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PharmEvo

PharmEvo (Pvt.) Ltd.

Document No. : QAC5023	Title : Raw Material Testing Report

Material :	**Hydrochlorothiazide USP.**		
Code No. :	01010101002000100023	**MRR No. :**	0379
Mfg Lot # :	503091327	**Quantity :**	40 Kg
Manufacturer	Polpharma	**Date Received :**	15/04/14
Supplier :	Pharmaceutical Works Polpharma SA	**Date Reported :**	19/04/14
Mfg Date :	13-SEP-13	**Expiry date :**	12-SEP-16
STM No. :	QCR-2017	**No. of containers :**	1
AR# :	RM-14044152	**Ref. Log Book# :**	RMT-13/0144
QC Lot No. :	14D0379R		

SNo.	Tests	Specification	Result	Analyst
1	Appearance	White or practically white, practically odorless, crystalline powder.	Complies	KM
2	Solubility	Slightly soluble in water; freely soluble in sodium hydroxide solution, in n-butylamine, and in dimethylformamide; sparingly soluble in methanol; insoluble in ether, in chloroform, and in dilute mineral acids.	Complies	KM
3	Identification	A. By IR: The IR spectrum of test material should correspond to that of Std. B. By UV Absorption: The spectrum of test solution should correspond to that of standard solution.	Complies	KM
4	Loss on Drying	Not more than 0.5%.	0.200 %	KM
5	Residue on Iginition	Not more than 0.1%	0.020 %	KM
6	Chloride	Not more than 0.035%	Complies	KM
7	Selenium	Not more than 0.003%	0.003 %	KM
8	Heavy Metals	Not more than 0.001%	Complies	KM
9	Related Compounds	Not more than 1.0% of benzothiadiazine related compound A. Not more than 0.5% of any other impurity. Not more than 0.9% of other total impurities.	0.210 %	KM
10	Assay by HPLC (On As is Basis)	97.51% ------ 101.49%	99.496 %	KM
11	Assay by HPLC (On Dried Basis)	98.0% ------102.0%	99.699 %	KM

Status	APPROVED	Retest Date	

Remarks Released on 99.50% as is Pharmevo result.

PharmEvo (Pvt.) Ltd.	
Document No. : QAC5023	**Title : Raw Material Testing Report**

Material : **Hydrochlorothiazide USP.**

Code No. : 01010101002000100023

Mfg Lot # : 503091327

Manufacturer Polpharma

Supplier : Pharmaceutical Works Polpharma SA

Mfg Date : 13-SEP-13

STM No. : QCR-2017

AR# : RM-14044152

QC Lot No. : 14D0379R

MRR No. : 0379

Quantity : 40 Kg

Date Received : 15/04/14

Date Reported : 19/04/14

Expiry date : 12-SEP-16

No. of containers : 1

Ref. Log Book# : RMT-13/0144

Analyzed By	Approved By
Khan Muhammad Quality Control Executive	Afzal Ahmed Manager Quality Assurance

polpharma

CERTIFICATE OF ANALYSIS

Product: **HYDROCHLOROTHIAZIDE Ph.Eur.**

Code: **QHRP-0001-000** Batch number: **502041327** Batch size: **1295 kg**
Manufacturing date: **30.03.2013** Analysis date: **30.04.2013** Retest date: **03.2016**
Manufacturer: **Pharmaceutical Works POLPHARMA S.A., POLAND**
Delivered to: **PK, PHARMEVO (PVT.) LTD.**

TEST	TEST METHOD	SPECIFICATION	RESULTS
Appearance	visual examination	white or almost white, crystalline powder	almost white, crystalline powder
Solubility	Ph. Eur.	very slightly soluble in water, soluble in acetone, sparingly soluble in ethanol (96%), it dissolves in dilute solutions of alkali hydroxides	conforms
Identification IR spectrum	Ph. Eur.	First identification: comparison with reference substance spectrum	conforms
Acidity or alkalinity	Ph. Eur.	not more than 0.4 mL of 0.01 M HCl	0.27 mL of 0.01 M HCl
Related substances (HPLC) - chlorothiazide **(impurity A)** - 4-amino-6-chlorobenzene-1,3-disulphonamide **(impurity B)** - 6-chloro-*N*-[(6-chloro-7-sulphamoyl-2,3-dihydro-4*H*-1,2,4-benzothiadiazin-4-yl 1,1-dioxide)methyl]-3,4-dihydro-2*H*-1,2,4-benzothiadiazine-7-sulphonamide 1,1-dioxide **(impurity C)** - unidentified single impurity - sum of impurities	Ph. Eur.	 not more than 0.50 % not more than 0.50 % not more than 0.50 % not more than 0.10 % not more than 1.0 %	 less than 0.05 % less than 0.05 % 0.21 % less than 0.05 % 0.21 %
Chlorides	Ph. Eur.	not more than 100 ppm	less than 100 ppm
Loss on drying	Ph. Eur.	not more than 0.5 %	0.12 %
Sulfated ash	Ph. Eur.	not more than 0.1 %	0.02 %
Assay calculated on the dried substance (HPLC)	Ph. Eur.	97.5 % to 102.0 %	99.6 %
Particle size D(v, 0.1) D(v, 0.5) D(v, 0.9)	POLPHARMA S/6-0134	for information	 6.9 µm 67 µm 297 µm

CONCLUSION: This material complies with the requirements of the **Ph. Eur., S/2-0006.05 ed. 07.**

Starogard Gdański, 18.11.2013

14D0379R
99.56%

Certification Team Coordinator
API Plant
Beata Orlikowska
18.11.2013

19/05/14

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