



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

ANALYTICAL SPECIFICATION FOR TERPINE HYDRATE 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 24 pg1607

Description : Colourless lustrous crystals or white powder. Has a slight odour, and efflorescens in dry air. A hot solution (1 in 100) is neutral to litmus. When dried under vacuum at 60° for 2 hours, it melts at about 103°; free from foreign particles. Complies/Does Not Comply

Solubility : Slightly soluble in water, in Chloroform and in ether (1 in 100-1000); very soluble in boiling alcohol (1 in 1-10); Soluble in alcohol (1 in 10-30); sparingly soluble in boiling water (1 in 30-100).
Complies/Does Not Comply

S.No.	Test	Reference	Result	Specification	Remark
1.	Identification A. IR	USP		IR absorption spectrum of test dried at over Silica gel for 4 hours is concordent with referance spectrum of USP Terpene hydrate RS.	



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

ANALYTICAL SPECIFICATION FOR TERPINE HYDRATE USP

S.No.	Test	Reference	Result	Specification	Remark
1.	Identification (continued) B. Reaction with Sulphuric Acid	USP		B. The liquid becomes turbid and developss a strongly aromatic odour.	
2.	Water	USP		Between 9.0 and 10.0 %	
3.	Residue on ignition	USP		Not More Than 0.1%	
4.	Residual terpentine	USP		It has no odour of turpentine.	
5.	Assay as $C_{10}H_{20}O_2$ (on anhydrous basis)	USP		Not less than 98.0 % and not more than 100.5 %	

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 : _____