



# PHARMA DEVILS

## QUALITY CONTROL DEPARTMENT

### ANALYTICAL SPECIFICATION FOR TINIDAZOLE IP

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

**Reference** : IP 1996 Page No. 764

**Description** : Pale yellow crystals or crystalline powder; odour slight and characteristic; free from foreign particles.  
Complies/Does Not Comply

**Solubility** : Sparingly soluble in water (1 in 30-100); Slightly Soluble in Ethanol (95%), Chloroform and in ether (1 in 100-1000).  
Complies/Does Not Comply

S.No.	Test	Reference	Result	Specification	Remark
1.	Identification (A,D) or (B,C,D)  A. IR  B. UV	IP		Note : Routinely identification A and D are followed.  A. IR absorption spectrum of test is concordant with WRS.  B. The light absorption in the range 230 to 360 nm exhibits	
1.	Identification (A,D) or (B,C,D) (Continued) B. UV  C. Colour Reaction  D. Melting point	IP		Maximum only at about 310 nm; absorbance at about 310 nm, about 0.35.  C. A greenish yellow colour is produced.  D. Melts between 125° and 128°C	
2..	Related Substances	IP		Any secondary spot in the chromatogram	



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S.No.	Test	Reference	Result	Specification	Remark
				obtained with solution (1) is not more than intense than the spot in the chromatogram obtained with solution (2) ( 1.0 %)	
3.	Sulphated Ash	IP		Not More Than 0.2%	
4.	Loss On Drying At 105 °C	IP		Not More Than 2.0 %	
5.	Assay as $C_8H_{13}N_3O_4S$ (On Dried Basis)	IP		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 : \_\_\_\_\_