WC-0239

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

CERTIFICATE NO. :

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. Alkaloids Private Limited,
25/3, Gundlapochampally, Medchal-Malkajgiri District,
Telangana-500100, India.

2. Manufacturer's license Number: 141/ RR/AP/95/B/R in Form 25 valid up to 31.12.2022

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 at Annexure- 01 & 02

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: 29th & 30th July, 2019

The Written Confirmation remains valid until: 02nd July, 2022

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

Stamp of the authority and date

Signature

25 NOV 2019

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

Annexure- 02

CERTIFICATE NO. : WC- 0239

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. Alkaloids Private Limited,
25/3, Gundlapochampally, Medchal-Malkajgiri
District, Telangana-500100, India

List of APIs:

Sl. No.	Name of the Active Substance (S)	Activity(ies)
1.	Hyoscine Ph. Eur.	Manufacturing & Packing

ITEM(S) One (1) 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 or sale in India.

The Written Confirmation remains valid until: 02nd July, 2022

Signature

Stamp of the authority and date

25 NOV 2019

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

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CERTIFICATE NO. :

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. Alkaloids Private Limited,
25/3, Gundlapochampally, Medchal-Malkajgiri District,
Telangana-500100, India.

2. Manufacturer's license Number: 141/ RR/AP/95/B/R in Form 25 valid up to 31.12.2022

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 at Annexure- 01 & 02

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: 29th & 30th July, 2019

The Written Confirmation remains valid until: 02nd July, 2022

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

Stamp of the authority and date

Signature

25 NOV 2019

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

Annexure- 01

CERTIFICATE NO. : WC- 0239

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. Alkaloids Private Limited,
25/3, Gundlapochampally, Medchal-Malkajgiri
District, Telangana-500100, India

List of APIs:

Sl. No.	Name of the Active Substance (S)	Activity(ies)
1.	Hyoscine Butylbromide BP/Ph. Eur.	Manufacturing & Packing
2.	Hyoscine Hydrobromide BP/Ph. Eur.	Manufacturing & Packing

ITEM(S) Two (2) Only

The Written Confirmation remains valid until: 02nd July, 2022

Signature

Stamp of the authority and date

25 NOV 2019