

N<sup>o</sup> A : 1811000198.

TEVA

## Certificate of Analysis

Page 1 of 2

Material: 7500314072

No of certificate: 40000023699

Quality: QDP0021465 V3

Name: EQUORAL-CYCLOSPORINA A 2 5MG (5X10) CPS.

Batch: 100008619

Quantity: 4525 each

Manufacturing Date: 08/2018

Expiry date: 07/2021

| Parameters                                         | Specification                                                                                                                                                                                                                                                                                                | Result                     |
|----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Description                                        | Opaque Yellow soft gel capsules (oval 5) containing yellowish to yellow-brown oily liquid. Each capsule is identified by printing depicting the "hourglass" logo and text: "25 mg".                                                                                                                          | complies                   |
| Identification of cyclosporine                     | The retention time of the major peak in the chromatogram of the Assay Preparation corresponds to that obtained from the Standard Preparation as directed in the Assay.                                                                                                                                       | complies                   |
| Capsule length                                     | 11.9 - 13.1 mm                                                                                                                                                                                                                                                                                               | 12.7 mm                    |
| Capsule width                                      | 6.0 - 7.4 mm                                                                                                                                                                                                                                                                                                 | 7.3 mm                     |
| Mass of capsules fill                              | 244.40 - 298.70 mg                                                                                                                                                                                                                                                                                           | 271.68 mg                  |
| Uniformity of Dosage Units: Content Uniformity     | Meets current USP <905>, Acceptance Value and range (as specified); L1=15.0 and L2=25.0                                                                                                                                                                                                                      | complies                   |
| Dissolution (1)                                    | C62H111N11O12 (cyclosporine) NLT 75(Q) % of the labeled amount                                                                                                                                                                                                                                               | 99 % of the labeled amount |
| Dissolution (2)                                    | 1) All the capsule rupture in not more than 15 minutes. If 1 or 2 tested capsules rupture in more than 15 minutes but not more than 30 minutes, repeat the test on 12 additional capsules. 2) Not more than 2 of 18 tested capsules rupture in more than 15 minutes but not more than 30 minutes. NMT 15 min | 9 min                      |
| Ethanol                                            | NLT 8.0 % (w/w)                                                                                                                                                                                                                                                                                              | 8.9 % (w/w)                |
| content of water                                   | NMT 3.0 % (w/w)                                                                                                                                                                                                                                                                                              | 2.8 % (w/w)                |
| D, L-alpha-tocopherol                              | 0.072 - 0.108 % (w/w)                                                                                                                                                                                                                                                                                        | 0.093 % (w/w)              |
| Content of cyclosporine                            | of cyclosporine 90 - 110 % of the labeled amount                                                                                                                                                                                                                                                             | 99 % of the labeled amount |
| Microbiological examination of nonsterile products |                                                                                                                                                                                                                                                                                                              |                            |
| - A) Total Aerobic Microbial Count                 | NMT 10 <sup>3</sup> CFU/g                                                                                                                                                                                                                                                                                    | < 50 CFU/g                 |
| - B) Total combined yeasts and molds count         | NMT 10 <sup>2</sup> CFU/g                                                                                                                                                                                                                                                                                    | < 50 CFU/g                 |
| - C) Escherichia coli                              | absent/g                                                                                                                                                                                                                                                                                                     | absent/g                   |

Mass of capsules fill - check is carried in a course of production (see in-process control).

I hereby certify that above mentioned information is authentic and accurate. This batch of product has been tested in full compliance with the GMP requirements of the local Regulatory Authority and with the registered specification of the importing country. The testing results were reviewed and found to be compliance with the registered specification.

TEVA Czech Industries s.r.o.

OSTRAVSKA 29/305, 747 70 OPAVA - KOMAROV

CZECH REPUBLIC

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**No of certificate:** 40000023699

**Quality:** QDP0021465 V3

**Name:** EQUORAL-CICLOSPORINA A 2 5MG (5X10) CPS.

**Batch:** 100008619

**Quantity:** 4525 each

**Manufacturing Date:** 08/2018

**Expiry date:** 07/2021

**Date:** 10.10.2018

**Approved by:** Pavel Mucha

QUALIFIED PERSON

This document has been created electronically in the system with electronic signature.

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## Batch Certificate

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Material number: 7500314072

No. of certificate: 40000023699

Quality: QDP0021465 V3

Name: EQUORAL-CICLOSPORINA A 2 5MG (5X10) CPS.

Strength / Potency: Ciclosporin 25 mg

Dosage form: Oral Soft Gelatin Capsules

Storage Conditions: Below 25°C, No cold

Pack Type: Blister

Batch: 100008619

Quantity: 4525 each

Manufacturing Date: 08/2018

Expiry date: 07/2021

Packaging Date: 04 Sep 2018

Country of origin: Czech Republic

Number of marketing authorization: F-14876 CL

Importing Country: CHILE

Investigation: NO

Process Validation Batch: NO

Manufacturing site: TEVA CZECH INDUSTRIES SRO., OSTRAVSKA 29/305, OPAVA KOMAROV, 747 70, Czech Republic

Authorization number: 22975/2/INS/98

Certificate of GMP: SUKLS163772/2014, SUKLS238001/2016

Packing site: TEVA CZECH INDUSTRIES SRO., OSTRAVSKA 29/305, OPAVA KOMAROV, 747 70, Czech Republic

Authorization number: 22975/2/INS/98

Certificate of GMP: SUKLS163772/2014, SUKLS238001/2016

Testing Site: TEVA CZECH INDUSTRIES SRO., OSTRAVSKA 29/305, OPAVA KOMAROV, 747 70, Czech Republic

Authorization number: 22975/2/INS/98

Certificate of GMP: SUKLS163772/2014, SUKLS238001/2016

Releasing Site: TEVA CZECH INDUSTRIES SRO., OSTRAVSKA 29/305, OPAVA KOMAROV, 747 70, Czech Republic

Authorization number: 22975/2/INS/98

Certificate of GMP: SUKLS163772/2014, SUKLS238001/2016

API Material Number: 4235701

API Batch: 5000003268

API Material Name: CICLOSPORIN, PH.EUR.

API manufacturer site: TEVA CZECH INDUSTRIES SRO, TAPI, OSTRAVSKA 29/305, OPAVA KOMAROV, 747 70, Czech Republic

### Artworks reference number:

FOLDING BOX Material: 4134605

Batch: 7000006882

Revision level: 04

FOLDING BOX Material: 4134605

Batch: 7000008623

Revision level: 04

BOOKLET Material: 4134504

Batch: 7000008401

Revision level: 03

BOOKLET Material: 4134504

Batch: 7000007573

Revision level: 03

I hereby certify that the above information is authentic and accurate. This batch of product has been fabricated/ manufactured, including packaging and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing

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Pack Type: Blister

Batch: 100008619

Quantity: 4525 each

Manufacturing Date: 08/2018

Expiry date: 07/2021

Packaging Date: 04 Sep 2018

Country of origin: Czech Republic

country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Date: 10.10.2018

Approved by: Pavel Mucha

QUALIFIED PERSON

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