



**MICRO LABS LIMITED,
API-BOMMASANDRA (ML-15)**

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CERTIFICATE OF ANALYSIS

Product Name : Dorzolamide Hydrochloride Ph.Eur. **Mfg. Date** : March-2018
Batch No. : DZM4P18010 **Retest/ Expiry date** : February-2023
AR No. : ARFP180119 **Date analyzed** : 26/04/2018
Batch/Dispatch Quantity : 15.000 Kg **Specification No.** : FPSPEP029/09
Name of the customer : M/s. Metapharmaceutical IND.SL, Spain **COA Number** : 0535/18

S. No.	Test	Results	SPECIFICATION
1	Appearance	White crystalline powder.	White or almost white crystalline powder.
2	Solubility	Soluble in water, slightly soluble in Methanol.	Soluble in water, slightly soluble in Methanol.
3	Identification by		
	a) IR	The IR spectrum of the sample is concordant with the IR spectrum of the Dorzolamide working standard.	The IR spectrum of the sample should be concordant with the IR spectrum of the Dorzolamide reference/working standard.
	b) HPLC	The retention time of the main peak in the test solution is corresponding to that in the chromatogram of the system suitability solution as obtained in the Impurity-A content by HPLC test.	The retention time of the main peak in the test solution corresponds to that in the chromatogram of the system suitability solution as obtained in the Impurity-A content by HPLC test.
	c) Test for chlorides	Complies	White curdy precipitate should form.
4	Loss on drying	0.30%w/w	Not more than 0.5%w/w
5	Sulphated ash	0.03%w/w	Not more than 0.1%w/w
6	Impurity-A content by HPLC	0.09%	Not more than 0.5%
7	Related substances by HPLC		
	a) Impurity-B	Below disregard limit (0.05%)	Not more than 0.10%
	b) Impurity-C	Below disregard limit (0.05%)	Not more than 0.10%
	c) Unspecified impurity	Below disregard limit (0.05%)	Not more than 0.10%
	d) Total impurities	Nil	Not more than 0.3%
8	Residual solvents by GC		
	a) Methanol	Below detection limit (4.15 ppm)	Not more than 3000 ppm
	b) Diethyl ether	Below detection limit (0.50 ppm)	Not more than 5000 ppm
	c) Acetonitrile	27 ppm	Not more than 410 ppm
	d) Tetrahydrofuran	Below detection limit (4.03 ppm)	Not more than 720 ppm
9	Assay by HPLC (on dried basis)	99.6%w/w	Not less than 99.0%w/w and Not more than 101.0%w/w

Remarks: The Product complies with the above specification. (CEP No: R1-CEP 2011-102-Rev 01).

Prepared by:

Date

gfb
27/04/18

Reviewed by:

Date

G. Lakshman
27/04/18

Approved by:

Date

[Signature]
27/04/18

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