



Chemical Distribution

Certificate of Analysis

BTC Europe GmbH

Please note that the certificates of analysis are also conveniently available online and around the clock at www.online-services.btc-europe.com

Fagron Services B.V.

MOLENWERF 13
120
1911 DB UITGEEST

Netherlands

2014-03-17
G-ENP/OQ
Briquet Anne
+4127/766.12.00
Certificate No 6269
Page 1 of 2

Inspection Certificate 3.1 according to EN 10204

Tetracaine Hydrochloride

10KG Fibre drum, Liner
Purchase Order/Customer Product#
BI140319 Wil Feemstra-Kuijs

Material	52713946
Order	3009892731 000010
Delivery	3093094032 000010
Lot	0010990834
Lot/Qty	30.000 KG
Total	30.000 KG
Transport	N-KP 1050

ANALYTICAL TESTS	SPECIFICATIONS	RESULTS
DESCRIPTION	white crystalline powder	Complies
ODOUR	odourless	Complies
IDENTIFICATION UV	abs. max. at approx. 310 nm	Complies
IDENTIFICATION IR	complies with reference	Complies
IDENTIF. CHLORIDES	test positive (chlorides)	Complies
IDENTIF. (MP)	about 131 °C	131.0 °C
CLARITY OF SOLUTION	clear solution (0.2 g / 10 ml EtOH)	Complies
COLOUR OF SOLUTION	colorless solution (0.2g/10ml EtOH, according to Eur. Ph. process II)	Complies
pH	4.5 - 6.5 (1 % aqueous solution)	5.6
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 %	0.00 %
ASSAY (HC104)	99.0 - 101.0 % (on the dried substance)	100.3 %
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 %	N/D
	any other impurity: max. 0.10 %	N/D
	sum of impurities: max. 0.5 %	N/D
RESIDUAL SOLVENTS	Ethanol: max. 1000 ppm	299 ppm

Reference: USP, JP, Ph. EUR.

Analytical number : 29712
Date of manufacture : 17-12-2013
Date of analysis : 19-12-2013

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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Total

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N-KP 1050

Date of retest : 16-12-2018

Released by : Briquet Anne

Released date : 04-02-2014

Conclusion : Complies

Manufacturer : BASF Pharma (Evionnaz) SA

Route du Simplon 1, 36

CH-1902 EVIONNAZ

Phone: +41 27 766 1200

This document was created electronically and is valid without signature.

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

14C18-003


Director Técnico S.

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