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Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT
WHOPIR
Desk Assessment of Finished Product Manufacturer

Part 1	**General information**
Company information	
Name of Manufacturer	Senador Laboratories Private Limited
Corporate address of manufacturer	Plot no. 2B & 2C, Biotech Park, Phase II, Medchal Malkajgiri, Hyderabad, Telangana, India, 500101
Inspected site	
Name & address of manufacturing site	Senador Laboratories Private Limited, Plot No. 20 & 21, PHARMEZ, Pharmaceutical SEZ, Sarkhej-Bavla NH No. 8A, Near Village Matoda, Taluka Sanand, Ahmedabad – 382213, Gujarat, India
Production Block/Unit	Not applicable (only 1 block at the site)
Manufacturing license number	G/28/1297 and G/25/1842 (FDCA Gujarat, India)
Desk assessment details	
Start and end dates of review	June 24 – 30, 2026 & July 3, 2026
Inspection record number	INSP-FPP-2023-0040
Products covered by this desk assessment	

WHO Product ID	**Generic name**	**Site activity**
RH049	Desogestrel/Ethinylestradiol Tablet + Placebo Tablet 150mcg/30mcg + 0mcg	Solid oral dosage form
RH037	Desogestrel/Ethinylestradiol Tablet 0.150mg/0.030mg	Solid oral dosage form
RH038	Ethinylestradiol/Levonorgestrel Tablet, Sugar coated + Ferrous (Fumarate) Tablet, Sugar coated 30mcg/150mcg + 75mg	Solid oral dosage form
RH013	Ethinylestradiol/Levonorgestrel Tablet, coated 30mcg/150mcg	Solid oral dosage form
RH035	Ethinylestradiol/Levonorgestrel Tablet, Sugar coated+Placebo Tablet, Film-coated 30µg/150µg+0mg	Solid oral dosage form
RH032	Levonorgestrel Tablet 750mcg	Solid oral dosage form

RH031	Levonorgestrel Tablet 1.5mg	Solid oral dosage form
RH057	Levonorgestrel Tablet, Film-coated 0.03mg	Solid oral dosage form
RH094	Misoprostol Tablet 200mcg	Solid oral dosage form
RH074	Medroxyprogesterone acetate Suspension for injection 150mg	Terminally sterilised FPP manufacture
	Emtricitabine/Ethinylestradiol/Levonorgestrel/Tenofovir disoproxil fumarate Tablet, Film-coated + Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 200mg/0.03mg/0.15mg/300mg + 200mg/300mg	Solid oral dosage form

List of documents submitted

On May 4, 2026, the company submitted the following documents:

a) A list of all regulatory inspections performed in the last 3 years (Inspections performed by the Dutch Health and Youth Care Inspectorate, Indian FDA, USFDA with their outcomes);
b) Inspection reports from the Dutch Heath and Youth care Inspectorate and the USFDA (this includes an email from the USFDA, dated 28 March 2026 regarding the current GMP status of the site);
c) Valid GMP certificate issued by Dutch Health and Youth Care Inspectorate, Indian FDA, USFDA (in the form of an EIR);
d) Manufacturing authorization issued by the competent authority;
e) A site master file whose approval date was not more than one year ago, and any forecast modifications, together with legible color printouts of water treatment and air-handling systems, including pipeline and instrumentation drawings;
f) The list of all the commercial products and dosage forms manufactured on-site;
g) Most recent product quality review (PQR) of WHO-prequalified products;
h) Completed batch manufacturing and packaging records, including the analytical part, for the most recently released batch of relevant products;
i) The list of any recalls in the past three years related to any product manufactured on site with quality defects (a statement that no recalls had taken place, was submitted instead);
j) A 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;

	k) Master batch manufacturing and packaging records of the WHO products of interest; l) Statement regarding the absence of any warning letter, or equivalent regulatory action, issued by any authority to which the site provides or has applied to provide the product; m) Statement regarding any recent or foreseen out-of-stock situations; n) Statement regarding notifications of upcoming inspections by competent national regulatory authorities in the next 6 months; o) Table to specify which parts of the manufacturing process for the concerned product was covered by the inspection of the competent SRA authorities performed in the last 3 years.	
Any documents missing?	Not applicable	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments**	
Dutch Health and Youth Care Inspectorate (IGJ)	Dates of inspection:	4-7 October 2023
	Type of inspection:	GMP inspection covering the manufacture of non-sterile finished pharmaceutical products, including dispensing and weighing, tablet manufacturing, primary and secondary packaging operations, quality control laboratories, utilities, and supporting quality systems. (The site also manufactures sterile injectables, but this was not within the scope of this inspection.)
	Block/Unit:	The entire site operates as a single block/unit with different zones. All zones were covered except to the zones dedicated to sterile manufacturing.
	Type of products/Dosage forms covered:	The inspection covered non-sterile solid oral dosage forms, focusing mostly on combination and single-ingredient hormonal tablet products manufactured at the Matoda site, but also looking at the manufacture of the placebo pills that are usually supplied alongside contraceptive hormones. No WHO prequalified products were directly covered by this inspection, but we can consider that the manufacturing processes, equipment, facilities and quality systems reviewed were directly applicable to all of the OSD products that were submitted to WHO Prequalification.
	Any sections of GMP not covered?	The scope of the inspection was comprehensive overall. No critical GMP systems relevant to the

		manufacture of non-sterile solid oral dosage forms were identified as not covered. (sterile manufacture, although occurring at the facility, was not covered)
USDFA	Dates of inspection:	17-24 November 2025
	Type of inspection:	Routine cGMP surveillance inspection
	Block/Unit:	Non-sterile solid oral and sterile dosage form manufacturing and packaging areas.
	Type of products/Dosage forms covered:	TCM and SVT profile classes, ie.: -Non-sterile solid oral dosage forms, including oral contraceptive tablets and placebo tablets. -Terminally sterilized injectables (Dedicated terminally sterilized injection manufacturing.)
	Any sections of GMP not covered?	No significant GMP systems relevant to non-sterile solid oral dosage form and sterile injectable manufacture were identified as not covered.
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	The most recent WHO onsite inspection was performed from 14 to 18 November 2022 and was closed as compliant. Before this, the site was inspected by WHO 18-21 April 2016 and was also closed as compliant.	
Summary of key information about the site	According to the site master file: Senador Laboratories Private Limited, Ahmedabad, is engaged in the manufacture of medicinal products, including solid oral dosage forms (hormonal and non-hormonal tablets) and injectable hormonal formulations (terminally sterilised suspensions). It is located in a so called “Pharma zone”, surrounded by other pharmaceutical companies. The Ahmedabad facility was commissioned in 2009 as part of Famy Care Limited. In May 2015, Famy Care demerged its female contraceptive business into a separate entity, Jai Pharma Limited. In November 2015, Mylan Laboratories Limited (a Viatris Company) acquired Famy Care’s female contraceptive business. On 20 November 2015, Jai Pharma Limited formally became part of Mylan Laboratories Limited. In October 2023, Viatris demerged its women’s healthcare business into a new entity named Senador Laboratories Private Limited, which was subsequently acquired by Insud Pharma. Insud Pharma is a leading Spanish multinational pharmaceutical company with headquarters in Madrid, Lugano and Buenos Aires, and operates a broad, integrated global manufacturing and commercial network across major pharmaceutical markets worldwide.	

	Senador Laboratories Private Limited has its corporate registered office in Hyderabad, Telangana, and operates manufacturing sites in Sarigam and Ahmedabad, India. Currently, the company exports its products to markets across North America, South America, Europe, Africa, Asia and Australia. The site operates as long large block that is divided into different departments with 3 main zones, one for hormonal tablets, one for general tablets and one for terminally sterilized injectable products.
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
NC	Non-conformity
NRA	National regulatory agency
PQR	Product quality review
PQS	Pharmaceutical quality system
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
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 3 years and their outcomes:

LIST OF HEALTH AUTHORITY INSPECTION (LAST 03 YEARS)

Name of Regulatory Authority	Inspection Date	Inspection Scope	Inspection Results
Food, Medicine and Health care Administration and control Authority of Ethiopia	March 15, 2023	Injection Line 2 (On site GMP Inspection)	Satisfactory
Therapeutic Goods Administration (TGA)-Australia	March 16, 2023	Oral Solid Dosage (Desk Assessment)	Satisfactory
Health and Youth care Inspectorate- The Netherlands	October 04-07, 2023	Oral Solid Dosage (On site GMP Inspection)	Satisfactory
Medicine Control Authority of Zimbabwe (MCAZ)	February 06-08, 2025	Oral Solid Dosage and Injectable (On site GMP Inspection)	Satisfactory
WHO GMP -CDSCO /FDCA joint Inspection India	September 10-11, 2025	Oral Solid Dosage and Injectable (On site GMP Inspection)	Satisfactory
National Drug Authority, Uganda	October 12, 2025	Oral Solid Dosage and Injectable (Desk Assessment)	Satisfactory
Food and Drug Administration (FDA), US	November 17-24, 2025	Oral Solid Dosage and Injectable (On site GMP Inspection)	Satisfactory
Food and drug Administration, Philippines	December 02, 2025	Injectable (Desk Assessment)	Satisfactory
National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria	February 05-06, 2026	Oral Solid Dosage and Injectable (On site GMP Inspection)	Satisfactory
Ministry of Health Pharmacy and Poison Board Kenya	23 March, 2026	Oral Solid Dosage and Injectable (Desk Assessment)	Satisfactory

b) Manufacturing authorization granted by national authorities:
GMP certificate No. G/28/1297 and G/25/1842 (FDCA Gujarat, India), covering the necessary dosage form manufacturing activities, was submitted and is valid until 05/11/2028.

c) Site master file:
A detailed SMF was submitted and found acceptable.

d) List of all the products and dosage forms manufactured on-site:
The list of all products manufactured on site was submitted. There are 58 different products in total. The list was reviewed for the presence of any products of particular concern and there are no specific concerns at this time, in view of the control measures taken by the company to prevent cross-contamination.

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

PQRs were not submitted for the following products:
Ethinylestradiol/Levonorgestrel Tablet, Sugar coated + Ferrous (Fumarate) Tablet, Sugar coated 30mcg/150mcg + 75mg
Ethinylestradiol/Levonorgestrel Tablet, coated 30mcg/150mcg

- Ethinylestradiol/Levonorgestrel Tablet, Sugar coated + Placebo Tablet, Film-coated 30µg/150µg + 0mg

Justification from the manufacturer:

"*Senador Sarigam is the primary manufacturing site from which supplies have been executed to date. Ahmedabad has been designated as an alternate manufacturing site for these products.*

We prefer to continue supplies from Sarigam, as the inclusion of the alternate site was intended solely to ensure manufacturing continuity in the event of any natural disruption affecting the Sarigam facility.

Since the product has not been commercialized at the Ahmedabad site, the recent commercial documents are not available for Ahmedabad."

- Emtricitabine/Ethinylestradiol/Levonorgestrel/Tenofovir disoproxil fumarate Tablet, Film-coated + Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 200mg/0.03mg/0.15mg/300mg + 200mg/300mg

Justification from the manufacturer:

"Since product is under assessment, no commercial batches made."

Levonorgestrel Tablets 1.5 mg:

The APQR covers the review period August 2024 to July 2025 and confirms that Levonorgestrel Tablets 1.5 mg were consistently manufactured at the Ahmedabad site in a validated and controlled state. All batches released during the period met approved specifications. No trends of concern were identified. Two OOS results were reported and investigated; both were attributed to laboratory or equipment-related causes, were not confirmed, and were closed without product impact. No OOT trends were identified. Change controls, deviations and investigations were reviewed and found appropriate. No product-related recalls were reported. Stability data remained within specifications. The PQR concludes that the process remains capable and under control, supporting continued manufacture of this product.

Levonorgestrel Tablets 750 µg:

The APQR (review period September 2024 – August 2025) confirms continued GMP compliance for Levonorgestrel Tablets 750 µg during the reviewed period. All batches manufactured and released complied with registered specifications. No critical deviations, recurring trends, or quality-related recalls were identified. Investigations and CAPAs were limited in number and effectively closed (only 1 OOT for the current review period and 1 OOS for the previous review period). Stability and complaint reviews did not reveal product quality concerns. No changes impacting product quality were identified. The overall assessment confirms a maintained state of control relevant to this product.

Desogestrel/Ethinylestradiol Tablet 0.150mg/0.030mg:

The APQR data (review period November 2024-October 2025) was available and despite the low number of batches manufactured over this period, it demonstrated consistent manufacture of desogestrel/ethinylestradiol tablets in compliance with approved specifications. Manufacturing and packaging processes operated within validated limits. No significant quality trends, critical deviations or recalls were reported. Minor investigations were addressed through the site PQS with effective CAPA. Stability performance remained acceptable. The PQR supports continued suitability of the manufacturing process for this product.

Desogestrel/Ethinylestradiol Tablet + Placebo Tablet 150mcg/30mcg + 0mcg):
Across the reviewed APQRs (review period of November 2024-October 2025, manufacturing was conducted within established parameters, with all batches meeting specification limits. No OOS or OOT results were reported for the inert tablet component, and only one non-OOS laboratory investigation was recorded, with no CAPA initiated and no trends identified. For the finished dosing product, limited isolated events were reported (1 OOS, 2 OOT, and minor investigations), all closed without trend identification or follow-up CAPA requirements.

Levonorgestrel Tablets 0.03 mg:
The APQR confirmed all batches met specification requirements. Two finished-product OOS dissolution results were reported, both laboratory-related and not confirmed, with no impact on released batches. No OOT trends were identified. No product-quality-related recalls occurred. Change controls and deviations were adequately managed. Stability data confirmed the approved shelf life. The PQR concludes that manufacturing and quality systems remain in a state of control, fully supporting continued supply of this product.

Medroxyprogesterone injectable suspension 150 mg
The APQR data (October 2024 – September 2025) covers the manufacture of 17 different product codes and markets. There were no reworks or rejected batches. 10 OOS events were reported, the majority of which were attributed to laboratory errors, and 6 OOTs, mainly related to content uniformity, and dosage unit variability. It was noted that there was no documented CAPA effectiveness assessment regarding these OOS's/OOT's, with repeated training as a CAPA. This should be verified during the next onsite inspection. Regarding CPPs: all were within acceptable limits. There were 12 complaints, but no recalls / no critical quality defects identified. All complaints were closed except for 1 that was still in progress. They were all filed from the USA and were closed each time on the basis that there was no unusual observation noticed during the manufacturing process or that the complaint was not related to the Senador product or manufacturing site.

Misoprostol tablets 200 mcg:
The APQR covers the period of January 2025 to December 2025. Key observations include:
-2 OOS events (1 in finished product, 1 in stability)
-2 manufacturing investigations
-No OOT, no recurring trend identified
-No CAPA initiated.
-10 Change controls were initiated.
The OOS and manufacturing events were considered to not be significant and the PQR supports a maintained state of control.

Overall conclusion on APQRs:
All products demonstrate a controlled state of manufacturing with no adverse trends. The PQRs were comprehensive and met general requirements.

f) Batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant product(s):

Executed batch records were submitted for the products that are actively being manufactured by the site. The executed batch records were not submitted for the other products for the same reasons as already explained for the APQRs. These were found acceptable overall.

g) Master batch manufacturing and packaging record(s) of the product(s) of interest:
Master batch manufacturing and packaging records were submitted for the products that are actively being manufactured by the site.

h) If any of the products are sterile, the completed batch records for the most recent media fill validation that is relevant to the product(s) of interest and report on its outcome:
Not relevant to this site as there was no aseptic product manufacture.

i) Recalls in the past three years related to products with quality defects:
A declaration letter was submitted, stating that no product recalls have been initiated in the past three years for any products manufactured at the site.

j) Confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the product(s) has been performed and all matters dealt with:
A confirmation was provided by the manufacture, stating that a full self-inspection programme was implemented at the site and conducted periodically according to predefined procedures.
It was confirmed that self-inspections and/or external audits dedicated to the relevant products have been performed. All observations, deficiencies, and recommendations identified during these activities have been appropriately addressed and closed within defined timelines.

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:
The company has formally declared that no warning letter, notice/deficiency communication or any equivalent regulatory action had been issued by any regulatory authority to which the site currently provides, or has applied to provide their products. Furthermore, the site was not subject to any ongoing or pending regulatory action, investigation, or enforcement proceedings by any such authority.

l) Out-of-stock situations:
A declaration letter was submitted, stating that there was no out-of-stock or potential out-of-stock situation foreseen for the products manufactured and supplied by Senador Laboratories Pvt Ltd. It was further stated that products were continuously manufactured and supplied under valid procurement arrangements, including tenders granted under WHO prequalification status where applicable.

m) Additional documents submitted:
A list of areas and equipment that were covered by USFDA and IGJ was submitted as well as a list of areas and equipment that were relevant to the WHO products.

Part 5	**Conclusion – Desk assessment outcome**

Based on the GMP evidence received and reviewed, it is considered that a desk assessment may be performed in lieu of a WHO Inspection. The site **Senador (Matoda),** located at **Senador Laboratories Private Limited, Plot No. 20 & 21, PHARMEZ, Pharmaceutical SEZ, Sarkhej-**

Bavla NH No. 8A, Near Village Matoda, Taluka Sanand, Ahmedabad – 382213, Gujarat, 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-eight Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2.
   Short name: WHO TRS No. 986, Annex 2
   https://www.who.int/publications/m/item/trs986-annex2

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
   https://www.who.int/publications/m/item/annex-2-trs-957

3. 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/publications/m/item/trs1010-annex9

4. 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 No. 1033, Annex 3
   https://www.who.int/publications/m/item/annex-3-trs-1033

5. 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
   https://www.who.int/publications/m/item/annex-4-trs-929

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
   https://www.who.int/publications/m/item/trs957-annex1

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
https://www.who.int/publications/m/item/trs957-annex3

8. 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
https://www.who.int/publications/m/item/Annex-8-trs-1010

9. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditionning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Third Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1019), Annex 2.
Short name: WHO TRS No. 1019, Annex 2
https://www.who.int/publications/m/item/trs1019-annex2

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
Short name: WHO TRS No. 1044, Annex 4
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1044-annex4-technology-transfer-in-pharmaceutical-manufacturing.pdf

11. WHO good manufacturing practices for sterile pharmaceutical products. Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
Short name: WHO TRS No. 1044, Annex 2
https://www.who.int/publications/m/item/trs1044-annex2

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***
https://www.who.int/publications/m/item/trs943-annex3

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
https://www.who.int/publications/m/item/trs961-annex2

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
https://www.who.int/publications/m/item/trs981-annex2

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
https://www.who.int/publications/m/item/annex-3-trs-981

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
https://www.who.int/publications/m/item/tr961-annex14

17. Good Manufacturing Practices: Guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Third Report Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3.
Short name: WHO TRS No. 1019, Annex 3
https://www.who.int/publications/m/item/trs1019-annex3

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
https://www.who.int/publications/m/item/trs992-annex4

19. 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
https://www.who.int/publications/m/item/trs961-annex9-modelguidanceforstoragetransport

20. 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
https://www.who.int/publications/m/item/trs992-annex5

21. WHO Recommendations for quality requirements when plant – derived artemisinin is used as a starting material in the production of antimalarial active pharmaceutical ingredients. WHO Expert

Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 6.
Short name: WHO TRS No. 992, Annex 6
https://www.who.int/publications/m/item/trs-992-annex-6

22. 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 No. 1033, Annex 4
https://www.who.int/publications/m/item/annex-4-trs-1033

23. 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 TRS No. 996, Annex 10
https://www.who.int/publications/m/item/trs966-annex10
24. 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
https://www.who.int/publications/m/item/trs1010-annex10

25. Points to consider when including Health-Based Exposure Limits 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 No. 1033, Annex 2
https://www.who.int/publications/m/item/annex-2-trs-1033

26. Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fourth Report Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 6.
Short name: WHO TRS No. 1025, Annex 6
https://www.who.int/publications/m/item/trs-1025-annex-6

27. 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/m/item/trs-1025-annex-3-water-for-injection

27. 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/m/item/trs1025-annex4