

MOEHS CATALANA, S.L.

Polígono Rubí Sur

César Martinell i Brunet, 12A - 08191 Rubí (Barcelona - SPAIN)

Tel. (34) 93 586 05 20

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N DE LOTE: -

0121222



CERTIFICATE OF ANALYSIS

Product: MEPIVACAINE HYDROCHLORIDE Ph. Eur. 10**Code:** 75410**Batch Nr:** 401**Manufacture:** 08/04/2022**Re-test Date:** 08/04/2027**Customer:** METAPHARMACEUTICAL S.L.**Shipment (Kg):** 10,00**Packs:** 1

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS		
Appearance	Crystalline powder	Conforms
Colour	White or almost white	Conforms
Melting point	About 260°C (dec.)	Conforms
Solubility	Conforms to Ph.Eur.	Conforms
IDENTIFICATION		
IR Spectrum	Conforms to Std.	Conforms
Chloride reaction	Positive	Conforms
TLC	Conforms to Std.	Conforms
SPECIFIC TESTS		
Clarity of solution S	Clear (Max. Ref. I opal)	Conforms
Colour of solution S	Maximum Ref. B-7	Conforms
Loss on drying	Maximum 0,5%	0,02 %
pH	4,0 to 5,0	4,5
Optical rotation	-0,10° to +0,10°	-0,00 °
ORGANIC IMPURITIES		
2,6-Dimethylaniline (Impurity A)	Maximum 20 ppm	< 1 ppm
Related Substances (HPLC)		
Any unspecified imp. (biggest)	Maximum 0,10%	< 0,02 %
Total impurities	Maximum 0,5%	< 0,02 %
INORGANIC IMPURITIES		
Sulfated ash	Maximum 0,1%	< 0,01 %
ASSAY		
Acidimetric Assay (on dried subst.)	98,5% to 101,0%	100,1 %

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 17/05/2022

CoA issued on 02/12/2022

Signed by Quality Control


Pilar Gallego
QC Manager

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ADDITIONAL TESTS		
MICROBIOLOGICAL QUALITY		
TAMC (Tot.aerobic micr.count)	Maximum 1000 CFU/g	Conforms
TYMC (Tot.comb.yeasts/moulds)	Maximum 100 CFU/g	Conforms
ELEMENTAL IMPURITIES	Complies ICH Q3D	Complies
RESIDUAL SOLVENTS		
Acetone	Maximum 1000 ppm	231 ppm

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