T A P I

170P000083

PRODUCT SPECIFICATIONS AND CERTIFICATE OF ANALYSIS

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 chromtogram of the Assay preparation corresponds to that in the chromtogram of the Standrad 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
5 Basel Street, P.O.Box 3190 Petach-Tikva 4951033, Israel

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

T A P I

PRODUCT SPECIFICATIONS AND CERTIFICATE OF ANALYSIS

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

Plantex Ltd
5 Basel Street, P.O.Box 3190 Petach-Tikva 4951033, Israel

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

TAPI

PRODUCT SPECIFICATIONS AND CERTIFICATE OF ANALYSIS

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*
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:	Signature**: PP\ Orna Cohen Zedek 4 September 2017 10:26:14
Aricla Abiri	Print Date: 4 September 2017

(*) 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.

Plantex Ltd
5 Basel Street, P.O.Box 3190 Petach-Tikva 4951033, Israel

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