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Hetero Drugs Limited(Unit-IV)
Survey No. 599, Temple Road, Bonthapally Village, Jinnaram Mandal, Medak District
Telangana, INDIA
Phone: (08458)275728/274015
Certificate Of Analysis

Name of the product : DORZOLAMIDE HYDROCHLORIDE		Reference STP no : DO-001-02		
Batch No. : DO0030115		Reference : USP		
Batch Qty : 31.70Kg		Analytical Report No. : DO004/15		
Date of Manufacture : January- 2015		Date of Retest : December-2019 ✓		
Date of Analysis : 04/02/2015		Status : Initial Certification		
SNO	TESTS		SPECIFICATIONS	RESULTS
01	Description		A White to Off-white Crystalline Powder	A White Crystalline Powder
02	Solubility		Soluble in Water.	Complies
03	Identification	By IR	The Infra Red absorption spectrum of the finely ground sample in mineral oil should exhibit maxima only at the same wave lengths as that of a similar preparation of Dorzolamide HCl Working Standard	Complies
		By HPLC	The retention time of the major peak in the chromatogram of the Assay preparation should correspond to that in the chromatogram of the standard preparation, as obtained in the assay by HPLC.	Complies
		By Chlorides	It meets the requirements for chloride test.	Complies
04	Water content by K.F		Not more than 0.5% w/w	0.24%w/w
05	Residue on Ignition		Not more than 0.1% w/w	0.06%w/w
06	Heavy metals		Not more than 0.001 %w/w	Less than 0.001%w/w
07	Limit Of Dorzolamide Hydrochloride Related Compound -A		Not more than 0.5%	0.26%
08	Chromatographic Purity By HPLC		Any Individual Impurity : Not more than 0.1%	0.05%
			Total impurities : Not more than 0.5%	0.09%
09	Assay By HPLC (On anhydrous Basis)		Not less than 99.0% and not more than 101.0% w/w	100.0%w/w
*10	*Residual Solvents By GC		Acetone : Not more than 2000 ppm	Not detected
			Ethyl Acetate : Not more than 2000 ppm	Not detected
			Tetrahydrofuran : Not more than 720 ppm	Not detected

* In-house specification

*No potential for any class 1 solvents as specified by ICH or USP <467> to be present in Dorzolamide Hydrochloride as they are not used in the manufacturing process. The material, if tested for these impurities, will comply with established standards.

The Product conforms to the above specifications.

Prepared By :

pauly

Checked By :

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Authorised Signatory:

[Signature]

Date :

09/04/2015

Date :

09/04/2015

Date :

09/04/2015

QC-DO-001-02

Effective: 10/02/2012
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