METAPHARMACEUTICAL IND SL
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TIMOLOL MALEATO (EUR. PH.)

PRODUCT CODE: 009675	CAS Nº: 26921-17-5	ANALYSIS Nº: 123/25	
MANUFACTURER BATCH:	025D020	CERTIFICATE ID:	46.435
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/04/2025
METAPH BATCH:	0090525	EXPIRY DATE:	30/03/2030

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder or colourless crystals	White crystalline powder
Solubility	Soluble in water and in ethanol (96 %)	Complies (*)
Melting point	About 199 ºC	199.2 ºC
Identification A	Complies	Complies
Identification B	Complies	Complies
Specific optical rotation	-6.2 / -5.7	-5.9
Appearance of solution	Clear solution and not more intensely coloured than ref. sol. B8	Complies
pH	3.8 - 4.3	4.0
Enantiomeric purity		
Impurity A	=< 1.0 %	0.1 %
Related substances		
Impurity B	=< 0.2 %	< 0.05 %
Impurity C	=< 0.2 %	< 0.05 %
Impurity D	=< 0.2 %	Not Detected
Impurity E	=< 0.2 %	Not Detected
Impurity F	=< 0.2 %	Not Detected
Unspecified impurities	=< 0.10 %	Not Detected
Total impurities	=< 0.4 %	< 0.05 %
Loss on drying	=< 0.5 %	0.02 %
Sulfated ash	=< 0.1 %	0.02 %
Assay	98.5 - 101.0 %	99.5 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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

All data controlled by Metapharmaceutical Industrial SL.
(*) Data adapted from the manufacturer's certificate of analysis.

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.

Analysis date: 02/07/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000299
FDC LIMITED
142-48 S.V. ROAD.
400102 MUMBAI
MAHARASHTRA(Índia)

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STORAGE

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

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