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

CERTIFICATE NO. : **WC-0155**

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. Vamsi Labs Ltd.,**
A-14/15, M.I.D.C. Area,
Chincholi, Solapur-413 255,
Maharashtra, India

2. Manufacturer's licence number: 25-PD/29

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

As per List enclosed as Annexure-1 & 2

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: 29.06.2021 & 30.06.2021

The Written Confirmation remains valid until: **02nd July, 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

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, Govt. of India
सत्यमेव जयते

13 JUN 2022

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

CERTIFICATE NO. :

Annexure-1
WC-0155

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

Name and address of site: **M/s. Vamsi Labs Ltd.,**
A-14/15, M.I.D.C. Area,
Chincholi, Solapur-413 255,
Maharashtra, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Formoterol Fumarate Dihydrate EP	Manufacturing & Packing
2.	Salmeterol Xinafoate EP	Manufacturing & Packing
3.	Tiotropium Bromide Monohydrate EP	Manufacturing & Packing
4.	Haloperidol EP	Manufacturing & Packing
5.	Budesonide EP	Manufacturing & Packing
6.	Clenbuterol Hydrochloride EP	Manufacturing & Packing
7.	Fluticasone Propionate EP	Manufacturing & Packing
8.	Ipratropium Bromide EP	Manufacturing & Packing

ITEM(S) Eight (08) ONLY

The Written Confirmation remains valid until: 02nd July, 2025

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization • Ministry of Health & Family Welfare, Govt. of India •

13 JUN 2022

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

CERTIFICATE NO. :

Annexure-2
WC-0155

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

Name and address of site: **M/s. Vamsi Labs Ltd.,**
A-14/15, M.I.D.C. Area,
Chincholi, Solapur-413 255,
Maharashtra, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Fenoterol Hydrobromide EP	Manufacturing & Packing

ITEM(S) One (01) ONLY

This certificate is being issued subject to condition that the firm shall obtain NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substances for the purpose of export only, as the above mentioned active substances are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 02nd July, 2025

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, Govt. of India
सत्यमेव जयते

13 JUN 2022