



GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

CERTIFICATE NO. : WC-0167

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: M/s. Mangalam Drugs and Organics Ltd.,
Unit-1, Plot No. 187, IInd Phase, GIDC Vapi,
Valsad-396195, Gujarat, India

2. Manufacturer's licence number : G/725

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

List of API(s):

As per list enclosed as Annexure-1

The issuing Regulatory Authority hereby confirms that:

The standards of good manufacturing practice applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection of the plant: 13/07/2022 & 14.07.2022

The Written Confirmation remains valid until: 22.07.2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority: Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road,
New Delhi- 110 002, India

Name and function of responsible person: Dr. V. G. Somani,
Drugs Controller General (India)

E-mail: dci@nic.in,

Telephone no.: +91-11-23236965

Fax no.: +91-11-23236973

Signature

Stamp of the authority and date



27 OCT 2022



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Annexure-1

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**1. Name and address of site: M/s. Mangalam Drugs and Organics Ltd.,
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 Valsad-396195, Gujarat, India**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Aciclovir EP	Manufacturing & Packing
2.	Allopurinol	Manufacturing & Packing
3.	Amodiaquine Hydrochloride IP/USP	Manufacturing & Packing
4.	Amodiaquine Hydrochloride IH	Manufacturing & Packing
5.	Artemether	Manufacturing & Packing
6.	Artesunate	Manufacturing & Packing
7.	Atrovastatin Calcium Trihydrate EP	Manufacturing & Packing
8.	Chloroquine Phosphate	Manufacturing & Packing
9.	Dihydroartemisinin Ph. Int.	Manufacturing & Packing
10.	Furosemide BP/IP/USP/EP	Manufacturing & Packing
11.	Hydroxy Chloroquine Sulphate BP/USP	Manufacturing & Packing
12.	Lumefantrine IH/Ph. Int.	Manufacturing & Packing
13.	Nimesulide BP/EP	Manufacturing & Packing
14.	Piperaquine Phosphate IH	Manufacturing & Packing
15.	Pregabalin IP/EP	Manufacturing & Packing
16.	Primaquine Diphosphate EP	Manufacturing & Packing
17.	Primaquine Phosphate IH/USP	Manufacturing & Packing
18.	Sulfadoxine USP/EP/Ph. Int.	Manufacturing & Packing
19.	Sulphadoxine IP	Manufacturing & Packing
20.	Tenofovir Disproxil Fumarate IH/IP/Ph. Int.	Manufacturing & Packing

ITEM(S) Twenty (20) ONLY

The Written Confirmation remains valid until: 22.07.2025

Signature

[Handwritten Signature]

Stamp of the authority and date



27 OCT 2022