



**REPUBLIC OF TURKEY**  
**MINISTRY OF HEALTH**  
**TURKISH MEDICINES AND MEDICAL DEVICES AGENCY**  
Certificate of a Pharmaceutical Product<sup>1</sup>

02.08/2018

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

Certificate No : 2018/2765

Exporting Country : Turkey  
Importing Country : Kazakhstan

1. Name and dosage form of product :  
DOBCARD 250 MG/20 ML I.V. CONCENTRATE FOR  
SOLUTION FOR INFUSION AMPOULE
- 1.1. Active ingredient(s)<sup>2</sup> and amount(s) per unit dose :<sup>3</sup>  
It contains 14 mg dobutamine hydrochloride that is  
equivalent to 12.5 mg dobutamine per ml. Each ampoule  
of 20 ml contains 280 mg dobutamine hydrochloride  
that is equivalent to 250 mg dobutamine.  
The formula (complete composition) attached/For  
complete qualitative composition including excipients<sup>4</sup>
- 1.2. Is this product licensed to be placed on the market for  
use in the exporting country?<sup>5</sup>  
YES
- 1.3. Is this product actually on the market in the exporting  
country ? 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.<sup>6</sup>
- 2A.1. Number of product licence<sup>7</sup> and date of issue :  
216/93-17 September 2008
- 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 :<sup>8</sup> a/b/c (key in  
appropriate category as defined in note 8) A
- 2A.3.1. For categories b and c the name and address of the  
manufacturer producing the dosage form are :<sup>9</sup>  
(Key in appropriate category as defined in note 8)
- 2A.4. Is Summary Basis of Approval appended ?<sup>10</sup>  
NO
- 2A.5. Is the attached, officially approved product information  
complete and consonant with the licence ?<sup>11</sup>  
Not Provided
- 2A.6. Applicant for certificate, if different from licence  
holder (name and address) :<sup>12</sup>
- This certificate is valid until 02.08.2020
- 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 :<sup>9</sup>
- 2B.3 Why is marketing authorization lacking ?  
Not required/not requested/under  
consideration/refused (key in as appropriate)
- 2B.4 Remarks :<sup>13</sup>
3. Does the certifying authority arrange for periodic  
inspection of the manufacturing plant in which the  
dosage form is produced ? yes/no/not applicable<sup>14</sup>  
YES
- 3.1 Periodicity of routine inspections (years) :  
3 YEARS
- 3.2 Has the manufacture of this type of dosage form been  
inspected ?  
YES
- 3.3 Do the facilities and operations conform to GMP as  
recommended by the World Health Organization )<sup>15</sup>  
YES
4. Does the information submitted by the applicant satisfy  
the certifying authority on all aspects of the  
manufacture of the product ?<sup>16</sup> yes/no (key in as  
appropriate) : YES  
If no, explain :

Address and certifying authority:  
REPUBLIC OF TURKEY  
TURKISH MEDICINES AND MEDICAL DEVICES AGENCY  
Söğütözü Mahallesi 2176 Sokak No: 5 06520 Çankaya/Ankara/Turkey  
Facsimile: +90 312 218 34 60 Phone: +90 312 218 30 00

Name of Authorized Person  
Uzm. Ec. Z. M. ÇELİKEL  
Bilgisayar Destek Ürünler  
Daire Başkanı





## 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.





DOBCARD 250 mg/20 ml Ampoule  
VEM İlaç San. ve Tic. A.Ş

UNIT FORMULA

UNIT FORMULA

**Name of the product:** DOBCARD 250mg/20ml I.V. Concentrate for Solution for Infusion Ampoule

**Pharmaceutical form:** Concentrate solution for infusion.

**Composition:**

Components	Quantity	Function	Reference
<b>Drug Substance</b>			
Dobutamine Hydrochloride	14 mg/ml (equivalent to 12.5 mg dobutamine base)	Drug substance (Inotropic agent)	USP
<b>Excipients</b>			
Sodium metabisulfite	0.24 mg	Preservative	USP
NaOH or HCl	adequate amount	pH adjustment (pH:3.9-4.1)	USP
Water for Injection	adequate amount (for 1 ml)	Solvent	USP

**Property of package:** Colorless, type I glass ampoule containing 20 ml solution.

**Packaging:** 10 x 20 ml ampoule/box

Tufan ŞAHAN  
Responsible Manager

**VEM İLAÇ**

SANAYİ VE TİCARET ANONİM ŞİRKETİ  
Eskişehir Mh. 2572 Sok. No:10 Kat:1 Çankaya/ANKARA  
Tel: (0312) 427 43 57-58 Fax: (0312) 427 43 59  
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