REPUBLIC OF TURKEY
MINISTRY OF HEALTH
TURKISH MEDICINES AND MEDICAL DEVICES AGENCY
Certificate of a Pharmaceutical Product[1]

...e conforms to the format recommended by the World Health Organization
(General instructions and explanatory notes attached)

Date: 02.11.2021

Certificate No : 2021/3424

Exporting Country : Turkey
Importing Country : Iraq

Name and dosage form of product : **Casomid 50 mg Film Coated Tablet**

1.1. Active ingredient(s)[2] and amount(s) per unit dose :[3] :
Bicalutamide -50 mg /tablet

For complete qualitative composition including excipients, see attached.[4]

1.2. Is this product licensed to be placed on the market for use in the exporting country?[5] yes/no *(key in as appropriate)* : **Yes**

1.3. Is this product actually on the market in the exporting country ? Yes/no/unknown *(key in as appropriate):* **Yes**

If the answer to 1.2. is yes, continue with section 2A and omit section 2B.
If the answer to 1.2. is no, omit section 2A and continue with section 2B.[6]

2A.1. Number of product licence[7] and date of issue :
08/11/2018-2018/611

2A.2. Product-licence holder (name and address) :
Onko İlaç Sanayi ve Tic. A.Ş.
Gebze OSB2 Mah. 1700. Sk. No: 1703/2 Çayırova/Kocaeli/Turkey
Manufacturing Site: Onko İlaç Sanayi ve Ticaret A.Ş GOSB 1700. Sk. No: 1703 Çayırova/Kocaeli/Turkey

2A.3. Status of product-licence holder :[8] a/b/c *(key in appropriate category as defined in note 8)*
a

2A3.1. For categories b and c the name and address of the manufacturer producing the dosage form are :[9]
(Key in appropriate category as defined in note 8)

2A.4. Is Summary Basis of Approval appended ?[10] yes/no *(key in as appropriate): No*

2A.5. Is the attached, officially approved product information complete and consonant with the licence ?[11] yes/no/not provided *(key in as appropriate): NOT PROVIDED*

2A.6. Applicant for certificate, if different from licence holder (name and address) :[12] ----------

2B.1. Applicant for certificate *(name and address)* :

2B.2. Status of applicant : a/b/c *(key in appropriate category as defined in note 8)*

2B.2.1. For categories b and c the name and address of the manufacturer producing the dosage form are :[9]

2B.3. Why is marketing authorization lacking ?
Not required/not requested/under consideration/refused (key in as appropriate)

2B.4. Remarks :[13]
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3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced ? yes/no/not applicable[14] *(key in as appropriate) :* **Yes**
If no or not applicable proceed to question 4.

3.1. Periodicity of routine inspections (years) :
In every 3 years.

3.2. Has the manufacture of this type of dosage form been inspected ? yes/no (key in as appropriate) : **Yes**

3.3. Do the facilities and operations conform to GMP as recommended by the World Health Organization)[15] yes/no/not applicable[14] *(key in as appropriate) :* **Yes**

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ?[16] yes/no *(key in as appropriate):* **Yes**

If no, explain :_____

This certificate is valid until 02.11.2023

Address and certifying authority:

REPUBLIC OF TURKEY
MINISTRY OF HEALTH
TURKISH MEDICINES AND MEDICAL DEVICES AGENCY
SÖĞÜTÖZÜ MAH. 2176 SOK. NO:5 ÇANKAYA/ANKARA
FAX: (0312) 218 30 03 PHONE: (0312) 218 30 00

Koyuncu

Name of authorized person

GUTAN KOYUNCU M.Sc. Pharm.
Medicines Departmen

Digitally signed by Gutan Ghenadie
Date: 2021.12.14 16:33:22 EET
Reason: MoldSign Signature
Location: Moldova

General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.

The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheets should be appended, as necessary, to accomodate remarks and explanations.

Explanatory notes

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.
3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.
4. Details of quantitative composition are preferred but their provision is subject to the agreement of the product-licence holder.
5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.
6. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market:
   (a) manufactures the dosage form;
   (b) packages and/or labels a dosage form manufactured by an independent company; or
   (c) is involved in none of the above.
9. This information can only be provided with the consent of the product-licence holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence has to be updated or it is no longer valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC)
12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to be provided to the authority by the applicant.
13. Please indicate the reason that the applicant has provided for not requesting registration.
   (a) the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of export;
   (b) the product has been reformulated with a view to improving its stability under tropical conditions;
   (c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
   (d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
   (e) any other reason, please specify.
14. Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
15. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).
16. This section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

3.2.P.1 Description and composition of the Drug Product

Bicalutamide tablets are white to off white, round, biconvex, film coated tablets debossed "B 50" on one side and plain on other side.

Unit composition:

Each film coated tablet contains:

Name of ingredients	Qty/ tablet in mg	Function	Reference to quality standards (current version)
Active ingredient:			
Bicalutamide*	50.000	Active	INH
Excipients:			
Lactose Monohydrate	56.000	Diluent	Ph. Eur.
Sodium starch glycolate Type A	15.000	Disintegrant	Ph. Eur.
Povidone K- 30	2.500	Binder	Ph. Eur.
Purified water**	q.s.	Vehicle	Ph. Eur.
Magnesium stearate	1.500	Lubricant	Ph. Eur.
Average of core tablet	**125.00**		
Film coating @ :			
Hypromellose E 5	2.650	Film former	Ph. Eur.
Titanium dioxide	0.820	Film former/ opacifier	Ph. Eur.
Macrogol 400	0.530	Plasticizer	Ph. Eur.
Purified water**	q.s.	Vehicle	Ph. Eur.
Average of coated tablet	**129.00**		

*Quantity of Bicalutamide is based on % 100 assay and % 0 LOD, its quantity shall be adjusted with lactose monohydrate.

**Lost during processing, shall not be present in final formulation.

@ Target film coat weight build up is in the range of 3% to 3.4% w/w, quantities are based on 100% coating efficiency.

Ph. Eur. : European Pharmacopoeia

INH : In-house.

Packaging Details (brief description)

Packaging description for bicalutamide Tablets 50 mg

Bicalutamide Tablets 50 mg manufactured by Intas Pharmaceuticals Limited is avaliable in PVC-PVdc blister/aluminium foil packs.

a. PVC/PVdC clear 250/90 is a clear transparent PVC film coated with PVdC and having a specification of 435.00 gsm.
b. Plain peelable aluminium fiol is doft, bright side waterproof laminated to sulphate paper with Heat Seal Lacquer coating on dull side and having a specification of 125.25 gsm.

Hatice SAYGI

Regulatory Affairs Manager

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Tic. Sic. No: 33689 Ilyasbey V.D.: 643 037 2352
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