



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

ANALYTICAL SPECIFICATION FOR TERBUTALINE SULPHATE IP

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.:
Control No./ A.R. No.:		Retest Date:

Reference : IP 96 Page No 739-740

Description : White or almost white, crystalline powder; odourless or almost odourless, free from foreign particles.
Complies/Does Not Comply

Solubility : Freely soluble in Water (1 in 1-10); slightly soluble in Ethanol(95%) (1 in 100-1000); practically insoluble in Chloroform and ether (More than 10,000).
Complies/Does Not Comply

S.No.	Test	Reference	Result	Specification	Remark
1.	Identification (A,D) or (B,C,D) A. IR	IP		Note : Routinely identification A,D followed. A) IR absorption spectrum of test concordant with reference spectrum of WRS	



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S.No.	Test	Reference	Result	Specification	Remark
1.	Identification (A,D) or (B,C,D) (continued) B. UV C. TLC D.Reaction A of Sulphate	IP		B) Exhibits two maxima at about 276nm and 280 nm, which may be fused; absorbance at both 276 nm and 280 nm, 0.46 to 0.49. C) In the test of Related substances,the principal spot in the chromatogram obtained with the solution (2) correspondes to that in the chromatogram obtained with solution (4). D) White precipitate is formed.	
2.	Acidity	IP		Not More Than 1.2 ml of 0.01 M Sodium Hydroxide is required to change the colour of solution to yellow.	
3.	Clarity and Colour Solution	IP		Solution is clear And absorbance of 2-cm layer is not more than 0.11.	
4.	Heavy metals	IP		Not more than 25 ppm	



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S.No.	Test	Reference	Result	Specification	Remark
5.	tert- Butyl amino-3,5 dihydroxyacetophenone	IP		Absorbance at about 330 nm , not more than 0.50.	
6.	Related Substances	IP		TLC : Any secondary spot obtained with solution (1) is not more intense than the spot in chromatogram obtained with solution (3).	
7.	Loss on drying	IP		Not more than 0.5 %	
8.	Assay as (C ₁₂ H ₁₉ NO ₃) ₂ , H ₂ SO ₄ (On dried basis)	IP		Not Less Than 98.0 % and Not More Than 101.0 %	

Additional Test:

9.	Sulphated Ash	IH		Not More Than 0.2 %	
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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 : _____