

MOEHS BCN, S.L.

Poligono Industrial Aquiberia

Zenc 12 - 08755 Castellbisbal (Barcelona - SPAIN)

Tel. (34) 93 586 05 20

Fax (34) 93 588 85 13



CERTIFICATE OF ANALYSIS

Product: LIDOCAINE Ph. Eur. 10 / USP 43

Code: 74870

Batch Nr: 74

Manufacture: 11/2020

Re-test Date: 11/2025

Customer: A.C.E.F. S.p.A.

Shipment (Kg): 50,00

Packs: 1

| TESTS | SPECIFICATIONS | RESULTS |
|----------------------------------|---|----------------------|
| CHARACTERS | | |
| Appearance | Conforms to Ph. Eur. & USP | Conforms |
| Solubility | Conforms to Ph. Eur. & USP | Conforms |
| IDENTIFICATION | | |
| Test B (USP) | Complies | Conforms |
| IR Spectrum | Conforms to Std. | Conforms |
| SPECIFIC TESTS | | |
| Water (KF) | Maximum 1,0% | 0,1 % |
| ORGANIC IMPURITIES | | |
| Related Substances (HPLC) | | |
| Impurity A (2,6-Dimethylaniline) | Maximum 0,01% | < 0,001 % |
| Any unspecified imp. (biggest) | Maximum 0,10% | < 0,05 % |
| Total impurities | Maximum 0,5% | < 0,05 % |
| INORGANIC IMPURITIES | | |
| Sulfated ash | Maximum 0,1% | 0,02 % |
| Chloride | Maximum 35 ppm | < 35 ppm |
| Sulfates | Maximum 0,1% | < 0,1% |
| ASSAY | | |
| Assay (HPLC) | 97,5% to 102,5% | 99,6 % |
| Assay (Potent.) (on anh. subs.) | 99,0% to 101,0% | 99,6 % |
| ADDITIONAL TESTS | | |
| ELEMENTAL IMPURITIES | | |
| Residual solvents (GC) | Complies ICH Q3D Ph.Eur. 5.4 & USP 467 | Complies 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 02/12/2020

CoA issued on 02/03/2021

Signed by Quality Control

Cristina Pérez
QC Manager

PO
2021-03-02
2021-03-02



MOEHS
PRODUCTOS QUÍMICOS