Pell Tech Health Care Pvt Ltd

Plot No. 20B, Tansa Farm Estate, Bhiwandi-Wada Road, Wada, THANE, MAHARASHTRA - 421312

CERTIFICATE OF ANALYSIS

Material Name	:	**Ibuprofen USP**				
Batch No.	:	IBM1511114	AR Number	:	2017-18/QCG/RMR/00286	
GRN No	:	RM-00181	Received Qty.	:	1000.000 Kg	
Manufacture Name	:	Shasun Pharma Ltd.	Received Date	:	20/06/2017	
Supplier Name	:	Raashi Nutraceuticales.	Sample Qty.	:	0.500 Kg	
Mfg. Date	:	Nov-2015	Sampling Date	:	22/06/2017	
Exp Date	:	Oct-2020	Rejected Qty.	:	0.000Kg	
Retest Date	:	09/07/2018	Released Date	:	10/07/2017	

SR. No.	Test	Specification	Observation
1	Description	White to off-white, crystalline powder, having a slight, characteristic odor.	White crystalline powder
2	Solubility	Very soluble in alcohol, in methanol, in acetone, and in chloroform; slightly soluble in ethyl acetate; practically insoluble in water.	Very soluble in alcohol, in methanol, in acetone, and in chloroform; slightly soluble in ethyl acetate; practically insoluble in water.
3	Identification A	By IR	Complies
4	Identification B	Absorptivities are calculated on the anhydrous basis, and do not differ by more than 3.0%	Complies
5	Identification C	The chromatogram of the Sample solution obtained as directed in the Assay exhibits a major peak for Ibuprofen, the retention time of which, relative to that of the internal standard, corresponds to that exhibited in the chromatogram of the Standard solution, obtained as directed in the Assay.	Complies
6	Residue on ignition	NMT 0.5%	0.04%
7	Heavy Metals	NMT 20 ppm	Complies
8	**Organic Impurity (Procedure 1)** Individual impurity Total impurities	 NMT 0.3% NMT 1.0%	 Complies Complies
9	**Organic impurities** Procedure 2	 NMT 0.1%	 0.0005%
10	Water Content By KF	NMT 1.0%	0.62 %
11	Assay on anhydrous basis	Between 97.0%–103.0% on the anhydrous basis	97.3 %

Conclusion: The conclusion of the undersigned about the above mentioned Raw Material **complies** as per United State Pharmacopoeia Laid down specification & is of a standard quality mentioned there in.

Prepared By Date 10/07/2017	Checked By Date 10/07/2017	Approved By Date 10/07/2017

Shahun®

Quality Control			
CERTIFICATE OF ANALYSIS			
Product Name	: **IBUPROFEN USP (SN Grade)**		
Batch No.	: IBM1511114		Batch Size : 3003.00Kg
Manufacturing Date	: Nov 2015		Retest date : Oct 2020
Date of Analysis	: 08-11-2015		A.R.No. : FPIBM151114
Specification No.	: SPEC-SCQY-033	Rev. No.: 08	Page No. : Page 1 of 2
Description of Packing : Sea Worthy Fibre Drum			

S.No	Test	Specification	Result
1.	Description	White to off-white crystalline powder with slight characteristic odour	White crystalline powder with slight characteristic odour.
2.	Solubility	Practically insoluble in Water, very soluble in alcohol, in methanol, in acetone and in chloroform, slightly soluble in ethyl Acetate	Complies
3.	Identification a) IR Absorption	The absorption spectrum of the test specimen, exhibits maxima only at same wave lengths as that of a corresponding working standard.	Complies
	b) UV Absorption	Respective absorptivities at 264 and 273 nm, calculated on the anhydrous basis, should not differ more than 3.0 % from Ibuprofen Working Standard.	(-) 1.10 % (AT264 nm) (-) 1.10 % (AT264 nm)
	c) HPLC	The chromatogram of the assay preparation obtained as directed in the Assay exhibits a major peak for Ibuprofen, the retention time of which, relative to that of the internal standard, corresponds to that exhibited in the chromatogram of the standard preparation obtained as directed in the assay.	Complies
4.	Water	NMT 1.00% (w/w)	0.07% (w/w)
5.	Residue on ignition	NMT 0.50% (w/w)	0.06% (w/w)
6.	Heavy metals	NMT 0.002% (w/w)	LT 0.002% (w/w)
7.	Chromatographic purity by HPLC		
	i) 2-(4-isobutyryl-phenyl) - propionic acid	NMT 0.05% (Area %)	0.018% (Area %)
	ii)Any unidentified impurity	NMT 0.05% (Area %)	0.030% (Area %)
	iii)Total impurities	NMT 0.50% (Area %)	0.045% (Area %)

SOP-CQA-005/F-07/00

SCQA/F-354/B

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Shahun®

Quality Control			
CERTIFICATE OF ANALYSIS			
ProductName	: **IBUPROFEN USP (SN Grade)**		
Batch No.	: IBM1511114		Batch Size : 3003.00Kg
Manufacturing Date	: Nov 2015		Retest date : Oct 2020
Date of Analysis	: 08-11-2015		A.R.No. : FPIBM151114
Specification No.	: SPEC-SCQY-033	Rev. No.: 08	Page No. : Page 1 of 2
Description of Packing	: Sea Worthy Fibre Drum		

S.No	Test	Specification	Result
8.	a. Assay (On anhydrous basis	97.0 to 103.0% (w/w)	98.7% (w/w)
	b. *Ibuprofen related compound C	NMT 0.10% (w/w)	0.0036% (w/w)
9.	Residual solvents i)Acetone ii)sopropyl alcohol iii)Hexanes iv)Trichloroethylene	 NMT 100ppm NMT 250ppm NMT 290ppm NMT 80ppm	 3 ppm BLD (LOD=0.13ppm) 18 ppm BLD (LOD=0.10ppm)
10.	Additional Test		
a.	Bulk Density Un tapped	 0.35-0.55g/mL	 0.40g/mL
	After 1250 tapings	0.50-0.75g/mL	0.70g/mL
b.	Mean particle size	60.0-90.0 Microns	69.3 Microns

* Ibuprofen related compound C: 4-Isobutyl aceto phenone
Note: NMT=Not more than LT=Less than BLD=Below Limit of detection LOD=Limit of detection
Remark: The material conforms to the specification.

	Prepared by	Reviewed by	Approved by
Signature			
Date	08/11/2015	08/11/2015	08/11/2015

SOP-CQA-005/F-07/00

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