

Kalchem International

Chemicals & Compounding Supplies

Certificate of Analysis

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LETSCO MEDICAL: Item/Lot Number(s)

Item: 685388 Lot: 1504100193	Item: 685391 Lot: 1504100194	Item: 685389 Lot: 1504100195	Item: 691044 Lot: 1504100196
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Description: Ibuprofen USP	Source Lot: C100-1409060M	Expiration Date: 09/17/2019
Date of MFG: 09/18/2014	Test Standard: USP36	

Test Criteria	Specifications	Results
Characteristics	White crystalline powder	Conforms
Solubility	Practically insoluble in water; very soluble in alcohol, in methanol, in acetone, and in chloroform; slightly soluble in ethyl acetate.	Conforms
Identification:		
A. IR	A. Sample IR spectrum corresponds to that of the standard	Conforms
B. UV	B. Sample UV spectrum does not differ from that of the standard by more than 3.0%	Conforms
C. HPLC	C. Retention time corresponds to that of the standard	Conforms
Water content	Not more than 1.0%	0.10%
Heavy Metals	Not more than 0.002%	<0.002%
Residue on Ignition	Not more than 0.5%	0.01%
Chromatographic Purity	2-[3-(2-methylpropyl)phenyl]propanoic acid: not more than 0.15%	0.02%
	2-(4-methylphenyl)propanoic acid: not more than 0.15%	Not detected
	2-(4-ethylphenyl)propanoic acid: not more than 0.15%	0.01%
	2-(4-propylphenyl)propanoic acid: not more than 0.15%	0.01%
	2-(4-butylphenyl)propanoic acid: not more than 0.1%	Not detected
	Any unknown impurity: not more than 0.05%	0.03%
	Total impurities: not more than 0.6%	0.07%
Ibuprofen Related Compound C (4-Isobutylacetophenone)	Not more than 0.1%	Not detected
Assay (Dry basis)	97.0-103.0%	99.9%
Residual Solvents (Petroleum ether)	Not more than 250ppm	43ppm
Additional Tests		
Bulk Density	0.20-0.50g/ml	0.31g/ml
Tapped Density	0.40-0.70g/ml	0.52g/ml
Median Particle Size	30-60um	43.3um
Conclusion: The product meets USP36 specifications		

Letco Medical QA Review By/Date: Amanda Kelsøe

Digitally signed by Amanda Kelsøe
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