

METAPHARMACEUTICAL

N DE LOTE:

0230724

24/07/2024

湖北亨迪药业股份有限公司
HUBEI BIOCAUSE HEILEN PHARMACEUTICAL CO.,LTD

Certificate of Analysis

COS covered batch.

COS No.: R1-CEP 2002-099-Rev 07

No.: 220424

Product: Ibuprofen

Test Standard: EP10.0

Batch#: C100-2203013M

Quantity: 1120kg

Manufacturing Date: 2022.03.02

Testing Date: 2022.03.03

Expiry Date: 2027.03.01

Items	Specifications	Results
Characteristics	White Crystalline Powder	Conforms
Solubility	Practically insoluble in water, freely soluble in acetone, in methanol and in methylene chloride. It dissolves in dilute solutions of alkali hydroxides and carbonates.	Conforms
Identification	A. Melting Point : 75.0—78.0℃	75.6—76.5℃
	C. IR Spectral Match	Conforms
Optical Rotation	-0.05°— +0.05°	0.00°
Appearance of Solution	Clear and Colorless	Conforms
Related Substances	2-[3-(2-methylpropyl)phenyl]propanoic acid(Impurity A): not more than 0.15%	0.03%
	2-[4-(2-methylpropanoyl)phenyl]propanoic acid(Impurity J): not more than 0.15%	Not detected
	2-(4-methylphenyl)propanoic acid(Impurity D): not more than 0.05%	Not detected
	2-(4-ethylphenyl)propanoic acid(Impurity N): not more than 0.15%	Not detected
	2-(4-propylphenyl)propanoic acid: not more than 0.05%	0.02%
	2-(4-butylphenyl)propanoic acid(Impurity B): not more than 0.05%	Not detected
	Any unknown impurity: not more than 0.05%	0.025%
	Total impurities: not more than 0.2%	0.09%
Loss on Drying	Not More Than 0.5%	0.11%
Sulfated Ash	Not More Than 0.1%	0.02%
Assay(Dry Basis)	98.5 - 101.0%	99.8%
Residual solvents	Petroleum ether not more than 250ppm	90ppm
	Methanol not more than 3000ppm	Not detected
	Toluene not more than 890ppm	Not detected
ADDITIONAL TESTS		
Bulk Density	0.25-0.50g/ml	0.41g/ml
Tapped Density	0.50-0.75g/ml	0.63g/ml
Median Particle Size	60-90um	77.0um
Conclusion: The product meets EP specifications.		
*Note: The test for impurity F described in the monograph is not necessary since this impurity cannot be present with the route of synthesis used.		

Qc supervisor: 廖敏杰

Checked by: 艾芸

Analyst(s): 欧苗 贺月 刘向雨 唐志芳

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