



Duke Chem
gentec pharmaceutical group

CERTIFICATE OF ANALYSIS

Product: Dorzolamide Hydrochloride USP/Eur Ph **Lot Number:** 182719300

Manufacturing date: November 2025

Control N°: 1144/25

Re-test date: November 2030

Specification: EPC501800-01

Description and Relative Solubility: White to off-white crystalline powder. Soluble in water, slightly soluble in methanol, very slightly soluble in anhydrous ethanol.

Test	Specification	Results
Appearance	White to off-white crystalline powder	White crystalline powder
Identification		
IR	Conforms to standard	Conforms to standard
HPLC	Conforms to standard	Conforms to standard
Chlorides	Positive	Positive
Water (KF)	≤ 0.5%	0.16%
Loss on Drying (105°C)	≤ 0.5%	< 0.10%
Residue of Ignition/ Sulphated Ash	≤ 0.1%	< 0.05%
Impurity A (HPLC)	≤ 0.5%	Not detected
Chromatographic Purity (HPLC) (as Dorzolamide Hydrochloride)	Known Ind Imp ≤ 0.10%	< 0.05%
	Unknown Ind. Imp. ≤ 0.10%	Not detected
	Total Impurities ≤ 0.3%	< 0.05%
Assay (HPLC)	99.0 – 101.0% (anhydrous subs.)	99.7%
Assay (Titration)	99.0 – 101.0% (dried substance)	100.0%
Microbiological Control	Total aerobic microbial count (TAMC)	
	≤ 10 ³ CFU/g	10 CFU/g
	Total combined yeast/moulds count (TYMC)	
	≤ 10 ² CFU/g	< 10 CFU/g

Product manufactured by Duke Chem S.A.U. on behalf of Curia Spain S.A.U.

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B. Mateos
Quality Manager

05 MAR. 2026

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