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Quality Control			
CERTIFICATE OF ANALYSIS			
Product Name : IBUPROFEN BP/Ph.Eur/USP (S250Grade)			
Batch No. :	IBD1711287	Batch Size :	2000.00 kg
Manufacturing Date :	November-2017	Retest date :	October -2022
Date of Analysis :	22-11-2017	A.R.No. :	FPIBD1711287
Specification No.: SPEC-A1-QC-126 & SPEC-A1-QC-071		Rev.No:R0	
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Description of Packing : Sea Worthy Fibre Drum			

No.	Test	Specification	Result
1.0	Appearance	White or almost white, fine crystalline powder or colourless crystals	White fine crystalline powder
2.0	Solubility	Freely soluble in acetone, in methanol and in methylene chloride. Dissolves in dilute solutions of alkali hydroxides and carbonates. Practically insoluble in water	Complies
3.0	Identification		
3.1	Melting Point	75.0°C to 78.0°C	76.8°C
3.2	IR	The IR spectrum of sample should be concordant with the spectrum of Ibuprofen WS	Complies
4.0	Appearance of solution	10% w/v solution in methanol should be clear and colourless	Complies
5.0	Optical rotation	- 0.05° to + 0.05°	0.00°
6.0	Related substances (by HPLC)		
6.1	Specified Impurities		
6.1.1	2-(4-Isobutyryl Phenyl) Propanoic Acid (Impurity J)	NMT 0.10 % (Area %)	BDL (Disregard Limit:0.03%)
6.1.2	(2RS)-2-[3-(2-methyl propyl) phenyl] Propanoic acid(Impurity A)	NMT 0.15 % (Area %)	BDL (Disregard Limit:0.03%)
6.1.3	(2RS)-2-[4-ethyl phenyl] Propanoic acid (Impurity N) *	NMT 0.15 % (Area %)	Not Detected
6.2	Other detectable impurities:		
6.2.1	Identified Unspecified impurities:		
6.2.1.1	2-(4-Butyl phenyl)propanoic acid(Impurity B)	NMT 0.05 % (Area %)	BDL (Disregard Limit:0.03%)

A1/QA/018/F-11/R0