

WRS  
T<sub>2</sub>-2

Unidrug Innovative  
Pharma Technologies Limited

WORKING STANDARD CERTIFICATE OF ANALYSIS TINIDAZOLE BP

Batch No.:	TNZ/1504041
Quantity:	1.0 gm
Date of Manufacture:	MAR - 15
Date of Expiry:	FEB - 20
Date of Analysis:	14/12/2015
Use Before	14/12/2016

Sr.No	Test	Result	Specification
01.	Appearance	Almost white, crystalline powder.	Almost white or pale yellow, crystalline powder.
02.	Solubility	Complies	Practically insoluble in water, soluble in acetone and in methylene chloride, sparingly soluble in methanol.
03.	Identification:		
	A).By Melting point	126.8 <sup>0</sup> C	125 <sup>0</sup> C to 128 <sup>0</sup> C
	C). By IR	Complies	Spectrum of sample must be concordant with Tinidazole working standard.
04.	Appearance of solution	The solution is clear and not more intensely colored than reference solution Y <sub>5</sub> .	The solution is clear and not more intensely colored than reference solution Y <sub>5</sub> .
05.	Related Substances: (By HPLC)		
	Impurity A	0.04%	Not more than 0.2%
	Impurity B	0.02%	Not more than 0.2%
	Unspecified impurities	Not detected	Not more than 0.1%
	Total impurities	0.12%	Not more than 0.4%
06.	Heavy metals	Less than 20 ppm	Not more than 20 ppm
07.	Loss on drying (at 105 <sup>0</sup> C)	0.12%	Not more than 0.5%
08.	Sulphated ash	0.03%	Not more than 0.1%
09.	Assay (on dried basis)	98.00% to 101.00% w/w	99.58%

Assay on AS IS BASIS

99.46%

Conclusion: The material as above complies with the BP Specification.

	Prepared By (QC)	Checked By (QC)	Approved By (QA)
Name	M. K. S. S.	R. S. S.	H. S. S.
Designation	Chemist	Chemist	Sr. Manager
Sign/Date	14/12/15	14/12/15	14/12/15

