

Certificate of Analysis

BENOXINATE HCL

Lot Number: 16344204
 Product Code: BENOXINATE HCL
 Product Grade: STANDARD
 Reference:

ANALYTICAL TESTS	SPECIFICATIONS	RESULTS
DESCRIPTION	white to almost white crystalline powder	Complies
ODOUR	odourless	Complies
UV IDENTIFICATION	complies with the reference	Complies
IR IDENTIFICATION	complies with the reference	Complies
CHLORIDES IDENTIF.	positive	Complies
MELTING POINT	158.0 - 162.0 °C	159.2 °C
COLOUR OF SOLUTION	less coloured than Y5 (Ph. Eur.)	Complies
SOLUBILITY	clear solution (10 % in H2O)	Complies
pH	from 5.0 to 6.0	5.5
LOSS ON DRYING	max. 0.5 %	0.0 %
SULPHATED ASHES	max. 0.1 %	0.0 %
HEAVY METALS	max. 10 ppm	Complies
PALLADIUM	max. 1 ppm (ICP-OES)	N/D
ORGANIC IMPURITIES	A 420 nm: max. 0.060 (10 % in H2SO4)	0.004
ASSAY (HClO4)	99.0 - 101.5 % (on the dried substance)	100.0 %
TLC	total of impurities: max. 0.1 %	Complies
IMPURITIES (HPLC)	any impurity: max. 0.10 %	0.09 %
	sum of impurities: max. 0.25 %	0.11 %
RESIDUAL SOLVENTS	Ethanol: max. 1000 ppm	192 ppm
OXYDABILITY	persistent coloration for approx. 2 min.	Complies

Reference: Ph. Eur, USP

Analytical number : 54465
 Date of manufacture : (YYYY-MM-DD) 2016-09-09
 Date of analysis : (YYYY-MM-DD) 2016-09-12
 Date of retest : (YYYY-MM-DD) 2021-09-08

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Released by : LAGE ANNE
Released date : (YYYY-MM-DD) 2016-11-04

Conclusion : Complies

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