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METAPHARMACEUTICAL

N DE LOTE: 0181222

22/12/2022

PRODUCT SPECIFICATIONS AND CERTIFICATE OF ANALYSIS

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 *Visually*	White or almost white crystalline powder or colourless crystals.	Complies
Identity (IR) *EP (2.2.24)*	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 (EP imp. C)	NMT 0.40 %	0.23%
8-hydroxyergotamine (EP imp. A)	NMT 0.20 %	0.06%
Ergotaminine (EP imp. B)	NMT 0.20 %	0.06%
Any unspecified impurities	NMT 0.10 %	0.05%
Total impurities	NMT 0.60 %	0.40%
Loss on drying *EP (2.2.32)*	NMT 6.0 %	0.9%

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TESTS AND METHODS	SPECIFICATIONS	RESULTS*
Assay (TITR) *EP (2.2.20)*	98.0 to 101.0 calculated on dried substance	100.1%
Organic residual solvents *AM-AQC-GC1025*		
Acetone	NMT 5000 ppm	Less than 20ppm
Toluene	NMT 890 ppm	30ppm
Methanol	NMT 3000 ppm	271ppm
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*
Related substances (HPLC) *AM-QC-LC026 or AM-AQC-LC1278*		
Ergostine	NMT 0.40 %	0.23%
8-hydroxyergotamine	NMT 0.30 %	0.06%
Ergotaminine	NMT 0.20 %	0.06%
Any unspecified impurities	NMT 0.10 %	0.05%
Total impurities	NMT 1.0 %	0.4%
Specific optical rotation *USP, <781S>*	-165 to -155° calculated on ergotamine base	-160°
Loss on drying *USP, <731>, AM-RD-OT033*	NMT 5.0 %	1.0%
Assay (TITR) *USP, Ergotamine tartrate*	97.0 to 100.5 % recalculated on dried substance	99.9%
Organic residul solvents *USP <476>, AM\AQC\GC1025*		
acetone	NMT 5000 ppm	Less than 20ppm
toluene	NMT 890 ppm	30ppm
methanol	NMT 3000 ppm	271ppm

CS01, rev.1 TESTS

TEVA Czech Industries s.r.o.

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TESTS AND METHODS	SPECIFICATIONS	RESULTS*
Particle size (laser) *AM-AQC-OT1012*		
D10	NMT 5 um	3um
D50	NMT 15 um	10um
D90	NMT 40 um	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 Q A

(**) This document was signed electronically and this is the manifestation of the electronic signature.

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