



Chemical Distribution

Certificate of Analysis

BTC Europe GmbH

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Fagron Services B.V.

MOLENWERF 13

1911 DB UITGEEST

Netherlands

2016-07-25

Q-UNIT

Briquet Anne

+4127/766.12.00

Certificate No 2372

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Inspection Certificate 3.1 according to EN 10204

Tetracaine Hydrochloride

10KG Fibre drum, Liner

Purchase Order/Customer Product#

BI160934 - Daniel van Herrikhuijzen

501008

Material	52713946
Order	3012453589 000010
Delivery	3096543979 000010
Lot	0014710369
Lot/Qty	60.000 KG
Total	60.000 KG
Transport	RPLT 234

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	130.6 °C
IDENTIFICATION HPLC	complies with the reference	Complies
CLARITY OF SOLUTION	clear solution (0.2 g / 10 ml H2O)	Complies
COLOUR OF SOLUTION	colorless solution (0.2 g / 10 ml H2O, 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)	0.0 %
WATER (KF)	max. 1.0 %	0.0 %
HEAVY METALS	max. 10 ppm	Complies
SULPHATED ASHES	max. 0.10 %	0.00 %
ASSAY (HClO4)	99.0 - 101.0 % (on the dried substance)	100.2 %
ASSAY (HPLC)	98.0 % - 102.0 % (calculated on the anhydrous basis)	98.9 %
IMPURITIES (HPLC) II	4-Aminobenzoic Acid: max. 0.05 %	N/D
	4-(Butylamino)benzoic Acid: max. 0.1 %	N/D
	Methyl 4-(Butylamino)benzoate: max. 0.1 %	0.0 %
	any other impurity: max. 0.10 %	N/D
	sum of impurities: max. 0.5 %	0.0 %
RESIDUAL SOLVENTS	Ethanol: max. 1000 ppm	237 ppm
ENDOTOXINS	[EU/g]: for information	<25 EU/g
MICROBIOLOGY	micro-organisms [CFU/g]: for information	<10

Reference: USP, JP, Ph. EUR.

The aforementioned data shall constitute the agreed contractual quality of the product at the time of passing of risk. The data are controlled at regular intervals as part of our quality assurance program. Neither these data nor the properties of product specimens shall imply any legally binding guarantee of certain properties or of fitness for a specific purpose. No liability of ours can be derived therefrom.



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Analytical number : 50768
Date of manufacture : (YYYY-MM-DD) 2016-02-02
Date of analysis : (YYYY-MM-DD) 2016-03-24
Date of retest : (YYYY-MM-DD) 2021-01-31

Released by : Briquet Anne
Released date : (YYYY-MM-DD) 2016-04-05

Conclusion :

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

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