

Tinidazole EP9.0

Batch no

250510-1

Mf date Retest

May 10 2025 May 09 2029

Molecular Structure

Molecular Formula

 $C_8H_{13}N_3O_4S$

Molecular Weight

247.3

CAS Registry Number

19387-91-8

Jun 24 2025

<u>Tests</u>	Specifications		Results
Appearance	Almost white or pale yellow crystalline powder		Pale yellow crystalline powder
Solubility	Practically insoluble in water, soluble in acetone and in methylene chloride, sparingly soluble in methanol		Conforms
Identification	IR		Positive
Melting point	125 ~ 128°C		125.6 ~ 127.8°C
Appearance of solution	5% solution in acetone should be clear and not more intensely colored than reference solution Y ₅		Conforms
Related substances (HPLC)	Impurity A	≤ 0.2%	ND
	Impurity B	≤ 0.2%	0. 12%
	Any unspecified impurity $\leq 0.1\%$		ND
	Total impurities	≤ 0.4%	0. 26%
Residual solvents (GC)	Ethanol	≤ 1000 ppm	70 ppm
	0-Xylene	≤ 195.3 ppm	20 ppm
Loss on drying (105°C)	≤ 0.5%	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	0.09%
Sulfated ash	≤ 0.1%		0. 02%
Assay (odb)	98.0 ~ 101.0%		99.6%
Packaging and storage	Preserved in tight a	nd light resistant co	ontainer,

Conclusion

Material complies with EP9.0

Temperature ≤ 30°C