

MA: 1908000311

TEVA

Certificate of Analysis

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Material: 7500314072

No of certificate: 40000034367

Quality: QDP0021465 V3

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

Batch: 100012483

Quantity: 2150 each

Manufacturing Date: 06/2019

Expiry date: 05/2022

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	12.6 mm
Capsule width	6.0 - 7.4 mm	6.9 mm
Mass of capsules fill	244.40 - 298.70 mg	272.71 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)	8.9 % (w/w)
content of water	NMT 3.0 % (w/w)	2.5 % (w/w)
D, L-alpha-tocopherol	0.072 - 0.108 % (w/w)	0.090 % (w/w)
Content of cyclosporine	of cyclosporine 90 - 110 % of the labeled amount	100 % of the labeled amount
Microbiological examination of nonsterile products		
- A) Total Aerobic Microbial Count	NMT 10 ³ CFU/g	< 50 CFU/g
- B) Total combined yeasts and molds count	NMT 10 ² 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 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.

Date / Time: 19.08.2019/16:23:54 CET

Approved by: Pavel Mucha
QUALIFIED PERSON

TEVA Czech Industries s.r.o.

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

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