

BENECHIM, S.R.L.
Rue René Magritte, 163 - 7860 (LESSINES - BELGIUM)
Tel. (+32-68) 33 49 13
Fax (+32-68) 33 35 81



CERTIFICATE OF ANALYSIS

Product: ARTICAINE HYDROCHLORIDE Ph. Eur. 11 / USP-NF 2024

Code: 94240

Batch Nr: 577

Manufacture: 06/11/2024

Re-test Date: 06/11/2029

Customer: METAPHARMACEUTICAL S.L.

Shipment (Kg): 5,00

Packs: 1

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS Appearance and solubility	Conforms to Ph.Eur & USP	Conforms
IDENTIFICATION IR Spectrum Chlorides reaction	Conforms to Std. Positive	Conforms Conforms
SPECIFIC TESTS Aspect of solution S Colour of solution S pH Loss on drying	Clear (Max. Ref. I Opal.) Maximum BY-6 4,2 to 5,2 Maximum 0,5%	Conforms Conforms 4,70 0,02 %
ORGANIC IMPURITIES Related substances (HPLC) Impurity A Any unspecified imp (biggest) Sum of impurities (other than A)	Maximum 0,2% Maximum 0,10% Maximum 0,5%	< 0,05 % < 0,05 % < 0,05 %
INORGANIC IMPURITIES Sulfated ash	Maximum 0,1%	< 0,01 %
ASSAY Acidimetric (on dried subst.)	98,5% to 101,0%	100,1 %

METAPHARMACEUTICAL

N DE LOTE:

0220725

14/07/2025

15/01/2025

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 15/01/2025
CoA issued on 04/07/2025
Signed by Quality Control

Donia Essaid
QC Supervisor

P.O.

BENECHIM, S.R.L.
Rue René Magritte, 163 - 7860 (LESSINES - BELGIUM)
Tel. (+32-68) 33 49 13
Fax (+32-68) 33 35 81



CERTIFICATE OF ANALYSIS

Product: ARTICAINE HYDROCHLORIDE Ph. Eur. 11 / USP-NF 2024

Code: 94240

Batch Nr: 577

Manufacture: 06/11/2024

Re-test Date: 06/11/2029

Customer: METAPHARMACEUTICAL S.L.

Shipment (Kg): 5,00

Packs: 1

TESTS	SPECIFICATIONS	RESULTS
ADDITIONAL TESTS MICROBIOLOGICAL TEST TAMC (Total Aerobic Microbial Count) TYMC (Total Yeast and Mold Count) Endotoxines ELEMENTAL IMPURITIES RESIDUAL SOLVENTS (GC) Propylamine RESIDUAL SOLVENTS (HS-GC) Acetone	Maximum 1000 CFU/g Maximum 100 CFU/g Maximum 1,1 EU/mg Complies ICH Q3D Maximum 100 ppm Maximum 1000 ppm	Conforms Conforms Conforms Conforms < 10 ppm 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 15/01/2025
CoA issued on 04/07/2025
Signed by Quality Control

Donia Essaid
QC Supervisor

P.O.