

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

Part 1	General information
Company information	
Name of Manufacturer	Ferring International Center SA
Corporate address of manufacturer	Chemin De la Vergognausaz 50, CH-1162 Saint-Prex, Switzerland.
Contact person	Susan Peng, Responsible person / Qualified person Tel: +86 760 88587858 Email: Susan.Peng@ferring.com
Inspected site	
Name & address of manufacturing site	Ferring Pharmaceuticals (China) Co Ltd No. 6 HuiLing Lu (Ferring Road), National Health Technology Park Zhongshan City, 528437, Guangdong Province, P.R. China Tel: +86 760 88587800 Fax: +86 760 88587801 Geographic location: - Latitude = 22· 34'23"N - Longitude = 113· 30'24"E D-U-N-S Number: 52-790-3976 FEI Number: 3009226362
Production Block/Unit	Sterile Injection Workshop
Manufacturing license number	Drug Production License No Y20160310 issued by Guandong Provincial MPA on 2 July 2025 (valid until 1 July 2030)
Desk assessment details	
Start and end dates of review	1 to 7 March 2026
Inspection record number	INSP-FPP-2024-0033
Products covered by this desk assessment	RH095 – Carbetocin Solution for injection 100 mcg/ml - glass ampoule 10x1 ml

Part 2	Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments	
<i>United States Food and Drug Administration</i>	Dates of inspection:	16 – 22 August 2025
	Type of inspection:	Pre-Approval inspection of a sterile diluent manufacturer
	Block/Unit:	Sterile Injection Workshop (Vial Line)
	Type of products/Dosage forms covered:	The inspection was conducted for 0.9 % sodium chloride solvent for injection (2ml, in vial) (diluent for Menotropin)
	Physical areas inspected:	Manufacturing area for the vial line sterile injection workshop (first floor of the main building), quality control area, and warehouse.
<i>State Social Services Agency of Land Schleswig- Holstein Department for Health and Consumer Protection, Germany</i>	Dates of inspection:	24 – 28 March 2025
	Type of inspection:	Inspection of terminally sterilized product 0,9 % sodium chloride solution for injection (5 ml ampoules and 2R and 6R vials) and aseptically manufactured product Carbetocin solution for injection (2R vials).
	Block/Unit:	Sterile Injection Workshop
	Type of products/Dosage forms covered:	<ol style="list-style-type: none"> 1. 0.9% Sodium chloride solvent for Zomacton, 3.5 ml, 5 ml ampoule 2. 0.9% Sodium chloride solvent for Menopur, 2.0 ml, 2R vial 3. 0.9% Sodium chloride solvent for Zomacton, 5.0 ml, 6R vial 4. Carbetocin solution for injection 0.1 mg/ml, 1.0 ml, 2R vial
	Physical areas inspected:	<p>The following rooms were included in the round tour:</p> <ol style="list-style-type: none"> 1. Warehouse <ul style="list-style-type: none"> 800 (warehouse including freezer and refrigerators), 801 (dispatch area), 804 (receiving area), 806 and 807 (cold rooms), L1/L2 (leaflets and labels area), receiving and dispatching area, mezzanine floor (general storage and reject area) 2. Aseptic Production Workshop <ol style="list-style-type: none"> a. 712 (corridor), 710/711 (gowning), 708 (corridor), 601, 629, 630, and 631

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		<p>(corridors), 625 (terminal sterilizing room)</p> <p>b. Ampoule line: 301 (material air lock), 302 (class D corridor), 303 (personnel air lock), 304 (gowning), 305 (shoe change), 306 (ampoule washing and drying), 307 (storage), 308 (tool washing), 309 (janitor washing), 400 (filling, through windows), 401 (class B corridor, through windows).</p> <p>c. Vial line: 335 (stopper washing and sterilizing), 336 (outer cleaning from warehouse), 337 (material airlock to production), 338 (class C corridor), 339 (disinfectant preparation), 340 (tools storage), 341 (janitor washing), 342 (personnel airlock), 343 (gowning), 344 (shoe change), 345 (autoclave), 346 (tool washing), 347 (compounding), 348 (weighing), 349 (filling and capping), 350 (vial washing and drying)</p> <p>3. Secondary packaging for injectable products</p> <p>633 (Visual inspection and secondary packaging: AVI areas A and B, counting area C), 634 and 636 (MVI rooms)</p> <p>4. Industrial Gas Storage</p> <p>5. Quality Control</p> <p>a. Microbiology: 1000 (microbiological lab), 1000-1 (gowning), 1000-2 (air lock), 1000-3 (biosafety cabinet), 1001 (load autoclave), 1002 (gowning), 1003 (air lock), 1004 (sterility test), 1004-1 (limit test), 1005 (gowning),</p> <p>b. Chemical Laboratory: 614 and 618 (corridors), 617 (stability test), 619 (retention sample room), 620 (chemical lab), 637 (storage room), 706 (change room), 900 (chemical lab), 901 (instrument lab), 902 (balance and weighing), 903 (instrument room), 904</p>
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		(high temp room), 905 (washing room), 906 (sample receiving room) c. Stability rooms: 3002 (walk in stability room, 30 °C/75 % rH), 3003 (stability room, cabinets), 3006 (walk in stability room, 25 °C/60 % rH), 3007 (stability room, 2-8 °C)
<i>State Social Services Agency of Land Schleswig-Holstein Department for Health and Consumer Protection, Germany</i>	Dates of inspection:	26, 27, 29, and 30 June 2023
	Type of inspection:	Distant Assessment.
	Block/Unit:	Production areas for 0.9% Sodium Chloride Solution 1 mL and 5 mL ampoules for injection including packaging (Sterile Injection Workshop-Ampoule Line)
	Type of products/Dosage forms covered:	0.9% NaCl Solution for Injection (ampoules 1 mL and 5 mL)
	Physical areas inspected:	None. Due to the Post Covid-19 Pandemic inspection situation, the inspection was still carried out as distant assessment. A thorough document assessment was supplemented by video conferences and live video streams. Rooms inspected via live video streams include: Room 625 (Autoclave Fedegari), Room 633 Area A (Brevetti Leak Detection and Automated visual inspection), Room 633 Area C (Counting Area and Packaging for Shipping), Room 634 (Manual Visual Inspection, Room 400 (Filling Room – with filling of Lot #192301T 0.9% NaCl Solution for Injection 1 mL ampoules was watched by live camera), and Room 306 (Washer and depyrogenation tunnel). The quality of the picture resolution video was adequate for the inspection. For some areas, photos were uploaded.
Part 3	Summary of the last WHO inspection	
Date and conclusion of most recent WHO inspection	25 – 29 March 2024. The company was considered to be operating at an acceptable level of compliance with WHO GMP guideline,	
Summary of manufacturing activities	Production, quality control and distribution of granules (powder for oral solution), small volume parenteral (SVP), and secondary packaging of imported bulk tablets, lyophilized powder for injections and small volume	

	<p>parenteral. The site comprised a production area of 1760 m², a warehouse of 1913 m², QC laboratories of 553 m², and utilities of 3318 m².</p> <p>The production area included: (1) an oral solid line, (2) sterile vial preparation and filling line, (3) a sterile ampoule preparation and filling line, and (4) a secondary packaging area.</p>
General Information about the company and manufacturing site	<p>Ferring Pharmaceuticals (China) Co., Ltd. - Zhongshan manufacturing plant is a subsidiary of Ferring Pharmaceuticals Ltd., which belongs to Ferring Group located in Saint-Prex, Switzerland. Originally founded as Nordiska Hormon Laboratories in 1950, it became Ferring Co. in 1954. Its portfolio includes innovative products in the fields of peptide and protein chemistry including urology, gynecology & obstetrics, gastroenterology, and endocrinology. The constructions of Ferring Zhongshan manufacturing plant started in March 2003 and were completed in February 2005. The pharmaceutical production comprises of sterile products and non-sterile products manufacturing.</p> <p>The granules (powder for oral solution) are manufactured in the oral solids area and this area is dedicated. Sterile products are manufactured in the sterile preparation production area.</p> <p>The site manufactures only pharmaceutical products. Non-pharmaceutical products were not manufactured on-site.</p> <p>Regulatory Affairs dossier submission, Marketing and Export related activities are handled by the Corporate Office according to the information provided by the company.</p>
Focus of the last WHO inspection	Initial on-site inspection related to the production of Carbetocin Solution for injection 100 mcg/ml in the ampoule preparation and filling line.
Areas inspected	<ul style="list-style-type: none"> • Quality management system. • Injectable Production Block (ampoule preparation and filling line). • Quality Control laboratories: Physical, chemical and microbiology labs. • Utilities include HVAC, water and nitrogen. • Warehouse.
Out of scope and restrictions (last WHO inspection)	The inspection was restricted to the production of the product listed in the inspection scope. All products and production areas/lines, other than those listed under the scope of the inspection, were not covered by this inspection and were not visited.
WHO products covered by the last WHO inspection	RH095 – Carbetocin Solution for injection 100 mcg/ml - glass ampoule 10x1
Additional products to be	None.

covered by this desk assessment	
Abbreviations	Meaning
AHU	Air handling unit
API	Active pharmaceutical ingredient
BMR	Batch manufacturing record
BPR	<i>Batch production record</i>
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
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a) List of all regulatory inspections performed in the last 5 years and their outcomes:

A comprehensive list of inspections conducted by various authorities was provided below:

No	Date of Inspection	Inspection Scope	Inspection Authority	Outcome
1.	February 2026	Oral Solid Product	Saudi Arabia Authority	Not received
2.	November 2025	Small volume parenteral solution and oral solid products	German Authority	Not received
3.	August 2025	Small volume parenteral solution and oral solid products	Turkey Authority	No critical or major observations.
4.	August 2025	Small volume parenteral solution	USFDA	No critical or major observations
5.	April 2025	Small volume parenteral solution and oral solid products	Russian Authority	No critical observations. 1 major observation.

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6.	March 2025	Small volume liquid (Solution for injection)	German Authority	No critical observations. 2 major observations.
7.	March 2025	Small volume parenteral solution and oral solid products	Chinese NMPA	No critical or major observations.
8.	November 2024	Oral solid products	Libya Authority	No critical or major observations.
9.	August 2024	Small volume liquid (Solution for injection)	Gabon Authority	No critical or major observations.
10.	July 2024	Small volume parenteral solution and oral solid products	Chinese NMPA	No critical or major observations.
11.	March 2024	Small volume liquid (Solution for injection)	WHO	No critical observations. 3 major observations.
12.	February 2024	Small volume liquid (Solution for injection)	Ethiopia Authority	No critical or major observations.
13.	November 2023	Small volume parenteral solution and oral solid products	Chinese NMPA	No critical or major observations.
14.	October 2023	Small volume liquid (Solution for injection)	Uganda Authority	No critical observations. 5 major observations.
15.	June 2023	Small volume liquid (Solution for injection)	German Authority	No critical observations. 1 major observation.
16.	February 2023	Small volume parenteral solution and oral solid products	Chinese NMPA	No critical or major observations.

b) Manufacturing authorization granted by national authorities:

The company submitted Drug Production License issued by Guandong Provincial MPA on 2 July 2025 (valid until 1 July 2030). The dosage forms covered by the license include granules and small volume injectables (including non-final sterilization).

c) Site Master File (SMF):

Site Master File was submitted. Overall, the content of the SMF has been in accordance with the WHO guidelines for drafting a site master file, WHO Technical Report Series, No. 961, Annex 14.

The firm has two workshops to manufacture the oral solid and the sterile injection workshops. The sterile workshop has lines for the vial filling and ampoule filling. The manufacturing of the WHO product was conducted in the ampoule filling line. Each area in the sterile injection workshop was physically separated. People enter the area through separate dedicated personnel flow. Ampoule filling lines include facilities for weighing, preparation of bulk solutions, steam sterilization (autoclave) and filling in ampoule (including RABS). The air characteristics in the compounding areas fulfil the

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requirements of grade C, while the air characteristics in filling and sealing area fulfil the requirements of grade B and local laminar air flow grade A (RABS).

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

The list of products, which include Carbetocin solution for injection (1ml) – Duratocin, Carbetocin Ferring was manufactured in the ampoule filling line, was submitted. No issues of concern were found with respect to the list provided.

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

2024 Annual Product Review Report (Carbetocin Solution for Injection (RTS) was submitted for review. The PQR contained comprehensive information about the quality of the prequalified product and did not raise any particular concern.

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

The completed batch manufacturing and packaging records, including the full analytical documentation, for the most recently manufactured batch of Carbetocin Solution for Injection were submitted.

The manufacturing processes of Carbetocin Solution for Injection were performed and recorded according to instructions in the batch production records.

g) Master batch manufacturing and packaging record(s) of the product(s) of interest:

The company submitted Master Batch Records. For packaging, the company submitted the Secondary Packaging Record of Carbetocin Ferring Solution for Injection. Master records did not raise any particular concern.

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:

Report for Aseptic Filling with Media Fill Runs 1 ml Ampoule conducted in 2025 was submitted for review and the same did not raise any particular concern.

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

The company submitted a signed declaration confirming that there were no recalls for any products over the past 3 years.

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:

The company submitted a signed declaration confirming that a full self-inspection 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:

The company submitted a signed declaration confirming that there were no warning letters or equivalent regulatory action issued by any authority to which the site provides or has applied to provide the product.

l) Out-of-stock situations:

The company submitted a signed declaration confirming that there were no recent or foreseeable out-of-stock situations.

m) Additional documents submitted:

In response to the WHO documentation request, the company informed that there were no notifications of upcoming inspections by competent national regulatory authorities in the next 6 months.

Part 5	Conclusion – Desk assessment outcome
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Based 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 **Ferring Pharmaceuticals (China) Co Ltd** located at No. 6 HuiLing Lu (Ferring Road), National Health Technology Park Zhongshan City, 528437, Guangdong Province, P.R. China 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
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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**
<https://digicollections.net/medicinedocs/documents/s21467en/s21467en.pdf>
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**
[untitled \(digicollections.net\)](https://digicollections.net/medicinedocs/documents/s23457en/s23457en.pdf)
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://digicollections.net/medicinedocs/documents/s23457en/s23457en.pdf>
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
[9789240020900-eng.pdf \(who.int\)](https://www.who.int/publications/m/item/9789240020900-eng)

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://digicollections.net/medicinedocs/documents/s21440en/s21440en.pdf>
6. 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://digicollections.net/medicinedocs/documents/s23455en/s23455en.pdf>
7. 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
<https://digicollections.net/medicinedocs/documents/s20108en/s20108en.pdf>
8. 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. 961, 957), Annex 1
<https://digicollections.net/medicinedocs/documents/s18681en/s18681en.pdf>
9. 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://digicollections.net/medicinedocs/documents/s22358en/s22358en.pdf>
10. 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
<https://digicollections.net/medicinedocs/documents/s19959en/s19959en.pdf>
11. 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
<https://digicollections.net/medicinedocs/documents/s18677en/s18677en.pdf>

12. 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://digicollections.net/medicinedocs/documents/s18683en/s18683en.pdf>
13. 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://digicollections.net/medicinedocs/#d/s21438en>
14. 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://digicollections.net/medicinedocs/documents/s18682en/s18682en.pdf>
15. 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://digicollections.net/medicinedocs/#d/s20177en/>
16. 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://digicollections.net/medicinedocs/#d/s20175en/>
17. 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
18. 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://digicollections.net/medicinedocs/documents/s23697en/s23697en.pdf>

19. 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
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** [Essential Medicines and Health Products Information Portal \(digicollections.net\)](https://digicollections.net)
21. 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** [9789240020900-eng.pdf \(who.int\)](https://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf)
22. WHO general guidance on variations to multisource pharmaceutical products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10. **Short name: WHO TRS No. 996, Annex 10** http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf
23. 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
24. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditioning 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://digicollections.net/medicinedocs/documents/s23699en/s23699en.pdf>
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** [9789240020900-eng.pdf \(who.int\)](https://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf)

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**
[9789240001824-eng.pdf \(who.int\)](https://www.who.int/publications-detail/978-92-4-000182-4)
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-detail/978-92-4-000182-4>
28. Good chromatography practice. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 4. **Short name: WHO TRS No. 1025, Annex 4**
<https://www.who.int/publications-detail/978-92-4-000182-4>