

**Prequalification Unit Inspection services  
WHO PUBLIC INSPECTION REPORT  
(WHOPIR)**

**Desk Assessment of Active Pharmaceutical Ingredient (API) Manufacturer**

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|--------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Part 1</b>                        | <b>General information</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Company information</b>           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Name of Manufacturer                 | Laurus Labs Limited                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Corporate address of manufacturer    | 2nd Floor, Serene Chambers,<br>Road No.: 7, Banjara Hills,<br>Hyderabad-500034, Telangana,<br>India                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Inspected site</b>                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Name & address of manufacturing site | <b>Unit 1:</b><br>Plot No. 21, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam-531021, Andhra Pradesh, India<br><br><b>Unit 3:</b><br>Plot No. 18, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam 531021 Andhra Pradesh, India                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Synthetic Unit/Block/Workshop        | Unit-1 and Unit-3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Desk assessment details</b>       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Date of review                       | 25 May - 03 June 2020                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| APIs covered by this desk assessment | <b>Unit 1</b><br>1 APIMF 090 Efavirenz (ELT)<br>2 APIMF 139 Emtricitabine (AECB)<br>3 APIMF 193 Abacavir Sulfate (CABS)<br>4 APIMF 195 Tenofovir Disoproxil Fumarate (Process-2)(BTDF)<br>5 APIMF 319 Sofosbuvir (CSSV)<br>6 APIMF 325 Dolutegravir Sodium (ADTGS)<br>7 APIMF 357 Darunavir (ADVR)<br>8 APIMF 369 Atazanavir Sulfate (AATZ)<br>9 APIMF 379 Oseltamivir Phosphate (AOTV)<br>10 APIMF 335 Daclatasvir Dihydrochloride (ADCTR)<br>11 APIMF 387 Dolutegravir Sodium (DDTGS)<br><br><b>Unit 3</b><br>1. APIMF 369 Atazanavir Sulfate (AATZ)<br>2. APIMF 139 Emtricitabine (AECB)<br>3. APIMF 346 Lamivudine (ALMD)<br>4. APIMF 398 Ritonavir (ARVR) |

|                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                            |
|---------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                   | 5. APIMF 195    Tenofovir Disoproxil Fumarate (Process 2) (BTDF)<br>6. APIMF 319    Sofosbuvir (CSSV)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                            |
| List of documents submitted                       | 1. A list of all regulatory inspections performed in the last 3 years and their outcomes;<br>2. The USFDA EIR report of the previous inspection held 10 -14 June 2019<br>3. CAPA implementation<br>4. Manufacturing Authorization & GMP certificate<br>5. SMF & Layouts, Declaration on modifications<br>6. The list of Manufactured products<br>7. Product quality review (PQR)<br>8. Batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant product(s);<br>9. A list of Recalls in the past 3 years<br>10. A confirmation of self-inspection<br>11. Master batch manufacturing and packaging records<br>12. Declaration on Any regulatory action<br>13. Declaration on out of stock situation<br>14. Declaration of upcoming inspections<br>Details of APIs covered in SRA inspection |                                                                                                                                                                                            |
| <b>Part 2</b>                                     | <b>Summary of SRA/NRA inspection evidence considered (from most recent to last)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                            |
| USA S, FDA                                        | Dates of inspection:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 18 <sup>th</sup> to 21 <sup>st</sup> November 2019                                                                                                                                         |
|                                                   | Type of inspection:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | API Pre-Approval Inspection                                                                                                                                                                |
|                                                   | Block/Unit/Workshop:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Unit 1 and Unit 3                                                                                                                                                                          |
|                                                   | Type of APIs covered:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Not known, EIR awaiting                                                                                                                                                                    |
| USA, FDA                                          | Dates of inspection:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 10 <sup>th</sup> -14 <sup>th</sup> June 2019                                                                                                                                               |
|                                                   | Type of inspection:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | "Voluntary Action Indicated" ("VAI"). Based on this inspection, this facility is in a minimally acceptable state of compliance with regards to current good manufacturing practice (cGMP). |
|                                                   | Block/Unit/Workshop:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Unit 1 and Unit 3                                                                                                                                                                          |
|                                                   | Type of APIs covered:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | API Efavirenz, Darunavir, Lamivudine, Hydroxychloroquine, Atorvastatin and Emtricitabine were covered in the inspection.                                                                   |
| <b>Part 3</b>                                     | <b>Summary of the last WHO inspection</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                            |
| Date and conclusion of most recent WHO inspection | September 4 <sup>th</sup> – 7 <sup>th</sup> , 2017<br><br>cGMP compliance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                            |

|                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|--------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Brief description of manufacturing activities                | The manufacturer was involved in the manufacturing, packaging, labeling, testing and storage of the APIs at Unit 1 & Unit 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| General information about the company and manufacturing site | <p>Laurus Labs Limited is a pharmaceutical services organization head-quartered in Hyderabad, India.</p> <p>One of the Laurus Labs Limited drug substance manufacturing facility is situated at Plot No: 18, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam-531021, Andhra Pradesh, India.</p> <p>Unit 3 is licensed to manufacture wide range of APIs and Intermediates to cater to various therapeutic segments. The products manufactured are licensed by Local Drug Control Authorities.</p> <p>Oncology and non-oncology drug substances are manufactured at this site in dedicated blocks. There are separate manufacturing facilities for oncology and non-oncology API manufacturing. No Penicillin, beta lactam antibiotics, pesticides or insecticides are manufactured at this site.</p> <p>Unit 1 is licensed to manufacture wide range of APIs and Intermediates to cater to various therapeutic segments. The products manufactured are licensed by Local Drug Control Authorities.</p> <p>Oncology and non-oncology drug substances are manufactured at this site in dedicated blocks. There are separate manufacturing facilities for oncology and non-oncology API manufacturing. No Penicillin, beta lactam antibiotics, pesticides or insecticides are manufactured at this site.</p> |
| Focus of the last WHO inspection                             | Production and quality control of APIs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Areas inspected                                              | <ul style="list-style-type: none"> <li>• Pharmaceutical Quality System</li> <li>• Documentation system</li> <li>• Production System</li> <li>• Facilities and Equipment System</li> <li>• Laboratory Control System</li> <li>• Packaging/labelling system</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Out of scope and restrictions (last WHO inspection)          | NA.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| WHO APIs covered by the last WHO inspection                  | <ol style="list-style-type: none"> <li>1. APIMF 090 Efavirenz (Unit-1)</li> <li>2. APIMF 141 Nevirapine anhydrous (Unit-1)</li> <li>3. APIMF 152 Lamivudine anhydrous (Unit-1&amp;3)</li> <li>4. APIMF 193 Abacavir hemisulfate (Unit-1)</li> <li>5. APIMF 139 Emtricitabine (Unit-1&amp;3)</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |

|                                                      |                                                                                                                                                                                                                                                         |
|------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                      | 6. APIMF 195 Tenofovir disoproxil fumarate (Unit -1&3)<br>7. APIMF 319 Sofosbuvir (Unit-1&3) - under assessment<br>8. APIMF 325 Dolutegravir Sodium (Unit-1) - under assessment<br>9. APIMF 335 Daclatasvir Dihydrochloride (Unit-1) - under assessment |
| Additional products covered by this desk assessment: | 1. APIMF 357 Darunavir (ADVR) (Unit-1)<br>2. APIMF 369 Atazanavir Sulfate (AATZ) (Unit-1&3)<br>3. APIMF 379 Oseltamivir Phosphate (AOTV) (Unit-1)<br>4. APIMF 387 Dolutegravir Sodium (DDTGS) (Unit-1)                                                  |
| <b>Abbreviations</b>                                 | <b>Meaning</b>                                                                                                                                                                                                                                          |
| BMR                                                  | Batch manufacturing record                                                                                                                                                                                                                              |
| BPR                                                  | Batch production record                                                                                                                                                                                                                                 |
| CAPA                                                 | Corrective and preventive action                                                                                                                                                                                                                        |
| CC                                                   | Change control                                                                                                                                                                                                                                          |
| 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                                                                                                                                                                                                                                     |
| SOP                                                  | Standard operating procedure                                                                                                                                                                                                                            |

|               |                                                              |
|---------------|--------------------------------------------------------------|
| <b>Part 4</b> | <b>Summary of the assessment of supporting documentation</b> |
|---------------|--------------------------------------------------------------|

- a) **Manufacturing authorization and GMP certificate granted by the local authority:**  
Provided. Reviewed and considered acceptable.
- b) **Site master file (SMF):**  
Provided. Reviewed and no objectional findings.
- c) **List of all the APIs or other products (intermediates, dosage forms) manufactured on-site:**  
Provided. Reviewed and no objectional findings.
- d) **List of all regulatory inspections performed in the last 3 years and their outcomes:**  
Provided and reviewed and no objectional findings.  
The EIR report of the latest US FDA inspection is awaiting.

- e) Most recent product quality review(s) (PQR)(s) of the concerned WHO API(s):**  
PQRs for the following products were provided, reviewed with no objectional findings.

**Unit 1 :**

1. Efavirenz (ELT)
2. Emtricitabine (AECB)
3. Abacavir Sulfate (CABS)
4. Tenofovir Disoproxil Fumarate (Process 2) (BTDF)
5. Sofosbuvir (CSSV) -
6. Dolutegravir Sodium (ADTGS)
7. Darunavir (ADVR)
8. Atazanavir Sulfate (AATZ)
9. Oseltamivir Phosphate (AOTV)
10. Daclatasvir Di Hydrochloride (ADCTR)
11. Dolutegravir sodium (DDTGS)

**Unit 3 :**

1. Atazanavir Sulfate (AATZ)
2. Emtricitabine (AECB)
3. Lamivudine (ALMD)
4. Ritonavir (ARVR)
5. Tenofovir Disoproxil Fumarate (Process 2) (BTDF)
6. Sofosbuvir side chain (ATBFC)

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

BMR, BPR and/or testing records of the product in scope were provided, reviewed with no objectional findings.

**Unit 1:**

1. Efavirenz (ELT)
2. Emtricitabine (AECB)
3. Abacavir Sulfate (CABS)
4. Tenofovir Disoproxil Fumarate (Process 2) (BTDF)
5. Sofosbuvir (CSSV) Declaration
6. Dolutegravir Sodium (ADTGS)
7. Darunavir (ADVR)
8. Atazanavir Sulfate (AATZ)
9. Oseltamivir Phosphate (AOTV)
10. Daclatasvir Di Hydrochloride (ADCTR)
11. Dolutegravir sodium (DDTGS)

**Unit 3:**

1. Atazanavir Sulfate (AATZ)
2. Emtricitabine (AECB)
3. Lamivudine (ALMD)
4. Ritonavir (ARVR)
5. Tenofovir Disoproxil Fumarate (Process 2) (BTDF)

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

Provided. Reviewed and considered acceptable.

**h) Recalls in the past three years related to APIs with quality defects:**

**Unit 1:**

One recall was conducted during 2019. Three batches of Darunavir API were recalled due to an unknown peak identified during residual solvent by GC-HS test.

**Unit 3:**

Confirmed no recalls during 2017 to 2020 (till date).

**i) Confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the API(s) has been performed and all matters dealt with:**

Provided. Reviewed and considered acceptable.

**j) Copy of any warning letter, or equivalent regulatory action, issued by any authority for their market, to which the site provides or has applied to provide the API(s):**

The company stated that “no warning letter and/or regulatory action” had been issued by any regulatory authority during the past 5 years.

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

Laurus Labs Limited (Unit 1 and Unit 3, Visakhapatnam) declared that "No Out-of-stock situation of any Drug Substance has been encountered recently or is foreseen in near future.

**l) Additional documents submitted:**

Upcoming inspection information was provided.

|               |                                             |
|---------------|---------------------------------------------|
| <b>Part 5</b> | <b>Conclusion – Desk assessment outcome</b> |
|---------------|---------------------------------------------|

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 **Laurus Labs Limited**

- **Unit 1**, located at **Plot No. 21, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam-531021 Andhra Pradesh, India** and
- **Unit 3**, located at **Plot No. 18, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam-531021 Andhra Pradesh, India**

is operating at an acceptable level of compliance with WHO GMP guidelines for APIs.

This WHOPIR will remain valid until **31 December 2021**, provided that the outcome of any inspection conducted during this period is positive.

|               |                                                                |
|---------------|----------------------------------------------------------------|
| <b>Part 6</b> | <b>List of guidelines referenced in this inspection report</b> |
|---------------|----------------------------------------------------------------|

1. 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 GMP for APIs or WHO TRS No. 957, Annex 2**  
<http://apps.who.int/medicinedocs/documents/s20119en/s20119en.pdf>
2. 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/](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/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/](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](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/](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](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. 961, 957, Annex 1**  
<http://www.who.int/medicines/publications/44threport/en/>
8. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2.  
**Short name: WHO TRS No. 957, Annex 2**  
<http://www.who.int/medicines/publications/44threport/en/>
9. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6.  
**Short name: WHO TRS No. 961, Annex 6**  
[http://whqlibdoc.who.int/trs/WHO\\_TRS\\_961\\_eng.pdf?ua=1](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](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](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](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](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/](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/](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](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](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](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf)

19. WHO Technical supplements to Model Guidance for storage and transport of time – and temperature – sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5. **Short name: WHO TRS No. 992, Annex 5**  
[http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/expert\\_committee/WHO\\_TRS\\_992\\_web.pdf](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf)
20. WHO Recommendations for quality requirements when plant – derived artemisin 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**  
[http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/expert\\_committee/WHO\\_TRS\\_992\\_web.pdf](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf)
21. Guidance on good data and record management practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 5.  
**Short name: WHO GDRMP guidance or WHO TRS No. 996, Annex 5**  
[http://www.who.int/medicines/publications/pharmprep/WHO\\_TRS\\_996\\_annex05.pdf](http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.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 Multisource guidance or WHO TRS No. 996, Annex 10**  
[http://www.who.int/medicines/publications/pharmprep/WHO\\_TRS\\_996\\_annex10.pdf](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](http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf)
24. 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>
25. 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>

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-detail/978-92-4-000182-4>

27. 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/medicines/areas/quality\\_safety/quality\\_assurance/TRS1010annex9.pdf?ua=1](https://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS1010annex9.pdf?ua=1)