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**PRODUCT
SPECIFICATIONS
AND
CERTIFICATE OF ANALYSIS**

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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 preparation 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
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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 Any individual impurity Total Impurities	Not more than 0.50 % Not more than 0.50 % Not more than 1.0%	Less than 0.10% Less than 0.10% Less than 0.10%
IN-HOUSE TESTS		
Related compounds IN-2525-IH Desacetyl Diltiazem HCl (DAD HCl) D-Lactam Acetyl-Lactam Trans-Diltiazem HCl Any individual impurity Total impurities	Not more than 0.20% Not more than 0.20% Not more than 0.20% Not more than 0.20% Not more than 0.10% Not more than 0.30%	0.04% Less than 0.01% Less than 0.01% Less than 0.01% 0.02% 0.08%
IN-HOUSE TESTS		

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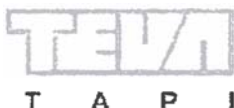
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TESTS AND METHODS	SPECIFICATIONS	RESULTS*
IN-HOUSE TESTS		
Residual Solvents IN-2525-H-RS Isopropanol Methylene Chloride Toluene Benzene	Not more than 850 ppm Not more than 50 ppm Not more than 400 ppm Not more than 2 ppm	333ppm Less than 10ppm 15ppm 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 Not less than 60% smaller than 53 µ Not less than 90 % smaller than 125 µ	72.3% 89.8% 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: Muneshvar Singh	Signature**: PP\ S.C. CHAUHANS 26 July 2016 10:47:17	
	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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