

Product Name: PROCAINE HYDROCHLORIDE		Certificate no.: 042	
Batch no.: PRC00124		Release Date: 13.02.2024	
Batch size: 400 kg		Packing: polyethylene bags + carton card box	
Manufacturing Date: 27.01.2024		Re-test date: 01.2027	
No.	TEST	SPECIFICATIONS	RESULTS
1	Description:	White or almost white crystalline powder or colorless crystals	White crystalline powder
2	Solubility	Easy soluble in water, soluble in ethanol 96%	conform
3	Identification A. Melting Point B. IR Spectrum C. Chemical reaction for chlorides	154 – 158 °C (EP 2.2.14) Consistent with structure (EP 2.2.24) Positive reaction (EP 2.3.1)	155.2 Positive Positive reaction
4	Appearance of solution	Clear and colorless	Conform
5	pH	5.0 – 6.5	5.95
6	Related Substances (HPLC): - 4-Aminobenzoic acid, % - Methyl 4-Aminobenzoate, % - Any Unknown Impurity, % - Total Impurities, %	Not more than 0.05 Not more than 0.05 Not more than 0.05 Not more than 0.2	< 0.025 N.D. < 0.025 < 0.025
7	Related Substances (TLC):, % - Any individual impurity	Not more than 0.05	< 0.05
8	Loss on Drying, %	Not more than 0.5	0.04
9	Sulphated Ash, %	Not more than 0.1	0.05
10	Assay (reference to dried substance): - Procaine hydrochloride, %	99.0 – 101.0	99.2
11	Residual Solvents (GC): - Methanol, ppm	Not more than 500	N.D.
12	Diethylaminoethanol (GC), ppm	Not more than 500	1
13	Microbial Contamination: Total aerobic microbial count (TAMC) Total yeast and mold count (TYMC)	Not more than 10 ² CFU/g Not more than 10 CFU/g	< 10 < 10
14	Bacterial Endotoxins, IU/mg	n.m.t. 0.03 IU/mg	< 0.03

Conclusion: The analyzed product is **Procaine Hydrochloride** and it obeys specification no. ST-PRC-01/2020/01.

Opinion: **APPROVED** (This batch has been produced in accordance with EU-GMP regulations).

Quality Control Manager

Chem. Eng. Irina Morărescu



QA Manager

Chem. Eng. Manuel Gârbea