



PRODUCT SPECIFICATIONS AND CERTIFICATE OF ANALYSIS

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Product Name: Hydrochlorothiazide	Order No.: DMF	
Control No.: 726106412	Client Packing Order:	
Customer Name: MERCK & COMPANY INC		
Quantity: 1243.000 KG	Quality Market: EUR	
Manufacturing Site: ABIC LTD. - NETANYA	Original Analysis Date: 16-December-2012	
Manufacturing Date: November 2012	Last Analysis Date: 03-September-2014	
	Re Test date: October 2017	
Packaging and storage: Preserve in well-closed containers at 25°C. Excursions permitted up to 40°C. Packed with desiccant		

TESTS AND METHODS	SPECIFICATIONS	RESULTS*
IN-HOUSE Based on Ph.Eur TESTS		
Characters	White or almost white, crystalline powder.	Conforms
Identification by IR Infrared Spectrophotometry (2.2.24)	The Infrared absorption spectrum of the sample compares with the spectrum obtained with Hydrochlorothiazide CRS.	Conforms
Acidity or Alkalinity	Conforms to test criteria	conforms
Chlorides (Ph.Eur.2.4.4)	Not more than 100ppm	Less than 100ppm
Loss on drying (Ph.Eur. 2.2.32)	Not more than 0.5%	0.12%
Sulphated ash (Ph.Eur. 2.4.14)	Not more than 0.1%	0.02%

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

Manufacturing site : Kiryat Sapir Industrial Zone, P.O. Box 8077 Netanya 4250483, Israel TEL. 972-9-8639616 FAX. 972-9-8639852



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Related substances (by HPLC) <i>(7261-IH-EP-Based)</i> 6-chloro-2H-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide (Impurity A - CLT) 4-Amino-6-Chlorobenzene-1,3-disulfonamide (sulfamide) (Impurity B - DSA) 6-chloro-N-[(6-chloro-7-sulphamoyl-2,3-dihydro-4H-1,2,4-benzothiadiazin-4-yl 1,1-dioxide)methyl]-3,4-dihydro-2H-1,2,4-benzothiadiazine-7-sulphonamide 1,1-dioxide (Impurity C - HCTZ Dimer) Any unspecified impurity Total impurities	Not more than 0.50% Not more than 0.40% Not more than 0.50% Not more than 0.10% Not more than 0.90%	0.07% 0.07% Less than 0.05% Less than 0.05% 0.14%
Assay (By HPLC)	97.5%-102.0% on dried substance.	100.1%
IN-HOUSE FOR EUR TESTS		
Solubility <i>(7261-IH-EUR)</i>	Soluble in Acetone and in dilute solutions of Alkali Hydroxides.	Conforms
Selenium <i>(USP<291>)</i>	Not more than 0.003%.	Less than 0.003%
Heavy metals <i>(USP<231>Mchod II)</i>	Not more than 0.001 %	Less than 0.001%

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TESTS AND METHODS	SPECIFICATIONS	RESULTS*
Merck Client Specific TESTS		
Particle size distribution by Laser diffraction (Malvern)	MV: 25-97µm	38µm
	SD Max: 72µm	31µm

Remarks:

1. Conforms to the requirements of the IN-HOUSE Based on Ph.Eur and IN-HOUSE FOR EUR and Merck Client Specific 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 European Pharmacopoeia.

Released by Quality Control Manager:

Ariela Abiri

Signature**: PP\ Sveta Shlahman

4 September 2014 15:02:11

Print Date: 4 September 2014

(*) 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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