**REPUBLIC OF TURKEY**

**Ek-1**

**MINISTRY OF HEALTH**

**Turkısh Medıcınes And Medıcal devıces Agency**

**Certificate of a Pharmaceutical Product1**

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

(General instructions and explanatory notes attached) Date:

Certificate No : Exporting Country :  Importing Country :

|  |  |
| --- | --- |
| 1. Name and dosage form of product : | 2B.1. Applicant for certificate *(name and address)* :  --------------------- |
| * 1. Active ingredient(s)2 and amount(s) per unit dose :3 :         For complete qualitative composition including excipients, see attached.4 | 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  --------------------- |
| * 1. Is this product licensed to be placed on the market for use in the exporting country?5 yes/no *(key in as appropriate)* : | 2B.3. Why is marketing authorization lacking ?  Not required/not requested/under  consideration/refused (key in as appropriate)  --------------------- |
| * 1. Is this product actually on the market in the exporting country ? Yes/no/unknown *(key in as appropriate):*   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 | 2B.4. Remarks :13  **----------------------**    3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced ? yes/no/not applicable14 *(key in as appropriate) :*  If no or not applicable proceed to question 4. |
| 2A.1. Number of product licence7 and date of issue : | * 1. Periodicity of routine inspections (years) : |
| 2A.2. Product-licence holder (name and address) : | * 1. Has the manufacture of this type of dosage form been inspected ? yes/no (key in as appropriate) : |
| 2A.3. Status of product-licence holder :8 a/b/c *(key in appropriate category as defined in* *note 8)* | * 1. Do the facilities and operations conform to GMP as recommended by the World Health Organization )15   yes/no/not applicable14 *(key in as appropriate) :* |
| 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)  --------------------- | 1. 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):* |
| 2A.4. Is Summary Basis of Approval appended ?10 yes/no *(key in as appropriate):* ***No*** | ***If no, explain :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*** |
| 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 Provıded*** |  |
| 2A.6. Applicant for certificate, if different from licence  holder (name and address) :12  --------------------- |  |

*This certificate is valid until .....................................*

*Address and certifiying authority:* ***Name of authorized person***

***Republıc of Turkey***

***mınıstry of health***

***Turkısh Medıcınes And Medıcal devıces Agency***

***Söğütözü Mah. 2176 Sok. No:5 Çankaya/ANKARA***

***Fax: (0312) 218 30 03 Phone: (0312) 218 30 00***

**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:
   1. manufactures the dosage form;
   2. packages and/or labels a dosage form manufactured by an independent company; or
   3. 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.
    1. the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of export;
    2. the product has been reformulated with a view to improving its stability under tropical conditions;
    3. the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
    4. the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
    5. 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.

**REPUBLIC OF TURKEY**

**Ek-2**

**MINISTRY OF HEALTH**

## Turkish Medicines and Medical Devices Agency

ANKARA

Date:

Certificate No:

In reply please refer to:

Issued for:

# **GMP and FREE SALES**

## **CERTIFICATE**

*We hereby certify that the below mentioned product produced by................................................................................*

*................................................................................................................................................................................................*

*(Licence holder: ....................................................................................................................................................................*

*...............................................................................................................................................................................................)*

has been authorized to be placed on the market for use in Turkey and is subject to our supervision as stipulated in Turkish Laws.

*Product Name* : .......................................................................................................................

*Registration date and No*  : .......................................................................................................................

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

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We also certify that the manufacturing plant is subject to inspections at suitable intervals and that the manufacturer conforms to the requirements for current GMP as recommended by the World Health Organization in respect to be sold or distributed within the country of origin or to be exported.

Name of authorized person

This certificate is valid until……………………….

Söğütözü Mahallesi 2176. sokak No: 5

Çankaya / ANKARA / TURKEY

PHONE : + 90 312 218 30 00

FAX : + 90 312 218 34 60

**REPUBLIC OF TURKEY**

**Ek-3**

**MINISTRY OF HEALTH**

**Turkısh Medıcınes And Medıcal devıces Agency**

**Certificate of a Pharmaceutical Product1**

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

(General instructions and explanatory notes attached) Date:

Certificate No : Exporting Country :  Importing Country :

|  |  |
| --- | --- |
| 1. Name and dosage form of product :   Local name: Türkiye’deki ismi (İngilizce olarak)  Exporting name: İhracatta kullanılacak ismi | 2B.1. Applicant for certificate *(name and address)* :  --------------------- |
| * 1. Active ingredient(s)2 and amount(s) per unit dose :3 :         For complete qualitative composition including excipients, see attached.4 | 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  --------------------- |
| * 1. Is this product licensed to be placed on the market for use in the exporting country?5 yes/no *(key in as appropriate)* : | 2B.3. Why is marketing authorization lacking ?  Not required/not requested/under  consideration/refused (key in as appropriate)  --------------------- |
| * 1. Is this product actually on the market in the exporting country ? Yes/no/unknown *(key in as appropriate):*   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 | 2B.4. Remarks :13  **----------------------**    3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced ? yes/no/not applicable14 *(key in as appropriate) :*  If no or not applicable proceed to question 4. |
| 2A.1. Number of product licence7 and date of issue : | * 1. Periodicity of routine inspections (years) : |
| 2A.2. Product-licence holder (name and address) : | * 1. Has the manufacture of this type of dosage form been inspected ? yes/no (key in as appropriate) : |
| 2A.3. Status of product-licence holder :8 a/b/c *(key in appropriate category as defined in* *note 8)* | * 1. Do the facilities and operations conform to GMP as recommended by the World Health Organization )15   yes/no/not applicable14 *(key in as appropriate) :* |
| 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)  --------------------- | 1. 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):* |
| 2A.4. Is Summary Basis of Approval appended ?10 yes/no *(key in as appropriate):* ***No*** | ***If no, explain :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*** |
| 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 Provıded*** |  |
| 2A.6. Applicant for certificate, if different from licence  holder (name and address) :12  --------------------- |  |

*This certificate is valid until .....................................*

*Address and certifiying authority:* ***Name of authorized person***

***Republıc of Turkey***

***mınıstry of health***

***Turkısh Medıcınes And Medıcal devıces Agency***

***Söğütözü Mah. 2176 Sok. No:5 Çankaya/ANKARA***

***Fax: (0312) 218 30 03 Phone: (0312) 218 30 00***

**REPUBLIC OF TURKEY**

**MINISTRY OF HEALTH**

**Ek-4**

## Turkish Medicines and Medical Devices Agency

ANKARA

Date:

Certificate No:

In reply please refer to:

Issued for:

# **GMP and FREE SALES**

## **CERTIFICATE**

*We hereby certify that the below mentioned product produced by................................................................................*

*................................................................................................................................................................................................*

*(Licence holder: ....................................................................................................................................................................*

*...............................................................................................................................................................................................)*

has been authorized to be placed on the market for use in Turkey and is subject to our supervision as stipulated in Turkish Laws.

*Product Name* : Local name: Türkiye’deki ismi (İngilizce olarak).........................................

Exporting name: ...........................................................................................

*Registration date and No*  : .......................................................................................................................

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

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We also certify that the manufacturing plant is subject to inspections at suitable intervals and that the manufacturer conforms to the requirements for current GMP as recommended by the World Health Organization in respect to be sold or distributed within the country of origin or to be exported.

Name of authorized person

This certificate is valid until……………………….

Söğütözü Mahallesi 2176. sokak No: 5

Çankaya / ANKARA / TURKEY

PHONE : + 90 312 218 30 00

FAX : + 90 312 218 34 60

**Ek-5**

**REPUBLIC OF TURKEY**

**MINISTRY OF HEALTH**

**Turkısh Medıcınes And Medıcal devıces Agency**

**Statement of Licensing Status of Pharmaceutical Product(s)1**

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

**Certificate No : DATE:**

**Exporting Country:**

**Importing Country :**

**Applicant (name/address):**

|  |  |  |  |
| --- | --- | --- | --- |
| Name of product | Dosage form | Active ingredient(s)2 and amount (s) per unit dose: | Product-licence no. and date of issue3 |
|  |  |  |  |
|  |  |  |  |
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|  |  |  |  |
|  |  |  |  |

The certifying authority undertakes to provide, at the request of the applicant (or, if different, the product-licence holder), a separate and complete Certificate of a Pharmaceutical Product in the format recommended by WHO, for each of the products listed above.

**Name of authorized person**

This statement only indicates the current situation as of the date on which the document was issued.

Söğütözü Mahallesi 2176. sokak No: 5

Çankaya / ANKARA / TURKEY

PHONE : + 90 312 218 30 00

FAX : + 90 312 218 34 60

**General instructions**

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

Forms should be completed using a typewriter to ensure legibility.

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

**Explanatory notes**

1 This statement is intended for use by importing agents who are required to screen bids made in response to an international tender and should be requested by the agent as a condition of bidding.

2 Use, whenever possible, International Non proprietary Names (INNs) or national nonproprietary names.

3 If no product licence has been granted, enter “not required”, “not requested”, “under consideration”, or “refused” as appropriate.

**Ek-6**

**TAAHHÜTNAME**

İmal/İthal ruhsatına sahip olduğumuz ‘’**A**’’ isimli ürünümüz ………….’a ‘’**B**’’ ismi ile ihraç edilecektir. ‘’**B**’’ isimli ürünümüzün formülasyonunun ‘’**A**’’ ile birebir aynı olduğunu ve ülkemizde ‘’**B**’’ markası ile ruhsatlı herhangi bir ürün bulunmadığını taahhüt ederiz.