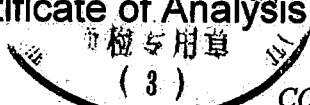


**biocause****湖北百科格莱制药有限公司**

HUBEI GRANULES-BIOCAUSE PHARMACEUTICAL CO., LTD

Certificate of Analysis*Ibuprofen*

COS covered batch.

COS No.: R1-CEP 2002-099-Rev 02

No.:102604Product: **Ibuprofen (75Grade)**Test Standard: **EP**Batch#: **C100-1012147M**Quantity: **1075kg**Manufacturing Date: **2010.12.20**Testing Date: **2011.03.11**Expiry Date: **2015.12.19***曹晓燕*

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℃	75.6-76.4℃
	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%	0.04%
	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%	0.03%
	2-(4-propylphenyl)propanoic acid: not more than 0.05%	0.02%
	2-(4-butylphenyl)propanoic acid(impurity B): not more than 0.05%	0.01%
	Any unknown impurity: not more than 0.05%	0.05%
	Total impurities: not more than 0.2%	0.15%
Heavy Metals	Not More Than 10ppm	<10ppm
Loss on Drying	Not More Than 0.5%	0.12%
Sulfated Ash	Not More Than 0.1%	0.01%
Assay(Dry Basis)	98.5 - 101.0%	100.1%
Residual solvents (Petroleum ether)	Not more than 250ppm	54ppm
ADDITIONAL TESTS		
Bulk Density	0.25-0.50g/ml	0.39g/ml
Tapped Density	0.50-0.75g/ml	0.63g/ml
Median Particle Size	60-90um	73.1um
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: 曹晓燕 Checked by: 胡士凤 Analyst(s): 曾梦月 唐志芳 叶金红 顿露林 程飞Site(s) of production: HuBei Granules-biocause pharmaceutical CO.,LTD.
122 Yangwan Road China-448000 Jingmen City, Hubei Province