

Certificación FDA



TEVA
HOSPITALS





DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

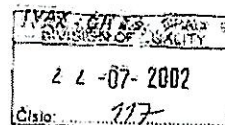
CENTER FOR DRUG EVALUATION AND RESEARCH

Division of Manufacturing and Product Quality
Foreign Inspection Team, HFD-322
7520 Standish Place
Rockville, Maryland, 20855-2737

TELEPHONE: (301) 594-0095
FAX: (301) 594-2202

JUL 10 2002

Dr. Ales Berka, Vice President for Quality
IVAX - CR a.s.
Ostravska 29/305
747 70 Opava - Komarov, Czech Republic



Dear Dr. Berka

We have completed review of the Establishment Inspection Report for the inspection of your non-sterile pharmaceutical manufacturing facility in Opava, by FDA Investigator Charles R. Cote, and Chemist Donald Lech, during March 2002. The inspection found deviations from current good manufacturing practices which were listed on an Inspectional Observations form FDA-483, issued to you at the conclusion of the inspection.

We have reviewed the May 14 & 20, 2002 written response to the FDA-483 submitted by you. The response appears to provide satisfactory corrections and commitments for the deviations listed on the FDA-483. Based on this response, we are currently classifying your facility as acceptable for the manufacturer of Active Pharmaceutical Ingredients and non-sterile pharmaceutical products. The corrections described in the response will be evaluated during the next routine inspection of your facility. It remains your responsibility to assure continued compliance with current good manufacturing practices.

In addition, we enclose a copy of the March 2002 establishment inspection report (EIR) which is provided to you for information purposes. The Agency is working to make its regulatory processes and activities more transparent to the regulated industry. Releasing this EIR to you is part of that effort. The copy provided to you comprises the narrative portion of the report and reflects redactions made by the Agency in accordance with the FOIA and C.F.R. Part 20. This, however, does not preclude you from requesting and possibly, obtaining any additional information under FOIA.

You may contact me at the address or telephone numbers given above if you have any questions regarding this letter. Reference Central File Number 9610088 on all correspondence to this office.

Edwin Meléndez
Compliance Officer

MAR. 29. 2005. 9:37AM FDA OGD CHEM3

NO. 551

ANDA 65-110



OFFICE OF GENERIC DRUGS

Food and Drug Administration
HFD-600, Metro Park North II
7500 Standish Place, Room E138
Rockville, MD 20855-2773
Fax: 301-827-9274

FAX TRANSMISSION COVER SHEET

DATE: Tuesday, March 29, 2005

TO: APPLICANT: IVAX Pharmaceuticals, Inc. TEL: 845-267-2444 X201

ATTN: Patricia Jaworski FAX: 845-268-0117

FROM: Ryan Nguyen, Pharm.D.

PROJECT MANAGER: 301-827-5739

TOTAL NUMBER OF PAGES: 2
(EXCLUDING COVER SHEET)

Special Instructions:

Congratulations!

RECEIVED

MAR 29 2005

Regulatory Affairs Dept.

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If received by someone other than the addressee or a person authorized to deliver this document to the addressee, you are hereby notified that any disclosure, dissemination, copying, or other action to the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us by mail at the above address.



NO. 551 P.



DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 65-110

Food and Drug Admin
Rockville MD 20857

MAR 29 2005

IVAX Pharmaceuticals Inc.
Attention: Patricia Jaworski
U.S. Agent for: IVAX Pharmaceuticals s.r.o.
125 Wells Avenue
Congers, NY 10920

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated October 31, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Cyclosporine Capsules USP (Modified), 25 mg, 50 mg, and 100 mg. We note that this product is subject to the exception provisions of Section 125(d)(2) of Title I of the Food and Drug Administration Modernization Act of 1997.

Reference is also made to your amendments dated July 15, August 2, December 4, and December 12, 2002; January 15, February 11, February 26, and June 6, 2003; March 23, June 24, June 29, June 30, and August 24, 2004; and March 17, 2005.

Reference is also made to the ANDA suitability petition submitted under Section 505(j)(2)(c) of the Act requesting the agency to determine whether Novartis Pharmaceuticals Corporation's Neoral Soft Gelatin Capsules, 50 mg, were withdrawn from sale for reasons of safety or effectiveness. This drug product currently appears in the "Discontinued" section of the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book". The agency determined that they were not withdrawn from sale for reasons of safety or effectiveness. This determination permitted you to file this ANDA, and allows the agency to approve ANDAs for Cyclosporine Capsules USP (Modified), 50 mg.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Cyclosporine Capsules USP (Modified), 25 mg,

and 100 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Neoral® Soft Gelatin Capsules, 25 mg, and 100 mg, respectively, of Novartis Pharmaceuticals, Corp.). The Division of Bioequivalence has also determined that your Cyclosporine Capsules USP (Modified), 50 mg, can be expected to have the same therapeutic effect as that of an equivalent dose of the reference listed drug product upon which the agency relied as the basis of safety and effectiveness. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising, and Communications, HFD-42
5600 Fishers Lane
Rockville, MD 20857

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,



Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 65-078

**OFFICE OF GENERIC DRUGS**

Food and Drug Administration
HFD-600, Metro Park North II
7500 Standish Place, Room E138
Rockville, MD 20855-2773
Fax: 301-827-9274

FAX TRANSMISSION COVER SHEETDATE: Friday, March 25, 2005TO: APPLICANT: IVAX Pharmaceuticals TEL: 845-267-2444 Ext 200ATTN: Patricia Jaworski FAX: 845-268-0117FROM: Ryan Nguyen, Pharm.D.PROJECT MANAGER: 301-827-5739TOTAL NUMBER OF PAGES: 2
(EXCLUDING COVER SHEET)

Special Instructions:

Congratulations!

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MAR 25 2005

Regulatory Affairs Dept.

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If received by someone other than the addressee or a person authorized to deliver this document to the addressee, you are hereby notified that any disclosure, dissemination, copying, or other action to the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us by mail at the above address.



MAR 25 2005 2:45PM FDA OGD CHEM3

NO. 533 P. 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 65-078

Food and Drug Administration
Rockville MD 20857

MAR 25 2005

IVAX Pharmaceuticals, Inc.
Attention: Patricia Jaworski
U.S. Agent for: IVAX Pharmaceuticals s.r.o.
125 Wells Avenue
Congers, NY 10920

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated October 31, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Cyclosporine Oral Solution USP (Modified), 100 mg/mL. We note that this product is subject to the exception provisions of Section 125(d)(2) of Title I of the Food and Drug Administration Modernization Act of 1997.

Reference is also made to your amendments dated January 8, and March 26, 2001; February 12, February 26, September 6, 2003; March 23, June 24, June 29, 2004; and March 17, 2005.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Cyclosporine Oral Solution USP (Modified), 100 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Neoral® Oral Solution, 100 mg/mL, of Novartis Pharmaceuticals Corp.).

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

MAR. 25. 2005 2:46PM FDA OGD CHEN3

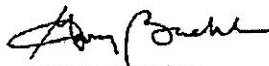
NO. 533 P. 3

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising, and Communications, HFD-42
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Rockville, MD 20857

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Sincerely yours,



Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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

[Back to list](#)



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

Date
17th January 12

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

No: suks259173/2011/1

page 2

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

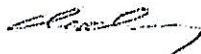
3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization?¹⁵
yes¹⁴

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

[Back to list](#)



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

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

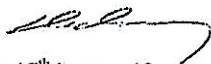
3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization?¹⁵
yes¹⁴

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

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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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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.

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(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.

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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: posla@sukl.cz
web: www.sukl.cz

Date
17th January 12

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

No: suks259173/2011/3

page 2

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

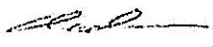
3.2 Has the manufacture of this type of dosage form been inspected? yes

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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(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;

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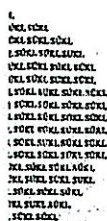
State Institute for Drug Control[Home](#) / [Medicinal products database](#) / [Detail of medicinal product](#)**EQUORAL**

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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web: www.sukl.cz

Date
17th January 12

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

Importing (requesting) country: **CHILE**

1.1 Active ingredient(s) ² and amount(s) per unit dose ³ : mg in 1 ml	
Ciclosporinum	100

Excipients:

Ethanolum anhydricum (120), Glyceromacrogoli hydroxystearas (280), Polyglyceroli (3) monooleas (310), Polyglyceroli (10) monooleas (190).

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: 59/084/02-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

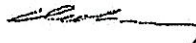
3.2 Has the manufacture of this type of dosage form been inspected? yes

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.