

NA: 1905000080

TEVA

# Certificate of Analysis

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Material: 7500315072

No of certificate: 40000030224

Quality: QDP0021465 V3

Name: EQUORAL-CYCLOSPORINA A 50MG (5X10) CPS.

Batch: 100011196

Quantity: 2240 each

Manufacturing Date: 02/2019

Expiry date: 01/2022

Parameters	Specification	Result
Description	Opaque Ochre-Yellow soft gel capsules (oblong 11) containing yellowish to yellow-brown oily liquid. Each capsule is identified by printing depicting the IVAX "hourglass" logo and text: "50 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	19.5 - 21.5 mm	20.8 mm
Capsule width	6.9 - 7.7 mm	7.2 mm
Mass of capsules fill	488.7 - 597.3 mg	546.9 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	100 % 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	7 min
Ethanol	NLT 8.0 % (w/w)	9.5 % (w/w)
content of water	NMT 3.0 % (w/w)	2.4 % (w/w)
D, L-alpha-tocopherol	0.072 - 0.108 % (w/w)	0.088 % (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

PHONE (QC DEP.): +420 553 644 521

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**Material:** 7500315072**No of certificate:** 40000030224**Quality:** QDP0021465 V3**Name:** EQUORAL-CICLOSPORINA A 50MG (5X10) CPS.**Batch:** 100011196**Quantity:** 2240 each**Manufacturing Date:** 02/2019**Expiry date:** 01/2022**Date:** 16.4.2019**Approved by:** Pavel Mucha

QUALIFIED PERSON

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## Batch Certificate

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**Material number:** 7500315072 **No. of certificate:** 40000030224  
**Quality:** QDP0021465 V3  
**Name:** EQUORAL-CICLOSPORINA A 50MG (5X10) CPS.  
**Strength / Potency:** Ciclosporin 50 mg  
**Dosage form:** Oral Soft Gelatin Capsules  
**Storage Conditions:** Below 25°C, No cold **Pack Type:** Blister  
**Batch:** 100011196 **Quantity:** 2240 each  
**Manufacturing Date:** 02/2019 **Expiry date:** 01/2022  
**Packaging Date:** 14 Mar 2019  
**Country of origin:** Czech Republic

**Number of marketing authorization:** F-14877  
**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:** 5000004444  
**API Material Name:** CICLOSPORIN, PH.EUR.  
**API manufacturer site:** TEVA CZECH INDUSTRIES SRO., OSTRAVSKA 29/305, OPAVA KOMAROV, 747 70, Czech Republic

### Artworks reference number:

FOLDING BOX	<b>Material:</b> 4134705	<b>Batch:</b> 7000010500	<b>Revision level:</b> 04
FOLDING BOX	<b>Material:</b> 4134705	<b>Batch:</b> 7000008465	<b>Revision level:</b> 04
BOOKLET	<b>Material:</b> 4134504	<b>Batch:</b> 7000010523	<b>Revision level:</b> 03
BOOKLET	<b>Material:</b> 4134504	<b>Batch:</b> 7000008710	<b>Revision level:</b> 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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## Batch Certificate

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**Material number:** 7500315072**No. of certificate:** 40000030224**Quality:** QDP0021465 V3**Name:** EQUORAL-CICLOSPORINA A 50MG (5X10) CPS.**Strength / Potency:** Ciclosporin 50 mg**Dosage form:** Oral Soft Gelatin Capsules**Storage Conditions:** Below 25°C, No cold**Pack Type:** Blister**Batch:** 100011196**Quantity:** 2240 each**Manufacturing Date:** 02/2019**Expiry date:** 01/2022**Packaging Date:** 14 Mar 2019**Country of origin:** Czech Republic

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

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**Date:** 16.04.2019**Approved by:** Pavel Mucha

QUALIFIED PERSON

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