# Desk Assessment of Active Pharmaceutical Ingredient (API) Manufacturer

## Part 1: General information

### Company information

<table>
<thead>
<tr>
<th>Name of Manufacturer</th>
<th>Aurore Pharmaceuticals Private Limited</th>
</tr>
</thead>
</table>
| Corporate address of manufacturer | Aurore Life Sciences Private Limited  
Plot No. 68, 69,  
2nd Floor Jubilee Heights, 
Hitech City, Near Shilparamam Madhapur, 
Hyderabad,  
500 081  
India |

### Inspected site

| Name & address of manufacturing site | Aurore Pharmaceuticals Private Limited,  
Unit 1, Plot Nos. 35, 36, 38 to 40, 49 to 51,  
Phase IV, IDA, Jeedimetla,  
Medchal-Malkajigiri District,  
Hyderabad, 500055,  
India |

**DUNS:** 91-656-8827  
Latitude N: 17° 31.842  
Longitude E: 78° 26.184

### Synthetic Unit/Block/Workshop

| Unit I |

### Desk assessment details

| Date of completion desk review | 15 August 2022 |
| Inspection record number | INSP-API-2022-0014 |
| APIs covered by this desk assessment | WHO API 435 / APIMF 435 Dolutegravir (sodium)  
APIMF 461 Nirmatrelvir  
WHO API 463 / APIMF 463 Ritonavir |

### List of documents submitted

- a) A list of all regulatory inspections performed in the last 5 years and their outcomes;  
- b) Current full inspection report(s), including deficiency letters, for inspections performed by a competent stringent regulatory authority in the past three years
with a certified translated copy where this is not in English;

c) Proof of CAPA implementation and final decision by the competent stringent regulatory authority related to observations or deficiencies noted in the latest inspection report or to any warning letter or equivalent regulatory action (production-line specific);

d) A copy of the manufacturing authorization and GMP certificate granted by the local national authority together with a certified translation, where this is not in English;

e) A site master file whose approval date was not more than one year ago, and any forecast modifications, together with legible colour printouts of water treatment and air-handling systems, including pipeline and instrumentation drawings in A3 or A2 format;

f) The list of all the products and dosage forms manufactured on-site. The list should include proprietary names and International Non-proprietary Names (INN), including all types of chemicals and products (e.g., pesticides, herbal medicines, chemicals or veterinary products, etc.);

g) The most recent product quality review(s) (PQR)(s) of the concerned product(s); PQR(s) or equivalent documentation covering all required subsections and trend results, including statistical evaluation; proprietary information for vaccines is not required – delete as appropriate;

h) The completed batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant product(s);

i) The list of any recalls in the past three years related to any product manufactured on site with quality defects;

j) A 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;

k) Master batch manufacturing and packaging record(s) of the WHO product(s) of interest;

l) 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;

m) Description of any recent or foreseen out-of-stock situations;

n) A list of notifications of upcoming inspections by competent national regulatory authorities in the next 6 months;

o) A table to specify which parts of the manufacturing process for the concerned product(s) were covered by the inspection of the competent SRA authorities.
<table>
<thead>
<tr>
<th>Part 2</th>
<th>Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HPRA (Ireland) and AGES (Austria)</strong></td>
<td>Dates of inspection: 28 June to 2 July 2021</td>
</tr>
<tr>
<td></td>
<td>Type of inspection: Remote inspection. GMP for APIs</td>
</tr>
<tr>
<td></td>
<td>Block/Unit/Workshop: Unit 1 (MB-1 &amp; MB-4)</td>
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<tr>
<td></td>
<td>APIs covered: Olanzapine, Amlodipine, Tadalafil, Emtricitabine</td>
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<tr>
<th>Part 3</th>
<th>Summary of the last WHO inspection</th>
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<tbody>
<tr>
<td>Date and conclusion of most recent WHO inspection</td>
<td>13 to 16 March 2018 for the site but when it was owned by Mylan as Mylan Unit III. The conclusion was that a follow-up inspection was required. However, different APIs were under the scope of the Mylan Unit III inspection and different manufacturing blocks as well (MB02 and Central Packing Area only were covered).</td>
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<tr>
<td>Brief summary of manufacturing activities</td>
<td>N/A</td>
</tr>
<tr>
<td>General information about the company and manufacturing site</td>
<td>N/A</td>
</tr>
<tr>
<td>Focus of the last WHO inspection</td>
<td>N/A</td>
</tr>
<tr>
<td>Areas inspected</td>
<td>N/A</td>
</tr>
<tr>
<td>Out of scope and restrictions (last WHO inspection)</td>
<td>N/A</td>
</tr>
<tr>
<td>WHO APIs covered by the last WHO</td>
<td>N/A</td>
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</table>
**Part 4**

**Summary of the assessment of supporting documentation**

a) **Manufacturing authorization and GMP certificate granted by the local authority:**

Submitted. License valid until 29 October 2023 (No. 99RR/AP/B/CC); DCA GMP certificate valid until December 2022.

b) **Site master file (SMF):**

SMF dated 8 March 2022 was submitted and found generally acceptable.

c) **List of all the APIs or other products (intermediates, dosage forms) manufactured on-site:**

A list of 98 APIs is available
d) List of all regulatory inspections performed in the last 3 years and their outcomes:

<table>
<thead>
<tr>
<th>S. No</th>
<th>Name of Regulatory Authorities (National and International)</th>
<th>Inspection dates</th>
<th>Inspection outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>CDSCO / DCA</td>
<td>5th January 2017 to 6th January 2017</td>
<td>Approved (Certificate Issued)</td>
</tr>
<tr>
<td>2.</td>
<td>WHO – GENEVA</td>
<td>13th March 2018 to 16th March 2018</td>
<td>Closing letter</td>
</tr>
<tr>
<td>3.</td>
<td>USFDA</td>
<td>21st May 2018 to 25th May 2018</td>
<td>Classified as NA (No action indicated)</td>
</tr>
<tr>
<td>4.</td>
<td>CDSCO / DCA</td>
<td>16th January 2019 to 19th January 2019</td>
<td>Approved (Certificate Issued)</td>
</tr>
<tr>
<td>5.</td>
<td>CDSCO / DCA</td>
<td>13th May 2019</td>
<td>Approved (Certificate Issued)</td>
</tr>
<tr>
<td>6.</td>
<td>CDSCO / DCA</td>
<td>3rd December 2019 to 5th December 2019</td>
<td>Approved (Certificate Issued)</td>
</tr>
<tr>
<td>7.</td>
<td>CDSCO / DCA</td>
<td>21st July 2020 to 22nd July 2020</td>
<td>Approved (Certificate Issued)</td>
</tr>
<tr>
<td>8.</td>
<td>CDSCO / DCA</td>
<td>8th December 2021</td>
<td>Approved (Certificate Issued)</td>
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<tr>
<td>9.</td>
<td>HPRA (Health Products Regulatory Agency)</td>
<td>28th June 2021 to 2nd July 2021</td>
<td>Complies (Certificate Issued)</td>
</tr>
<tr>
<td>10.</td>
<td>CDSCO / DCA</td>
<td>17th January 2022 to 19th January 2022</td>
<td>Approved (Certificate Issued)</td>
</tr>
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e) Most recent product quality review(s) (PQR)(s) of the concerned WHO API(s):

Nirmatrelvir and Ritonavir – no PQR yet as started manufacturing in 2022.
Dolutegavir sodium (DSG): January to December 2021 manufactured in block 1, 3 and 4. However, no batches were manufactured in this period.

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

Manufacturing record: Ritonavir April 2022

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

Not Applicable

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

No recalls were executed in the last 3 years

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:

Self-inspection documentation was submitted
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):

No warning letter had been issued

k) Out-of-stock situations:

No unforeseen out-of-stock situation is foreseen

l) Additional documents submitted:

N/A

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<tr>
<th>Part 5</th>
<th>Conclusion – Desk assessment outcome</th>
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Based on the GMP evidence received and reviewed, it is considered that a desk assessment may be performed in lieu of a WHO Inspection. The site **Aurore Pharmaceuticals Private Limited** located at, **Unit 1, Plot Nos. 35, 36, 38 to 40, 49 to 51, Phase IV, IDA, Jeedimetla, Medchal-Malkajigiri District, Hyderabad, 500055, India**, is considered to be operating at an acceptable level of compliance with WHO GMP guidelines for APIs.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

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<thead>
<tr>
<th>Part 6</th>
<th>List of guidelines referenced in this inspection report</th>
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   [untitled (digicollections.net)](https://digicollections.net/medicinedocs/documents/s21467en/s21467en.pdf)


9789240020900-eng.pdf (who.int)


https://digicollections.net/medicinedocs/#d/s21438en


https://digicollections.net/medicinedocs/#d/s20177en/

https://digicollections.net/medicinedocs/#d/s20175en/

http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1


Essential Medicines and Health Products Information Portal (digicollections.net)

9789240020900-eng.pdf (who.int)

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


9789240020900-eng.pdf (who.int)

9789240001824-eng.pdf (who.int)