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

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	
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	5.5
Related substances (HPLC) *AM-AQC-LC1278*		
Ergostine	NMT 0.40 %	0.15%
8-hydroxyergotamine	NMT 0.20 %	0.09%
Ergotaminine	NMT 0.20 %	0.07%
Any unspecified impurities	NMT 0.10 %	Less than 0.05%
Total impurities	NMT 0.60 %	0.31%
Loss on drying *EP, (2.2.32)* *AM-RD-OT033*	NMT 6.0 %	1.2%
Assay (TITR) *EP, (2.2.20)*	98.0 to 101.0 % calculated on dried substance	100.0%

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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 toluene methanol	 NMT 5000 ppm NMT 890 ppm NMT 3000 ppm	 Less than 20ppm Less than 20ppm 1240ppm
	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 %	0.15%
8-hydroxyergotamine	NMT 0.30 %	0.09%
Ergotaminine	NMT 0.20 %	0.07%
Any unspecified impurities	NMT 0.10 %	Less than 0.05%
Total impurities	NMT 1.0 %	0.3%
Specific optical rotation *USP, <781S>*	-165 to -155° calculated on ergotamine base	-160°
Loss on drying *USP, <731>, AM-RD-OT033*	NMT 5.0 %	1.5%
Assay (TITR) *USP, Ergotamine tartrate*	97.0 to 100.5 % recalculated on dried substance	100.4%
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	1240ppm
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 03.

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Quality Control Manager:	**Signature**:** PP\ Marketa Szebestova 23 September 2020 11:49:08
Bohumir Biba	**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.