12. Aripiprazole Tablets 2 mg, 5 mg, 10 mg, 15 mg, 20 mg & 30 mg WHO products under PQ were not specifically covered
Part 3	Summary of the last WHO inspection	
Date of inspection and conclusion of most recent WHO inspection	The last WHO inspection was conducted from 30 October to 3 November 2017 with the resolution stating, based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the deficiencies listed in the Inspection Report, a decision on the compliance of Hetero Laboratories Limited (Unit-V) located at, Sy. No. Part of 439, 440, 441 & 458, APIIC, Pharma SEZ, Polepally (village), Jadcherla (Mandal), Mahaboob Nagar (Dist.), 509 301, India with WHO GMP guidelines will be made after the manufacturer's response to the deficiencies has been assessed. CAPAs were submitted and assessed by the PQT: Inspection Team and the inspection, following the review of the CAPA, was closed on 24 November 2019 as compliant.	

Summary of manufacturing activities as of November 2017	Hetero Labs Unit V has three blocks manufacturing blocks (Block-V, Block-VA, and Block-VB) on the site with different multi-product formulation and packaging modules. Block V and Block VA were in the inspection scope. Cytotoxic products were manufactured in Block VB which was out of the scope of this inspection.
General information about the company and manufacturing site as of November 2017	Hetero Labs Unit V has three blocks manufacturing blocks (Block-V, Block-VA, and Block-VB) on the site with different multi-product formulation and packaging modules. Block V and Block VA were in the inspection scope. Cytotoxic products were manufactured in Block VB which was out of the scope of this inspection.
Focus of the last WHO inspection	• Efavirenz Tablets 600mg • Efavirenz/Emtricitabine/Tenofovir Tablets 600/200/300 mg • Lamivudine/Nevirapine/Zidovudine Tablets 150/200/300 mg Lamivudine/Tenofovir Tablets 300mg/300mg • Lamivudine/Zidovudine Tablets 150mg/300mg • Linezolid Tables 600mg • Moxifloxacin Tablets 400mg • Abacavir (as Sulfate) + Lamivudine 600mg/300mg • Sofosbuvir Tablets 400mg • Entecavir Tablets 0.5mg • Entecavir Tablets 1.0mg • Acyclovir Tablets 400mg • Valganciclovir (hydrochloride) Tablet, Film-coated 450mg • Efavirenz / Lamivudine / Tenofovir Disoproxil Fumarate Tablets 600mg/300mg/300mg
Areas inspected	Document reviewed including but not limited • Organization Chart • Job descriptions for key personnel • Product Quality Review • Quality Risk Management • Management Review • Responsibilities of the quality units and production • Complaints and Recalls • Deviation control and change control • OOS and investigation • CAPA procedure • Validation and qualification • Data integrity • Sampling and testing of materials • Batch processing records • Materials management system Site visited: • Oral Solid Dosage (OSD) Production operations

	• Stability study QC laboratory and control system • Starting material and finished Goods warehouse
Out of scope and restrictions (last WHO inspection)	Products not submitted to WHO for Prequalification
Abbreviations	Meaning
API	Active pharmaceutical ingredient
BMR	Batch manufacturing record
BPR	Batch production record
CAPA	Corrective and preventive action
FPP	Finished pharmaceutical product
GMP	Good manufacturing practices
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 agency	Dates of Inspection	Outcome
01	INFARMED –Portugal	21st to 24th January 2020	Complies
02	FMHACA – Ethiopia (Food Medicine and Healthcare Administration and control Authority of Ethiopia)	30th September to 2nd October 2019	Complies
03	SFDA - Saudi (Saudi Food and Drug Administration)	15th to 17th July 2019	Complies
04	USFDA (United States Food and Drug Administration)	18th to 26th April 2019	Official Action Indicated (OAI) letter received
05	NDA – Uganda (National Drug Authority)	18th to 19th March 2019	Complies
06	INFARMED –Portugal	21st to 25th January 2019	Complies
07	Health Canada, Canada	3rd to 6th December 2018	Complies
08	TFDA – Tanzania (Tanzania Food and Drugs Authority)	8th to 9th October 2018	Complies
09	MOH – Belarus (Ministry of Health)	30th to 31st July 2018	Complies
10	MOH-Russia (Ministry of Health)	12th to 14th July 2018	Complies
11	ZaZiBoNa (Zambia, Zimbabwe, Botswana, Namibia)	20th to 24th April 2018	Complies
12	MOH – Oman (Ministry of Health)	16th to 17th April 2018	Complies

Sr. No	Regulatory agency	Dates of Inspection	Outcome
13	INVIMA – Colombia (Colombia Health Authority)	4th to 8th December 2017	Complies
14	MOH – Yemen (Ministry of Health)	2nd December 2017	Complies
15	ANVISA – Brazil (National Health Surveillance Agency)	6th to 10th November 2017	Complies
17	NAFDAC (National agency for food and drug administration and control)	26th to 27th April 2017	Complies
18	MCC – South Africa (Medicines Control Council)	18th to 21st March 2017	Complies
19	USFDA, USA (United States Food and Drug Administration)	7th to 16th December 2016	Warning Letter (WL) received
20	MOH-Russia (Ministry of Health)	31st May to 2nd June 2016	Complies
21	LAGeSo – Berlin, Germany (Berlin Health Authority)	29th February 2016 to 1st March 2016	Complies
22	INFARMED –Portugal (The National Institute of Pharmacy and Medicines) (European Union)	1st to 4th February 2016	Complies
23	NMPB – Sudan (National Medicines and Poisons Board)	30th November to 3rd December 2015	Complies
24	PPB – Kenya (Pharmacy and Poisons Board)	31st August to 1st September 2015	Complies
25	COFEPRIS – Mexico	3rd to 14th August 2015	Complies

b) Manufacturing authorization granted by national authorities:
License No 50/MN/AP/2009/F/R, Form 25, valid up to 18/12/2024
GMP certificate L.Dis.No.33261/TS/2020. Dated 6-3-2020

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:

Totally 151 APIs are manufactured at Unit V, therapeutic groups: List provided in mail

1) Anti-Viral
2) Anti-Allergic
3) Anti -depressants
4) Anti – diabetic
5) Anti- Malarial
6) Anti – Diarrhoea
7) Anti- Alzheimer's

8) Anti-Arrhythmic
9) Anti-Asthmatic
10) Anti-Bacterial
11) Anti-Coagulant
12) Anti-Dementia
13) Anti-Epileptic
14) Anti-Fungal
15) Anti-Hyperlipidemic
16) Anti-Hypertensive
17) Anti-Muscuranic
18) Anti-inflammatory
19) Anti-Platelet
20) Anti-Psychotic
21) Anti-TB
22) Benign Prostate Hyperplasia
23) Calcimimetic
24) Chronic Hepatitis C
25) Dsypareunia
26) Erectile Dysfunction
27) Fibromyalgia
28) Gluco Cartico Steroid Gout flares & Familial Mediterranean Fever
29) Huntington's chorea
30) Immunomodulatory
31) Inhibit Gastric acid Secretion
32) Irritable Bowel Syndrome with Diarrhea
33) Non-benzodiazepine hypnotic
34) Non-nucleoside reverse transcriptase Inhibitor
35) Phosphodiesterase type 5 inhibitor & Selective Serotonin Reuptake inhibitor
36) Proton Pump Inhibitor
37) Platelet Inhibitor
38) Selective vasopressin V2-receptor antagonist
39) Stimulant Laxative
40) Thrombopoietin receptor agonist
41) Treatment for male pattern hair loss Androgenetic Alopecia
42) Treatment of Epilepsy & peripheral neuropathic pain
43) Xanthine oxidase inhibitor
44) Pulmonary Fibrosis
45) Trematodicide

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

Submitted:

1) Abacavir sulfate & Lamivudine 60mg/30mg
2) Artemether & Lumefantrine tablets 20mg/120mg

Submitted and checked:

1) Daclatasvir tablets 30mg
2) Daclatasvir tablets 60mg
3) Dolutegravir tablets 50mg
4) Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg

5) Entecavir 1 mg tablets
6) Linezolid 600 mg tablets
7) Tenofovir Disoproxil Fumarate and Lamivudine tablets 300 mg/ 300 mg
8) Lamivudine, Nevirapine, Zidovudine tablet 150mg/200mg/300mg
9) Efavirenz, Lamivudine, Tenofovir tablet 600mg/ 300mg/300mg
10) Efavirenz, Lamivudine and Tenofovir disoproxil fumarate tablets 400mg/300mg/300mg

Submitted and reviewed:
1) Entecavir 0.5 mg tablets
2) Moxifloxacin Hydrochloride
3) Sofosbuvir tablets 400mg
4) Lamivudine and Zidovudine tablets 150 mg/300 mg
5) Valganciclovir Tablet 450 mg
6) Efavirenz / Emtricitabine / Tenofovir Tablet 600mg / 200mg / 300mg
7) Abacavir / Lamivudine Tablet 600mg / 300mg

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

Submitted and checked:
1) Sofosbuvir Tablet 400mg
2) Dolutegravir Tablet 30mg
3) Linezolid Tablet 600mg
4) Efavirenz / Emtricitabine / Tenofovir Disoproxil Fumarate Tablet 600mg/200mg/300mg
5) Efavirenz / Lamivudine / Tenofovir Disoproxil Fumarate Tablet 600mg/300mg/300mg
6) Dolutegravir, Lamivudine, Tenofovir Tablet 50mg/300mg/300mg
7) Lamivudine, Tenofovir Tablet 300mg/300mg
8) Daclatasvir Tablet 60mg
9) Moxifloxacin Tablet 400mg
10) Lamivudine, Zidovudine Tablet 150mg/300mg
11) Valganciclovir Tablet 450mg
12) Entecavir Tablet 500 mg

Submitted and reviewed:
1) Abacavir sulfate, Lamivudine tablet 600 mg /300 mg
2) Entecavir Tablet 1 g
3) Artemether, Lumefantrine 20mg, 120mg
4) Efavirenz, Lamivudine, Tenofovir Tablet 400mg, 300mg, 300mg
5) Lamivudine, Zidovudine, Nevirapine Tablets 150mg, 300mg, 200mg
6) Daclatasvir (dihydrochloride) Tablet, Film-coated 30mg
7) Abacavir (sulfate)/Lamivudine Tablet 60mg/30mg

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

Submitted and checked:
1. Valganciclovir Tablet
1) Lamivudine, Zidovudine Tablet
2) Lamivudine, Tenofovir Tablet
3) Efavirenz, Lamivudine, Tenofovir Tablet
4) Dolutegravir, Lamivudine, Tenofovir Tablet

5) Daclatasvir Tablet 30mg
6) Daclatasvir Tablet 60mg
7) Linezolid Tablets 600mg
8) Moxifloxacin Tablet 400mg
9) Dolutegravir Tablet 50mg
10) Efavirenz, Emtricitabine, Tenofovir Tablet
11) Abacavir, Lamivudine Tablet
12) Sofosbuvir Tablet 400mg
13) Entecavir Tablet 0.5 mg
14) Entecavir Tablet 1mg
15) Abacavir, Lamivudine tablet 60mg, 30mg
16) Artemether, Lumefantrine 20mg, 120mg
17) Dolutegravir Tablet 50mg
18) Efavirenz, Lamivudine, Tenofovir Tablet 400mg, 300mg, 300mg
19) Lamivudine, Zidovudine, Nevirapine Tablets 150mg, 300mg, 200mg

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:
32 batches of different products have been recalled in last 3 years

j) Confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the product) has been performed and all matters dealt with:
Declaration submitted - a full self-inspection or external audit dedicated to the product) 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:**
FDA warning letter, dated 15 August 2017, related to the inspection 7 – 16 December 2016

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

l) Additional documents submitted:
SOP "Product Quality Review"
SOP CQA029-01 "Data trending"

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 ***Hetero Labs Ltd, Unit 5 (manufacturing blocks V, VA and VC)*** located at ***Survey No 439, 440, 441 & 458 TSIIC Formulation SEZ, Polepally Village, Jadcherla (M), Mahaboob Nagar District, Telangana, 509 301, 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 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
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