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	Sun Pharmaceutical Industries Limited
Corporate address of manufacturer	Sun Pharmaceutical Industries Limited Sun House, CTS No.201 B/1, Western Express Highway, Goregaon E, Mumbai 400063, India +912243244324
Inspected site	
Name & address of manufacturing site	Sun Pharmaceutical Industries Limited Village Ganguwala, Paonta Sahib, District Sirmour, Himachal Pradesh, 173 025 India +911704227779 GPS coordinates: 30.438°N 77.624°E DUNS: 650456754
Production Block/Unit	A, B, C, D, E, F, G and H
Desk assessment details	
Start and end dates of review	19 – 27 November 2020
Products covered by this desk assessment	

	PQ number	Product name
1	HA286	Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg
2	HA699	Dolutegravir (Sodium)/Lamivudine/Tenofovir Disoproxil fumarate 50mg/300mg/300mg Film-coated Tablet
3	HA698	Abacavir (sulfate)/Lamivudine 600mg/300mg Film-coated Tablet
4	HA306	Efavirenz Tablet, Film-coated 600mg
5	HA323	Lamivudine/Nevirapine/Zidovudine Tablet, Film-coated 150mg/200mg/300mg
6	HA525	Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 300mg/300mg
7	HA551	Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 200mg/300mg
8	HA708	Dolutegravir (Sodium) Tablet, Film-coated 50mg requalified
9	HA742	Atazanavir (sulfate)/Ritonavir Tablet, Film-coated 300mg/100mg

List of documents submitted	1. Manufacturing authorization issued by Health & Family Welfare Department H.P. Drugs Control Administration HP Office of the Zonal Licensing Authority No MNB/95/2 & MB/95/2 valid till 31 December 2022

	2. GMP certificate No NL/H17/2001788A, issued by Dutch Health Care and Youth Care Inspectorate on 19 August 2019 3. TGA post inspection letter 4. TGA inspection report 5. TGA CAPAs acceptance document 6. Master manufacturing instructions: a. Atazanavir blend of Atazanavir and Ritonavir tablets 300mg/100mg, product code XX b. Atazanavir blend of Atazanavir and Ritonavir tablets 300mg/100mg, product code YY c. Ritonavir blend of Atazanavir and Ritonavir tablets 300mg/100mg, product code XX d. Ritonavir blend of Atazanavir and Ritonavir tablets 300mg/100mg, product code YY e. Atazanavir (sulfate)/Ritonavir Tablet 300mg/100mg, product code XX f. Atazanavir (sulfate)/Ritonavir Tablet 300mg/100mg, product code YY g. Lamivudine/Zidovudine Tablet 150mg/300mg, product codes XX, YY, ZZ, VV h. Dolutegravir (Sodium)/Lamivudine/Tenofovir Disoproxil fumarate blend 50mg/300mg/300mg Film-coated Tablet, product code XX i. Dolutegravir (Sodium)/Lamivudine/Tenofovir Disoproxil fumarate 50mg/300mg/300mg Film-coated Tablet, product code YY j. Abacavir (sulfate)/Lamivudine 600mg/300mg Tablet, product code XX k. Efavirenz 600mg Tablet, product code XX l. Lamivudine/Nevirapine/Zidovudine Tablet 150mg/200mg/300mg product codes XX, YY m. Lamivudine/Tenofovir disoproxil fumarate Tablet 300mg/300mg, product code XX n. Emtricitabine/Tenofovir disoproxil fumarate Tablet 200mg/300mg, product code XX o. Dolutegravir (Sodium) Tablet 50mg, product code XX p. Nevirapine Tablet 200 mg, product code YY 7. Master packaging instructions: a. Atazanavir (sulfate)/Ritonavir Tablet 300mg/100mg, product code XX b. Atazanavir (sulfate)/Ritonavir Tablet 300mg/100mg, product code YY c. Atazanavir (sulfate)/Ritonavir Tablet 300mg/100mg, product code ZZ d. Atazanavir (sulfate)/Ritonavir Tablet 300mg/100mg, product code AA e. Atazanavir (sulfate)/Ritonavir Tablet 300mg/100mg, product code BB f. Lamivudine/Zidovudine Tablet 150mg/300mg, product code XX g. Dolutegravir (Sodium)/Lamivudine/Tenofovir Disoproxil fumarate 50mg/300mg/300mg Film-coated Tablet, product codes XX, YY, ZZ h. Abacavir (sulfate)/Lamivudine 600mg/300mg Tablet, product codes XX, YY, ZZ i. Efavirenz 600mg Tablet, product code XX j. Lamivudine/Tenofovir disoproxil fumarate Tablet, 300mg/300mg, product codes XX, YY, ZZ, AA k. Emtricitabine/Tenofovir disoproxil fumarate Tablet 200mg/300mg, product code XX l. Dolutegravir (Sodium) Tablet 50mg, product codes XX, YY, ZZ, AA

	m. Nevirapine Tablet 200 mg, product codes XX, YY 8. BMR/BPR and analytical raw data: a. Atazanavir blend of Atazanavir and Ritonavir tablets 300mg/100mg, product code XX, batch YY b. Ritonavir blend of Atazanavir and Ritonavir tablets 300mg/100mg, product code XX, batch YY c. Efavirenz 600mg Tablet, product code XX, batch YY d. Lamivudine/Nevirapine/Zidovudine Tablet 150mg/200mg/300mg, product code XX, batch YY e. Dolutegravir (Sodium)/Lamivudine/Tenofovir Disoproxil fumarate 50mg/300mg/300mg Tablet blend, and Tablet product code XX, batch YY f. Atazanavir (sulfate)/Ritonavir Tablet 300mg/100mg, batch XX g. Lamivudine/Zidovudine Tablet 150mg/300mg, product code XX, batch YY (BMR/BPR) – parent batch h. Lamivudine/Zidovudine Tablet 150mg/300mg, product code XX, batch YY (BPR) i. Lamivudine/Zidovudine Tablet 150mg/300mg, batches XX, YY (analytical raw data) j. Dolutegravir (Sodium)/Lamivudine/Tenofovir Disoproxil fumarate 50mg/300mg/300mg Tablet blend, product code XX, batch YY 9. PQRs: a. Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg Jan 2019 – Dec 2019, product code XX b. Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg Jan 2019 – Dec 2019, product code XX c. Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg Jan 2019 – Dec 2019, product code XX d. Efavirenz Tablet, Film-coated 600mg Jan 2019 – Dec 2019, product code XX e. Lamivudine/Nevirapine/Zidovudine Tablet, Film-coated 150mg/200mg/300mg Jan 2019 – Dec 2019, product code XX f. Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg Jan 2018 – Dec 2018, product code XX g. Dolutegravir (Sodium)/Lamivudine/Tenofovir Disoproxil fumarate 50mg/300mg/300mg Film-coated Tablet Jan 2018 – Dec 2018, product codes XX and YY 10. Self-inspection (Quality system Audit) schedule – execution details 11. List of manufacturing blocks covered by TGA inspection 22 – 24 November 2017 12. List of Upcoming inspections in the next 6 months 13. List of recalls from 2017 – 2020 14. List of GMP inspections last 5 years 15. List of products manufactured at the site 16. SMF SPILP/DF/SMF/008, dated 28 Jan 2020 and 8 Appendixes
Any documents missing?	No

Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments**	
TGA Australia	Dates of inspection:	22-24 November 2017
	Type of inspection:	GMP inspection
	Block:	Blocks: A, C, E, F, G and H
	Type of products/Dosage forms covered:	Tablets and hard-shell capsules WHO products under PQ were not specifically covered
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	10 – 12 October 2017 joint inspection WHO and Dutch Health Care and Youth Care Inspectorate. CAPAs were evaluated and accepted by WHO and Dutch Health Care and Youth Care Inspectorate and inspection was closed as GMP compliant on 5 April 2018.	
Summary of manufacturing activities as of October 2017	Sun Pharmaceutical Industries Limited (hereafter named "Sun"), located in Paonta Sahib, Himachal Pradesh, India, is a large multiproduct manufacturing site for pharmaceutical finished dosage forms.	
General information about the company and manufacturing site as of October 2017	Sun manufactures a wide range of generic medicinal products for worldwide markets including the EU market. Dosage forms are tablets, hard capsules and soft capsules. The annual capacity is over 6000 million tablets and capsules.	
Focus of the last WHO inspection	All authorized EU and WHO products were included in the scope.	

Areas inspected	All products for the EU market and WHO programs (refer to the list above) including all activities and areas involved including manufacturing, QC testing and warehousing. Manufacturing plants within scope are A, B, C, D, E, F, G and H.
	• Pharmaceutical Quality System
	  o Management review
	  o PQR
	  o Deviations and CAPA
	  o Validation Master Plan
	  o Quality agreement with EU import sites
	• Personnel
	• Premises and equipment
	  o Qualification of manufacturing areas, equipment and utilities
	  o Preventative maintenance and calibration
	  o Water systems
	  o Process gases
	  o HVAC systems
	  o Environmental monitoring	

	• Documentation
	  o Batch records
	• Production
	  o Process validation
	  o Cleaning validation
	• Quality control
	  o OOS
	  o Outsourced activities
	• Complaints and product recall
	• Self-inspection

Out of scope and restrictions (last WHO inspection)	All areas, activities and products that are not relevant for EU and WHO products
WHO products covered by the last WHO inspection	HA323 – Lamivudine/Nevirapine/Zidovudine Tablet, Film-coated 150mg/200mg/300mg HA306 – Efavirenz Tablet, Film-coated 600mg HA298 – Nevirapine 200mg Tablet HA286 – Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg HA698 – Abacavir (sulfate)/Lamivudine 600mg/300mg Film-coated Tablet HA699 – Dolutegravir (Sodium)/Lamivudine/Tenofovir Disoproxil fumarate 50mg/300mg/300mg Film-coated Tablet
Additional products to be covered by this desk assessment:	N/A

Abbreviations	**Meaning**
BMR	Batch manufacturing record
BPR	Batch production record
CAPA	Corrective and preventive action
CC	Change control
FPP	Finished pharmaceutical product
GMP	Good manufacturing practices
PQR	Product quality review
SMF	Site master file
SOP	Standard operating procedure
SRA	Stringent regulatory authority

Part 4 – Summary of the assessment of supporting documentation

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

Name of Authority	Country	Inspection Date	GMP Certificate Number	Certificate validity
MoH- Belarus	Belarus	10 -11 Feb-2020	Not Available	Not Available
PPB-Kenya	Kenya	25 – 27 Nov 2019	PPB/INS/MAA/RPT /190/19	25, Nov, 2022
DPML (Department of	Republic of Ivory Coast	04 Oct 2019	3240/MSHP/DGS/D PML	07 Nov-2024

Name of Authority	Country	Inspection Date	GMP Certificate Number	Certificate validity
Pharmaceuticals and Medicines)				
MOIT-Russia	Russia	15 – 17 Jul 2019	GMP-01248/19/IN	27 Aug-2022
CDSCO -India	India	29 - 30 Aug2018	HFW-H[Drugs] 67/95	20 Aug-2021
MCAZ- Zimbabwe	Zimbabwe	05- 07 Jul 2018	B/279/4/19/2019	06 Jul-2020
GCC (Gulf Corporation Council)	UAE/ Saudi Arabia/ Kuwait/ Bahrain/ Qatar/ Yemen/ Oman	02 – 6 Feb 2018	GRC/498/11	23 May-2023
Therapeutic Goods Administration (TGA)	Australia	22 - 24 Nov 2017	MI-2016-CE-01416-1	24 May-2021
IGZ +WHO	Netherlands	10 – 12 Oct 2017	NL/H 17/2001788A	12 Oct-2020 Extended Until end of 2021
State service of Ukraine on medicines & drugs control	Ukraine	05 – 8 Jun 2017	027/2018/GMP	08 Jun-2020
TFDA (Tanzania)	Tanzania	24 – 25 May 2017	Not Available	Not Available
ZaZiBoNa	Zambia, Zimbabwe, Botswana, Namibia	07 – 9 Dec 2015	MRA 6/3/1/Vol I (24)	11 Nov-2021

b) Manufacturing authorization granted by national authorities:
Manufacturing authorization issued by Health & Family Welfare Department H.P. Drugs Control Administration HP Office of the Zonal Licensing Authority No MNB/95/2 & MB/95/2 valid till 31 December 2022

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:
Tablet /Capsule (Hard Gelatin /Soft Gelatin Capsules)
Therapeutic Groups:

- Antiretroviral
- Antihypertensive
- Antidepressant
- Anti-ulcerative
- Analgesic +anti-inflammatory
- Anti-rehumatic

- Diuretics
- Anti-inflammatory
- Antiviral
- Antiepileptic
- Antibacterial
- Antihistaminic
- Anti-diabetic
- Anti-psychotic
- Anti-hyperlipoproteinemic
- Calcium Regulator
- Lipid lowering agent
- Anti-hyperlipidemic
- Anti-aids
- Angiotensin II receptor blocker
- Phosphodiesterase (PDE) inhibitors

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

Submitted:

1. Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg Jan 2019 – Dec 2019, product code XX
2. Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg Jan 2019 – Dec 2019, product code XX-YY
3. Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg Jan 2019 – Dec 2019, product code XX

Submitted and reviewed:

1. Efavirenz Tablet, Film-coated 600mg Jan 2019 – Dec 2019, product code XX:
2. Lamivudine/Nevirapine/Zidovudine Tablet, Film-coated 150mg/200mg/300mg Jan 2019 – Dec 2019, product code XX:
3. Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg Jan 2018 – Dec 2018, product code XX:
4. Dolutegravir (Sodium)/Lamivudine/Tenofovir Disoproxil fumarate 50mg/300mg/300mg Film-coated Tablet Jan 2018 – Dec 2018, product codes XX and YY:

Note:

The following products have not been commercially manufactured:

HA551	Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 200mg/300mg
HA525	Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 300mg/300mg
HA698	Abacavir (sulfate)/Lamivudine 600mg/300mg Film-coated Tablet
HA708	Dolutegravir (Sodium) Tablet, Film-coated 50mg requalified
HA742	Atazanavir (sulfate)/Ritonavir Tablet, Film-coated 300mg/100mg

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

Note:

The following products have not been commercially manufactured:

HA551	Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 200mg/300mg
HA525	Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 300mg/300mg
HA698	Abacavir (sulfate)/Lamivudine 600mg/300mg Film-coated Tablet
HA708	Dolutegravir (Sodium) Tablet, Film-coated 50mg requalified
HA742	Atazanavir (sulfate)/Ritonavir Tablet, Film-coated 300mg/100mg

Submitted and reviewed:

a. Atazanavir blend of Atazanavir and Ritonavir tablets 300mg/100mg, product code XX, batch YY
b. Ritonavir blend of Atazanavir and Ritonavir tablets 300mg/100mg, product code XX, batch YY
c. Efavirenz 600mg Tablet, product code XX, batch YY
d. Lamivudine/Nevirapine/Zidovudine Tablet 150mg/200mg/300mg, product code XX, batch YY
e. Dolutegravir (Sodium)/Lamivudine/Tenofovir Disoproxil fumarate 50mg/300mg/300mg Tablet blend, and Tablet product code XX, batch YY
f. Atazanavir (sulfate)/Ritonavir Tablet 300mg/100mg, batch XX
g. Lamivudine/Zidovudine Tablet 150mg/300mg, product code XX, batch YY (BMR/BPR) – parent batch
h. Lamivudine/Zidovudine Tablet 150mg/300mg, product code XX, batch YY (BPR)
i. Lamivudine/Zidovudine Tablet 150mg/300mg, batches XX and YY (analytical raw data)
j. Dolutegravir (Sodium)/Lamivudine/Tenofovir Disoproxil fumarate 50mg/300mg/300mg Tablet blend, product code XX, batch YY

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

Submitted and checked:

Master manufacturing instructions:

a. Atazanavir blend of Atazanavir and Ritonavir tablets 300mg/100mg, product code XX
b. Atazanavir blend of Atazanavir and Ritonavir tablets 300mg/100mg, product code YY
c. Ritonavir blend of Atazanavir and Ritonavir tablets 300mg/100mg, product code XX
d. Ritonavir blend of Atazanavir and Ritonavir tablets 300mg/100mg, product code YY
e. Atazanavir (sulfate)/Ritonavir Tablet 300mg/100mg, product code XX
f. Atazanavir (sulfate)/Ritonavir Tablet 300mg/100mg, product code YY
g. Lamivudine/Zidovudine Tablet 150mg/300mg, product codes XX, YY, VV, AA
h. Dolutegravir (Sodium)/Lamivudine/Tenofovir Disoproxil fumarate blend 50mg/300mg/300mg Film-coated Tablet, product code XX
i. Dolutegravir (Sodium)/Lamivudine/Tenofovir Disoproxil fumarate 50mg/300mg/300mg Film-coated Tablet, product code YY
j. Abacavir (sulfate)/Lamivudine 600mg/300mg Tablet, product code XX
k. Efavirenz 600mg Tablet, product code XX
l. Lamivudine/Nevirapine/Zidovudine Tablet 150mg/200mg/300mg product codes XX, YY
m. Lamivudine/Tenofovir disoproxil fumarate Tablet 300mg/300mg, product code XX
n. Emtricitabine/Tenofovir disoproxil fumarate Tablet 200mg/300mg, product code YY
o. Dolutegravir (Sodium) Tablet 50mg, product code XX

Master packaging instructions:

a. Atazanavir (sulfate)/Ritonavir Tablet 300mg/100mg, product code XX
b. Atazanavir (sulfate)/Ritonavir Tablet 300mg/100mg, product code YY
c. Atazanavir (sulfate)/Ritonavir Tablet 300mg/100mg, product code VV
d. Atazanavir (sulfate)/Ritonavir Tablet 300mg/100mg, product code AA
e. Atazanavir (sulfate)/Ritonavir Tablet 300mg/100mg, product code BB
f. Lamivudine/Zidovudine Tablet 150mg/300mg, product code XX
g. Dolutegravir (Sodium)/Lamivudine/Tenofovir Disoproxil fumarate 50mg/300mg/300mg Film-coated Tablet, product codes XX, YY, VV
h. Abacavir (sulfate)/Lamivudine 600mg/300mg Tablet, product codes XX, YY, VV
i. Efavirenz 600mg Tablet, product code XX
j. Lamivudine/Tenofovir disoproxil fumarate Tablet, 300mg/300mg, product codes XX, YY, VV, AA
k. Emtricitabine/Tenofovir disoproxil fumarate Tablet 200mg/300mg, product code XX
l. Dolutegravir (Sodium) Tablet 50mg, product codes XX, YY, VV, AA

Note:
Master manufacturing and packaging instructions submitted, not checked - HA298 Nevirapine 200mg Tablet withdrawn.

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:

Ref number	Product name	Batch number	Market/class	Date of recall
003/17	Cifran 500 mg Tablet	2739568 & 2747898	Russia Class-II	28/Feb/2017
004/17	Cifran 500 mg Tablet	2756899	Russia Class-II	21/Mar/2017
RL1- 01	Valsartan+HCTZ Tablets80+12.5/160+12.5/160+25 mg	Total 116 batches	Germany, France, Italy & Spain Class-II	23/Jul/2018
294820	Pregabalin 150 Capsule	AA10305	Germany Class- II	08/May/2019
312334	Raciper 20 mg tablet (ESOMEPRAZOLE MG GR TAB 20mg)	3983744	Vietnam Class-II	31/May/2019
377066	ATORVASTATIN ORION TAB 20/80 mg ESOMEPRAZOL ORION TAB 20/40mg	AA32283 AA20389 AA22774 AA22765 AA25469 AA02384 AA12234	Finland Class-II	23/Aug/2019

j) Confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the products has been performed and all matters dealt with:
Self-inspection execution details submitted

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:
Confirmation submitted: no warning letter, or equivalent regulatory action, issued by any authority

l) Out-of-stock situations:
Confirmation submitted: no out-of-stock situations

m) Additional documents submitted:
SOP "Annual Product Review (Product Quality Review)

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 ***Sun Pharmaceutical Industries Limited (blocks A, B, C, D, E, F, G and H)***, located at ***Village Ganguwala, Paonta Sahib, District Sirmour, Himachal Pradesh, 173 025 India*** is considered to be operating at an acceptable level of compliance with WHO GMP guidelines.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 6	List of guidelines referenced in this inspection report

1. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eighth Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. ***Short name: WHO TRS No. 986, Annex 2***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

2. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. ***Short name: WHO TRS No. 957, Annex 2***
http://www.who.int/medicines/publications/44threport/en/

3. WHO good manufacturing practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-sixth Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2.
Short name: WHO TRS No. 970, Annex 2
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/

4. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
   Short name: WHO TRS No. 929, Annex 4
   http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

5. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8. **Short name: WHO TRS No. 1010, Annex 8**
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en/

6. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4.
   Short name: WHO TRS No. 937, Annex 4
   http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

7. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1.
   Short name: WHO TRS No. 957, Annex 1
   http://www.who.int/medicines/publications/44threport/en/

8. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 3.
   Short name: WHO TRS No. 957, Annex 3
   http://www.who.int/medicines/publications/44threport/en/

9. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6.
   Short name: WHO TRS No. 961, Annex 6
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7.
    Short name: WHO TRS No. 961, Annex 7
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

11. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9. ***Short name: WHO TRS No. 961, Annex* 9**
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

12. General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-first Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3. ***Short name: WHO TRS No. 943, Annex 3***
http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

13. WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2.
Short name: WHO TRS No. 961, Annex 2
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

14. WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2. ***Short name: WHO TRS No. 981, Annex 2***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

15. WHO guidelines on variation to a prequalified product. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 3. ***Short name: WHO TRS No. 981, Annex 3***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

16. WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14. ***Short name: WHO TRS No. 961, Annex 14***
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

17. WHO Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 3. ***Short name: WHO TRS No. 992, Annex 3***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

18. WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4. ***Short name: WHO TRS No. 992, Annex 4***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

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