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NO. 524/MFG/CERT/DFDA/2018/ 3008
GOVERNMENT OF GOA,
DTE. OF FOOD & DRUGS ADMN.
'DHANWANTARI',
OPP. SHRINE OF THE HOLY CROSS
BAMBOLIM, GOA - 403 202
DATED: 16/11/2018

Certificate No. : 524/MFG/WHO-GMP/DFDA/2018/

On the basis of the inspection carried out on 18/06/2018 and 19/06/2018, 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 Medispray Laboratories Pvt. Ltd. Plot No. 344/345, Kundaim Industrial Estate, Kundaim, Goa

2. Manufacturers license number:

323 in form 25

3. Table 1.

Dosage form(s)	Category(ies)	Activity(ies)
Inhalers	General	Production, packaging, quality control

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 12.11.2021. 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.

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:

JYOTI J. SARDESAI, DIRECTOR

Telephone no.: 0832-2459230, 0832-2459226 Fax no.: 0832-2459223

Website: www.dfda.goa.gov.in

Signature:



Stamp and date:

16 NOV 2018



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TRUE COPY

GAURAV K. LAMBAT
NOTARY PUBLIC (GOVT. OF INDIA)



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 licence for the site this number should be specified.
Record "not applicable" in case where there is no legal framework for the issuing of a licence.
- (4) Table 1
List the dosage forms, starting materials, categories and activities. Examples give below.

Example 1

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

Example 2

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

Pharmaceutical Products:

Any medicine intended for human use or veterinary product administered to food-producing animals, presented in its finished dosage form 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.

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.



(Signature)
(JYOTI J. SARDESAI)
Director
Food And Drugs Administration.