ISLAMIC REPUBLIC OF IRAN
MINSTRY OF HEALTH AND MEDICAL EDUCATION

FOOD AND DRUG ADMINISTRATION

REF: 665/146419

Date: 12/2/2018

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:
Syria

1.1. Name and dosage form of the product:
Oncocap, 500 mg Tablet

1.2. Active ingredient(s) and amount(s) per unit dose:
Capecitabine, 500 mg Tablet

1.3. Excipient(s) and amount(s) per unit dose:
Lactose Anhydrous USP 38/NF 32, Croscarmellose Sodium USP 38/NF 32, Microcrystalline Cellulose USP 38/NF 32, Hydroxypropyl Methylcellulose USP 38/NF 32, Magnesium Stearate USP 38/NF 32, Purified water USP 38 /NF 32, OPADRY In house, Methanol USP 38 /NF 32, Dichloromethane USP 38/NF 32

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:
The registration number of Oncocap 500 mg is: 4425988429744583 and the date of issue is: 20.May.2017

2.A.2. Product license holder (name and address):
Baran Chemical & Pharmaceutical Co.
1st Floor, No. 4, Alborz the First Alley, North Isargaran Ave., North Yadegar Emam Highway, Tehran, Iran. Tel: (+98) 21 22072571

2.A.3. Status of product license holder:
☑a ☐b ☐c
The product license holder manufactures the dosage form in **Sobhan Oncology Pharmaceutical Co.** manufacturing site.
Address: No. 357, 3rd St., Sanat 2 Blvd., Rasht Industrial City, Rasht, Iran. P.O. Box: 4337188657

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 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

(IFDA)