SÚKL

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Ref. No.: sukls24108/2018 Ref.: R. Holubová Date: 1st February 2018

Certificate of a Pharmaceutical Product[1]

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

No. of Certificate: **sukls24108/2018/1**

Exporting (certifying) country: **CZECH REPUBLIC**

Importing (requesting) country: **CHILE**

1. Name and dosage form of the product: **EQUORAL 25mg, soft-gelatine capsules**
In CZ named as **EQUORAL 25mg, měkká tobolka**

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3]: **mg in capsule**

Ciclosporinum (Ciclosporin) **25**

Excipients:
Ethanolum anhydricum (Absolute ethanol)
Polyglyceroli (3) monooleas (Polyglyceryl-3 oleate)
Polyglyceroli (10) monooleas (Polyglyceryl-10 oleate)
Glyceromacrogoli hydroxystearas (Macrogolglycerol hydroxystearate)
Tocoferolum alfa (Alpha-Tocopherol)

Gelatina (Gelatin)
Glycerolum 85% (Glycerol (85 per cent))
Sorbitolum 70% non cristallisabile (Sorbitol 70 per cent (non-crystallising))
Ferri oxidum flavum (Iron oxide yellow)
Titanii dioxidum (Titanium dioxide)
Glycinum (Glycine)

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.**

2.A.1 Number of product licence[7] and date of issue: **59/081/02-C 3rd April 2002/ 30th April 2014**

2.A.2 Product-licence holder (name and address):
Teva Czech Industries s.r.o., Ostravská 29, č.p. 305, 747 70 Opava - Komárov, Czech Republic

2.A.3 Status of product-licence holder:[8]
A (manufacture, primary and secondary packaging, QC, release)

Name: František Chuchma
Phone number: +420 272 185 832, e-mail: posta@sukl.cz
Signature of the authorised person of the competent authority

2.A.3.1	For categories b and c the name and address of the manufacturer producing the dosage form are:[9] ----------
2.A.4	Is a Summary Basis of Approval appended?[10] **No.**
2.A.5	Is the attached, officially approved product information complete and consonant with the licence?[11] **Not provided.**
2.A.6	Applicant for certificate, if different from licence holder (name and address):[12] ----------
2.B.1	Applicant for certificate (name and address):
2.B.2	Status of applicant: **A/B/C**
2.B.2.1	For categories b and c the name and address of the manufacturer producing the dosage form are:[9]
2.B.3	Why is marketing authorization lacking? **Not required/ not requested/ under consideration/ refused.**
2.B.4	Remarks[13]:
3.	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? **Yes.**
3.1	Periodicity of routine inspections (years): **In a two years period.**
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?[15] **Yes.**[14]
4.	Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product[16]: **Yes.** If no, explain:

Address of certifying authority: **STATE INSTITUTE FOR DRUG CONTROL**
Šrobárova 48, 100 41 Prague 10, Czech Republic

Telephone number: **+420 272 185 111**
Fax number: **+420 271 732 377**

Name of authorized person: František Chuchma Director of the Inspection Section

Signature:

Stamp and date: 1st February 2018

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 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 a Summary of 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:
   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 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.

Name: František Chuchma
Phone number: +420 272 185 832, e-mail: posta@sukl.cz
Signature of the authorised person of the competent authority

APOSTILLE
(CONVENTION DE LA HAYE DU 5 OCTOBRE 1961)

1. *Česká republika / Czech Republic*

   tato veřejná listina / this public document
2. *byla podepsána / has been signed by*

   František Chuchma
3. *ve funkci / acting in the capacity of*

   úředník
4. *opatřena razítkem / bears the seal/stamp of*

   Státní ústav pro kontrolu léčiv

OVĚŘENO / CERTIFIED

5. *v Praze / in Prague* 6. *dne / the* 21.03.2018
7. *Ministerstvem zahraničních věcí České republiky / by the Ministry of Foreign Affairs of the Czech Republic*
8. *čís.* 3045 / 2018 - A
9. *pečeť/razítko / seal/stamp:*
10. *podpis / signature:*

    Bc. David Tichý