EK-5

REPUBLIC OF TÜRKİYE
MINISTRY OF HEALTH
TURKISH MEDICINES AND MEDICAL DEVICES AGENCY

Certificate of a Pharmaceutical Product[1]

This certificate conforms to the format recommended by the World Health Organization
(General instructions and explanatory notes overleaf)

Certificate No : **Date:**
Exporting Country : TÜRKİYE
Importing Country :

1. Name and dosage form of product :
Local name:
Exporting name:

1.1. Active ingredient(s)[2] and amount(s) per unit dose :[3] :

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)* :

1.3. 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]

2A.1. Number of product licence[7] and date of issue :

2A.2. Product-licence holder (name and address) :

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

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)*:

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

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]
---

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)* :
If no or not applicable proceed to question 4.

3.1. Periodicity of routine inspections (years) :

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

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)* :

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)*:

If no, explain :_____

Name of authorized person

Address: Söğütözü Mahallesi 2176. Sok. No:5 06520 Çankaya/ANKARA
P. + 90 312 218 30 00