

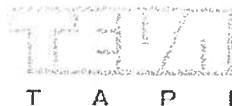
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T A P I

PRODUCT SPECIFICATIONS AND CERTIFICATE OF ANALYSIS		
Page 1 of 3		
Product Name: Amitriptyline Hydrochloride		
Control No.: 202090017	Order No.: 6U70023001	Client Packing Order: 225240
Customer Name: LABORATORIO CHILE S.A.		
Quantity: 150.000 KG	Quality Market: USA	
Manufacturing Site: PLANTEX LTD. - NETANYA	Original Analysis Date: 10-July-2017	
Manufacturing Date: May 2017		
Re Test date: May 2022		
Packaging and storage: Preserve in tight containers at 25°C. Excursions permitted between 15°C and 40°C.		
TESTS AND METHODS	SPECIFICATIONS	RESULTS*
USP Based TESTS		
Description	White or practically white, crystalline powder or small crystals.	Conforms
Identification by FT-IR (USP<197>)	The infrared absorption spectrum of the preparation of the test specimen exhibits maxima only at the same wavelengths as that of a similar preparation of the corresponding USP Reference standard	Conforms
Identification by Chlorides (USP<191>)	Conforms to test criteria.	Conforms
Identification (by HPLC)	The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay.	Conforms
Loss on drying (USP<731>)	Not more than 0.50 %	Less than 0.05%
Residue on ignition (USP<281>)	Not more than 0.10 %	Less than 0.05%
pH (USP<791>)	between 5.0 and 6.0 (in solution 1 in 100)	5.5
Heavy metals (USP Method II<231>)	Not more than 10 ppm	Less than 10ppm

Plantex Ltd
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Manufacturing site : 1 Hakadar St., Industrial Zone, PO. Box 160 Netanya 4210101, Israel TEL. 972-9-8604333
FAX. 972-9-8339063

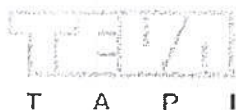


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PRODUCT SPECIFICATIONS AND CERTIFICATE OF ANALYSIS		
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Product Name: Amitriptyline Hydrochloride Control No.: 202090017 Order No.: 6U70023001 Client Packing Order: 225240 Customer Name: LABORATORIO CHILE S.A. Quantity: 150.000 KG Quality Market: USA Manufacturing Site: PLANTEX LTD. - NETANYA Original Analysis Date: 10-July-2017 Manufacturing Date: May 2017 Re Test date: May 2022 Packaging and storage: Preserve in tight containers at 25°C. Excursions permitted between 15°C and 40°C.		
TESTS AND METHODS	SPECIFICATIONS	RESULTS*
USP Based TESTS		
Organic Impurities		
Amitriptyline related compound A	Not more than 0.05%	Less than 0.02%
Amitriptyline related compound B	Not more than 0.15%	Less than 0.03%
Nortriptyline	Not more than 0.15%	Less than 0.03%
Cyclobenzaprine	Not more than 0.15%	Less than 0.03%
Any individual unspecified impurity	Not more than 0.10 %	Less than 0.03%
Total impurities	Not more than 1.0%	Less than 0.1%
Assay	98.0 % - 102.0 % (on dried basis)	101.0%
IN-HOUSE GENERAL TESTS		
Residual Solvents (2020-IH-RS)		
Acetone	Not more than 500 ppm	19ppm
Toluene	Not more than 890 ppm	41ppm
IN-HOUSE PHYSICAL PROPERTIES TESTS		
Particle size distribution (2020-PHY)		
	Not less than 55 % smaller than 38µm	67% smaller than 38µm
	Not less than 65 % smaller than 53µm	80% smaller than 53µm
	Not less than 95 % smaller than 125µm	98% smaller than 125µm

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Packaging and storage: Preserve in tight containers at 25°C. Excursions permitted between 15°C and 40°C.

TESTS AND METHODS	SPECIFICATIONS	RESULTS*
IN-HOUSE PHYSICAL PROPERTIES TESTS		
Bulk density	0.300 g/cm ³ - 0.440 g/cm ³	0.369g/cm ³
Tapped density	0.500 g/cm ³ - 0.700 g/cm ³	0.568g/cm ³

Remarks:

1. Conforms to the requirements of the USP Based and IN-HOUSE GENERAL and IN-HOUSE PHYSICAL PROPERTIES Specifications.
2. The product meets the requirements for residual solvents USP <467> and ICH guide Q3C. The non-ICH solvents are supported by suitable qualification information.
3. Corresponds to Current USP Pharmacopeia.

Released by Quality Control Manager: Ariela Abiri	Signature**: PP\Orna Cohen Zedek 4 September 2017 10:26:14 Print Date: 4 September 2017
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(*) 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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