



TEVA CZECH INDUSTRIES S.R.O., Ostravska 29/305, 747 70 OPAVA-KOMAROV, CZECH REPUBLIC

**PRODUCT  
SPECIFICATIONS  
AND  
CERTIFICATE OF ANALYSIS**

Page 1 of 5

**Product Name:** CYCLOSPORINE

**Control No.:** 74151000218

**Order No.:** JU80019802

**Client Packing Order:** 4500013301

**Customer Name:** TEVA CZECH INDUSTRIES S.R.O.

**Quantity:** 134.200 KG

**Quality Market:** EUR

**Manufacturing Site:** Opava. Czech Republic

**Original Analysis Date:** July 2018

**Manufacturing Date:** July 2018

**Re Test date:** July 2023

**Packaging and storage:** Preserve in tight, light-resistant containers at a temperature up to 25 °C.

TESTS AND METHODS	SPECIFICATIONS	RESULTS*
SV-741410-01, rev.1 TESTS		
<b>Description</b> <i>Visual</i>	White or almost white powder.	Complies
<b>Identity (IR)</b>  <i>EP 2.2.24</i>	IR spectrum of the tested substance exhibits maxima at the same wavelengths as the spectrum of the reference standard obtained under the same conditions.	Complies
<b>Identity (HPLC)</b>  <i>EP, AM-QC-LC002</i>	The retention time of the principle peak in chromatogram of tested sample corresponds to the retention time of the peak in chromatogram of the reference standard	Complies
<b>Assay (HPLC)</b> <i>EP, AM-QC-LC002</i>	98.5 to 101.5 % calculated on dried substance	100.8%

Ostravska 29, c.p. 305, 747 70 Opava-Komarov Czech Republic

Manufacturing site : Ostravska 29/305, 74770, Opava - Komarov, Czech Republic TEL. +420 553 64 1111



TEVA CZECH INDUSTRIES S.R.O., Ostravska 29/305, 747 70 OPAVA-KOMAROV, CZECH REPUBLIC

**PRODUCT  
SPECIFICATIONS  
AND  
CERTIFICATE OF ANALYSIS**

Page 2 of 5

**Product Name:** CYCLOSPORINE

**Control No.:** 74151000218

**Order No.:** JU80019802

**Client Packing Order:** 4500013301

**Customer Name:** TEVA CZECH INDUSTRIES S.R.O.

**Quantity:** 134.200 KG

**Quality Market:** EUR

**Manufacturing Site:** Opava. Czech Republic

**Original Analysis Date:** July 2018

**Manufacturing Date:** July 2018

**Re Test date:** July 2023

**Packaging and storage:** Preserve in tight, light-resistant containers at a temperature up to 25 °C.

TESTS AND METHODS	SPECIFICATIONS	RESULTS*
SV-741410-01, rev.1 TESTS		
<b>Related substances</b> <i>EP, AM-QC-LC002</i> [Abu]5cyclosporine Cyclosporine U Cyclosporine H Dihydrocyclosporine A + cyclosporine V Cyclosporine D Isocyclosporine A Any unspecified impurities Total impurities	NMT 0.30 % NMT 0.40 % NMT 0.30 % NMT 0.60 %  NMT 0.20 % NMT 0.50 % NMT 0.10 % NMT 1.20 %	Less than 0.02% 0.08% Less than 0.02% 0.31%  0.05% 0.13% 0.07% 0.71%
<b>Appearance of solution</b> <i>EP (2.2.1)</i> clarity	Clear	Complies
<b>Appearance of solution</b> <i>EP (2.2.2) Method II</i> colour	NMT Y5, BY5 or R7	Complies
<b>Specific optical rotation</b> <i>EP, (2.2.7)</i>	-193 to -185 ° calculated on dried substance	-189°
<b>Loss on drying</b> <i>EP, (2.2.32)</i>	NMT 2.0 %	0.5%

Ostravska 29, c.p. 305, 747 70 Opava-Komarov Czech Republic

Manufacturing site : Ostravska 29/305, 74770, Opava - Komarov, Czech Republic TEL. +420 553 64 1111



TEVA CZECH INDUSTRIES S.R.O., Ostravska 29/305, 747 70 OPAVA-KOMAROV, CZECH REPUBLIC

**PRODUCT  
SPECIFICATIONS  
AND  
CERTIFICATE OF ANALYSIS**

Page 3 of 5

**Product Name:** CYCLOSPORINE

**Control No.:** 74151000218

**Order No.:** JU80019802

**Client Packing Order:** 4500013301

**Customer Name:** TEVA CZECH INDUSTRIES S.R.O.

**Quantity:** 134.200 KG

**Quality Market:** EUR

**Manufacturing Site:** Opava, Czech Republic

**Original Analysis Date:** July 2018

**Manufacturing Date:** July 2018

**Re Test date:** July 2023

**Packaging and storage:** Preserve in tight, light-resistant containers at a temperature up to 25 °C.

TESTS AND METHODS	SPECIFICATIONS	RESULTS*
SV-741410-01, rev.1 TESTS		
<b>Residual solvents</b> <i>EP (5.4), AM-QC-GC001</i> Acetone Toluene Hexanes Ethyl acetate	NMT 2000 ppm NMT 100 ppm NMT 100 ppm NMT 100 ppm	13ppm Less than 5ppm Less than 1ppm Less than 10ppm
Factors TESTS		
<b>Assay (PhEur)</b> as is	no limit	99.5%
<b>Assay (USP)</b> as is	no limit	99.5%
CS12, rev.0 TESTS		
<b>Particle size</b> <i>AM-QC-OT001</i> 50 % 90 %	NMT 12 um NMT 25 um	3um 6um
IH-01 TESTS		
<b>Heavy metals</b> <i>EP (2.4.8), method C</i>	NMT 20 ppm	Less than 20ppm

Ostravska 29, c.p. 305, 747 70 Opava-Komarov Czech Republic

Manufacturing site : Ostravska 29/305, 74770, Opava - Komarov, Czech Republic TEL. +420 553 64 1111



TEVA CZECH INDUSTRIES S.R.O., Ostravska 29/305, 747 70 OPAVA-KOMAROV, CZECH REPUBLIC

**PRODUCT  
SPECIFICATIONS  
AND  
CERTIFICATE OF ANALYSIS**

Page 4 of 5

**Product Name:** CYCLOSPORINE

**Control No.:** 74151000218

**Order No.:** JU80019802

**Client Packing Order:** 4500013301

**Customer Name:** TEVA CZECH INDUSTRIES S.R.O.

**Quantity:** 134.200 KG

**Quality Market:** EUR

**Manufacturing Site:** Opava, Czech Republic

**Original Analysis Date:** July 2018

**Manufacturing Date:** July 2018

**Re Test date:** July 2023

**Packaging and storage:** Preserve in tight, light-resistant containers at a temperature up to 25 °C.

TESTS AND METHODS	SPECIFICATIONS	RESULTS*
IH-01 TESTS		
Residual solvents EP (5.4), AM-QC-GC001 methanol	NMT 100 ppm	Less than 15ppm

**Remarks:**

1. Conforms to the requirements of the SV-741410-01, rev.1 and Factors and CS12, rev.0 and IH-01 Specifications.
2. Conforms to the current EP monograph.
3. The following residual solvents Class 1, as defined in the ICH Q3C, benzene, carbon tetrachloride, 1,2-Dichloroethane, 1,1-Dichloroethene and 1,1,1- Trichloroethane are not present in the Active Pharmaceutical ingredient.
4. The product meets the requirements for residual solvents USP <467>, EP 5.4 and ICH guide Q3C.
5. The product has been produced and controlled in compliance with GMP rules and valid documentation. Tested parameters comply with the approved specification.
6. We declare that the batch was produced according to the currently valid R1-CEP 2002-152-Rev 04.

Ostravska 29, c.p. 305, 747 70 Opava-Komarov Czech Republic

Manufacturing site : Ostravska 29/305, 74770, Opava - Komarov, Czech Republic TEL. +420 553 64 1111



TEVA CZECH INDUSTRIES S.R.O., Ostravska 29/305, 747 70 OPAVA-KOMAROV, CZECH REPUBLIC

**PRODUCT  
SPECIFICATIONS  
AND  
CERTIFICATE OF ANALYSIS**

Page 5 of 5

**Product Name:** CYCLOSPORINE

**Control No.:** 74151000218

**Order No.:** JU80019802

**Client Packing Order:** 4500013301

**Customer Name:** TEVA CZECH INDUSTRIES S.R.O.

**Quantity:** 134.200 KG

**Quality Market:** EUR

**Manufacturing Site:** Opava. Czech Republic

**Original Analysis Date:** July 2018

**Manufacturing Date:** July 2018

**Re Test date:** July 2023

**Packaging and storage:** Preserve in tight, light-resistant containers at a temperature up to 25 °C.

**Released by Quality Control Manager:**

**Bohumir Biba**

**Signature\*\*:** PP\ Martina Stonova

**27 July 2018 10:46:09**

**Print Date:** 27 July 2018

**QA Approval:** Marek Dominik

(\*) Upon completion of the 'Results' column this document becomes a certificate of analysis **End of C.O.A.**

(\*\*) This document was signed electronically and this is the manifestation of the electronic signature.

Ostravska 29, c.p. 305, 747 70 Opava-Komarov Czech Republic

Manufacturing site : Ostravska 29/305, 74770, Opava - Komarov, Czech Republic TEL. +420 553 64 1111