IFDA
Iran Food and Drug Administration

ISLAMIC REPUBLIC OF IRAN

MINISTRY OF HEALTH AND MEDICAL EDUCATION

Ref: 665/92964
Date: 9/2/2024
Attach: No

CERTIFICATE of PHARMACEUTICAL PRODUCT

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

Exporting / Certifying country:
Islamic Republic of Iran

Importing / Requesting country:
Azerbaijan

1.1. Name and dosage form of the product:
Paclinab 100 mg (Paclitaxel albumin-bound particles)
Lyophilized powder for suspension for infusion

1.2. Active ingredient(s) and amount(s) per unit dose:
Paclitaxel 100 mg

1.3. Excipient(s) and amount(s) per unit dose:
Human serum albumin solution (4744.80 mg), Acetone (1500 mg), Water for injection-WFI (16567 mg)
[Sodium hydroxide, Hydrochloric acid: for pH adjustment]

1.4. Is this product licensed to be placed on the market for use in the exporting country?
☑Yes ☐No

1.5. Is this product actually on the market in the exporting country?
☑Yes ☐No

2.A.1. Number of product license and date of issue:
The registration number is: 1706300113695039.
The number of product license is: 5922596448887503 and the date of issue is: 11/05/2023.

2.A.2. Product license holder (name and address):
Nano Daru Pajuhan Pardis
No. 18, Between Motahari St. & South Etaati St., Marzdaran Blvd., Tehran, Iran.
Tel: +98 (21) 58107
Fax: +98 (21) 8611 1563
Email: Info@nanodaru.com

Digitally signed by Ostapciuc Alexandr
Date: 2024.04.27 12:07:49 EEST
Reason: MoldSign Signature
Location: Moldova

Manufacturing Site: Behnood Pharmed Incubation Center, No. 110, Bahman St., Karafarinan Blvd., Sepehr Industrial Zone, Nazarabad City, Alborz Province, Iran.

Central Building of Iran Food and Drug Administration No.:30,Fakhr Razi St.,Enghelab Ave.,Tehran,Iran Zip Code: 1314715311 Tel:+98 (21) 61927000 Fax:+98 (21) 66405571

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

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 an appropriate frequency based on risk

3.3. Has the manufacture of this type of dosage form been inspected?
☑Yes ☐No

3.4. Do the facilities and operations conform to the GMP as recommended by the World Health Organization?
☑Yes ☐No

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 Central Bldg., No. 30, Fakhr Razi St., Enghelab Ave., Tehran, Iran
Postal Code: 1314715311
Tel: (+98)-21-61927000
Fax: (+98)-21-66405571

Dr. Mohammad Peikanpour
IFDA Director General for
Drugs and Controlled Materials

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