

Certificate of Analysis

TETRA HCL

Lot Number: 17114181
 Product Code: TETRACAINE HCL
 Product Grade: STANDARD
 Reference:

ANALYTICAL TESTS	SPECIFICATIONS	RESULTS
DESCRIPTION	white crystalline powder	Complies
IDENTIFICATION IR	complies with reference	Complies
IDENTIF. CHLORIDES	test positive (chlorides)	Complies
IDENTIF. (MP)	about 131 °C	131.0 °C
IDENTIFICATION HPLC	complies with the reference	Complies
CLARITY OF SOLUTION	clear solution (0.2 g / 10 ml H ₂ O)	Complies
COLOUR OF SOLUTION	colorless solution (0.2 g / 10 ml H ₂ O, according to Eur. Ph. process II)	Complies
pH	4.5 - 6.5 (1 % aqueous solution)	5.3
LOSS ON DRYING	max. 1.0 % (2 h at 105 °C)	0.1 %
WATER (KF)	max. 1.0 %	0.0 %
HEAVY METALS	max. 10 ppm	Complies
SULPHATED ASHES	max. 0.10 %	0.04 %
ASSAY (NaOH)	99.0 - 101.0 % (on the dried substance)	99.4 %
ASSAY (HClO ₄)	99.0 - 101.0 % (on the dried substance)	100.0 %
ASSAY (HPLC)	98.0 % - 102.0 % (calculated on the anhydrous basis)	100.8 %
IMPURITIES (HPLC) II	4-Aminobenzoic Acid: max. 0.05 %	N/D
	4-(Butylamino)benzoic Acid: max. 0.1 %	0.1 %
	Methyl 4-(Butylamino)benzoate: max. 0.1 %	N/D
	any other impurity: max. 0.10 %	N/D
	sum of impurities: max. 0.5 %	0.1 %
RESIDUAL SOLVENTS	Ethanol: max. 1000 ppm	235 ppm

Reference: USP, JP, Ph. EUR.

Analytical number : 60475

Siegfried

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Date of manufacture : (YYYY-MM-DD) 2017-03-27
Date of analysis : (YYYY-MM-DD) 2017-03-28
Date of retest : (YYYY-MM-DD) 2022-03-26

Released by : Briquet Anne
Released date : (YYYY-MM-DD) 2017-05-02

Conclusion : Complies

Manufacturer : SIEGFRIED Evionnaz SA
Route du Simplon 1, 36
CH-1902 EVIONNAZ
Phone: +41 27 766 1200

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FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

AG-03-307

Director Técnico