



Pell Tech Health Care Pvt Ltd

Plot No. 20B, Tansa Farm Estate, Bhiwandi-Wada Road, Wada, Thane, Maharashtra - 421312

CERTIFICATE OF ANALYSIS

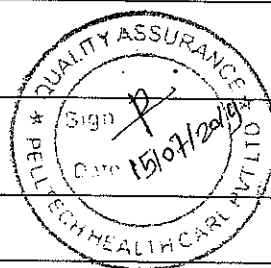
Product : FG753 IBUPROFEN TABLETS USP 400 mg		AR No : 2019-20/QCP/FGR/00279	
Analysis Date : 03/07/2019		Completion Dt : 15/07/2019	
Batch : 75319F03		Mfg. Date : Jun,2019	
Batch Size : 1500000 Nos		Exp. Date : May,2021	
Sample Type : Finished Product		Sampled Date : 03/07/2019	
Mfg. Lic. No. : KD-622		Sample Qty. : 300.000 Nos	
Spec. No. : FPS/FG753/06		Sampled By : SHARMA SURESH M	
		Sample Approved	

SR. No.	Test	Specification	Observation
1	Description	Pink coloured circular biconvex, glossy film coated tablets plain on both sides	Pink coloured circular biconvex, glossy film coated tablets plain on both sides
2	Identification Identification A Identification B	The IR absorption spectrum of a mineral oil dispersion of the residue exhibits maxima only at the same wavelengths as that of a similar preparation of USP Ibuprofen WS. The retention time of the major peaks from the Sample solution corresponds to that of the Standard solution, both relative to the internal standard, as obtained in the Assay.	IR absorption spectrum of a mineral oil dispersion of the residue exhibits maxima only at the same wavelengths as that of a similar preparation of USP Ibuprofen WS. Retention time of the major peaks from the Sample solution corresponds to that of the Standard solution, both relative to the internal standard, as obtained in the Assay.
3	Weight of 20 tablets	10.840 gm +/- 5% (10.298 gm to 11.382 gm)	10.93 gm
4	Average weight of tablets	542.0mg +/- 5% (514.90mg - 569.10mg)	546.45 mg
5	Uniformity of weight	+/- 5.0% of average weight of tablets	Complies
6	Water Content By KF	Not More Than 5.0 % w/w	3.13%
7	Hardness *	Between 6.0Kg - 12.0 Kg/cm2 (Kp)	13.689 Kg/cm2 (Kp) *
8	Diameter	Between 12.7mm +/- 0.5mm (12.2mm - 13.2mm)	12.80 mm
9	Thickness	Between 5.20 +/- 0.5mm (4.7mm - 5.7mm)	5.17 mm
10	Friability	Not more than 1.0%w/w	0%
11	Disintegration Time	Not more than 30mins	Max. 03 minutes, 36 seconds

ANIS BAIK LTD.
PSCCHSGC

2000915

MALAY WEST BRANCH



Analysed By	Checked By	Approved By
Date 15/07/2019	Date 15/07/2019	Date 15/07/2019



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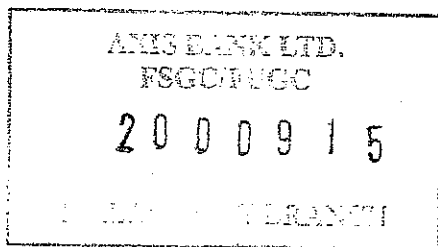
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12	Dissolution	Not less than 80% (Q) of the labeled amount of C13H18O2 is dissolved in 1hr.	100.2%	
13	Uniformity of dosage units (by weight)	AV : NMT L1- 15.0 or L2 -25.0	7.6	
14	Related Substance			
	Limit of Related Compound C	Not more than 0.25%	0.0376%	

ASSAY CONTENT

Name of the ingredient	Label contents Each film coated tablet contains	Actual contents Each film coated tablet contains	Potency (%)	Limit
Ibuprofen USP	400mg	415.485 mg	103.9%	Between 360.0mg - 440.0mg (Between 90.0% - 110.0%) of label claim

Conclusion : The conclusion of the undersigned about the above mentioned product **Complies** as per United State Pharmacopoeia Laid down specification and is of a standard quality mentioned there-in and released for Packing / Distribution.

* Released on Deviation (NO - DEV/19/PR-004)



Analysed By	Checked By	Approved By
Date: 15/07/2019	Date: 15/07/2019	Date: 15/07/2019