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## CERTIFICATE OF ANALYSIS

Code: 15504

Product : LIDOCAINE Ph. Eur. 8 / USP 38

Batch Nr: 721

Manufacture: 02/2016

Re-test Date: 02/2021

Client : LABORATORIOS CHILE S.A.

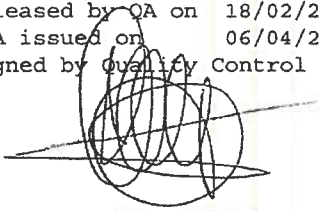
Shipment (Kg): 50.00

Packs: 1

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS .Appearance .Solubility  IDENTIFICATION .IR Spectrum .Test B (USP)  TESTS Melting Range Related substances (HPLC) .Impurity A (Dimethylaniline) .Any unspecified imp (biggest) .Total impurities Chloride Sulfate Heavy metals Water Sulfated ash  ASSAY .Potentiom. (on anhydr. subs.) .HPLC  ADDITIONAL TESTS Residual solvents (GC) .Toluene (periodic test)	Conforms to Ph.Eur. & USP Conforms to Ph.Eur. & USP Conforms to Ph.Eur. & USP  Conforms to St Complies  Between 66°C and 69°C  Maximum 0.01 p.cent Maximum 0.10 p.cent Maximum 0.5 p.cent Maximum 35 ppm (0.0035%) Maximum 0.1 p.cent Maximum 20 ppm (0.002%) Maximum 1.0 p.cent Maximum 0.1 p.cent  99.0 to 101.0 p.cent 97.5 to 102.5 p.cent  Ph.Eur. 5.4 & USP 467 Maximum 89 ppm	Conforms Conforms Conforms  Conforms Conforms  66.4-67.6 °C  < 0.001 p.cent < 0.05 p.cent < 0.05 p.cent < 35 ppm < 0.1 p.cent < 20 ppm 0.05 p.cent < 0.01 p.cent  100.2 p.cent 98.7 p.cent  Conforms < 89 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 18/02/2016  
 CoA issued on 06/04/2016  
 Signed by Quality Control



Pag.: 1/1