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FOOD, MEDICINE AND HEALTH CARE

ADMINISTRATION AND CONTROL AUTHORITY OF ETHIOPIA

ቀን: 02 NOV 2021

Date:

Certificate No:-*FMGMP-008*

Certificate of GMP Compliance

On the basis of the inspection carried out **August 2 – 04, 2021** 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 of the manufacturer: **Bafna pharmaceuticals limited**
2. Address of inspected the site: **147 madhavarame red hills road grantlyon village vadakarai Chennai taminaladu, india**
3. Manufacturer's license number: NA

Table 1. List of Pharmaceutical Products, Dosage forms, Categories and Activities

S. No.	*Pharmaceutical products*	Dosage forms	Category(ies)	Activity(ies)
1	**Sterile**			
	1.8 Aseptically prepared	NA		
	1.2 Terminally sterilized	NA		
	1.3 Testing or batch release only	NA		
	Non Sterile			
2	**2.1 Non Sterile products**	• **Tablets** • **Capsules (Hard Gelatin)**	General	• **Manufacturing,Packaging, Laboratory Testing, Batch Control and Batch Release**
	2.2 Testing and batch release only	NA		
3	Biological medicinal products (specify product types under the relevant sections e.g. allergens, antibodies, Vaccines, viral vaccines, rDNA etc.)			
	3.1 Blood products	NA		
	3.2 Immunological products	NA		

ስ.ክ/Fax: 011-1-52 41 22/52 41 23 E-mail: regulatory@efmhaca.gov.et

IN REPLY REFER TO OUR Ref. No.

Medicine Facility Inspection Directorate Director

General Authority for Food, Medicine and Health Care Administration and Control Federal Democratic Republic of Ethiopia

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Date:

3.3 Cell therapy products	NA		
3.4 Gene therapy products	NA		
3.5 Biotechnology products	NA		
3.6 Human or animal extracted products	NA		
3.7 testing and batch release only	NA		

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 FOR 5 years starting from date of inspection. It becomes in valid if the activities and/or categories certified here with are changed or if the site is no longer considered to be in compliance with GMP.

Address of certifying authority: **Food, Medicine and Healthcare Administration and Control Authority, Kirkos Subcity, Africa Avenue, Addis Ababa, Ethiopia**

Tel: +251-115534120

Fax: +251-115521392

Signature: Stamp and date:

Medicine Facility Inspection Directorate Director

Explanatory notes

(1) This certificate certifies the status of the Site listed on the certificate.

(2) The certification number should be traceable within the regulatory authority issuing the certificate.

(3) Where the regulatory authority issues a license for the site this number should be specified.