

15/03/2022

CERTIFICATE OF ANALYSIS

Code: 94240

Product : ARTICAINE HYDROCHLORIDE Ph. Eur. 10 / USP-NF 2021

Batch Nr: 350

Manufacture: 01/2022

Re-test Date: 01/2027

Client : METAPHARMACEUTICAL SL

Shipment (Kg): 1.00

Packs: 1

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS APPEARANCE AND SOLUBILITY IDENTIFICATION .IR spectrum .Chloride reaction TESTS Aspect of solution S Colour of solution S pH Related substances (HPLC) .Impurity A .Any unspecified imp (biggest) .Sum of impur. other than A	Conforms to Ph.Eur. & USP Conforms to St Positive Clear (Max Ref I opal) Maximum BY-6 4.2 to 5.2 Maximum 0.2 p.cent Maximum 0.10 p.cent Maximum 0.5 p.cent	Conforms Conforms Conforms Conforms Conforms 4.82 < 0.05 p.cent < 0.05 p.cent < 0.05 p.cent
Loss on drying Sulfated ash ASSAY (Potent.) (ods) ADDITIONAL TESTS ELEMENTAL IMPURITIES Residual solvents .Acetone Propylamine Endotoxine (LAL-Test) MICROBIOLOGICAL QUALITY .TAMC (Tot.aerobic micr.count) .TYMC (Tot.comb.yeasts/moulds)	Maximum 0.5 p.cent Maximum 0.1 p.cent 98.5 to 101.0 p.cent Complies ICH Q3D Maximum 1000 ppm (0.1%) Maximum 100 ppm Maximum 1,1 EU/mg Maximum 1000 CFU/g Maximum 100 CFU/g	0.06 p.cent < 0.01 p.cent 100.2 p.cent Conforms 74 ppm 48 ppm Conforms Conforms Conforms
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 15/02/2022 CoA issued on 22/02/2022 Signed by Quality Control 	Pag.: 1/1