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

PRODUCT SPECIFICATIONS AND CERTIFICATE OF ANALYSIS

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	
Description *Visual*	White to almost white crystalline powder.	Complies
Identity (IR) *EP, (2.2.24), EP monograph*	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 *EP, (2.2.3)*	4.0 to 5.5	5.3
Related substances (HPLC) *AM-AQC-LC1278*		
Ergostine	NMT 0.40 %	0.26%
8-hydroxyergotamine	NMT 0.20 %	0.09%
Ergotaminine	NMT 0.20 %	0.10%
Any unspecified impurities	NMT 0.10 %	0.05%
Total impurities	NMT 0.60 %	0.50%
Loss on drying *EP, (2.2.32)* *AM-RD-OT033*	NMT 6.0 %	1.4%
Assay (TITR) *EP, (2.2.20)*	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	
Organic residual solvents *EP, (5.4)* *AM-AQC-GC1025*		
acetone	NMT 5000 ppm	Less than 20ppm
toluene	NMT 890 ppm	Less than 20ppm
methanol	NMT 3000 ppm	1900ppm
	SV-721110-12, rev.5 TESTS	
Description *Visual*	Colourless crystals or white to yellowish-white, crystalline powder.	Complies
Identity HPLC *AM-AQC-LC026 or AM-AQC-LC1278*	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		
Related substances (HPLC) *AM\QC\LC026 or AM-AQC-LC1278*		
Ergostine	NMT 0.40 %	0.26%
8-hydroxyergotamine	NMT 0.30 %	0.09%
Ergotaminine	NMT 0.20 %	0.10%
Any unspecified impurities	NMT 0.10 %	0.05%
Total impurities	NMT 1.0 %	0.5%
Specific optical rotation *USP, <781S>*	-165 to -155° calculated on ergotamine base	-163°
Loss on drying *USP, <731>, AM-RD-OT033*	NMT 5.0 %	1.4%
Assay (TITR) *USP, Ergotamine tartrate*	97.0 to 100.5 % recalculated on dried substance	99.8%
Organic residul solvents *USP <476>, AM\AQC\GC1025*		
acetone	NMT 5000 ppm	Less than 20ppm
toluene	NMT 890 ppm	Less than 20ppm
methanol	NMT 3000 ppm	1900ppm
CS01, rev.1 TESTS		

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TESTS AND METHODS	SPECIFICATIONS	RESULTS*
	CS01, rev.1 TESTS	
Particle size (laser) *AM-AQC-OT1012*		
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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Released by Quality Control Manager:	Signature**: PP\ Jaroslav Hanzal 21 November 2017 10:42:45
Bohumir Biba	Print Date: 21 November 2017
	QA Approval: Branko Balla

(*) 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.