

CERTIFICATE OF ANALYSIS

Material No: **701520**

Name: **Benoxinate HCl**
OXYBUPROCAINE HCL

Quality: **Ph. Eur, USP**

Batch No: **24154037** Manufacturing date: **18-Apr-2024**

CAS No. **5987-82-6** Retest date: **18-Apr-2029**

Formula: **-** Specification date: **15-Mar-2024**

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	158.8 °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)	0.018
ASSAY (HClO ₄)	10610__DEF12700	99.0 - 101.5 % (on the dried substance)	100.0 %
	10610__DEF12700	EP test : 98.5 - 101.5 % (on the dried substance)	100.0 %
IMPURITIES (HPLC)	10610__DEF07300	any impurity: max. 0.10 %	0.04 %
	10610__DEF07300	sum of impurities: max. 0.25 %	0.06 %
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	137 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: **31-May-2024 09:35 (UTC+02:00)**
on behalf of Siegfried Evionnaz SA

Released By: **LAGE ANNE**
QA-Manager

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