



## Clearance

### Variation: Application Details

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**Applicant's Ref:** GMP clearance- Bafna Pharmaceuticals  
**Status:** Active  
**Original Tracking Number:** MI-2023-CL-12637-1  
**Tracking Number:** MI-2020-CL-11031-1  
**Variation Type:** Change Clearance Status

### Client Details

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**Variation Status:** Extend

### Applicant Details

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**Applicant Name:** KSJ Pharmatech  
**Client Id:** 62915  
**Address:** PO BOX 111  
**Suburb:** West Pennant Hills **State:** NSW  
**Postcode:** 2125 **Country:** Australia

### Sponsor

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**Sponsor Name:** SUNMED PHARMA PTY LTD  
**Who will be invoiced for this clearance?** Applicant  
**Client Id:** 78508  
**Address:** Unit 9 5-7 Anella Avenue  
**Suburb:** Castle Hill **State:** NSW  
**Postcode:** 2154 **Country:** Australia

### Contact Details

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**Who to contact for further information?** Applicant  
**Contact Name:** Jai Shankar Kanuru  
**Phone:** 0401 858 985 **Fax:**  
**Mobile:**  
**Email:** jai@ksjpharmatech.com.au

### Existing Manufacturer

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**Manufacturer Name:** Bafna Pharmaceuticals Limited  
**Manufacturer ID:** 54379  
**Existing Manufacturing Site:**  
**Manufacturer Site:** No. 147 Madhavaram - Red Hills Road  
 Grantlyon Village  
**Manufacturer Site ID:** 78576  
**Suburb:** Vadakarai Chennai **State:** Tamil Nadu  
**Postcode:** IN 600052 **Country:** India

### API/Product Details

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Product	<u>Manufacturer Type</u>	<u>Sterility</u>	<u>Manufacturing Class</u>	<u>Dosage Form</u>	<u>Product Code</u>	<u>Manufacturing Steps</u>
Medicine manufacture	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Solid Unit Dosage Forms - Hard Capsules	Registered Therapeutic Good	Finished Product Manufacture

Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Solid Unit Dosage Forms - Tablets	Registered Therapeutic Good	Finished Product Manufacture
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### Status

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**Select new status:** Extend  
**Reason for Extension:** Awaiting GMP Clearance application assessment by TGA  
**Is this your first extension request?** Y  
**Description:** We are submitting this extension application as per the e-mail advice received from TGA on 15 SEP 2023. We request an approval at the earliest as we need to submit OTC applications in the month of October.

### Conditions

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**Expiry Date:** 30/03/2024  
**Conditions:** This GMP clearance is issued on the condition that the GMP agreement will be updated to include dosage form hard capsules prior to commencing commercial supply to Australia.

### Declaration

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In submitting this application on behalf of SUNMED 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.