Ph: (0832)-2459230, 2459226
FAX: (0832)-2459223
Website :www.dfda.goa.gov.in

No.774/MFG/CERT/DFDA/2017/ 2644
Government of Goa,
Dte. Of Food & Drugs Admn.,
"DHANWANTARI"
Opp. Shrine of the Holy Cross
Bambolim, Goa - 403 202
Dated : 19/09 **/2017**

CERTIFICATE

On the basis of the inspection carried out by the Inspecting team for WHO-GMP Certification on **29.05.2017 and 30.05.2017,** this is to 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 Medispray Laboratories Private Limited Plot No. 344/345, Kundaim Industrial Estate, Kundaim, Goa C/o M/s Cipla Ltd. Plot No. L-139 to L-146, Verna Industrial Estate, Verna-Goa

2. Manufacturers license number:
   596/L in Form 25A
   840/L in Form 28A

3. Table 1.

Dosage form(s)	Category(ies)	Activity(ies)
Nasal Sprays	General	Production, packaging, quality control
Eye Drops	General	
Respules	General	
Oral Liquids	General	
Inhalers	General	
Tablets	General	
Capsules	General	
Powder for Inhalation	General	

*** Manufactured in Dedicated facilities.**

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 **17.08.2019.** 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.

Address of certifying authority:
Director, Directorate of Food & Drugs Administration, Govt. of Goa, 'DHANWANTARI', opp. Shrine of the Holy Cross, Bambolim, Goa – 403 202, INDIA.

Name and function of responsible person:
Mr. Salim A. Veljee, Director
Email: Website: **www.dfda.goa.gov.in** Telephone no.: **0832-2459230, 2459226**
Fax no.: **0832-2459223**

Signature:

DIRECTORATE OF FOOD & DRUGS ADMN. BAMBOLIM-GOA

Stamp and date: 19 SEP 2017

Cont.....2/-

[1]This model certificate for GMP is not part of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

Explanatory notes

(1) This certificate, which is in the format recommended by WHO, certifies the status of the site listed in point 1 of 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. Record "not applicable" in case where there is no legal framework for the issuing of a license.

(4) Table 1

List the dosage forms, starting materials, categories and activities.
Examples give below.

Example1

Pharmaceutical Products (s)[2] Dosage form(s)	Category(ies)	Activity(ies)
Metered Dose Inhaler	Anti-Asthamatic	Production, packaging, quality control

Example 2

Pharmaceutical Products (s)[2] Starting materials(s)	Category(ies)	Activity(ies)
Salbutamol Sulphate	Anti- Asthamatic	Synthesis, Purification, packing, labelling

[2] Pharmaceutical Products:
Any medicine intended for human use or veterinary product administered to food-producing animals, presented in its finished dosage for or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.

[3] Starting Materials:
Any substance of a defined quality used in the production of a pharmaceutical product but excluding packaging materials.

Use, whenever available, International Non proprietary Names (INNs) or otherwise national nonproprietary names.

(5) The Certificate remains valid until the specifies date: The certificate becomes invalid if the activities and/or categories certifies are changed or if the site is no longer considered to be in compliance with GMP.

(6) The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials, Good manufacturing practices and inspection, Volume 2, 1999. World Health Organisation, Geneva and subsequent updates.

DIRECTORATE OF FOOD & DRUGS ADMN.
BAMBOLIM-GOA

(Salim A. Veljee)
Director
Food And Drugs Administration.