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.

දුරකථන / தொலைபேசி / Telephone) 0112698896/7) 0112695173
ෆැක්ස් / தொலைநகல் / Fax) 0112689704
වෙබ් අඩවිය / இணையத்தளம் / Website)
විද්‍යුත් තැපෑල / மின்னஞ்சல் முகவரி / e-mail)

මගේ අංකය / எனது இல. / My No.)

ඔබේ අංකය / உமது இல. / Your No.) NMRA/MP/026

දිනය / திகதி / Date) 26/09/2016

ජාතික ඖෂධ නියාමන අධිකාරිය

தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார 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	• Need GMP Inspection, within six months, because of the past history quality failures otherwise, after one year NMRA Will stop the process dossiers. • Provide WHO-GMP Certificate for the oral suspension and oral powders
Recommendation	Approved for the products other than betalactum ,sex hormones & cytotoxics.
Evaluated by	.... Pharmacist/NMRA 2016-10-06 Date
Recommendation of the CP Evaluation Committee	Separate company profile dossiers should be submitted for the separate manufacturing plants (For the unit I plant) 1. 2. 3.
Decision	The site is approved/~~not approved/can be considered once above conditions are fulfilled~~ .... CEO/NMRA 6/10/16 Date

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*

350

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 & cytotxic)	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.,

Director of Drugs Control
Chennai-600 006

Director of Drugs Control,
Tamil Nadu.

16/8/19

Email:tndcad@gmail.com **Telephone No.**: 91-44-2433 5068 **Fax No.**:91-44-2432 1830