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PRODUCT SPECIFICATIONS AND CERTIFICATE OF ANALYSIS

Product Name: Diltiazem Hydrochloride
Control No.: 2525901016
Order No.: EU60048901
Client Packing Order: 217925
Customer Name: LABORATORIO CHILE S.A.
Quantity: 60.000 KG
Quality Market: USA
Manufacturing Site: TEVA API INDIA GAJRAULA
Original Analysis Date: 14/June/2016
Manufacturing Date: March 2016
Re Test date: February 2021

Packaging and storage: Preserve in tight,light-resistant containers at 25°C,Excursions permitted up to 40°C.

TESTS AND METHODS	SPECIFICATIONS	RESULTS*
	USP TESTS	
Description	White ,crystalline powder or small crystals.	Conforms
Identification		
Infrared absorption (USP<197K>)	The infrared absorption spectrum of the preparation of the test specimen exhibits maxima only at the same wavelengths as that of a similar prepration of the corresponding USP Reference standard.	Conforms
HPLC	The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that of the Standard preparation obtained as directed in the Assay.	Conforms
Chloride (USP<191>)	Conforms to test criteria.	Conforms
Specific rotation USP<781S>	Between +110° and +116°	114.2°
Loss on drying (USP<731>)	Not more than 0.50%	0.13%
Residue on ignition USP<281>	Not more than 0.10%	0.02%
Heavy Metals (USP<231>)	Not more than 20 ppm	Less than 20ppm

Teva API India Pvt Limited
M-34, Saket, New Delhi - 110 017 India

Manufacturing site : Plot Nos. A-2, A-2/1 ,A-2/2, UPSIDC Industrial Area, Bijnor Road, Distt :Amroha Gajraula-244235 (Uttar Pradesh)India TEL +91-5924-252591,92,9 FAX +91-5924-252590

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TESTS AND METHODS	SPECIFICATIONS	RESULTS*
	USP TESTS	
Assay (on dried basis) IN-2525-USP	98.0 to 102.0 %	101.0%
Related Compounds IN-2525-USP		
Desacetyl Diltiazem HCl	Not more than 0.50 %	Less than 0.10%
Any individual impurity	Not more than 0.50 %	Less than 0.10%
Total Impurities	Not more than 1.0%	Less than 0.10%
	IN-HOUSE TESTS	
Related compounds IN-2525-IH		
Desacetyl Diltiazem HCl (DAD HCl)	Not more than 0.20%	0.04%
D-Lactam	Not more than 0.20%	Less than 0.01%
Acetyl-Lactam	Not more than 0.20%	Less than 0.01%
Trans-Diltiazem HCl	Not more than 0.20%	Less than 0.01%
Any individual impurity	Not more than 0.10%	0.02%
Total impurities	Not more than 0.30%	0.08%
	IN-HOUSE TESTS	

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TESTS AND METHODS	SPECIFICATIONS	RESULTS*
	IN-HOUSE TESTS	
Residual Solvents IN-2525-IH-RS		
Isopropanol	Not more than 850 ppm	333ppm
Methylene Chloride	Not more than 50 ppm	Less than 10ppm
Toluene	Not more than 400 ppm	15ppm
Benzene	Not more than 2 ppm	Less than 0.5ppm
	IN-HOUSE FOR PHYSICAL TESTS	
Particle size distribution IN-2525-PHY by Alpine Jet Sieve	Not less than 45% smaller than 38 µ	72.3%
	Not less than 60% smaller than 53 µ	89.8%
	Not less than 90 % smaller than 125 µ	100.0%
Bulk Density	0.350 - 0.600 g/ml	0.404g/ml
Tapped Density	0.550 - 0.850 g/ml	0.674g/ml

Remarks:

1. Conforms to the requirements of the USP and IN-HOUSE and IN-HOUSE and IN-HOUSE FOR PHYSICAL 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. All residual solvents were tested by in-house method.
4. Corresponds to Current USP Pharmacopeia .

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Released by Quality Control Manager:	Signature**: PP\ S,C. CHAUHANS 26 July 2016 10:47:17
Muneshvar Singh	Print Date: 26 July 2016
	QA Approval: AJAY KUMAR GOUD

(*) 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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