

**MOEHS CATALANA, S.L.**

Polígono Rubí Sur

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

Tel. (34) 93 586 05 20

Fax (34) 93 588 85 13

**CERTIFICATE OF ANALYSIS****Product:** SOTALOL HYDROCHLORIDE Ph. Eur. 11**Code:** 78050**Batch Nr:** 871-MC**Manufacture:** 16/04/2024**Re-test Date:** 16/04/2029**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
ORGANIC IMPURITIES Related Substances (HPLC)		
Impurity A	Maximum 0,3%	< 0,05 %
Any unspecified imp. (biggest)	Maximum 0,10%	< 0,05 %
Total impurities	Maximum 0,5%	< 0,05 %
INORGANIC IMPURITIES Sulfated ash	Maximum 0,1%	0,01 %
ASSAY Assay (Potent.) (on dried subst.)	99,0% to 101,0%	99,7 %

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 23/04/2024****CoA issued on 06/11/2024****Signed by Quality Control**Rosa Torras  
QC Manager

**MOEHS CATALANA, S.L.**

Polígono Rubí Sur

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

Tel. (34) 93 586 05 20

Fax (34) 93 588 85 13

**CERTIFICATE OF ANALYSIS****Product:** SOTALOL HYDROCHLORIDE Ph. Eur. 11**Code:** 78050**Batch Nr:** 871-MC**Manufacture:** 16/04/2024**Re-test Date:** 16/04/2029**Customer:** A.C.E.F. S.p.A.**Shipment (Kg):** 2,00**Packs:** 1

TESTS	SPECIFICATIONS	RESULTS
ADDITIONAL TESTS ELEMENTAL IMPURITIES RESIDUAL SOLVENTS Methanol	Complies ICH Q3D Complies Ph.Eur. 5.4 Maximum 300 ppm	Complies Conforms < 30 ppm

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 23/04/2024  
CoA issued on 06/11/2024  
Signed by Quality Control

Rosa Torras  
QC Manager