

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:** ERGOTAMINE TARTRATE

**Control No.:** 72111001217

**Order No.:** JU70087101

**Client Packing Order:** 303198

**Customer Name:** DCS PHARMA AG

**Quantity:** 25.000 KG

**Quality Market:** EUR,USA

**Manufacturing Site:** Opava. Czech Republic

**Original Analysis Date:** November 2017

**Last Analysis Date:** November 2017

**Manufacturing Date:** October 2017

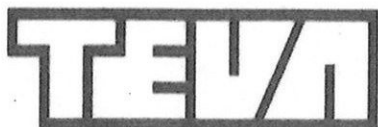
**Re Test date:** October 2022

**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	5.3
<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 %	0.26% 0.09% 0.10% 0.05% 0.50%
<b>Loss on drying</b> <i>EP, (2.2.32)</i> <i>AM-RD-OT033</i>	NMT 6.0 %	1.4%
<b>Assay (TITR)</b> <i>EP, (2.2.20)</i>	98.0 to 101.0 % calculated on dried substance	99.7%

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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 1900ppm
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> AM\QC\LC026 or AM-AQC-LC1278 Ergostine 8-hydroxyergotamine Ergotaminine Any unspecified impurities Total impurities	NMT 0.40 % NMT 0.30 % NMT 0.20 % NMT 0.10 % NMT 1.0 %	0.26% 0.09% 0.10% 0.05% 0.5%
<b>Specific optical rotation</b> USP, <781S>	-165 to -155° calculated on ergotamine base	-163°
<b>Loss on drying</b> USP, <731>, AM-RD-OT033	NMT 5.0 %	1.4%
<b>Assay (TITR)</b> USP, Ergotamine tartrate	97.0 to 100.5 % recalculated on dried substance	99.8%
<b>Organic residual solvents</b> USP <476>, AM\AQC\GC1025 acetone toluene methanol	NMT 5000 ppm NMT 890 ppm NMT 3000 ppm	Less than 20ppm Less than 20ppm 1900ppm
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

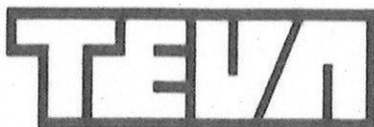
**Remarks:**

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 02.

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<b>Released by Quality Control Manager:</b>  <b>Bohumir Biba</b>	<b>Signature**:</b> PP\Jaroslav Hanzal      21 November 2017 10:42:45
	<b>Print Date: 21 November 2017</b>
	<b>QA Approval: Branko Balla</b>

(\*) 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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