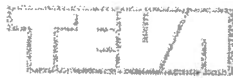


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T A P I

**PRODUCT
SPECIFICATIONS
AND
CERTIFICATE OF ANALYSIS**

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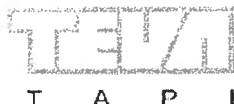
Product Name: Imipramine Hydrochloride**Control No.:** 200100817**Order No.:** 6U60039801**Client Packing Order:** 220743**Customer Name:** LABORATORIO CHILE S.A.**Quantity:** 100.000 KG**Quality Market:** USA**Manufacturing Site:** PLANTEX LTD. - NETANYA**Original Analysis Date:** 13-July-2017**Last Analysis Date:** 16-July-2017**Manufacturing Date:** June 2017**Re Test date:** June 2022

Packaging and storage: Preserve in tight containers at 25°C. Excursions permitted up to 40°C.
Packed with desiccant.

TESTS AND METHODS	SPECIFICATIONS	RESULTS*
IN-HOUSE USP BASED TESTS		
Description 2001-IH-USP Based	White to off-white, crystalline powder.	Conforms
Identification (By IR) Infrared absorption <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 Standrd.	Conforms
Identification (By HPLC) 2001-IH-USP Based	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
Identification by Chemical Reaction 2001-IH-USP Based Chemical reaction	Conforms to test criteria.	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%

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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



PRODUCT SPECIFICATIONS AND CERTIFICATE OF ANALYSIS

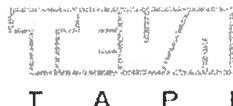
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Product Name: Imipramine Hydrochloride	Order No.: 6U60039801
Control No.: 200100817	Client Packing Order: 220743
Customer Name: LABORATORIO CHILE S.A.	
Quantity: 100.000 KG	Quality Market: USA
Manufacturing Site: PLANTEX LTD. - NETANYA	Original Analysis Date: 13-July-2017
	Last Analysis Date: 16-July-2017
Manufacturing Date: June 2017	Re Test date: June 2022
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TESTS AND METHODS	SPECIFICATIONS	RESULTS*
IN-HOUSE USP BASED TESTS		
Heavy metals <i>USP <Method II 281></i>	Not more than 0.001 %	Less than 0.001%
Related compounds (by HPLC) <i>2001-IH-USP Based</i>		
Iminodibenzyl	Not more than 0.10 %	Less than 0.05%
N-(dimethylaminopropyl)iminostilben c	Not more than 0.10 %	Less than 0.05%
Any other impurity	Not more than 0.10 %	Less than 0.05%
Total impurities	Not more than 1.0 %	Less than 0.05%
Assay (on dried basis) <i>2001-IH-USP Based</i> (by HPLC)	98.0%-102.0%	99.9%
IN-HOUSE TESTS		
Residual Solvents <i>(2001-RS)</i>		
Acetone	Not more than 500 ppm	299ppm
Toluene	Not more than 500 ppm	Less than 50ppm
IN-HOUSE PHYSICAL PROPERTIES TESTS		

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**PRODUCT
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Product Name: Imipramine Hydrochloride

Control No.: 200100817

Order No.: 6U60039801

Client Packing Order: 220743

Customer Name: LABORATORIO CHILE S.A.

Quantity: 100.000 KG

Quality Market: USA

Manufacturing Site: PLANTEX LTD. - NETANYA

Original Analysis Date: 13-July-2017

Last Analysis Date: 16-July-2017

Manufacturing Date: June 2017

Re Test date: June 2022

Packaging and storage: Preserve in tight containers at 25°C. Excursions permitted up to 40°C.
Packed with desiccant.

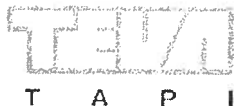
TESTS AND METHODS	SPECIFICATIONS	RESULTS*
IN-HOUSE PHYSICAL PROPERTIES TESTS		
Particle size distribution <i>2001-PHY</i>	Not less than 50 % smaller than 106µm Not less than 95 % smaller than 250µm	85% smaller than 106µm 100% smaller than 250µm
Bulk density <i>2001-PHY</i>	0.380 g/cm ³ - 0.530 g/cm ³	0.440g/cm ³
Tapped density <i>2001-PHY</i>	0.590 g/cm ³ - 0.760 g/cm ³	0.705g/cm ³

Remarks:

1. Conforms to the requirements of the IN-HOUSE USP BASED and IN-HOUSE 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.

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**PRODUCT
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Product Name: Imipramine Hydrochloride	
Control No.: 200100817	Order No.: 6U60039801
Client Packing Order: 220743	
Customer Name: LABORATORIO CHILE S.A.	
Quantity: 100.000 KG	Quality Market: USA
Manufacturing Site: PLANTEX LTD. - NETANYA	Original Analysis Date: 13-July-2017
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Released by Quality Control Manager:

Ariela Abiri

Signature:** Ariela Abiri

17 July 2017 08:51:33

Print Date: 17 July 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.

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