

PRODUCT SPECIFICATIONS AND CERTIFICATE OF ANALYSIS

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Product Name: ERGOTAMINE TARTRATE

Control No.: 72111000822

Order No.: J220016001

Client Packing Order: 13241362 OP

Customer Name: IMCD SWITZERLAND AG

Quantity: 25.000 KG

Quality Market: EUR,USA

Manufacturing Site: TEVA Czech Industries s.r.o.

Original Analysis Date: April 2022

Manufacturing Date: April 2022

Re Test date: April 2027

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.7 TESTS		
Description <i>Visually</i>	White or almost white crystalline powder or colourless crystals.	Complies
Identity (IR) <i>EP (2.2.24)</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
pH value <i>EP (2.2.3)</i>	4.0 to 5.5	5.3
Related substances (HPLC) <i>AM-AQC-LC1278</i> Ergostine (EP imp. C) 8-hydroxyergotamine (EP imp. A) Ergotaminine (EP imp. B) Any unspecified impurities Total impurities	NMT 0.40 % NMT 0.20 % NMT 0.20 % NMT 0.10 % NMT 0.60 %	0.23% 0.06% 0.06% 0.05% 0.40%
Loss on drying <i>EP (2.2.32)</i>	NMT 6.0 %	0.9%

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TESTS AND METHODS	SPECIFICATIONS	RESULTS*
Assay (TITR) <i>EP (2.2.20)</i>	98.0 to 101.0 calculated on dried substance	100.1%
Organic residual solvents <i>AM-AQC-GC1025</i> Acetone Toluene Methanol	NMT 5000 ppm NMT 890 ppm NMT 3000 ppm	Less than 20ppm 30ppm 271ppm
SV-721110-12, rev.5 TESTS		
Description <i>Visual</i>	Colourless crystals or white to yellowish-white, crystalline powder.	Complies
Identity HPLC <i>AM-AQC-LC026 or 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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Related substances (HPLC) <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 %	0.23% 0.06% 0.06% 0.05% 0.4%
Specific optical rotation <i>USP, <781S></i>	-165 to -155° calculated on ergotamine base	-160°
Loss on drying <i>USP, <731>, AM-RD-OT033</i>	NMT 5.0 %	1.0%
Assay (TITR) <i>USP, Ergotamine tartrate</i>	97.0 to 100.5 % recalculated on dried substance	99.9%
Organic residual solvents <i>USP <476>, AMAQC\GC1025</i> acetone toluene methanol	NMT 5000 ppm NMT 890 ppm NMT 3000 ppm	Less than 20ppm 30ppm 271ppm
CS01, rev.1 TESTS		

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TESTS AND METHODS	SPECIFICATIONS	RESULTS*
Particle size (laser) <i>AM-AQC-OT1012</i> D10 D50 D90	NMT 5 um NMT 15 um NMT 40 um	3um 10um 22um

Remarks:

1. Conforms to the requirements of the SV-721110-01, rev.7 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 USP <467>, EP 5.4 and ICH guide Q3C.
6. The product meets the requirements for residual solvents according to the current USP <467>, PhEur Chapter 5.4 and ICH Q3C
7. The product has been produced and controlled in compliance with GMP rules and valid documentation. Tested parameters comply with the approved specification.
8. 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:

Jiri Hendrych

Signature:** PP\Jaroslav Hanzal

18 May 2022 15:23:16

Print Date: 18 May 2022

Approval: Tomas Kolasin

(*) 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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