Prequalification Team Inspection services  
WHO PUBLIC INSPECTION REPORT  
(WHOPIR)  
Desk Assessment of Active Pharmaceutical Ingredient (API) Manufacturer

### Part 1  General information

#### Company information
- **Name of Manufacturer**: Chromo Laboratories India Private Limited  
- **Corporate address of manufacturer**: Plot No. 43 & 44, Phase II, I.D.A, Pashamylaram, Patancheru Mandal, Sangareddy District-502 307, Telangana State, India  
  - Tel.: +91 9490757602, Fax: +91 8455 297020  
  - E mail: info@chromolabs.com  
  - 24-hour telephone numbers: +91 9490757602

#### Inspected site
- **Name & address of manufacturing site**: Chromo Laboratories India Private Limited, Plot No. 43 & 44, Phase II, I.D.A, Pashamylaram, Patancheru Mandal, Sangareddy District-502 307, Telangana State, India  
  - GPS details:  
    - Latitude:17º32´20.90"N  
    - Longitude:78º10´56.80"E(Gate)  
    - D-U-N-S Number:91 5368300  
    - Tel.: +91 9490 757602  
    - Fax: +91 8455 297020

- **Synthetic Unit/Block/Workshop**: Block-A & Block-C (Module-1)

#### Desk assessment details
- **Date of review**: 17 September 2019  
- **APIs covered by this desk assessment**: Moxifloxacin Hydrochloride

- **List of documents submitted**  
  - List of regulatory inspections performed at the site during the last 5 years.  
  - EDQM inspection report, proof of CAPA implementation and final decision by the EDQM.  
  - GMP Confirmation letter written by Central Drugs Standard Control Organization, India.  
  - Manufacturing license, number 16/MD/AP/2008/B/R issued on the 12/06/2018 by the Drugs Control Administration (Telangana State) valid till 15/06/2023.  
  - GMP Certificate, number 8627/E1/2018 issued on the 28/01/2019 by the Drugs Control Administration (Telangana State) valid for one year  
  - Site master file, effective date 24.08.2019
• list of all the products manufactured on-site
• The APQR report for Moxifloxacin Hydrochloride.
• Completed BMRs for Moxifloxacin Hydrochloride.
• Blank BMR for Moxifloxacin Hydrochloride.
• Recall statement: that no recalls were executed in the past three years.
• Self-inspections statement: self-inspections were performed for Moxifloxacin Hydrochloride and all matters are dealt with.
• A regulatory inspection statement by the Dy. Manager-Quality Assurance, mentioning that no notice of concern, warning letter or equivalent regulatory actions were issued to Chromo Laboratories India Private Limited by any Authority.
• A statement by the Dy. Manager-Quality Assurance, confirming that out of stock situation is not applicable.

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<tr>
<th>Part 2</th>
<th>Summary of SRA/NRA inspection evidence considered (from most recent to last)</th>
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<tr>
<td>EDQM</td>
<td>Dates of inspection: 5-7/2/2018&lt;br&gt;Type of inspection: Pre-approval inspection&lt;br&gt;Block/Unit/Workshop: Block-A and Block-C&lt;br&gt;Type of APIs covered: API by chemical synthesis</td>
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<th>Part 3</th>
<th>Summary of the last WHO inspection</th>
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<tr>
<td>Date and conclusion of most recent WHO inspection</td>
<td>None</td>
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<tr>
<td>Brief description of manufacturing activities</td>
<td>According to the SMF, the site is involved in manufacturing of advanced intermediates and API only. Cephalosporins, Hormones and cytotoxic drugs are not manufactured at the site.</td>
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<tr>
<td>General information about the company and manufacturing site</td>
<td>According to the SMF, the site is advanced intermediates and API facility comprises of manufacturing facility and process development lab, Quality control department, Quality Assurance department, Safety, Health and environment department, Warehouse facilities and Human resources department.</td>
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<tr>
<th>Abbreviations</th>
<th>Meaning</th>
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<tr>
<td>BMR</td>
<td>Batch manufacturing record</td>
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<td>BPR</td>
<td>Batch production record</td>
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<td>CAPA</td>
<td>Corrective and preventive action</td>
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<td>CC</td>
<td>Change control</td>
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<td>GMP</td>
<td>Good manufacturing practices</td>
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<tr>
<td>NC</td>
<td>Non-conformity</td>
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<td>NRA</td>
<td>National regulatory agency</td>
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Part 4  Summary of the assessment of supporting documentation

a) Manufacturing authorization and GMP certificate granted by the local authority:
   - Manufacturing license, No. 16/MD/AP/2008/B/R
   - Issued: 12/06/2018 by the Drugs Control Administration (Telangana State)
   - Valid: 15/06/2023
   - Levofloxacin Hemihydrate-USP&IP, Moxifloxacin HCl-BP/USP/Ph.Eur were approved according to the License.

   - GMP Certificate, No. 8627/E1/2018
   - Issued: 28/01/2019 by the Drugs Control Administration (Telangana State)
   - Valid: one year

b) Site master file (SMF):
   Site master file, effective date 24.08.2019, with annexures of legible color printouts of water treatment and air handling systems, including pipeline and instrumentation drawings was reviewed and found acceptable and in line with the WHO TRS No. 961, Annex 14.

c) List of all the APIs or other products (intermediates, dosage forms) manufactured on-site:
   1. Atazanavir sulfate
   2. Atorvastatin Calcium (ATR)
   3. Candesartan Cilexetil
   4. Chlorthalidone
   5. Dolutegravir
   6. Levocitrizine hydrochloride
   7. Levofloxacin Hemihydrate
   8. Moxifloxacin hydrochloride
   9. Olanzapine
   10. Olmesartan Medoxomil
   11. Repaglinide
   12. Telmisartan
   13. Terbinafine Hydrochloride
   14. Valsartan
   15. Vardenafil Hydrochloride
16. Voriconazole
17. Zafirlukast
18. Zafirlukast Premix
19. Ziprasidone

There were no beta-lactam or cytotoxic products manufactured at the site.

d) List of all regulatory inspections performed in the last 3 years and their outcomes:
The only SRA inspection conducted at the site within the last 3 years was by EDQM from the 5.2.2018 to 7.2.2018. EDQM-GMP compliant.

e) Most recent product quality review(s) (PQR)(s) of the concerned WHO API(s):
Annual Product Quality Review of Moxifloxacin Hydrochloride shows that there are two stages for Moxifloxacin Hydrochloride production. The PQR reviewed the intermediates, key starting material, primary packaging material, in-process quality control tests, critical process parameters, intermediate quality and finished product quality. All batches trend data found well within the acceptance limits.

f) Batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant API(s):
- Moxifloxacin Hydrochloride Stage-1 (MNC-1) executed Batch production record (Batch No.XXX), manufacture date 18/04/2019.
- Moxifloxacin Hydrochloride Stage-1 (MNC-1) executed analytical record (Batch No. XXX), report date 30/04/2019.
- Moxifloxacin Hydrochloride Stage-2 (MNC-2) executed Batch production record (Batch No. XXX), manufacture date 08/06/2019.
- Moxifloxacin Hydrochloride Stage-2 (MNC-2) executed analytical record (Batch No.XXX).
- Moxifloxacin Hydrochloride Packing record (Batch No. XXX), manufacture date 07/2019.
- Moxifloxacin Hydrochloride Certificate of analysis (COA, Batch No. XXX)

g) Master batch manufacturing and packaging record(s) of the API(s) of interest:
Blank master batch manufacturing and packaging records of the above listed PQ products were submitted.

h) Recalls in the past three years related to APIs with quality defects:
Recall statements from the Dy. Manager-Quality Assurance stating that no recalls were executed in the past three years for products manufactured at Chromo Laboratories India Private Limited.

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:
A statement by the Dy. Manager-Quality Assurance mentioning that self-inspections were performed for Moxifloxacin Hydrochloride and all matters are dealt with.
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):
   A regulatory inspection statement by the Dy. Manager-Quality Assurance, mentioning that no notice of concern, warning letter or equivalent regulatory actions were issued to Chromo Laboratories India Private Limited by any Authority.

k) Out-of-stock situations:
   A statement by the Dy. Manager-Quality Assurance, confirming that out of stock situation is not applicable.

l) Additional documents submitted:
   None.

### Part 5 | Conclusion – Desk assessment outcome

Based on the previous WHO inspections and on the GMP evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site Chromo Laboratories India Private Limited located at Plot No. 43 & 44, Phase II, I.D.A, Pashamylaram, Patancheru Mandal, Sangareddy District, Telangana, 502 307, India is considered to be operating at an acceptable level of compliance with WHO GMP guidelines for APIs.

This WHOPIR will remain valid until 7 February 2021 (3 years from the last EDQM GMP inspection), provided that the outcome of any inspection conducted during this period is positive.

### Part 6 | List of guidelines referenced in this inspection report


https://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS1010annex9.pdf?ua=1

http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/

http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

https://apps.who.int/iris/bitstream/handle/10665/312316/9789241210287-eng.pdf?ua=1

https://apps.who.int/iris/bitstream/handle/10665/312316/9789241210287-eng.pdf?ua=1

*Short name: WHO TRS No. 957, Annex 3*

*Short name: WHO TRS No. 961, Annex 6*
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

*Short name: WHO TRS No. 961, Annex 7*
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

*Short name: WHO TRS No. 961, Annex 9*
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

*Short name: WHO TRS No. 943, Annex 3*
http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

*Short name: WHO TRS No. 961, Annex 2*
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

*Short name: WHO TRS No. 981, Annex 2*
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/
*Short name: WHO TRS No. 981, Annex 3*
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

*Short name: WHO TRS No. 961, Annex 14*
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1


http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf

   **Short name:** WHO TRS No. 996, Annex 10  

   **Short name:** WHO TRS No. 992, Annex 6  