

De nuestra consideración:

En relación a la licitación de la referencia (en adelante, "Licitación"), cumplimos con explicar a continuación las razones por las cuales la oferta que se presenta por Laboratorio Chile S.A., cumple con el *criterio técnico* N° 2 y *observación* respectiva del cuadro N° 1, relacionado con los criterio de evaluación técnica, en lo que se refiere a la aprobación de la *European Medicines Agency* ("EMA").

A. El Producto Equoral® (25 mg, 50 mg y 100 mg) Se Encuentra Aprobado de Acuerdo a las Normas de la Unión Europea Utilizadas por la EMA

- El producto Equoral® (cuyo principio activo es ciclospolnira en presentaciones de 25 mg, 50 mg y 100 mg) se encuentra registrado ante el *State Institute for Drug Control* (SÚKL) de la República Checa,¹ según consta en los correspondientes certificados de productos farmacéuticos (*Certificate of Pharmaceutical Product*) que se acompañan (registros sanitarios N°s 59/081/02-C, correspondiente a la presentación de 25 mg; 59/082/02-C, correspondiente a la presentación de 50 mg; y, 59/083/02-C, correspondiente a la presentación de 100 mg).

¹ Véase <http://www.sukl.eu/index.php?lang=2>

- La República Checa es un Estado miembro de la Unión Europea.²
- Todas las agencias de medicamentos nacionales de la Unión Europea (incluida la checa) así como la EMA, deben analizar las solicitudes de registro sanitario de acuerdo a una norma jurídica común que es la *Directiva 2001/83/CE del Parlamento Europeo y del Consejo, de 6 de noviembre de 2001, por la que se establece un código comunitario sobre medicamentos para uso humano*³ ("Código Europeo de Medicamentos").
- Por ello, tanto los registros emitidos por la EMA como por cualquiera de las agencias de medicamentos nacionales de los Estados miembros de la UE (incluida la agencia checa), resuelven las solicitudes de registros sanitarios bajo el mismo estándar regulatorio.

B. Sólo Algunos Productos Farmacéuticos Son Registrados en la EMA

- El registro de un producto farmacéutico dentro de la UE se realiza por dos vías:
 - Mediante la coordinación de instituciones descentralizadas, regulada en el Código Europeo de Medicamentos, es decir, por cada agencia de medicamentos nacional (como es el caso de Equoral®); o
 - El sistema Centralizado, regulado en el *Reglamento (CE) n° 726/2004 del Parlamento Europeo y del Consejo de 31 de marzo de 2004 por el que se establecen procedimientos comunitarios para la autorización y el control de los medicamentos de uso humano y veterinario y por el que se crea la Agencia Europea de Medicamentos ("Reglamento 726")*,⁴ que es el llevado a cabo por la EMA.
- En el Anexo del Reglamento 726, se indican cuáles productos farmacéuticos *deben* aprobarse en forma centralizada, es decir, por la EMA,⁵ que es un listado

² Véase http://europa.eu/about-eu/countries/index_es.htm

³ Disponible en: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0083:ES:HTML>

⁴ Disponible en: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0001:0033:ES:PDF>

⁵ 1. Medicamentos de uso humano desarrollados por medio de uno de los siguientes procesos biotecnológicos: (técnica del ADN recombinante; expresión controlada de codificación de genes para las proteínas biológicamente activas en procariotas y eucariotas, incluidas las células de mamífero transformadas; métodos del hibridoma y del anticuerpo monoclonal.

restrictivo que busca priorizar en qué materias debe focalizar su actuar conforme a criterios de epidemiológicos.

- Equoral® dado que no cae dentro de los criterios del referido listado, sólo puede ser registrado ante una agencia de medicamentos nacional (en este caso la elegida fue la checa), lo que no significa en forma alguna, que el registro sanitario en su análisis de fondo difiera de uno otorgado por la EMA, dado que, como se señaló, ocupan el mismo estándar regulatorio contenido en el Código Europeo de Medicamentos.

C. Interpretación Correcta del Requisito de Aprobación EMA

- En base a lo señalado, el requisito contenido en el *criterio técnico* N° 2 y *observación* respectiva del cuadro N° 1, relacionado con los criterio de evaluación técnica, en lo que se refiere a la aprobación de la EMA sólo puede interpretarse en el sentido que se cumple con tal exigencia, tanto con un registro EMA como de cualquiera otra agencia de medicamentos nacional de un Estado miembro de la UE.

D. Conclusiones

- El producto Equoral® (cuyo principio activo es ciclosporina en presentaciones de 25 mg, 50 mg y 100 mg) se encuentra registrado ante el *State Institute for Drug Control* (SÚKL) de la República Checa, es decir, conforme al Código Europeo de Medicamentos.
- Por tanto cumple plenamente con el requisito contenido en el *criterio técnico* N° 2 y *observación* respectiva del cuadro N° 1, relacionado con los criterio de

2. Medicamentos veterinarios empleados principalmente como potenciadores para fomentar el crecimiento o aumentar el rendimiento de los animales tratados.

3. Medicamentos de uso humano que contengan una sustancia activa nueva que, cuya indicación terapéutica sea el tratamiento de alguna de las enfermedades siguientes:

- el síndrome de inmunodeficiencia adquirida

- el cáncer

- los trastornos neurodegenerativos

- la diabetes,

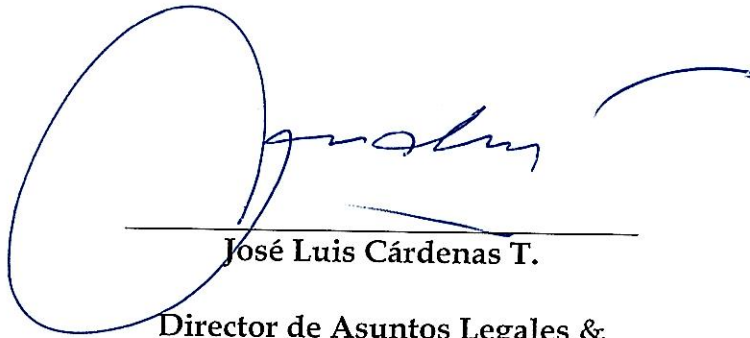
- las enfermedades autoinmunes y otras disfunciones inmunes

- las enfermedades víricas.

4. Los medicamentos designados como medicamentos huérfanos

evaluación técnica, dado que cuenta con un registro sanitario otorgado por una agencia de medicamentos nacional de un Estado miembro de la UE.

Atentamente,

A handwritten signature in blue ink, consisting of a large, stylized 'J' followed by 'Luis Cárdenas T.' and a long horizontal stroke.

José Luis Cárdenas T.
**Director de Asuntos Legales &
Regulatorios**
Laboratorio Chile S.A.
Abogado Universidad de Chile
Master & Doctor en Derecho de
la Universidad de Friburgo
(Alemania)

State Institute for Drug Control[Home](#) / [Medicinal products database](#) / [Detail of medicinal product](#)**EQUORAL 25 MG**

POR CPS MOL 50X25MG

[Main](#) [Texts](#) [Price and reimbursement](#) [Foreign language batch](#) [Specific therapeutic programme](#)

SÚKL code	0010183
Registration Number	59/ 081/02-C
Type of MA	National
Name of the product	EQUORAL 25 MG
Supplement	POR CPS MOL 50X25MG
Route	Oral use
Pharmaceutical form	Capsule, soft
Package	50
Strenght	25MG
Language of the pack	Czech
Wrap type	
Legal status	Prescription-only medicinal products
MA status	R - active MA/authorised medicinal product
MA Holder	TEVA Czech Industries s.r.o., Opava-Komárov
MA Holder country	ČESKÁ REPUBLIKA
Active substance	CICLOSPORIN (CICLOSPORINUM)
ATC group	<u>L04AD01</u>
ATC group name	Cyklosporin

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Ref. No
sukls259173/2011

Ref.
R.Holubová

Date
17th January 12

Certificate of a Pharmaceutical Product¹

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

No. of Certificate: **sukls259173/2011/1**

Exporting (certifying) country: CZECH REPUBLIC

Importing (requesting) country: **CHILE**

1. Name and dosage form of product: EQUORAL 25mg , soft gelatine capsules

1.1 Active ingredient(s)² and amount(s) per unit dose³: mg in capsule

Ciclosporinum

25,00

Excipients:

Ethanolum anhydricum, Glyceromacrogoli hydroxystearas, Polyglyceroli (3) monooleas, Polyglyceroli (10) monooleas, Tocopherolum alfa RRR, Gelatina, Glycerolum 85%, Sorbitolum 70% non cristallisabile, Ferri oxidum flavum, Titanii dioxidum, Glycinum, Atramentum ceruleum.

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

2A.1 Number of product licence⁷ and date of issue: 59/081/02-C 21st May 2008

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

TEVA Czech Industries s.r.o., Ostravská 29, č.p.305, 747 70 Opava-Komárov, Czech Republic

2A.3 Status of product-licence holder:⁸ a

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are:⁹ ---

2A.4 Is Summary Basis of Approval appended?¹⁰ **no**

2A.5 Is the attached, officially approved product information complete and consonant with the licence?¹¹ **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

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

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**

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
yes¹⁴

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** Chief of the Inspection section

Signature:



Stamp and date: **17th January 12**



STATE INSTITUTE FOR DRUG CONTROL
Šrobárova 48, 100 41 PRAGUE 10, CZECH REPUBLIC

Certificate of a Pharmaceutical Product¹

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.

State Institute for Drug Control[Home](#) / [Medicinal products database](#) / [Detail of medicinal product](#)**EQUORAL 50 MG**

POR CPS MOL 50X50MG

[Main](#) [Texts](#) [Price and reimbursement](#) [Foreign language batch](#) [Specific therapeutic programme](#)

SÚKL code	0010184
Registration Number	59/ 082/02-C
Type of MA	National
Name of the product	EQUORAL 50 MG
Supplement	POR CPS MOL 50X50MG
Route	Oral use
Pharmaceutical form	Capsule, soft
Package	50
Strenght	50MG
Language of the pack	Czech
Wrap type	
Legal status	Prescription-only medicinal products
MA status	R - active MA/authorised medicinal product
MA Holder	TEVA Czech Industries s.r.o., Opava-Komárov
MA Holder country	ČESKÁ REPUBLIKA
Active substance	CICLOSPORIN (CICLOSPORINUM)
ATC group	<u>L04AD01</u>
ATC group name	Cyklosporin

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e-mail: posta@sukl.cz
web: www.sukl.cz

Ref. No
sukls259173/2011

Ref.
R.Holubová

Date
17th January 12

Certificate of a Pharmaceutical Product¹

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

No. of Certificate: **sukls259173/2011/2**

Exporting (certifying) country: CZECH REPUBLIC

Importing (requesting) country: **CHILE**

1. Name and dosage form of product: EQUORAL 50mg , soft gelatine capsules

I.I Active ingredient(s) ² and amount(s) per unit dose ³ : mg in capsule	
Ciclosporinum	50,00

Excipients:

Ethanolum anhydricum, Glyceromacrogoli hydroxystearas, Polyglyceroli (3) monooleas, Polyglyceroli (10) monooleas, Tocopherolum alfa RRR, Gelatina, Glycerolum 85%, Sorbitolum 70% non cristallisable, Ferri oxidum flavum, Titanii dioxidum, Glycinum, Atramentum ceruleum.

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**

2A.1 Number of product licence⁷ and date of issue: 59/082/02-C 21st May 2008

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

TEVA Czech Industries s.r.o., Ostravská 29, č.p.305, 747 70 Opava-Komárov, Czech Republic

2A.3 Status of product-licence holder:⁸ a

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are:⁹ ---

2A.4 Is Summary Basis of Approval appended?¹⁰ no

2A.5 Is the attached, officially approved product information complete and consonant with the licence?¹¹ **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

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

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**

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
yes¹⁴

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** Chief of the Inspection section

Signature:



Stamp and date: **17th January 12**



STATE INSTITUTE FOR DRUG CONTROL
Šrobárova 48, 100 41 PRAGUE 10, CZECH REPUBLIC

Certificate of a Pharmaceutical Product¹

General instructions

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Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

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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.

State Institute for Drug Control[Home](#) / [Medicinal products database](#) / [Detail of medicinal product](#)**EQUORAL 100 MG**

POR CPS MOL 50X100MG

[Main](#) [Texts](#) [Price and reimbursement](#) [Foreign language batch](#) [Specific therapeutic programme](#)

SÚKL code	0010185
Registration Number	59/ 083/02-C
Type of MA	National
Name of the product	EQUORAL 100 MG
Supplement	POR CPS MOL 50X100MG
Route	Oral use
Pharmaceutical form	Capsule, soft
Package	50
Strenght	100MG
Language of the pack	Czech
Wrap type	
Legal status	Prescription-only medicinal products
MA status	R - active MA/authorised medicinal product
MA Holder	TEVA Czech Industries s.r.o., Opava-Komárov
MA Holder country	ČESKÁ REPUBLIKA
Active substance	CICLOSPORIN (CICLOSPORINUM)
ATC group	<u>L04AD01</u>
ATC group name	Cyklosporin

[Back to list](#)

e-mail: posta@sukl.cz
web: www.sukl.cz

Ref. No
sukls259173/2011

Ref.
R.Holubová

Date
17th January 12

Certificate of a Pharmaceutical Product¹

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

No. of Certificate: **sukls259173/2011/3**

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

Importing (requesting) country: **CHILE**

1. Name and dosage form of product: **EQUORAL 100mg , soft gelatine capsules**

1.1 Active ingredient(s)² and amount(s) per unit dose³: mg in capsule

Ciclosporinum

100.00

Excipients:

Ethanololum anhydricum, Glyceromacrogoli hydroxystearas, Polyglyceroli (3) monooleas, Polyglyceroli (10) monooleas, Tocopherolum alfa RRR, Gelatina, Glycerolum 85%, Sorbitolum 70% non cristallisable, Ferri oxidum fuscum, Titanii dioxidum, Glycinum, Atramentum ceruleum.

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**

2A.1 Number of product licence⁷ and date of issue: 59/083/02-C 21st May 2008

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

TEVA Czech Industries s.r.o., Ostravská 29, č.p.305, 747 70 Opava-Komárov, Czech Republic

2A.3 Status of product-licence holder:⁸ a

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are:⁹ -----

2A.4 Is Summary Basis of Approval appended?¹⁰ **no**

2A.5 Is the attached, officially approved product information complete and consonant with the licence?¹¹ **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

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

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**

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
yes¹⁴

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** Chief of the Inspection section

Signature: 

Stamp and date: **17th January 12**



STATE INSTITUTE FOR DRUG CONTROL
Šrobárova 48, 100 41 PRAGUE 10, CZECH REPUBLIC

Certificate of a Pharmaceutical Product¹

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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.

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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.

State Institute for Drug Control[Home](#) / [Medicinal products database](#) / [Detail of medicinal product](#)**EQUORAL**

POR SOL 1X50ML/5GM

[Main](#) [Texts](#) [Price and reimbursement](#) [Foreign language batch](#) [Specific therapeutic programme](#)

SÚKL code	0006408
Registration Number	59/ 084/02-C
Type of MA	National
Name of the product	EQUORAL
Supplement	POR SOL 1X50ML/5GM
Route	Oral use
Pharmaceutical form	Oral solution
Package	50ML
Strenght	100MG/ML
Language of the pack	Czech
Wrap type	
Legal status	Prescription-only medicinal products
MA status	R - active MA/authorised medicinal product
MA Holder	TEVA Czech Industries s.r.o., Opava-Komárov
MA Holder country	ČESKÁ REPUBLIKA
Active substance	CICLOSPORIN (CICLOSPORINUM)
ATC group	<u>L04AD01</u>
ATC group name	Cyklosporin

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Date
17th January 12

2B.2 Status of applicant: a /b/c

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

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**

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
yes¹⁴

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** Chief of the Inspection section

Signature: 

Stamp and date: **17th January 12**



STATE INSTITUTE FOR DRUG CONTROL
Šrobárova 48, 100 41 PRAGUE 10, CZECH REPUBLIC

Certificate of a Pharmaceutical Product¹

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.