CERTIFICATE OF A PHARMACEUTICALS PRODUCT

Certificate No : **MFG/COPP/2023/0073239073**

Valid Up To :**Two Years from the Date of Issue**

Exporting (Certifying) Country : **India**

Importing (Requesting) Country : **Nepal**

1 Name and dosage form of products : (Brand Name if any) : **Medroxyprogesterone Acetate Injectable Suspension USP 150mg / ml**

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1.1 Active ingredient(s) and amount(s) per unit dose : **Each ml contains:**

Composition	Ingredients	Standards	Strength	UOM	Equivalent to
API	Medroxyprogesterone Acetate	USP	150	Milligram	
Excipients	Excipients	--	0	QS	
Vehicle/Solvent	Water for Injection	USP	0	QS	

1.2 Is this product licensed to be placed on the market for use in the exporting country? **Yes**

1.3 Is the product actually on the market in the exporting country? **Yes**

2A.1	No. of Product license and Date of issue **Product License in Form 28 bearing no. G/28/1808 Date of Issue : 18/06/2021**	2B.1	Applicant for certificate (name and address): **Not Applicable**
2A.2	Product License holder :(Name and address) **SHREE VENKATESH INTERNATIONAL LTD, BLOCK NO. 311, KOSMABA PARDI ROAD, NANDAV, TA.- MANGROL, - 394 125, DISTRICT.- SURAT, GUJARAT, INDIA**	2B.2	Status of Applicant: **Not Applicable**
2A.3	Status of Product-license holder: **manufactures the dosage form**	2B.2.1	For categories b & c have the name and address of the Manufacturer producing the dosage form are: **Not Applicable**
2A.3.1	For category b and c the name and address of the manufacturer producing the dosage form are **Not Applicable**	2B.3	Why is marketing authorization lacking? **Not Applicable**
2A.4	Is Summary Basis of Approval appended? **Not Applicable**	2B.4	Remarks: **Not Applicable**
2A.5	Is the attached, officially approved product information complete and consonant with the license? **Not Applicable**	2B.5	Applicant for certificate, if different from license holder: **Not Applicable**
2A.6	Applicant for certificate, if different from license holder: **No**		

3 Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? **Yes**

3.1 Periodicity of routine inspection (years) : **Once in a Year**

3.2 Has the manufacturer of this type of dosage form been inspected? **Yes**

4 Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the products? **Not Applicable**

Address of Certifying Authority :

The Commissioner
Food & Drugs Control Administration,
Gujarat State, Jivraj Mehta Bhavan,
Block No. 8, 1st Floor, Gandhinagar (INDIA)
Tel:+91-79232-53 417,
Fax: +91-79232-253400

Name & Signature :

(This Document is Digitally Signed)

Bhavika N. Vyas

Asstt. Commissioner
Food & Drugs Control Administration
Gujarat State - Gandhinagar

Date of Issue : **06-Dec-2023**

NOTARY (INDIA) K. D. BAGADIYA SURAT CITY (Guj.) Regd. No. 707 Exp. Dt. 11-2-2024 GOVT. GUJARAT

Digitally signed by Moraru Grigore
Date: 2023.12.14 14:51:09 EET
Reason: MoldSign Signature
Location: Moldova

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K. D. BAGADIYA
NOTARY
SURAT (GUJARAT)
GOVT. OF GUJARAT

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Date: 2023.12.06 14:24:35:30
Reason: Sign
Location: AHD

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