



TECHNICAL DATA SHEET

009675-TDS-ENG-2023

TIMOLOL MALEATO - EP		
DESCRIPTION DCI: TIMOLOL MALEATE		DESCRIPTION DOE: TIMOLOL MALEATO
CAS Nº: 26921-17-5	EC Nº: 248-111-5	AEMPS CODE: 1158MA
MOL. WEIGHT: 432.39	MOL. FORMULA: C ₁₃ H ₂₄ N ₄ O ₃ S·C ₄ H ₄ O ₄	ARTICLE CODE: 009675

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder or colourless crystals
Solubility	Soluble in water and in ethanol (96 %)
Identification A	Complies
Identification B	Complies
Specific optical rotation	-6.2 / -5.7
Appearance of solution	Clear solution and not more intensely coloured than ref. sol. B8
pH	3.8 - 4.3
Enantiomeric purity	
Impurity A	=< 1.0 %
Related substances	
Impurity B	=< 0.2 %
Impurity C	=< 0.2 %
Impurity D	=< 0.2 %
Impurity E	=< 0.2 %
Impurity F	=< 0.2 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.4 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.5 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep the container tightly closed in a dry, cool and well-ventilated place.

REMARKS

Timolol Maleate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.