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

Certificate of a Pharmaceutical Product[1]

...cate conforms to the format recommended by the World Health Organization
...al instructions and explanatory notes attached)

16./10./ 2018

Certificate No: 2018/3707

Exporting Country :TURKEY
Importing Country: KYRGYZSTAN

1. Name and dosage form of product :
Adrimisin 10mg Lyophilized Powder for Solution for Injection

1.1. Active ingredient(s)[2] and amount(s) per unit dose :[3]
Doxorubicin HCl* ***10.0mg***
**** Doxorubicin HCl amount is calculated according to the 100% potency.***
(The formula (complete composition) attached)
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 :
228/44- 03.01.2011

2A.2. Product-licence holder (name and address) :
LICENCE HOLDER: SABA İLAÇ SAN.VE TİC.A.Ş
Halkalı Merkez mah. Basın Ekspres cad. No:1
Küçükçekmece-İstanbul/TURKEY

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

2A.3.1. 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)
MANUFACTURING SITE :Powder: DEVA HOLDİNG A.Ş. Çerkezköy Organize Sanayi Bölgesi, Karaağaç Mah.,Fatih Bulvarı, No: 26 Kapaklı Tekirdağ/Turkey
MANUFACTURING SITE : Diluent: DEVA HOLDİNG A.Ş Dumlupınar Mah. Ankara Cad. No: 2 Kartepe, Kocaeli/ Turkey

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]
---

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) : ***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 : ***NOT APPLICABLE***

Name of Authorized Person

F. Handan ÇELİKEL, Pharm. M. Sc.
Head of Herbal and Supportive Medicines Department

This certificate is valid until 16/10/2020

Address and certifying authority:
REPUBLIC OF TURKEY
TURKISH MEDICINES AND MEDICAL DEVICES AGENCY
Söğütözü Mah. 2176. Sokak No:5 Çankaya /Ankara /Turkey
Facsimile: +90 312 218 30 03 Phone: +90 312 218 30 00

Digitally signed b
Date: 2021.09.09
Reason: MoldSig
Location: Moldov

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 accommodate 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 be provided only 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 must be updated or it will cease to be 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 a Summary of Product Characteristics (SPC).

12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission must 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 that 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 7 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.

09.10.2018

ADRIMISIN 10 MG LYOPHILIZED POWDER FOR SOLUTION FOR INJECTION

Name of the Ingredients	Unit Formula (mg/vial)
Doxorubicin HCL*	10.00
Lactose Monohydrate	52.63
Methyl Paraben	1.05 (1.00 + 5 % excess)
Diluent	
Water for injection	5.0 ml

* Doxorubicin HCl amount is calculated according to the 100% potency.

Quality Operations Manager
Seçkin Mazlumoğlu

DEVA HOLDING A.Ş.
Halkalı Merkez Mahallesi
Basın Ekspres Caddesi No:1
34303 K.Çekmece / İST.

ISTANBUL
CHAMBER OF COMMERCE
Member Registry Department

12/12/2018

DEVA HOLDİNG ANONİM ŞİRKETİ

COMPANY HAS BEEN REGISTERED TO OUR CHAMBER UNDER THE REGISTRATION NUMBER 70061

PRESENT APPROVAL DOES NOT COVER THE CONTENT OF THE DOCUMENT.

for the SECRETARY GENERAL
OF THE ISTANBUL CHAMBER OF COMMERCE
MUSTAFA TELCİ

APOSTILLE

(Convention de La Haye du 5 Octobre 1961)

1. Ülke/Country/Pays/Staat TÜRKİYE - LA TURQUIE

İşbu resmi belge/This public document/Le présent acte public/Dieses zeugnis wurde

2. Mustafa TELCİ tarafından imzalanmıştır./Has been signed by/a été signé par/durch ... unterschrieben

3. İmzalayanın sıfatı Yetkili'dır./Acting in the capacity of/Agissant en qualité de/Titel des Unterzeichneten

4. İstanbul Ticaret Odası 'nin mühür/damgasını taşımaktadır-bears the seal/stamp of-/est revétu du sceau/timbre de-trägt Siegel/Stempel von

TASDİK / CERTIFIED / ATTESTE / BEGLAUBIGUNG:

5. Bağcılar Kaymakamlığı' da/at/à/in

6. 12.12.2018 günü/the/le/Am

7. Yazı İşleri Md. Ferda AKSAK tarafından/by/par/durch den/die

8. No : 21195 ile tasdik edilmiştir./No:/sous No:/unter Nr.

9. Mühür - Damga/Seal-stamp/Sceau-timbre/Siegel-Stempel

.....

10. İmza/Signature/Signature/Unterschrift:

.....