



SWAPNROOP DRUGS & PHARMACEUTICALS

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CERTIFICATE OF ANALYSIS

Product Name	BENFOTIAMINE - IH	CAS No:	22457-89-2.
Batch No.	2605001	Manufactured by	-
Date of Mfg.	MAY-2026	Date of Analysis	20/05/2026
Batch Quantity	-	Retest Date	APR2031

Sr No	Test	Acceptance Criteria	Results
1	Description	White to off white crystalline powder.	White crystalline powder
2	Solubility	It should slightly be soluble in water, very slightly soluble in ethanol, insoluble in ether, insoluble in chloroform.	Complies
3	Identification – By HPLC	Retention time by HPLC: In this test the principal peak in the chromatogram obtained for sample solution has the same retention time as that of the peak in the chromatogram obtained with the standard solution of Benfotiamine	Complies
4	Clarity and colour of solution	The solution should be Clear and colorless to faint yellow solution observed.	Complies
5	Chloride	Not more than 0.05%	Complies
6	Heavy metals	Not more than 20 ppm	Complies
7	Loss on drying	Not more than 2.0% w/w	1.0%
8	Related substances by HPLC TMP	Not more than 0.5%	0.05%
9	Related substances by HPLC Benzoic acid	Not more than 1.0%	0.24%
10	Related substances by HPLC Maximum Unknown impurity	Not more than 1.0%	0.40%
11	Related substances by HPLC Thiamine	Not more than 0.5%	<0.05%
12	Related substances by HPLC Total impurities	Not more than 2.0%	1.51%

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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