REPUBLIC OF TURKEY
MINISTRY OF HEALTH
Turkish Medicines and Medical Devices Agency
Certificate of a Pharmaceutical Product[1]

24/07/2018

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

Certificate No: 2018/3334

Exporting Country: Turkey

Importing Country: Albania

1. Name and dosage form of product:
MİLRİCOR 10 MG/10 ML I.V. SOLUTION FOR INJECTION/INFUSION, AMPOULE

1.1. Active ingredient(s)[2] and amount(s) per unit dose :[3] :
Each ampoule (10 ml) contains 10 mg milrinone.

The formula (complete composition) attached/
For complete qualitative composition including excipients[4]

1.2. Is this product licensed to be placed on the market for use in the exporting country?[5]
YES

1.3. Is this product actually on the market in the exporting country? YES
If the answerto1.2. 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 :
248/18-11 February 2013

2A.2. Product-licence holder (name and address) :
VEM İLAÇ San. ve Tic. A.Ş.
Söğütözü Mahallesi 2177.Cad. No:10 B/49
Çankaya/ANKARA/TURKEY
Factory address:
Çerkezköy Organize Sanayi Bölgesi
Karaağaç Mahallesi Fatih Bulvarı No:38
Kapaklı/TEKİRDAĞ/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

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 : _____

This certificate is valid until 24/07/2020

Address and certifying authority:
REPUBLIC OF TURKEY
Turkish Medicines and Medical DevicesAgency
Söğütözü Mahallesi 2176. Sokak No:5 06520Çankaya/Ankara/Turkey
Facsimile: +90 312 218 34 60 Phone: +90 312 21830 00

Name of Authorized Person
Uğurcan Bahadır ÇELİKEL
Biyolojik ve Destek Ürünler
Daire Başkanı

Digitally signed by Harea Ştefan
Date: 2019.03.19 09:11:45 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 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.

UNIT FORMULA

Name of the product: MİLRİCOR 10 mg/10 ml I.V. Solution for Injection/Infusion, Ampoule

Pharmaceutical form: Sterile apyrogen solution for injection and infusion

Dosage form: 10 mg milrinone in an ampoule of 10 ml

Nominal ampoule capacity: 10 ml

Composition (Ampoule of 10 ml):

	Components	Quantity	Function	Reference
	Active substance			
1	Milrinone	10 mg	Active substance	USP
	Excipients			
2	Anhydrous dextrose	517.10 mg	Osmotic agent	E.P
3	Lactic acid*	q.s for pH=3.2-4.0 (9.5 – 12.9 mg)	Preservative and pH adjuster	E.P
4	Sodium hydroxide**	pH: 3.2 – 4.0	pH adjuster	E.P
5	Water for injection	10 ml	Solvent	E.P

* %90 lactic acid solution is used as preservative and pH adjuster.

** % 10 NaOH solution is used in pH adjustment.

Appearance of solution: Clear, colorless-straw yellow, particle-free solution.

Property of package: Type I, glass, colorless, ampoule with 10 ml capacity

Packaging : 1 x 10 ml ampoule/box

Responsible Manager

Tufan ŞAHAN

VEM İLAÇ SANAYİ VE TİCARET ANONİM ŞİRKETİ
Söğütözü Mh. 2177. Cd. No: 29 06510 Çankaya/ANKARA
Tel: (0.312) 427 43 57-58 Faks: (0.312) 427 43 59
Çankaya Vergi Dairesi 004 048 8027