



SWAPNROOP DRUGS & PHARMACEUTICALS

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CERTIFICATE OF ANALYSIS

Product Name	Trimetazidine Dihydrochloride BP	CAS No:	13171-25-0
Batch No.	2605001	Manufactured by	-
Date of Mfg.	MAY-2026	Date of Analysis	20/05/2026
Batch Quantity	-	Retest Date	APR-2031

Sr No	Test	Acceptance Criteria	Results
1	Description	A white or almost white crystalline powder, slightly hygroscopic.	White crystalline powder, slightly hygroscopic.
2	Solubility	Freely soluble in water, sparingly soluble in alcohol.	Freely soluble in water, sparingly soluble in alcohol.
3	Identification by - IR	IR spectrum should be concordant with that of reference standard	Complies
4	Identification by - chlorides	A curdy white precipitate is formed	Complies
5	Appearance of solution	A 10 % w/v solution is clear and not more intensely colored than reference solution BY6	Complies
6	Related substances (By HPLC) Trimetazidine Impurity A	Not more than 0.1%	Not detected
7	Related substances (By HPLC) Trimetazidine Impurity B	Not more than 0.1%	0.02%
8	Related substances (By HPLC) Trimetazidine Impurity C	Not more than 0.1%	Not detected
9	Related substances (By HPLC) Trimetazidine Impurity D	Not more than 0.1%	Not detected
10	Related substances (By HPLC) Trimetazidine Impurity E	Not more than 0.1%	Not detected
11	Related substances (By HPLC) Trimetazidine Impurity F	Not more than 0.1%	Not detected
12	Related substances (By HPLC) Trimetazidine Impurity F	Not more than 0.1%	Not detected
13	Related substances (By HPLC) Trimetazidine Impurity G	Not more than 0.1%	0.02%
14	Related substances (By HPLC) Trimetazidine Impurity H	Not more than 0.1%	Not detected
15	Related substances (By HPLC) Any other impurity	Not more than 0.1%	0.03%
16	Related substances (By HPLC) Total impurities	Not more than 0.2%	0.07%
17	Trimetazidine impurity G (By TLC)	Any secondary spot corresponding to trimetazidine impurity G is not more intense than the spot in the	Complies

Sr No	Test	Acceptance Criteria	Results
		chromatogram obtained with reference solution (0.1%)	
18	Sulphated Ash	Not more than 0.1 % w/w	0.04%
19	Loss on drying (LOD) at 105°C and reduced pressure (such as 15 kPa)	Not more than 2.5% w/w	0.79%
20	Assay (By Potentiometric titration)	Not less than 98.5% and not more than 101.5 % calculated on dried basis	99.57 %
21	Residual Solvent By GCHS Methanol	Not more than 3000ppm	680ppm
22	Residual Solvent By GCHS Acetone	Not more than 5000ppm	173ppm
23	Residual Solvent By GCHS Isopropyl Alcohol	Not more than 5000ppm	Not detected
24	Residual Solvent By GCHS Dichloromethane	Not more than 600ppm	Not detected

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

Prepared By  Sonali Nirmal Date: 23/05/2026	Checked by  Dadarao Kakde Date: 23/05/2026	Approved By  Nayna Nehete Date: 23/05/2026 
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