

Application Details

Applicant's Ref: BLOSSOMS CLEARANCE RENEWAL
 Status: Active
 Tracking Number: MI-2019-CL-13500-1
 Application Type: CV - Non-Sterile Finished Product

Client Details

Applicant Details

Applicant Name: Opal Pharmaceuticals Pty Ltd
 Client Id: 67822
 [Redacted] [Redacted] [Redacted] [Redacted]
 [Redacted]

Sponsor Name: Opal Pharmaceuticals Pty Ltd
 Client Id: 67822
 [Redacted] [Redacted] [Redacted] [Redacted] a

Contact Details

Who to contact for further information?
 [Redacted] Applicant
 [Redacted] [Redacted]

Existing Manufacturer

Manufacturer Name: Blossom Pharmaceuticals
 Manufacturer ID: 67858
Existing Manufacturing Site:
 Manufacturer Site: Plot no 21-22 Tivim Industrial estate
 Karaswada Tivim
 Manufacturer Site ID: 108525
 Suburb: Bardez State: Goa
 Postcode: 403 526 Country: India

API/Product Details

Product
Manufacturer Type Sterility Manufacturing Class Dosage Form Product Code Manufacturing Steps

Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Cream	Registered Therapeutic Good	Finished Product Manufacture
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Evidence

Is this GMP Clearance application related to a product listing/registration submission or variation of an Australian Register of Therapeutic Goods (ARTG) entry?	Y
Submission Type:	OTC medicine
Product submission number:	New Antiseptic Cream Dossier as TGA sent Notice to delete the current registrations of Antiseptic cream due to Bufexamac content
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 -File Name: 1 Certificate.pdf -Last Inspection Date: 11/02/2019
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Mandatory Evidence

<input type="checkbox"/> N/A	<input type="checkbox"/> 2 Most recent inspection report	Upload Evidence -File Name: 2 Inspection Report.pdf -Last Inspection Date: 11/02/2019
<input type="checkbox"/> N/A	<input type="checkbox"/> 3 Regulatory Inspections list	Upload Evidence -File Name: 3 Regulatory Inspection List.pdf
<input type="checkbox"/> N/A	<input type="checkbox"/> 4 Regulatory Actions Details	Upload Evidence -File Name: 4 Regulatory Action Details.pdf
<input type="checkbox"/> N/A	<input type="checkbox"/> 5 Site Master File / Quality Manual or equivalent	Upload Evidence -File Name: 5 SMF .zip
<input type="checkbox"/> N/A	<input type="checkbox"/> 6 GMP / Quality / Technical Agreement or equivalent	Upload Evidence -File Name: 6 GMP .pdf
<input type="checkbox"/> N/A	<input type="checkbox"/> 7 List of products intended for supply in Australia	Upload Evidence -File Name: 7 Product list.pdf
<input type="checkbox"/> N/A	<input type="checkbox"/> 8 Release for supply procedure	Upload Evidence -File Name: 8 Release SOP .pdf
<input type="checkbox"/> N/A	<input type="checkbox"/> 9 Validation Master Plan	Upload Evidence -File Name: 9 VMP .pdf
<input type="checkbox"/> N/A	<input type="checkbox"/> 10 Latest Product Quality Review	Upload Evidence -File Name: 10 PQR.pdf
<input type="checkbox"/> N/A	<input type="checkbox"/> 11 Authorised laboratory tests	Select delivery method

Optional Evidence

<input type="checkbox"/> 12 Manufacturer's declaration for Active Pharmaceutical Ingredients (APIs)	Select delivery method
<input type="checkbox"/> 13 Certified translation statement	Select delivery method
<input type="checkbox"/> 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
<input type="checkbox"/> 15 Cover letter detailing extension request & reason	Select delivery method
<input type="checkbox"/> 16 Cover letter requesting change	Upload Evidence -File Name: 16 Letter.pdf
<input type="checkbox"/> 17 Botanical ingredients evidence for authenticated standard reference materials	Select delivery method
<input type="checkbox"/> Other	Select delivery method

Conditions

Expiry Date: 14/08/2022
Conditions:

Declaration

In submitting this application on behalf of Opal Pharmaceuticals 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 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.