

MOEHS CATALANA, S.L.

Polígono Industrial Rubí Sur  
C/ César Martinell Brunet, 12 A 08191 RUBÍ (BARCELONA - SPAIN)  
Tel. (34) 93 586 05 20\* - (34) 93 699 60 54\*  
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### CERTIFICATE OF ANALYSIS

Code: 15502

Product : LIDOCAINE HYDROCHLORIDE Ph. Eur. 8 / USP 37

Batch Nr: 604

Manufacture: 10/2014

Re-test Date: 10/2019

Client : FARMALABOR SRL

Shipment (Kg): 105.00

Packs: 3

TESTS	SPECIFICATIONS	RESULTS
<b>CHARACTERS</b> .Aspect .Colour .Solubility	Conforms to Ph.Eur. & USP Crystalline powder White to almost white Very soluble in water Freely sol in Ethanol 96% Soluble in chloroform Insoluble in ether	Conforms Conforms Conforms Conforms
<b>IDENTIFICATION</b> .IR Spectrum .Chloride reaction .HPLC	Conforms to St Positive Conforms	Conforms Conforms Conforms
<b>TESTS</b> Aspect of solution S Colour sol S pH (0.5 p.cent sol) Melting range Related substances (HPLC) .Impurity A (Dimethylaniline) .Impurity E = Imp.K (Ph.Eur.) .Unspecified impurities .Total impurities Heavy metals Sulfate Water Sulfated ash	Clear (Max Ref I opal) Colourless (Max Ref B-9) 4.0 to 5.5 74 to 79°C  Maximum 0.01 p.cent Maximum 0.10 p.cent Maximum 0.10 p.cent Maximum 0.50 p.cent Maximum 5 ppm (0.0005%) Maximum 0.1 p.cent 5.5 to 7.0 p.cent Maximum 0.1 p.cent	Conforms Conforms 5.47 74.4-77.5 °C  < 0.001 p.cent < 0.05 p.cent < 0.05 p.cent < 0.05 p.cent < 5 ppm < 0.1 p.cent 5.89 p.cent < 0.01 p.cent
<b>ASSAY</b> .Potentiom. (on anhydr. subs.) .HPLC (oas)	99.0 to 101.0 p.cent 97.5 to 102.5 p.cent	100.0 p.cent 98.9 p.cent

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 22/10/2014  
CoA issued on 04/11/2014  
Signed by Quality Control

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ADDITIONAL TESTS Residual solvents (GC) .Acetone	Ph.Eur. 5.4 & USP 467 Maximum 2000 ppm (0.2%)	Conforms 1,430 ppm

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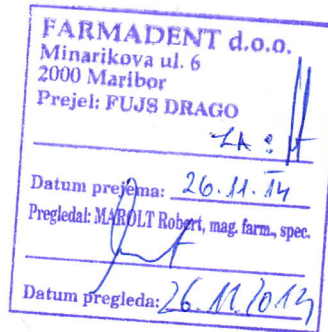
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TESTS	SPECIFICATIONS	RESULTS
ADDITIONAL TESTS ACCORDING TO CLIENT SPECIFICATIONS		
CUSTOMER SPECIFICATIONS  MICROBIOLOGICAL QUALITY .TAMC (Tot.aerobic micr.count) .TYMC (Tot.comb.yeasts/moulds)  Endotoxine (LAL-Test)	Maximum 1000 CFU/g Maximum 100 CFU/g  Maximum 1.1 EU/mg	Conforms Conforms  < 1.1 EU/mg



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