

CERTIFICATE OF ANALYSIS

Material No: **701520**
Name: **Benoxinate HCl**
OXYBUPROCAINE HCL
Quality: **Ph. Eur, USP**
Lot No: **20264044** Manufacturing date: **13-Jul-2020**
CAS No. **5987-82-6** Retest date: **13-Jul-2025**
Formula: **-** Specification date: **16-Jun-2020**
Molecular Weight: **-**

Test	Method	Specification	Result
DESCRIPTION	10610__DEF00100	white to almost white crystalline powder	Complies
UV IDENTIFICATION	10610__DEF00300	complies with the reference	Complies
IR IDENTIFICATION	10610__DEF00400	complies with the reference	Complies
CHLORIDES IDENTIF.	10610__DEF00500	positive	Complies
MELTING POINT	10610__DEF02800	158.0 - 162.0 °C	160.1 °C
COLOUR OF SOLUTION	10610__DEF00800	less coloured than Y5 (Ph. Eur.)	Complies
SOLUBILITY	10610__DEF00700	clear solution (10 % in H ₂ O)	Complies
pH	10610__DEF01000	from 5.0 to 6.0	5.6
LOSS ON DRYING	10610__DEF01200	max. 0.5 %	0.0 %
SULPHATED ASHES	10610__DEF01300	max. 0.1 %	0.0 %
HEAVY METALS	10610__DEF02200	max. 10 ppm	Complies
ORGANIC IMPURITIES	10610__DEF06800	A 420 nm: max. 0.060 (10 % in H ₂ SO ₄)	0.009
ASSAY (HClO ₄)	10610__DEF12700	99.0 - 101.5 % (on the dried substance)	99.6 %
	10610__DEF12700	EP test : 98.5 - 101.5 % (on the dried substance)	99.8 %
IMPURITIES (HPLC)	10610__DEF07300	any impurity: max. 0.10 %	0.03 %
	10610__DEF07300	sum of impurities: max. 0.25 %	0.05 %
IMPURITIES (HPLC) II	10610__DEF07900	any impurity: max. 0.10 %	0.00 %
	10610__DEF07900	sum of impurities: max. 0.25 %	0.00 %
RESIDUAL SOLVENTS	10610__DEF18600	Ethanol: max. 1000 ppm	98 ppm
OXYDABILITY	10610__DEF18100	persistent coloration for approx. 2 min.	Complies
TLC	10610__DEF03600	total of impurities: max. 0.1 %	Complies

Release comment: **meets specification**Released On: **24-Aug-2020 09:28 (UTC+02:00)**
on behalf of Siegfried Evionnaz SAReleased By: **LAGE ANNE**
QA-Manager

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