



Venkata Narayana Active Ingredients Private Limited

CERTIFICATE OF ANALYSIS

Product : Tetracaine Hydrochloride
Batch No. : TH0111124
Reference : Ph.Eur 11.0
Dispatch Qty.: 125.000 Kg



CAS No. : [136-47-0]
Date of Mfg: November-2024
Retest Date: October-2029

Storage condition: In an air tight container, protected from light.

S.No	TEST	SPECIFICATION	RESULT
1.0	Appearance	White or almost white, slightly hygroscopic, crystalline powder	White, Slightly hygroscopic, crystalline powder
2.0	Solubility	Freely soluble in water, soluble in ethanol (96%), practically insoluble in heptane.	Complies
3.0	Melting range (°C)	134 to 150	147.2-148.3
4.0	First Identification Test:		
4.1	Infrared absorption spectrophotometry (Test-A)	The IR spectrum of the test sample should be concordant with the spectrum obtained from Tetracaine Hydrochloride working /RS standard.	Complies
4.2	Reaction of chlorides (Test-D)	Should respond to the test for chlorides	complies
5.0	Second Identification Test:		
5.1	Chemical test -B	Should respond to the test	complies
5.2	Chemical test -C	Should develop a violet colour	complies
6.0	Appearance of solution	Solution should be clear and colour less	Complies
7.0	pH	Between 4.5 and 6.5	5.93
8.0	Related substances by HPLC (in %)		
8.1	Impurity-A	Not more than 0.05	Not detected
8.2	Impurity-B	Not more than 0.15	Not detected
8.3	Impurity-C	Not more than 0.15	Not detected
8.4	Maximum unspecified impurities	Not more than 0.10	0.01 (Below disregard limit: 0.05)
8.5	Total impurities	Not more than 0.5	0.01 (Below disregard limit: 0.05)
9.0	Loss on drying (% w/w)	Not more than 1.0	0.51
10.0	Sulphated ash (% w/w)	Not more than 0.1	0.06
11.0	Assay by Potentiometry (on dried basis) (% w/w)	Not less than 99.0 and not more than 101.0	100.0

Prepared By: *[Signature]*

Date: 30/11/2024

Checked By: *[Signature]*

Date: 30/11/24

Approved By: *[Signature]*

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S.No	TEST	SPECIFICATION	RESULT
12.0	Assay by HPLC (on dried basis) (% w/w)	Not less than 99.0 and not more than 101.0	99.4
13.0	Residual solvents by GC (in ppm)		
13.1	Methanol	Not more than 3000	85(Below detection limit:150)
13.2	Acetone	Not more than 5000	285(Below quantitation limit:750)
13.3	Hexanes	Not more than 290	Not detected
13.4	Toluene	Not more than 890	Not detected
14.0	Genotoxic impurities content by GC(ppm)(In-House)		
14.1	N-Butyl bromide	Not more than 15	Not detected
14.2	N,N-dimethyl amino ethyl chloride HCl	Not more than 15	Not detected

Remarks: The product Complies as per the above specification.

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