

3.1. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?

Yes No Not provided

3.2. Periodicity of routine inspections (years):

At least once a year

3.3. Has the manufacture of this type of dosage form been inspected?

Yes No

3.4. Do the facilities and operations conform with the GMP as recommended by the World Health Organization?

Yes No

All the facilities and operations conform with the GMP as recommended by the WHO.

4.1. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?

Yes No

Address of the certifying authority:

Division of Pharmaceutical and Narcotic Affairs of Ministry of Health

Food and Drug Adm.

M O H

FDA Bldg., No. 3, Fakhr-E-Razi St., Enghelab Ave., Tehran 1314715311, IRAN

P.O.Box: 13145-719

Tel: (+98)-21-66466939

Fax: (+98)-21-66469142

For And On Behalf of

Dr. M. Karimi



REF: 665/18074
Date: 22/5/2018

CERTIFICATE OF PHARMACEUTICAL PRODUCT

This certificate conforms with the format recommended by the World Health Organization.

Exporting / Certifying country:

Islamic Republic of Iran

Importing / Requesting country:

Taiwan

1.1. Name and dosage form of the product:

Noscapine Base API

1.2. Active ingredient(s) and amount(s) per unit dose:

Noscapine Base API

1.3. Excipient(s) and amount(s) per unit dose:

1.4. Is this product licensed to be placed in the market for use in the exporting country?

Yes No

1.5. Is this product actually in the market in the exporting country?

Yes No

2.A.1. Number of product license and date of issue:

665/62299 , July.02.2016

2.A.2. Product license holder (name and address):

Alborz Pharmed

Office: 1st Floor, No. 4, Alborz the First Alley, North Isargaran Ave., North Yadegar Emam Highway, Tehran-Iran. Tel: +98-21-22072571

Factory: No. 2561, 4th Golfam St., 3rd Golnoush St., West Hesabi St., Abouraihan Blvd., Eshtehard industrial neighbourhood, Karaj-Iran.

2.A.3. Status of product license holder:

a b c

2.A.4. Is a summary basis for approval appended?

Yes No

2.A.5. Is the attached, officially approved product information complete and consistent with the license?

Yes No Not provided

REF: 665/18089

Date: 22/5/2018

FREE SALE CERTIFICATE

Name and Dosage Form of the product: Noscapine Base API

Number of Product License: 665/62299

Date of Issue of Product License: July 02.2016

Renewal Date of License:

Approved Composition:

Noscapine Base API

Excipients:

Authorized for sale Under Brand Name of: Noscapine Base

Manufacturer: Alborz Pharmed

Address: Office: 1st Floor, No. 4, Alborz the First Alley, North Isargaran Ave., North Yadegar Emam Highway, Tehran-Iran. Tel: +98-21-22072571
Factory: No. 2561, 4th Golfam St., 3rd Golnoush St., West Hesabi St., Abouraihan Blvd., Eshtehard industrial neighbourhood, Karaj-Iran.

This is to certify that the above-mentioned product has been approved for marketing in the Islamic Republic of IRAN.

For And On Behalf of
Dr M. Karimi

