

MOEHS CATALANA, S.L.

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**CERTIFICATE OF ANALYSIS**

Code: 15782

Product : SOTALOL HYDROCHLORIDE Ph. Eur. 7Batch Nr: 394-MCManufacture: 11/2013Re-test Date: 11/2018Client : METAPHARMACEUTICAL SLShipment (Kg): 2.00Packs: 1

Lte: 0040414

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS APPEARANCE	Powder White or almost white	Conforms
SOLUBILITY .In Water	Freely soluble	Conforms
.In Alcohol	Soluble	Conforms
.In Dichlorometane	Pract. insoluble	Conforms
IDENTIFICATION .IR spectrum	Conforms to St	Conforms
.Chloride reaction	Positive	Conforms
TESTS Clarity of solution S	Maximum ref susp III	Conforms
Colour of solution S	Maximum Y-6	Conforms
pH (5% solution)	4.0 to 5.0	4.43
Optical rotation (5% sol)	Between +0.10° and -0.10°	0.00 °
Related substances (HPLC) .Impurity B (Ph.Eur.)	Maximum 0.1 p.cent	< 0.05 p.cent
.Biggest other impurity (A,C,D)	Maximum 0.3 p.cent	< 0.05 p.cent
.Other impurities>0.1% (A,C,D)	Maximum 1	0
.Biggest unknown impurity	Maximum 0.10 p.cent	< 0.05 p.cent
.Total impurities (excluding B)	Maximum 0.5 p.cent	< 0.05 p.cent
Palladium	Maximum 0.5 ppm	< 0.5 ppm
Heavy metals	Maximum 20 ppm (0.002%)	< 20 ppm
Loss on drying	Maximum 0.5 p.cent	0.01 p.cent
Sulfated ash	Maximum 0.1 p.cent	< 0.01 p.cent
ASSAY .Potentiom. (on dried subs.)	99.0 to 101.0 p.cent	99.5 p.cent
ADDITIONAL TESTS Residual solvents (GC)	Complies Ph.Eur. 5.4	Conforms
.Methanol	Maximum 300 ppm (0.03%)	< 50 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 Q7A.

Released by QA on 05/12/2013
CoA issued on 22/04/2014
Signed by Quality Control

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