

CEFA-CILINAS BIOTICS PVT LTD

PLOT NO. W-8, CHIKALTHANA MIDC, AURANGABAD -431001, MH INDIA.

19.01.2024

CERTIFICATE OF ANALYSIS

Product Name	Ibuprofen BP		
CAS No.	15687-27-1	HS Code	30049063
Batch No	CEFA-IBPFN-20240001		

Sr No	Item	Specifications	Results
1	Appearance	White to almost white crystalline powder or colorless crystals	White crystalline Powder
2	Solubility	Partially insoluble in water, freely soluble in acetone, methanol and methylene chloride. It dissolves in dilute solutions of alkali hydroxides and carbonates.	Partially insoluble in water, freely soluble in acetone, methanol and methylene chloride. It dissolves in dilute solutions of alkali hydroxides and carbonates.
3	Identification by		
A	Melting Point by DSC	Peak maxima should be between 75 - 78°C	76°C
B	UV	Ultra violet and visible absorption spectrometry at 264 nm and 272 nm and shoulder at 258 nm. Absorption ratio 1.20 to 1.30 and 1.00 to 1.10	At 264 nm:1.24 At 272 nm:1.02
C	IR	The IR spectrum of the test sample should be similar to that of standard.	The IR spectrum of the test sample should be similar to that of standard.
D	TLC	The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution.	The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution.



4	Appearance of Solution	The solution is clear and colorless	The solution is clear and colorless
5	LOD at 55°C for 3 Hrs under vacuum (%w/w)	NMT 0.5%	0.23%
6	Optical Rotation [α] ₂₀ ⁵⁸⁹	Between -0.05 and +0.05°	0.004
7	Sulphated Ash (%w/w)	NMT 0.1	0.07
8	Related Substances by HPLC		
A	Ibuprofen Impurity- A	NMT 0.15%	0.03
B	Ibuprofen Impurity- J	NMT 0.15%	BDL(0.003)
C	Ibuprofen Impurity- N	NMT 0.15%	BDL(0.002)
D	Unspecified Impurities	NMT 0.05%	BDL(0.007)
E	Total Impurities	NMT 0.20%	0.03%
9	Assay by Titration (% w/w)	NLT 98.5 and NMT 101.0% calculated on dried substances	99.5%
10	Ibuprofen Impurity-F by GC(% Area)	NMT 0.10%	Not Detected
11	Related Solvents by HSGC (ppm)		
A	Isopropyl Alcohol	NMT 5000	53
B	Hexanes	NMT 290	21
C	Toluene	NMT 890	13

Remarks: The Material complies as per the above specifications



Sharad R Ahire
Mr Sharad R Ahire
Dept of Quality Control (QC)