

CERTIFICATE OF ANALYSIS

Material No: **702298**
Name: **Tetracaine HCl**
Quality: **USP, JP, Ph. EUR.**
Lot No: **20324071** Manufacturing date: **28-Aug-2020**
CAS No. **136-47-0** Retest date: **28-Aug-2025**
Formula: **-** Specification date: **17-Dec-2019**
Molecular Weight: **-**

Test	Method	Specification	Result
DESCRIPTION	17550__DEF00100	white crystalline powder	Complies
IDENTIFICATION IR	17550__DEF00400	complies with reference	Complies
IDENTIF. CHLORIDES	17550__DEF00500	test positive (chlorides)	Complies
IDENTIF. (MP)	17550__DEF24000	about 131 °C	131.6 °C
IDENTIFICATION HPLC	17550__DEF06100	complies with the reference	Complies
CLARITY OF SOLUTION	17550__DEF00700	clear solution (0.2 g / 10 ml H ₂ O)	Complies
COLOUR OF SOLUTION	17550__DEF00800	colorless solution (0.2 g / 10 ml H ₂ O, according to Eur. Ph. process II)	Complies
pH	17550__DEF01000	4.5 - 6.5 (1 % aqueous solution)	5.3
LOSS ON DRYING	17550__DEF01200	max. 0.5 % (2 h at 105 °C)	0.0 %
WATER (KF)	17550__DEF01100	max. 1.0 %	0.1 %
HEAVY METALS	17550__DEF02200	max. 10 ppm	Complies
SULPHATED ASHES	17550__DEF01300	max. 0.10 %	0.00 %
ASSAY (NaOH)	17550__DEF12600	99.0 - 101.0 % (on the dried substance)	99.5 %
ASSAY (HClO ₄)	17550__DEF12700	99.0 - 101.0 % (on the dried substance)	99.7 %
ASSAY (HPLC)	17550__DEF03400	98.0 % - 102.0 % (calculated on the anhydrous basis)	99.4 %
IMPURITIES (HPLC) II	17550__DEF07900	4-Aminobenzoic Acid: max. 0.05 %	0.00 %
	17550__DEF07900	4-(Butylamino)benzoic Acid: max. 0.1 %	0.0 %
	17550__DEF07900	Methyl 4-(Butylamino)benzoate: max. 0.1 %	0.0 %
	17550__DEF07900	any other impurity: max. 0.10 %	0.00 %
	17550__DEF07900	sum of impurities: max. 0.5 %	0.1 %
ENDOTOXINS	17550__DEF22400	[EU/g]: for information	<25 EU/g
MICROBIOLOGY	17550__DEF09600	micro-organisms [CFU/g]: for information	<20
RESIDUAL SOLVENTS	17550__DEF26200	Ethanol: max. 1000 ppm	76 ppm

CERTIFICATE OF ANALYSIS

Material No:	702298		
Name:	Tetracaine HCl		
Quality:	USP, JP, Ph. EUR.		
Lot No:	20324071	Manufacturing date:	28-Aug-2020
CAS No.	136-47-0	Retest date:	28-Aug-2025
Formula:	-	Specification date:	17-Dec-2019
Molecular Weight:	-		

Release comment: **meets specification**

Released On: 25-Sep-2020 15:31 (UTC+02:00)
on behalf of Siegfried Evionnaz SA

Released By: Strychalska Emilia
QA-Manager

This document was created electronically and is valid without signature.