# Clearance

## Application Details

| | |
|---|---|
| **Applicant's Ref:** | Hemofarm - injections |
| **Status:** | Active |
| **Tracking Number:** | MI-2021-CL-06387-1 |
| **Application Type:** | CV - Sterile / Biotech Finished Product |

## Client Details

### Sponsor

| | | | |
|---|---|---|---|
| **Sponsor Name:** | Hameln Pharma Pty Ltd | | |
| **Client Id:** | 71203 | | |
| **Address:** | Level 3 302 Burwood Rd | | |
| **Suburb:** | Hawthorne | **State:** | VIC |
| **Postcode:** | 3122 | **Country:** | Australia |

### Contact Details

| | | | |
|---|---|---|---|
| **Contact Name:** | Tony Whittaker | | |
| **Phone:** | + 61 (0) 412 800 845 | **Fax:** | |
| **Mobile:** | + 61 (0) 412 800 845 | | |
| **Email:** | tonyw@category1pharma.com | | |

### Existing Manufacturer

| | | | |
|---|---|---|---|
| **Manufacturer Name:** | Hemofarm AD | | |
| **Manufacturer ID:** | 47377 | | |
| **Existing Manufacturing Site:** | | | |
| **Manufacturer Site:** | Beogradski Put bb | | |
| **Manufacturer Site ID:** | 65662 | | |
| **Suburb:** | | **State:** | Vrsac |
| **Postcode:** | 26300 | **Country:** | Serbia - Republic of |

## API/Product Details

Product

| Manufacturer Type | Sterility | Manufacturing Class | Dosage Form | Product Code | Manufacturing Steps |
|---|---|---|---|---|---|
| Medicine manufacture | Sterile | Multiple manufacturing steps/Multiple products | Injection, solution | Registered Therapeutic Good | Sterile Finished Product Manufacturer - Excluding Release for Supply |

## Evidence

| | |
|---|---|
| **Is this GMP Clearance application related to a product listing/registration submission or variation of an Australian Register of Therapeutic Goods (ARTG) entry?** | N |
| **Is this a Compliance Verification Assessment?** | Y |

| | |
|---|---|
| **In the Evidence to be provided are you using a Letter of Access to Clearance or Evidence?** | N |

**Supporting Documents**

**Mandatory Certificates or Letters**

| | |
|---|---|
| 1 Current GMP Certificate | Upload Evidence<br>-File Name: 1 Certificate.pdf<br>-Last Inspection Date: 29/04/2020 |

**Mandatory Evidence**

| | | |
|---|---|---|
| ☐ N/A | ☑ 2 Most recent inspection report | Manufacturer to Provide<br>-Delivery Date: 01/07/2021 |
| ☐ N/A | ☑ 3 Regulatory Inspections list | Upload Evidence<br>-File Name: 3 Regulatory Inspection List.pdf |
| ☐ N/A | ☑ 4 Regulatory Actions Details | Upload Evidence<br>-File Name: 4 Regulatory action details.pdf |
| ☐ N/A | ☑ 5 Site Master File / Quality Manual or equivalent | Upload Evidence<br>-File Name: 5 SMF.pdf |
| ☐ N/A | ☑ 6 GMP / Quality / Technical Agreement or equivalent | Upload Evidence<br>-File Name: 6 GMP agreement.pdf |
| ☐ N/A | ☑ 7 List of products intended for supply in Australia | Upload Evidence<br>-File Name: 7 Product list.pdf |
| ☐ N/A | ☑ 8 Release for supply procedure | Upload Evidence<br>-File Name: 8 Release SOP.pdf |
| ☐ N/A | ☑ 9 Validation Master Plan | Upload Evidence<br>-File Name: 9 VMP.pdf |
| ☐ N/A | ☑ 10 Latest Product Quality Review | Upload Evidence<br>-File Name: 10 PQR.pdf |
| ☑ N/A | ☐ 11 Authorised laboratory tests | Select delivery method |

**Optional Evidence**

| | |
|---|---|
| ☐ 12 Manufacturer's declaration for Active Pharmaceutical Ingredients (APIs) | Select delivery method |
| ☐ 13 Certified translation statement | Select delivery method |
| ☐ 14 Copy of the certificate of registration or a letter from the registrar in the manufacturer's country confirming the change of name | Select delivery method |
| ☐ 15 Cover letter detailing extension request & reason | Select delivery method |
| ☐ 16 Cover letter requesting change | Select delivery method |
| ☐ 17 Botanical ingredients evidence for authenticated standard reference materials | Select delivery method |
| ☐ Other | Select delivery method |

## Conditions

| | |
|---|---|
| **Expiry Date:** | 10/05/2023 |
| **Conditions:** | · Clearance limited to ampoule products manufactured in Injections Production Plant (PIP AMP - Ampoules) – Building 23 and visual inspection and leak testing performed in PSP.<br>· Evidence supporting renewal of this clearance must include inspection of aseptically prepared and terminally sterilised product manufacturing lines and processes for the products supplied to Australia.<br>· Issued with TGA COVID-19 extended expiry assessment.<br>· If more recent evidence is available prior to the extended expiry a renewal application should be submitted. |

## Declaration

In submitting this application on behalf of Hameln Pharma Pty Ltd, I **DECLARE** that:

- I am a person authorised to make this application; and
- this application, and any supporting material provided with this application, does not contain any information that is inaccurate, false or misleading.

Further, I **UNDERSTAND** that:

- giving inaccurate, false or misleading information, or omitting to give information in relation to a material particular, is a serious offence under the Criminal Code Act 1995.

By clicking on the Agree button below, I AGREE with all of the above statements.

☑ Agree

We encourage applicants to save a copy of their application prior to submitting their application.