



Certificate of analysis

Product name :Dorzolamide Hydrochloride

Cas number: **130693-82-2**Molecular Formula: C₁₀H₁₆N₂O₄S₃HCl

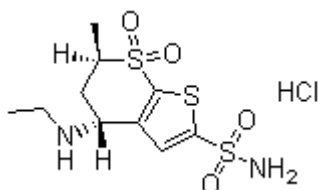
Molecular Weight: 360.89

Date of production: May. 19, 2018

Batch NO: 20180519

Exp Date: May. 18, 2020

Chemical structure:



ITEMS	SPECIFICATION	RESULTS
DESCRIPTION	WHITE OR ALMOST WHITE CRYSTALLINE POWDER	CONFORMS
IDENTIFICATION	(a)I.R.SPECTRUM (b)By HPLC (c)CHLORIDES	CONFORMS
WATER CONTENT	NOT MORE THAN 0.5 % (Using 0.4g)	0.14 %
RESIDUE ON IGNITION	NOT MORE THAN 0.1 %	0.05 %
HEAVY METALS	NOT MORE THAN 0.001 %	CONFORMS
LIMIT OF DORZALAMIDE HCl RELATED COMPOUND "A"	NOT MORE THAN 0.5 %	0.12 %
CHROMATOGRAPHIC PURITY	INDIVIDUAL IMPURITY: NOT MORE THAN 0.1 % TOTAL IMPURITIES: NOT MORE THAN 0.5 %	0.08 % 0.14 %
ORGANIC VOLATILE IMPURITIES	ACETONE: NOT MORE THAN 5000ppm ACETONITRILE: NOT MORE THAN 410ppm ETHYL ACETATE: NOT MORE THAN 5000ppm HEXANE: NOT MORE THAN 290ppm METHANOL: NOT MORE THAN 3000ppm TETRAHYDROFURAN: NOT MORE THAN 720ppm TOLUENE: NOT MORE THAN 890ppm ISO PROPYL ALCOHOL: NOT MORE THAN 5000ppm CHLOROFORM: NOT MORE THAN 60ppm DIOXANE: NOT MORE THAN 380ppm TRICHLOROETHYLENE: NOT MORE THAN 80ppm DICHLOROMETHANE: NOT MORE THAN 600ppm	CONFORMS
ASSAY (ON ANHYDROUS BASIS)	99.0 % ~ 101.0 % (C ₁₀ H ₁₆ N ₂ O ₄ S ₃ .HCl)	99.9 %

Conclusion: It complies with the USP36 Standard.