

HANGZHOU SARTORT BIOPHARMA CO., LTD

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CERTIFICATE OF ANALYSIS

Product Name:	Timolol maleate		
CAS No.:	26921-17-5	Quantity:	26 kg
Batch No:	ST23012002	Test date:	2023.1.20
Manufacturing date:	2023.1.20	Expire date:	2025.1.19

Item	Standard	Results
Appearance	White or almost white, crystalline powder or colourless crystals	Almost white, crystalline powder
Solubility	Soluble in water and in ethanol (96 percent) Conform	
Melting point	199°C~203°C	199°C~201°C
Specific optical rotation	-5.70° ~ -6.20°	-6.0°
Identification (IR)	IR spectrum of sample corresponds to the IR spectrum of reference standard	Conform
Solution color and clarity	Solution is clear and not more intensely coloured than reference solution B ₈	Conform
pН	3.8~4.3	4.2
Loss on drying	Not more than 0.5%	0.06%
Residue on ignition	Not more than 0.1%	Conform
Single unknown impurity	Not more than 0.10%	Not detected
Total impurities	Not more than 0.4%	0.001%
R-isomer Content	Not more than 1.0%	Not detected
Assay (dried substance)	98.5% ~ 101.0%	100.6%

Conclusion The batch is in compliance with established requirements.

QA:

Cathy Shen

QC:

May Liu

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