NOTE ACOFARMA: 161864

MOEHS CATALANA, S.L.
Polígono Rubí Sur
César Martinell i Brunet, 12A - 08191 Rubí (Barcelona - SPAIN)
Tel. (34) 93 586 05 20
Fax (34) 93 588 85 13

MOEHS PRODUCTOS QUÍMICOS

CERTIFICATE OF ANALYSIS

Product: LIDOCAINE HYDROCHLORIDE Ph. Eur. 8 / USP 39 **Code:** 74850

Batch Nr: 710 **Manufacture:** 10/2016 **Re-test Date:** 10/2021

Customer: ACOFARMA DISTRIBUCION SA

Shipment (Kg): 175,00 **Packs:** 5

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS		
Appearance	Crystalline powder	Conforms
Colour	White or almost white	Conforms
SOLUBILITY		
In Water	Very Soluble	Conforms
In Ethanol (96%)	Freely Soluble	Conforms
In Chloroform	Soluble	Conforms
In Ether	Insoluble	Conforms
IDENTIFICATION		
IR Spectrum	Conforms to Std.	Conforms
HPLC	Conforms to Std.	Conforms
Chloride reaction	Positive	Conforms
SPECIFIC TESTS		
Water (KF)	5,5% to 7,0%	6,31 %
Aspect of solution S	Clear (Max. Ref. I opal)	Conforms
Colour of solution S	Colourless (Max. Ref. B-9)	Conforms
pH (0.5% Sol.)	4,0 to 5,5	4,88

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 *26/10/2016*
CoA issued on 16/11/2016
Signed by Quality Control

Pilar Gallego
QC Manager

LOTE ACOFARMA: 161864

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TESTS	SPECIFICATIONS	RESULTS
ORGANIC IMPURITIES		
Rel. Substances (HPLC) (Ph.Eur.)		
Impurity A	Maximum 0,01%	< 0,001 %
Impurity K	Maximum 0,10%	< 0,05 %
Any unspecified imp. (biggest)	Maximum 0,10%	< 0,05 %
Total impurities	Maximum 0,5%	< 0,05 %
Related Compounds (USP)		
Ropivacaine related compound A	Maximum 0,01%	< 0,001 %
Lidocaine related compound H	Maximum 0,10%	< 0,05 %
Any ind. unspecified imp. (biggest)	Maximum 0,10%	< 0,05 %
Total impurities	Maximum 0,5%	< 0,05 %
INORGANIC IMPURITIES		
Sulfated ash	Maximum 0,1%	0,02 %
Heavy Metals	Maximum 5 ppm	< 5 ppm
Sulfates	Maximum 0,1%	< 0,1%
ASSAY		
Assay (HPLC) on anhydrous subs.	97,5% to 102,5%	100,5 %
Assay (Potent.) (on anh. subs.)	99,0% to 101,0%	99,9 %
ADDITIONAL TESTS		
MICROBIOLOGICAL QUALITY		
TAMC (Tot.aerobic micr.count)	Maximum 1000 CFU/g	Conforms
TYMC (Tot.comb.yeasts/moulds)	Maximum 100 CFU/g	Conforms
RESIDUAL SOLVENTS	Ph.Eur. 5.4 & USP 467	Conforms
Acetone	Maximum 2000 ppm	< 200 ppm

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ACOFARMA DISTRIBUCIÓN, S.A.
C.Llobregat, 20
08223 Terrassa

To whom it may concern

November 7th 2016

RESIDUAL SOLVENTS STATEMENT

Active ingredient: **LIDOCAINE HYDROCHLORIDE**

Class 1 Residual Solvents

We hereby attest, based on knowledge of the manufacturing process and controlled handling and storage of the above material, that there is no potential for Class 1 residual solvents listed in USP- General Chapter: <467> Residual Solvents and ICH Guideline Q3C "Residual Solvents". Class 1 solvents are not used in the manufacturing process of Lidocaine Hydrochloride.

Class 2 Residual solvents

We hereby certify that the only Class 2 solvent used in the manufacturing process of Lidocaine Hydrochloride is Toluene. The content of Toluene in Lidocaine Hydrochloride has been found less than 89 ppm, below 890 ppm, the limit established in the USP General Chapter <467> Residual Solvents and ICH Guideline Q3C "Residual Solvent". It has been demonstrated that Toluene is far below the 10% of the acceptable concentration limit stated according to CPMP/QWP/450/3&EMEA/CVMP/511/03 "Annexes to: CPMP/ICH/283/95 & CVMP/VICH/502/99". Thus, Lidocaine Hydrochloride is not required to be routinely tested for Toluene content.

Class 3 Residual Solvents

We hereby certify that Class 3 solvent, Acetone is likely to be present in Lidocaine Hydrochloride manufactured by Moehs. The content in Acetone is determined by a validated GC analytical method with a limit of 0.2%, in compliance with <467> Residual solvents and ICH Guideline Q3C "Residual solvents "requirements.

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Other solvents

Water is used in the manufacturing process, and its content in the active substance is by karl Fisher and limited to 5.5 to 7.0 p. Cent.
These limits are in compliance with current ICH Guideline on residual solvents ICH Q3C (CPMP/ICH/283/95), EP monograph 5.4 *Residual Solvents* as well as the USP General Chapter <467> *Residual Solvents*.

Yours faithfully,

MOEHS IBERICA, S.L.
Tel. 93 586 05 20
RUBI

Antonia Alonso
Regulatory Affairs Manager