

MOEHS CATALANA, S.L.

Polígono Rubí Sur

César Martinell i Brunet, 12A - 08191 Rubí (Barcelona - SPAIN)

Tel. (34) 93 586 05 20

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CERTIFICATE OF ANALYSIS

Product: SOTALOL HYDROCHLORIDE Ph. Eur. 10

Code: 78050

Batch Nr: 777-MC

Manufacture: 11/06/2022

Re-test Date: 11/06/2027

Customer: A.C.E.F. S.p.A.

Shipment (Kg): 2,00

Packs: 1

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS		
Appearance	White or almost white powder	Conforms
SOLUBILITY		
In Water	Freely Soluble	Conforms
In Ethanol (96%)	Soluble	Conforms
In Dichloromethane	Practically insoluble	Conforms
IDENTIFICATION		
IR Spectrum	Conforms to Std.	Conforms
Chloride reaction	Positive	Conforms
SPECIFIC TESTS		
Clarity of solution S	Maximum Ref. Suspension III	Conforms
Colour of solution S	Maximum Ref. Y-6	Conforms
Loss on drying	Maximum 0,5%	< 0,01 %
pH (5% Sol.)	4,0 to 5,0	4,6
Optical rotation (5% Sol.)	-0,10° to +0,10°	-0,00 °
ORGANIC IMPURITIES		
Related Substances (HPLC)		
Impurity B (Ph.Eur.)	Maximum 0,1%	< 0,05 %
Biggest other impurity (A,C,D)	Maximum 0,3%	< 0,05 %
Other impurities > 0.1% (A,C,D)	Maximum 1	0
Any unspecified imp. (biggest)	Maximum 0,10%	< 0,05 %
Total of other impurities (excluding B)	Maximum 0,5%	< 0,05 %
INORGANIC IMPURITIES		
Sulfated ash	Maximum 0,1%	< 0,01 %

We hereby certify that the above information is authentic and accurate. This batch has been manufactured, including packaging and quality control, in the above mentioned site in full compliance with the GMP requirements. The batch processing, packaging and analysis records were reviewed and found to be in compliance with ICH Q7, EU GMP Part II and 21 CFR Parts 210 & 211.

Released by QA on 22/06/2022

CoA issued on 22/11/2022

Signed by Quality Control

Pilar Gallego
QC Manager

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TESTS	SPECIFICATIONS	RESULTS
ASSAY Assay (Potent.) (on dried subst.)	99,0% to 101,0%	100,0 %
ADDITIONAL TESTS ELEMENTAL IMPURITIES RESIDUAL SOLVENTS Methanol	Complies ICH Q3D Complies Ph.Eur. 5.4 Maximum 300 ppm	Complies Conforms < 30 ppm

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