Format No. QC/01-039/F01

Pell Tech Health Care Pvt Ltd

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

CERTIFICATE OF ANALYSIS

		CERTIFICATE OF AN	NALYSIS		
Proc	duct : FG753 IBUPROFEN TAE	BLETS USP 400 mg	AR No :2019-20/QCP/FGR/00279		
			Completion Dt : 15/07/2019	1	
	lysis Date : 03/07/2019		Mfg. Date : Jun,2019		
Bato			Exp. Date : May,2021		
Batch Size : 1500000 Nos			Sampled Date : 03/07/2019		
	ple Type : Finished Product		Sample Qty. : 300.000 Nos	1	
	Lic. No. : KD-622		Sampled By : SHARMA SURESH M	ĺ	
Spec. No. : FPS/FG753/06			Sample Approved		
SR. No.	Test	Specification	Observation		
т	Danisi				
1 Description		Pink coloured circular biconvex,	Pink coloured circular biconvex,		
		glossy film coated tablets plain on	glossy film coated tablets plain on		
		both sides	both sides	l	
2	Identification			l	
	Identification A	The IR absorption spectrum of a	ID observation and the second		
		mineral oil dispersion of the residue	IR absorption spectrum of a mineral		
		<u>-</u>	oil dispersion of the residue exhibits		
		exhibits maxima only at the same	maxima only at the same wavelengths		
		wavelengths as that of a similar	as that of a similar preparation of		
		preparation of USP Ibuprofen WS.	USP Ibuprofen WS.		
	Identification B	The retention time of the major peaks	Retention time of the major peaks		
		from the Sample solution corresponds	from the Sample solution corresponds		
		to that of the Standard solution, both			
			to that of the Standard solution, both		
		relative to the internal standard, as	relative to the internal standard, as		
		obtained in the Assay.	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 AMIS WARREN	•	
5	Uniformity of weight	+/- 5.0% of average weight of tablets	Complies		
6	Water Content By KF		200091	5	
-	water Content by Ar	Not More Than 5.0 % w/w	3.13% V. L. V. L. V. BRAN	ICH	
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 (* (Sign) (Out of 100) [1]		
10	Friability	Not more than 1.0%w/w	0% PARALINER		
11	Disintegration Time	Not more than 30mins	Max. 03 minutes, 36 seconds		
	lysed By	Checked By	Approved By		
Anal		Chocked By	1 tropic ved by 1 2 is seen a seen a seen a		
Anal	15/07/2019	Date: 15107ho19	Approved By Date: Date:		

Pell Tech Health Care Pvt Ltd

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

CERTIFICATE OF ANALYSIS

Product :FG7	AR No :2019-	AR No : 2019-20/QCP/FGR/00279			
			Completion Dt]:	15/07/2019
Analysis Date : 03/07/2019			Mfg. Date	:	Jun,2019
Batch : 75319F03			Exp. Date	:	May,2021
Batch Size	: 1500000 Nos	1500000 Nos		:	03/07/2019
Sample Type	: Finished Product	: Finished Product		:	300.000 Nos
Mfg. Lic. No.	: KD-622	KD-622		 	SHARMA SURESH M
Spec. No.	: FPS/FG753/06		Sample Approv	ed	
12 Dissoluti	on	Not less than 80% (Q) of the labeled amount of C13H18O2 is dissolved in 1hr.	100.2%		Alban and Art - Ar
{	Uniformity of dosage units AV: NMT L1- 15.0 or L2 -25.0 (by weight)		7.6		
l i	Substance 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.

* Rueased on periation (NO = DEV/19/PR-004)

ANIS BLANK LTD.
FSGC/FUGC

2000915



Analysed B		Checked By	<i>n</i>	Approved By	10
Date	151043019	Date:	157.7/2019	Date:	Ja John J
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