



# National Medicines Regulatory Authority Sri Lanka

Application FMSA/2020/00229

The Managing Director,  
Pharma Associates,  
116, Layards Broadway, Colombo 14  
2020-02-24

Attention: Manager, Regulatory

## **LETTER OF APPROVAL OF FOREIGN PHARMACEUTICAL MANUFACTURING SITE OF FINISHED DOSAGE FORMS**

Dear Sir/Madam,

NMRA refer to the application dated 2020-01-13 for approval of manufacturing site of: Bafna Pharmaceuticals Ltd.

**Address of the Office of the Manufacturer:** Bafna Tower, New No. 68, Old No. 299, Thambu Chetty Street, Chennai- 600 001, India

**Address of the Manufacturing Site:** No. 147, Madhavaram Redhills High Road, Grantylon Village, Vadakarai Post, Chennai- 600 052, India

Type(s), category (ies) and dosage form(s) of products currently manufactured on

**Category(ies) of Product :** General

**Dosage Form(s) of Products :** Capsules, Tablet

**Product Type(s) :** Non sterile

Evaluation of application for pharmaceutical manufacturing site has been completed.

Approval is granted for the above manufacturing site for the categories of products and Dosage Forms mentioned above.

Approval could be granted, because this is a previously approved manufacturing facility in Sri Lanka.

Yours faithfully,

Dr. Kamal Jayasinghe

CEO/Director General  
National Medicines Regulatory Authority



NB: If you wish to add more types or categories or dosage forms of products other than approved, prior approval of NMRA is mandatory.

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 My No. : 15

රැස්ම අංක : NMRA/MP/026  
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 Your No. :  
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 Date : 26/09/2016

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 தேசிய மருந்துகள் ஒழுங்குமுறை அதிக்கார, சபை  
 National Medicines Regulatory Authority

Evaluation report on Pharmaceutical Manufacturing Facility

Company profile No.	NMRA/MP/026
Name of the Local Agent	Pharma Associates
Address of the Local Agent	No:116, Layards Broadway, Colombo 14.
Name of the Manufacturer	Bafna Pharmaceuticals Ltd.
Address of the Manufacturer-Head Office	Bafna Towers, No.299, Thambu Chetty Street, Chennai-600001.
Address of the Manufacturer-Manufacturing plant	Unit-II: No.147, Madhavaram Redhills High Road, Grantlyon Village, Vadakarai Post, Chennai-600052
Categories of product/s manufactured at site	Tablets Capsules (According to the GMP Certificate)
Evaluation Comments	<ul style="list-style-type: none"> <li>Need GMP Inspection, within six months, because of the past history quality failures otherwise, after one year NMRA Will stop the process dossiers.</li> <li>Provide WHO-GMP Certificate for the oral suspension and oral powders</li> </ul>
Recommendation	Approved for the products other than betalactum ,sex hormones & cytotoxics
Evaluated by	<i>[Signature]</i> Pharmacist/NMRA Date: 2016-10-06
Recommendation of the CP Evaluation Committee	Separate company profile dossiers should be submitted for the separate manufacturing plants (For the unit I plant)  1. <i>[Signature]</i> 2. <i>[Signature]</i> 3. <i>[Signature]</i>
Decision	The site is approved/not approved/can be considered once above conditions are fulfilled  <i>[Signature]</i> CEO/NMRA Date: 6/10/16

Note: This approval letter should be attached to all registration dossiers and sample license applications.  
 Major changes of the manufacturing facility should be immediately informed to the NMR A, Sri Lanka

Established under the National Medicines Regulatory Authority Act no 5 of 2015 and came into operation by gazette bearing no. 1920/28 dated 25.06.2015

No: 120, Norris Canal Road, Colombo 10, Sri Lanka.

*[Signature]*



DEPARTMENT OF FOOD SAFETY AND DRUGS CONTROL ADMINISTRATION  
GOVERNMENT OF TAMILNADU  
359, Anna Salai, Chennai - 600 006, Tamil Nadu.

**CERTIFICATE OF GOOD MANUFACTURING PRACTICES**

[This certificate conforms to the format recommended by the world health organization (general instructions and explanatory notes attached)]

Certificate No: K. Dis. No: 19385/D1/4/2018, Dated: 16.08.2019

On the basis of the inspection carried out 07.03.2019, 08.03.2019 and 20.06.2019 we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

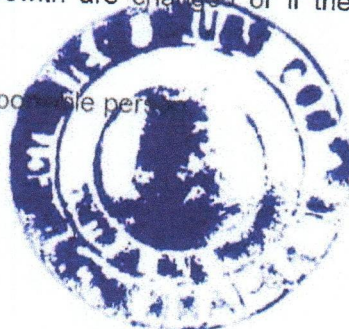
- 1 Name and address of site: M/s. Bafna Pharmaeuticals Ltd., No. 1/15B, New No. 147, Survey No. 30/3, 30/4, 30/5, 30/6, 30/7 & 30/12, Madhavaram Redhills High Road, Grantylon Village, Vadakarai Post, Chennai – 600052.
- 2 Manufacturer's licence number: Form 25 Bearing No: TN00002269 Dated: 08.12.2006  
Form 28 Bearing No. TN00002270 Dated: 08.12.2006

3	Table 1:		
	Dosage form(s)	Category(ies)	Activity(ies)
	Tablets & Capsules (Vide List Attached)	General (Other Than Betalactum, sex hormones & cytotoxic)	Manufacturer

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until **31.12.2021** It becomes invalid if the activities and/or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Name and function of responsible person



K. Sivabalan, B.Pharm.,

*K. Sivabalan*  
16/8/19  
Director of Drugs Control  
Chennai-600 006  
Tamil Nadu.

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