PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

ANALYTICAL SPECIFICATION FOR TROMETHAMINE USP

Manufacturer Name:		**Supplier Name:**
Manufacturer's Batch No.:		**Manufacturer's Batch Size:**
Manufacturing Date:		**Expiry Date:**
Quantity Received:		**Test Quantity:**
Document No.:	**Effective Date:**	**Change Control No.: N/A**
Control No./ A.R. No.:		**Retest Date:**

Reference : USP 25

Description : White, crystalline powder having a slight, characteristic odor.
Complies/Does Not Comply

Solubility : Freely soluble in water and in low molecular aliphatic alcohols (1 in 1-10); practically insoluble in chloroform, in benzene, and in carbon tetrachloride (1 in more than 10,000).
Complies/Does Not Comply

S.No.	Test	Reference	Result	Specification	Remark
1.	Identification A. IR B. C.	USP		A. IR absorption spectrum of test is concordent with reference spectrum of USP tromethamine RS. B. A yellow color is produced. C. The colour changes form light yellow to orange.	
2.	Melting range	USP		Between 168° to 172°	
3.	pH	USP		Between 10.0 and 11.5	
4.	Loss on drying	USP		Not More Than 1.0 %	
5.	Residue on ignition	USP		Not More Than 0.1 %	
6.	Heavy metals	USP		Not More Than 0.001 %	
7.	Assay as $C_4H_{11}NO_3$ (on dried basis)	USP		Not Less Than 99.0 % and not more than 101.0 %	

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ANALYTICAL SPECIFICATION FOR TROMETHAMINE USP

Raw Data Reference:

Analyst Name :

Analyst Name :

Analyst Name :

Analyst Hard Book No.: Page No.:

Analyst Hard Book No.: Page No.:

Analyst Hard Book No.: Page No.:

Results: Sample Conforms / Does Not Conform to Specification

Analyzed By: _____ Date: _____

Checked By: _____ Date: _____

Approved By: _____ Date: _____