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Granules India Limited	CERTIFICATE OF ANALYSIS	Page 1 of 3
Dept.: Quality Control		

Manufacturing Site:
Granules India Limited
Survey No.160/A,161/E,162 &174/A
Gagillapur village,
Dundigal-Gandimaisamma Mandal,
Medchal-Malkajgiri Dist-500043,
Telangana,INDIA
Ph. No.: 91-8418-306401
Fax: 91-8418-306402

Corporate Address:
Granules India Limited
2nd Floor, 3rd Block,
My Home Hub, Adj to Cyber Towers,
Madhapur,Hyderabad – 500 081
E-mail: mail@granulesindia.com
Telephone: 91-40-66760000
Fax: 91-40-23115145

Product Name :COMPRESSO IBU 66S (IBUPROFEN GRANULES DC 66%)

Batch No.:	3040747	A.R. No.:	FP/0268/0120
Mfg. Date:	JAN'2020	Exp. Date:	DEC'2022
Spec. No.:	GGFPS110-R	Rev. No.:	02
Batch Size:	6000.00 Kg	Analysis completion date:	31/01/2020

S.No.	TEST	SPECIFICATION	RESULT
1.	Characteristics	White free flowing granules with characteristic odor.	White free flowing granules with characteristic odor.
2.	Identification Ibuprofen a. UV Absorption in the range of 240-300 nm of 0.025% w/v solution in 0.1M Sodium hydroxide	Absorption Maxima at about 264 nm and 273 nm.	Maxima at 264 and 273 nm
	b. IR Spectrum	The IR spectrum of test sample shall be concordant with that of Reference spectrum	The IR spectrum of test sample is concordant with that of Reference spectrum
	c. By HPLC	The retention time of the Ibuprofen peak in the chromatogram of the Assay preparation correspond to the chromatogram of the standard preparation, as obtained in the Assay.	The retention time of the Ibuprofen peak in the chromatogram of the Assay preparation correspond to the chromatogram of the standard preparation, as obtained in the Assay.
3.	Moisture content (by K.F Method)	2.3 - 3.3% w/w	2.9% w/w

Prepared by QC Sign & Date	Approved by QC Sign & Date	Authorized by QA Sign & Date
		31/01/2020
R. [illegible] Naidu Executive -QC	P. Venkateswara Rao Dy. Manager - QC	J. Sanjeeva Reddy Dy. Manager - QA

Granules India Limited Dept.: Quality Control	CERTIFICATE OF ANALYSIS	Page 2 of 3

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S.No.	TEST	SPECIFICATION	RESULT
4.	Ibuprofen Content (by HPLC Method) (On anhydrous basis)	65.00 to 68.00% w/w	67.45% w/w
5.	Limit of 4-Isobutylacetophenone	NMT 0.1%	Below LOQ (LOQ=0.0043%)
6.	Related substances a.2-(4-butylphenyl) propionic acid b. Impurity-j(2-4-Isobutyryllphenyl) propionic acid c. Any other impurity d. Total other impurities	 NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.7%	 Not detected Not detected 0.06% 0.06%
7.	Bulk Density in g/ml a. Tapped b. Untapped	 For Information For Information	 0.725 g/ml 0.562 g/ml
8.	Sieve Analysis(Particle size distribution) ASTM Mesh No. #20 #60 #100 #200 PAN	% Cumulative retention 0.0 – 7.0% 35.0 – 65.0% 55.0 – 80.0% 75.0 – 95.0% NMT 25.0%	% Cumulative retention 5.4% 44.6% 62.1% 82.1% 17.9%

Prepared by QC Sign & Date	Approved by QC Sign & Date	Authorized by QA Sign & Date

R. Nallapu Naidu
Executive - QC

P. Venkateswara Rao
Dy. Manager - QC

J. Sanjeeva Reddy
Dy. Manager - QA

Granules India Limited Dept.: Quality Control	CERTIFICATE OF ANALYSIS	Page 3 of 3

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Batch Size:	6000.00 Kg	Analysis completion date:	31/01/2020

S.No.	TEST	SPECIFICATION	RESULT
09.	Residue on ignition	NMT 1.8% w/w	1.2 % w/w
*10.	Residual Solvents	Shall meet the requirement as per USP<467>	Not Applicable
11.	Microbial Limit Test a.Total Aerobic Microbial Count b.Total Yeast and Moulds Count c. Pathogens i) Salmonella *species* ii)(*E.Coli*, Pseudomonas *aeruginosa*, Staphylococcus *aureus* and Candida *albicans*)	 NMT 1000 cfu/g NMT 100 cfu/g Shall be absent/ 10g Shall be absent/ g	 < 10 cfu/g < 10 cfu/g Absent / 10g Absent / g

Report: Product complies with the above specifications.

*Remarks: Residual solvents test is not applicable as no solvent used in the manufacturing process and Drug product complies with the requirements USP General chapter <467>.

Disclaimer statement: The product meets the requirements listed in the recommendations of ICH Q3D (Guideline for Elemental Impurities) and USP <232/233>.

Prepared by QC Sign & Date	Approved by QC Sign & Date	Authorized by QA Sign & Date
28/01/2020	28/01/2020	30/01/2020
R. Pallapu Naidu Executive -QC	P. Venkateshwara Rao Dy. Manager - QC	J. Sanjeeva Reddy Dy. Manager - QA