

ALKALOIDS PRIVATE LIMITED (Unit-I)

Manufacturing Site: 25/3, Gundlapochampally, Medchal-Malkajgiri District, Telangana - 500100, INDIA

Ph No: +91-40-23792010

CERTIFICATE OF ANALYSIS

Product Name : **Oxybuprocaine Hydrochloride Ph.Eur.** Reference : Ph.Eur
(CAS No. 5987-82-6)

Batch No. : 4511220 Quantity : 15.500 Kg

A.R.No. : QC/FG/001/21 Date of Analysis : 06/01/2021

Date of Manufacturing : Dec-2020 Retest Date : May-2022

S. No.	PARAMETERS	SPECIFICATIONS	RESULT
1.	Appearance	White or almost white, crystalline powder or colorless crystals	Complies
2.	Solubility	Very soluble in water; Freely soluble in ethanol (96 per cent)	Complies
3.	Identification		
	A) Melting point	Should be melt between 158°C to 162°C	158.7°C
	B) IR method	The I.R Spectrum of the sample must be concordant with that of Reference Standard /Working Standard.	Complies
	C) By TLC	The principal spot in the chromatogram obtained with the test solution is similar position, colour and size to the principal spot in the chromatogram obtained with reference solution(a)	Complies
	D) By Chemical test for chloride	Should be positive	Complies
4.	Appearance of solution (10% w/v solution)	Should be clear and colorless	Complies
5.	pH of a solution (10% w/v solution)	Should be about 4.5 to 6.0	5.2
6.	Related substances (by HPLC)		

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S. No.	PARAMETERS	SPECIFICATIONS	RESULT
	A) Impurity-A (4-aminobenzoic acid)	NMT 0.10%	Below Disregard Limit
	B) Impurity-B (4-amino-3-butoxybenzoic acid)	NMT 0.10%	Below Disregard Limit
	C) Impurity-C (4-amino-3-hydroxybenzoic acid)	NMT 0.10%	Below Disregard Limit
	D) Any other individual impurity	NMT 0.10%	0.04%
	E) Total Impurities	NMT 0.25%	0.08%
7.	Loss on drying	NMT 0.50% w/w	0.34%
8.	Sulfated ash	NMT 0.10% w/w	0.05%
9.	Assay (by Perchloric acid Titration)	NLT 98.50% & NMT 101.50% w/w, calculated on dried basis.	101.26%
10.	Residual Solvents by GC-MS		
	Ethanol	5000 ppm	Below Detection Limit
	Isopropyl Alcohol	5000 ppm	Below Detection Limit
	Ethyl Acetate	5000 ppm	Below Detection Limit
	Dimethyl formamide	880 ppm	Below Detection Limit

Remarks:- The product conforms / does not conform to Ph.Eur specifications.

Storage Conditions: Store in air-tight containers protected from light

Compiled By *v. hmy*
(Analyst-QC) 23/04/2021

Approved By *Ar* 23/04/2021
(HOD-QC)