

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

METAPHARMACEUTICAL

N DE LOTE:

0050122

12/01/2022

**PRODUCT  
SPECIFICATIONS  
AND  
CERTIFICATE OF ANALYSIS**

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**Product Name:** ERGOTAMINE TARTRATE

**Control No.:** 72111001620

**Order No.:** JU00044001

**Client Packing Order:** 305646

**Customer Name:** DCS PHARMA AG

**Quantity:** 24.000 KG

**Quality Market:** EUR,USA

**Manufacturing Site:** Opava, Czech Republic

**Original Analysis Date:** September 2020

**Last Analysis Date:** September 2020

**Manufacturing Date:** August 2020

**Re Test date:** August 2025

**Packaging and storage:** Preserve in tight, light-resistant containers at a temperature from +2 °C to +8°C. Primary package should be maintained in polyethylene bag with desiccant.

TESTS AND METHODS	SPECIFICATIONS	RESULTS*
SV-721110-01, rev.6 TESTS		
<b>Description</b> <i>Visual</i>	White to almost white crystalline powder.	Complies
<b>Identity (IR)</b>  <i>EP, (2.2.24), EP monograph</i>	The IR spectrum of the tested substance exhibits maxima at the same wavelengths as that of the reference standard obtained under the same conditions	Complies
<b>pH value</b> <i>EP, (2.2.3)</i>	4.0 to 5.5	5.5
<b>Related substances (HPLC)</b> <i>AM-AQC-LC1278</i> Ergostine 8-hydroxyergotamine Ergotaminine Any unspecified impurities Total impurities	NMT 0.40 % NMT 0.20 % NMT 0.20 % NMT 0.10 % NMT 0.60 %	0.15% 0.09% 0.07% Less than 0.05% 0.31%
<b>Loss on drying</b> <i>EP, (2.2.32)</i> <i>AM-RD-OT033</i>	NMT 6.0 %	1.2%
<b>Assay (TITR)</b> <i>EP, (2.2.20)</i>	98.0 to 101.0 % calculated on dried substance	100.0%

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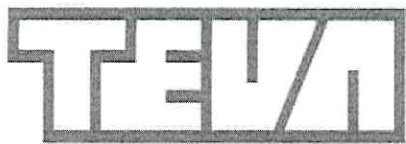
**Re Test date:** August 2025

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TESTS AND METHODS	SPECIFICATIONS	RESULTS*
SV-721110-01, rev.6 TESTS		
<b>Organic residual solvents</b> <i>EP, (5.4)</i> <i>AM-AQC-GC1025</i> acetone toluene methanol	NMT 5000 ppm NMT 890 ppm NMT 3000 ppm	Less than 20ppm Less than 20ppm 1240ppm
SV-721110-12, rev.5 TESTS		
<b>Description</b> <i>Visual</i>	Colourless crystals or white to yellowish-white, crystalline powder.	Complies
<b>Identity HPLC</b>  <i>AM-AQC-LC026 or</i> <i>AM-AQC-LC1278</i>	Retention time of the principal peak in the chromatogram of the tested substance corresponds to the retention time of the peak in chromatogram of the reference standard.	Complies

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TESTS AND METHODS	SPECIFICATIONS	RESULTS*
SV-721110-12, rev.5 TESTS		
<b>Related substances (HPLC)</b> <i>AM-QC-LC026 or</i> <i>AM-AQC-LC1278</i> Ergostine 8-hydroxyergotamine Ergotaminine Any unspecified impurities Total impurities	NMT 0.40 % NMT 0.30 % NMT 0.20 % NMT 0.10 % NMT 1.0 %	0.15% 0.09% 0.07% Less than 0.05% 0.3%
<b>Specific optical rotation</b> <i>USP, &lt;781S&gt;</i>	-165 to -155° calculated on ergotamine base	-160°
<b>Loss on drying</b> <i>USP, &lt;731&gt;, AM-RD-OT033</i>	NMT 5.0 %	1.5%
<b>Assay (TITR)</b> <i>USP, Ergotamine tartrate</i>	97.0 to 100.5 % recalculated on dried substance	100.4%
<b>Organic residual solvents</b> <i>USP &lt;476&gt;, AM\AQC\GC1025</i> acetone toluene methanol	NMT 5000 ppm NMT 890 ppm NMT 3000 ppm	Less than 20ppm Less than 20ppm 1240ppm
CS01, rev.1 TESTS		

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TESTS AND METHODS	SPECIFICATIONS	RESULTS*
CS01, rev.1 TESTS		
<b>Particle size (laser)</b> <i>AM-AQC-OT1012</i>		
D10	NMT 5 um	3um
D50	NMT 15 um	10um
D90	NMT 40 um	21um

**Remarks:**

1. Conforms to the requirements of the SV-721110-01, rev.6 and SV-721110-12, rev.5 and CS01, rev.1 Specifications.
2. Conforms to the current EP monograph and the In house tests.
3. Conforms to the current USP monograph.
4. 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.
5. The product meets the requirements for residual solvents according to the current USP <467>, PhEur Chapter 5.4 and ICH Q3C
6. The product has been produced and controlled in compliance with GMP rules and valid documentation. Tested parameters comply with the approved specification.
7. We declare that the batch was produced according to the currently valid R1-CEP 2007-328-Rev 03.

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**Quality Control Manager:**

**Bohumir Biba**

**Signature\*\*:** PP\ Marketa Szebestova 23 September 2020 11:49:08

**Print Date:** 23 September 2020

**Approval:** Martina Handlova

(\*) 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.

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