CERTIFICATE OF A PHARMACEUTICALS PRODUCT

Certificate No : **MFG/STATE GMP/COPP/2026/6642299012** Valid Up To :**08/12/2027**

Exporting (Certifying) Country : **India** Importing (Requesting) Country : **Bhutan**

1 Name and dosage form of products : (Brand Name if any) : **Betahistine Dihydrochloride Tablets BP 16 mg**

1.1 Active ingredient(s) and amount(s) per unit dose : **Each Uncoated Tablet Contains:**

Composition	Ingredients	Standards	Strength	UOM	Equivalent to
API	Betahistine Dihydrochloride	BP	16	Milligram	
Excipients	Excipients:	--	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 25 bearing no. G/25/163 Date of Issue : 06/05/2022**	2B.1	Applicant for certificate (name and address): **Not Applicable**
2A.2	Product License holder :(Name and address) **WEST-COAST PHARMACEUTICAL WORKS LTD., F.P.NO.-17&16/5,MELDI ESTATE,B/S. MELDI MATA TEMPLE, NR.GOTA RAILWAY CROSSING, AT & POST.- GOTA , TAL : CITY & DIST : AHMEDABAD - 382 481**	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**

3.3 Do the facilities and operations conform to State GMP as per Schedule M of Drugs and Cosmetic Act 1940 and Rules there under? **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)

RAVAT H. L.

Joint Commisioner
Food & Drugs Control Administration
Gujarat State - Gandhinagar

Date of Issue : **09-Jan-2026**