World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

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

| **Part 1** | **General information** |
|---|---|
| **Company information** | |
| Name of Manufacturer | Sovereign Pharma Pvt. Ltd. |
| Corporate address of the manufacturer | 72-73, 7th Floor, Plot 215,<br>Free Press House,<br>Free Press Journal Marg,<br>Nariman Point, Mumbai,<br>Maharashtra, India - 400021<br>Tel.: +91- (022) 35200800<br>Website: www.sovereignpharma.net |
| **Inspected site** | |
| Name & address of manufacturing site | Survey No. 46/1-4, Village Kadaiya<br>Daman, 396210 India<br>Tel.: + 91-260-6635400 / 6635420.<br>Website: www.sovereignpharma.net<br>D-U-N-S: 858344110 |
| Production Block/Unit | • Manufacturing line 4 (ampoules – terminally sterilized) |
| Manufacturing license number | Sovereign Pharma Private limited held a valid manufacturing license on form 28 issued by the Office of the Drugs Licensing Authority of the U.T. Administration of Dadra & Nagar Haveli and Daman & Diu. The license number is DD/449 granted on 26/11/2004 and renewed on 5/11/2024 with validity up to 25/11/2029 (document reference no. DCA/D&D/LA/2024-2025/5325). |
| **Desk assessment details** | |
| Start and end dates of review | 2 – 3 June 2025 |
| Inspection record number | INSP-FPP-2025-0005 |
| Products covered by this desk assessment | Diluent Sodium Chloride Injection BP 5.0ml 0.9% w/v ampoules for the following products:<br>• MA194: Artesunate Powder for solution for injection 120mg<br>• MA152: Artesunate Powder for solution for injection 60mg |
| List of documents submitted | a) A list of all regulatory inspections performed in the last three years and their outcomes.<br>b) Current full inspection reports, including deficiency letters, issued by competent stringent regulatory authorities, with certified translations where necessary. |

| | | |
|---|---|---|
| | c) Proof of CAPA implementation and final decisions by the relevant authorities related to observations or deficiencies, including production-line-specific details.<br>d) A copy of the manufacturing authorization and GMP certificate granted by the local national authority, with translations if applicable.<br>e) The current Site Master File (dated within the past year), along with legible color printouts of the water treatment and air-handling systems, including pipeline and instrumentation drawings.<br>f) A comprehensive list of all products and dosage forms manufactured on-site, including proprietary and international non-proprietary names.<br>g) Product Quality Reviews (PQRs) of Sodium Chloride Injection 0.9% IP 5.0mL.<br>h) The completed batch manufacturing and packaging records, including the analytical components, for the most recently released batch of Sodium Chloride Injection 0.9% IP 5.0mL.<br>i) Completed batch records and outcome reports for the most recent media fill validation relevant to sterile product manufacturing.<br>j) A declaration confirming that there have been no product recalls in the past three years for any product manufactured on-site.<br>k) Confirmation by the senior Quality Assurance representative that a full self-inspection or external audit has been conducted and all related matters have been addressed.<br>l) Master batch manufacturing and packaging records for the product of interest.<br>m) A statement confirming that no warning letters or equivalent regulatory actions have been issued by any authority in relation to the site or its products.<br>n) A declaration stating that there are no recent or anticipated out-of-stock situations for commercial drug products.<br>o) A statement confirming that no inspections are scheduled in the next six months by any competent authority. | |
| Any documents missing? | No | |
| **Part 2** | **Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments** | |
| National Center for Public Health and Pharmacy, Hungary | Dates of inspection: | 30 September – 4 October 2024 |
| | Type of inspection: | NA |
| | Block/Unit: | The inspection covered:<br>• Line 2: Vials (liquid, Lyophilized), Cartridges and Pre-filled syringes with Aseptic and Terminally sterilized method.<br>• Line 4: Ampoules (Aseptic & Terminally Sterilized)<br>The inspection was requested for Sugammadex injection 200 mg/2 mL and 500 mg/5 mL, produced on Line 2, terminally |

<table>
<tr><td></td><td></td><td>sterilized. On request of the company, agreed with the inspectors, the scope of the inspection was extended to other Line 2 products and Line 4 as well, producing terminally sterilized and aseptically produced ampoules.</td></tr>
<tr><td></td><td>Type of products/Dosage forms covered:</td><td>This EU GMP inspection involved the inspection of terminally sterilized and aseptically filled medicinal products for human use produced in vials, ampoules, cartridges and pre-filled syringes.</td></tr>
<tr><td></td><td>Physical areas inspected:</td><td>Areas involved in this inspection:<br>• Line 2 – vials, ampoules, cartridges and pre-filled syringes.<br>• Line 4 – ampoules.</td></tr>
<tr><td rowspan="4">Medicines and Healthcare products Regulatory Agency (MHRA), UK</td><td>Dates of inspection:</td><td>23 – 27 September 2024</td></tr>
<tr><td>Type of inspection:</td><td>NA</td></tr>
<tr><td>Block/Unit:</td><td>While the report did not give a full list of blocks, units or lines covered, it referred to:<br>• Line 2 (vials – terminally sterilized)</td></tr>
<tr><td>Type of products/Dosage forms covered:</td><td>The report is suggestive that terminally sterilized products were covered during the inspection.</td></tr>
<tr><td>Part 3</td><td colspan="2">Summary of the last WHO inspection</td></tr>
<tr><td>Date and conclusion of most recent WHO inspection</td><td colspan="2">This desk assessment is conducted in conjunction with the initial inspection of Sovereign Pharma Private limited as the site was not inspected by WHO: neither through onsite inspection nor desk assessment, in the past.</td></tr>
<tr><td>Summary of manufacturing activities</td><td colspan="2">The production Lines qualified for commercial supply as follows:
<table>
<tr><th>Line</th><th>Start year</th><th>Dosage forms</th><th>Processing</th></tr>
<tr><td>1</td><td>2005</td><td>Ampoules</td><td>Terminal sterilization</td></tr>
<tr><td>2</td><td>2007/2008</td><td>• Vials (liquid and lyophilized),<br>• PFS<br>• Cartridge</td><td>Terminal sterilization and aseptic filling.</td></tr>
<tr><td>3</td><td>2008</td><td>Ampoules</td><td>Terminal sterilization and aseptic filling.</td></tr>
<tr><td>4</td><td>2014</td><td>Ampoules</td><td>Terminal sterilization and aseptic filling.</td></tr>
</table></td></tr>
<tr><td>General Information about the company and manufacturing site</td><td colspan="2">Sovereign Pharma Pvt. Ltd is an Indian Pharmaceutical company. The company was established in year 2003 having its registered office at Mumbai, India. The manufacturing facility of Sovereign Pharma Pvt. Ltd. is situated at Nani Daman, a Union Territory, approximately 190 km. away from Mumbai at Maharashtra state, India. Plant is about 8 Km away from the Udwada Railway station & 14 Km away from Vapi Railway Station. National Highway No.8 is about 8 Km away from the site.</td></tr>
</table>

| | |
|---|---|
| The focus of the last WHO inspection | Not applicable. |

| **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 |
| SSCC | Serial shipping container code |

| **Part 4** | **Summary of the assessment of supporting documentation** |
|---|---|

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

The list of regulatory inspections performed in the last five years was documented in Annexure 3 of the SMF, as follows:

| Regulatory Agency | Date(s) of Inspection | Outcome |
|---|---|---|
| ANVISA, Brazil | 22 – 25 August 2022 | GMP compliant |
| COFEPRIS, Mexico | 16 – 20 January 2023 | GMP compliant |
| EFDA, Ethiopia | 6, 7 and 9 March 2023 | GMP compliant |
| MCAZ, Zimbabwe | 5 – 6 May 2023 | GMP compliant |
| FDA Ghana, Ghana | 22 – 26 May 2023 | GMP compliant |
| Russia FPI SID & GP, Russia | 29 May – 1 June 2023 | GMP compliant |
| Eurasian Economic Union (EAEU) | 13 – 16 June 2023 | GMP compliant |
| MOPH, Yemen | 23 – 24 June 2023 | GMP compliant |
| BOMRA, Botswana | 19 – 20 October 2023 | GMP compliant |
| MHRA, UK | 23 – 27 September 2024 | GMP compliant |

| | | |
|---|---|---|
| National Center for Public Health and Pharmacy, Hungary | 30 September – 4 October 2024 | GMP compliant |
| MOH, Ukraine | 3 – 7 March 2025 | GMP compliant |

**b) Manufacturing authorization granted by national authorities:**
Sovereign Pharma Private limited held license (DD/449) for the manufacturing of small volume parenteral products in ampoules, vials (liquids, lyophilized), pre-filled syringes and cartridges. The manufacturing license on form 28 was issued by the Office of the Drugs Licensing Authority of the U.T. Administration of Dadra & Nagar Haveli and Daman & Diu. The license number is DD/449 granted on 26/11/2004 and renewed on 5/11/2024 with validity up to 25/11/2029 (document reference no. DCA/D&D/LA/2024-2025/5325).

**c) Site master file:**
The Site Master File of Sovereign Pharma Private limited has been prepared in line with the format and guidance provided in WHO Technical Report Series No. 961, Annex 14. It comprehensively described the facility, operations, quality systems, and regulatory compliance status, supporting transparency and readiness for GMP inspections by national and international authorities. It also recorded the site's regulatory inspection history and licensing status.

The review of the submitted SMF revealed no non-conformities.

**d) List of all the products and dosage forms manufactured on-site:**
Sovereign Pharma Private limited manufactured a wide range of sterile pharmaceutical products, primarily in the form of:

- Aseptically prepared (processing operations for the following dosage forms)
  - Lyophilisates (in vials).
    - Examples included minocycline for injection, acyclovir for injection, pantoprazole for injection and omeprazole for injection.
  - Small volume liquids (in ampoules, vials, prefilled syringes and cartridges).
    - Examples included enoxaparin sodium for injection, carbetocin for injection, and oxytocin for injection.
- Terminally sterilised (processing operations for the following dosage forms)
  - Small volume liquids (in ampoules, vials, and prefilled syringes).
    - Examples included sterile water for injections, sodium chloride injections, ondansetron injection, ferric carboxymaltose injection, hyoscine butyl bromide injection and pentoxifylline injection.

**e) Most recent product quality review(s) (PQR)(s) of the concerned WHO product(s):**
Sovereign Pharma Private limited submitted the PQR of Sodium Chloride Injection IP 5.0 ml 0.9 % w/v produced on line 4 for the period from January to December 2024. It should be noted that the product related to this desk assessment is Sodium Chloride Injection BP 5.0 ml 0.9 % w/v which has not been manufactured in the last years. Rather, the manufacturing of this product started in 2025. Consequently, no PQR was provided for this product. In compensation, the submitted PQR pertains to the IP grade, considering the equivalency in both the manufacturing process and analytical testing methods.

The submitted Product Quality Review was comprehensive and covered the review of materials, processes, specifications, deviations, non-conformities, investigations, CAPA, complaints, recalls, returns, OOS, OOT, changes, technical agreements, regulatory approvals and submissions, equipment qualification, process validation, water quality, and environmental monitoring.

The review of the submitted PQR revealed no non-conformities.

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

Sovereign Pharma Private limited submitted the batch manufacturing and packaging record(s), including the analytical part, of the following batch:

- Product name: Sodium Chloride Injection 5.0 ml ampoules 0.9% w/v
- Batch number: SP25012
- Manufacturing date May 2025
- Expiry date: April 2029
- Quantity released for dispatch: 288000 ampoules

The batch manufacturing and packaging records were in line with the master records (please refer to below item g). The batch manufacturing and packaging record demonstrated that the batch was produced under validated and GMP-compliant conditions.

Batch SP25012 of Sodium Chloride Injection BP 5.0 ml ampoules 0.9%w/v was manufactured, tested, and packed in compliance with GMP requirements. The provided BMR, BPR, and Certificates of Analysis (CoAs) confirmed the batch was released with no critical deviations, and that all quality control parameters met their respective specifications. The documentation is complete, traceable, and suitable to support GMP compliance for desk review purpose.

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

The manufacturing and packaging of Sodium Chloride Injection 5.0 ml ampoules 0.9%w/v at Sovereign Pharma Private Limited were based on formally approved and version-controlled Master Batch Manufacturing Records (MBMR) and Master Batch Packing Records (MBPR). The following information has been submitted:

MBMR Title: Batch Manufacturing Record – Sodium Chloride Injection BP 5.0 ml ampoules
Production Line: 4
Market: Export
For: Macleods Pharmaceutical Limited

MBPR Title: Batch Manufacturing Record – Sodium Chloride Injection BP 5.0 ml ampoules
Production Line: 4
Market: Export
For: Macleods Pharmaceutical Limited

Both master records defined validated and detailed instructions for each stage of the manufacturing and packaging processes. They included information on designated equipment, material specifications, sampling points, in-process controls, and reconciliation steps. Relevant SOPs were referenced throughout, covering critical activities such as line clearance, gowning, dispensing, filling, sterilization,

visual inspection, labeling, coding, and shipper configuration. Each document was formally reviewed and signed by responsible production and quality assurance personnel, confirming their approved and controlled status.

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

Sovereign Pharma Private limited has formally declared that the responsibility for product recall lies with respective contract giver as Sovereign Pharma Private limited did not have its own supply chain / distribution network for any of the product manufactured at site. In the event of receipt of any information directly from any regulatory authority related to defective product, defect identified in a product complaint investigation or defect observed related to Safety, Identity, Strength, Purity and Quality of the product, Sovereign Pharma Private Limited Head QA/Designee in coordination with recall committee should inform to respective contract giver.

**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:**

Sovereign Pharma Private limited has confirmed, via a signed declaration dated 18 Match 2025, that a periodic self-inspection program, on annual basis, is actively implemented. The self-inspections critical areas of operations, including, but not limited to, the following GxP systems:

- Documentation Practices & Data Integrity
- Manufacturing Practices
- Laboratory Practices
- Warehousing Practices
- Engineering Practices
- Safety and Work Instructions
- Computerized Systems

**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:**

Sovereign Pharma Private limited has confirmed, via a signed declaration dated 17 Match 2025, that no warning letter, or equivalent regulatory action, has been issued by any competent national regulatory authorities to which the site provides or has applied to provide the product.

**l) Out-of-stock situations:**

Sovereign Pharma Private limited has confirmed, via a signed declaration dated 17 Match 2025, that no recent or foreseen event has occurred regarding the out-of-stock situations.

**m) A list of notifications of upcoming inspections by competent national regulatory authorities in the next 6 months:**

Sovereign Pharma Private limited has confirmed, via a signed declaration dated 19 Match 2025, that a regulatory inspection by Iraq's Ministry of Health has been scheduled from the 31 March to 1 April 2025 (two days), and that no other regulatory audits have been scheduled within the next 6 months, except for the Iraq regulatory audit.

**l) Additional documents submitted:**

Not applicable

| Part 5 | Conclusion – Desk assessment outcome |
|---|---|

Based on the GMP evidence received and reviewed, a desk assessment is acceptable in lieu of a WHO onsite inspection. The site ***Sovereign Pharma Pvt. Ltd.*** located at **Survey No. 46/1-4, Village Kadaiya Daman, 396210 India**, particularly **Line 4** 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***
   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. Fifty-seventh Report. Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1052), Annex 4.
   ***Short name: WHO TRS No. 1052, Annex 4***
   https://www.who.int/publications/i/item/9789240091030

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-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://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. Fiftieth 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

28. Good trade and distribution practices for pharmaceutical starting materials. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 6.
***Short name: WHO TRS No. 996, Annex 6***
https://www.who.int/publications/m/item/annex-6-trs-996

29. WHO guidelines for preparing a laboratory information file. *WHO Expert Committee on Specifications for Pharmaceutical Preparations.* Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 13.
***Short name: WHO TRS No. 961, Annex 13***
https://www.who.int/publications/m/item/trs961-annex13

30. WHO good manufacturing practices for excipients used in pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-seventh Report. Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1052), Annex 1.
***Short name: WHO TRS No. 1052, Annex 1***
https://www.who.int/publications/i/item/9789240091030