

MOEHS CATALANA, S.L.

Polygono Industrial Rubí Sur -
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CERTIFICATE OF ANALYSIS

Code: 15502

Product: LIDOCAINE HYDROCHLORIDE Ph. Eur. 8 / USP 38

Batch No: 644

Manufacture: 06/2015

Re-test Date: 06/2020

Client: FARMALABOR SRL

Shipment (Kg): 35.00

Packs: 1

TESTS	SPECIFICATIONS	RESULTS
<p>CHARACTERS</p> <p>. Aspect . Colour . Solubility</p> <p>IDENTIFICATION</p> <p>. IR Spectrum . Chloride reaction . HPLC</p> <p>TESTS</p> <p>Aspect of solution S Colour sol S pH (0.5 p.cent sol) Melting range Related substances (HPLC) . Impurity A (Dimethylaniline) . Impurity B = Imp. X (Ph. Eur.) . Unspecified impurities . Total impurities Heavy metals Sulfate Water Sulfated ash</p> <p>ASSAY</p> <p>. Potentiom. (on anhydr. subs.) . HPLC (cas)</p>	<p>FARMADEN d.o.o. Minarikova ul. 6 2000 Maribor Prejel: PUJS DRAGO</p> <p>Datum pregleda: 3.8.2015 Prejedat: FARMALABOR, sog. farm. spec.</p> <p>Datum pregleda: 3.8.2015</p> <p>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</p> <p>Conforms to St Positive Conforms</p> <p>Clear (Max Ref I opal) Colourless (Max Ref B-9) 4.0 to 5.5 74 to 79°C</p> <p>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</p> <p>99.0 to 101.0 p.cent 97.5 to 102.5 p.cent</p>	<p>Conforms Conforms Conforms Conforms</p> <p>Conforms Conforms Conforms</p> <p>Conforms Conforms Conforms</p> <p>Conforms Conforms 4.93 74.7-76.2 °C</p> <p>< 0.001 p.cent < 0.15 p.cent < 0.05 p.cent < 0.05 p.cent < 5 ppm < 0.1 p.cent 6.42 p.cent 0.03 p.cent</p> <p>100.6 p.cent 100.3 p.cent</p>

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 place in full compliance with the GMP requirements. The batch processing, packaging and analysis records were reviewed and found to be in compliance with the G.P. EU GMP Part II and EU GMP Parts III & IV.

Released by QA on 02/07/2015
CoA issued on 17/07/2015
Signed by Quality Control

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CERTIFICATE OF ANALYSIS

Code: 15502

Product : LIDOCAINE HYDROCHLORIDE Ph. Eur. 8 / USP 38

Batch Nr.: 644

Manufacture: 06/2015

Re-test Date: 06/2020

Client : FAPMALABOR SRL

Shipment (Kg): 35.00

Packs: 1

TESTS	SPECIFICATIONS	RESULTS
ADDITIONAL TESTS Residual solvents (GC) .Acetone	Ph.Eur. 5.4 & USP 467 Maximum 2000 ppm (0.2%)	Conforms 343 ppm

We hereby certify that the above information is accurate and appropriate. 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 II GMP Annex 115 & 116.

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CERTIFICATE OF ANALYSIS

Code: 15502

Product : LIDOCAINE HYDROCHLORIDE Ph. Eur. 8 / USP 38

Batch No: 644

Manufacture: 06/2018

Re-test Date: 06/2020

Client : FARMALABOR SRL

Shipment (Kg): 35.00

Packs: 1

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

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