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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 2 nd Floor, 3 rd 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
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Product Name : COMPRESSO PAP 90 CPC (Acetaminophen Directly compressible Granules)			
Batch No.:	2002295	A.R. No.:	FP/1775/0620
Mfg. Date:	JUN'2020	Exp. Date:	MAY'2024
Spec. No.:	GGFPS145-R	Rev. No.:	05
Batch Size:	6050.0 kg	Analysis completion date:	15/06/2020

S.No.	TEST	SPECIFICATION	RESULT
1.	Characteristics	White free flowing granules	White free flowing granules
2.	Identification		
	I.Acetaminophen		
	a. Reaction with Iron (III) chloride	Shall develop Blue-violet colour	Developed Blue-violet colour.
	b.UV-Absorption in Methanolic Solution.	Maxima at about 249 nm	Maxima at 248 nm
	c.Melting Point	About 169°C	170°C
	II. Starch	Shall develop Deep Blue colour	Developed Deep Blue colour
3.	Related Substances (by HPLC Method)		
	i) Impurity J (4- Chloroacetanilide)	NMT 10 ppm	Not Detected
	ii) Impurity K (4-Aminophenol)	NMT 50 ppm	2 ppm
	iii) Impurity F (4-Nitrophenol)	NMT 0.05%	Not Detected
	iv) Any other impurity	NMT 0.05%	Below Disregard Limit
	v) Total other impurities	NMT 0.1%	0.0%
4.	Moisture content (by K.F Method)	1.0% – 1.5% w/w	1.1 %w/w

Prepared by QC Sign & Date	Approved by QC Sign & Date	Authorized by QA Sign & Date
R. Putaji Naidu 15/06/20	K. Brahmaiah 15/06/20	A. Sanjeeva Reddy 16/06/2020

R. Putaji Naidu
Executive-QC
Ref. No.: GGQC021/F-04-01

K. Brahmaiah
Dy. Manager-QC

A. Sanjeeva Reddy
Dy. Manager-QA



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5.	Acetaminophen Content (by UV Method) (On as is basis)	87.50 to 92.50% w/w	89.72% w/w
6.	Bulk density (Tapped) in g/ml	For Information	0.714 g/ml
7.	Angle of Repose in degrees(°)	For information	27.98°
8.	Sieve Analysis (Particle size distribution) ASTM Mesh No. #12 #20 #40 #60 #100 #200 Pan	% Cumulative retention NIL 5.0 - 25.0% 30.0 - 60.0% 50.0 - 90.0% 75.0 - 95.0% 85.0 - 100.0% NMT 15.0%	% Cumulative retention NIL 15.6% 50.3% 73.0% 85.7% 94.2% 5.4%
9.	Sulphated Ash	NMT 0.14% w/w	0.05% w/w
10.	Iron	NMT 50 ppm	Less than 50ppm
*11.	Residual Solvents	Shall meet the requirement as per USP <467>	Not Applicable

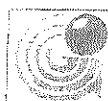
Prepared by QC Sign & Date <i>R. P. Subrahmanya</i>	Approved by QC Sign & Date <i>R. P. Subrahmanya</i> 15/06/20	Authorized by QA Sign & Date <i>S. V. S. S. S.</i> 16/06/2020
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R. P. Subrahmanya
Executive-QC

Ref. No.: GGQC021/F-04-01

K. Brahmaiah
Dy. Manager-QC

S. V. S. S. S.
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Formula:**A) Active Ingredient**

Acetaminophen USP 90.00% w/w

B) Excipients

- 1.Pregelatinised starch USP NF/Ph.Eur -8.40%w/w
- 2.Povidone (PVPK-30) USP /Ph.Eur -0.60%w/w
- 3.Stearic Acid USP NF/Ph.Eur - 1.00%w/w

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
R 15/06/20	R 15/06/20	J. Sridheva R. Ach 16/06/2020

R. Pulaji Naray
Executive-QC
Ref. No.: GGQC021/F-04-01

K. Brahmaiah
Dy. Manager-QC

J. Sridheva R. Ach
Dy. Manager-QA

COMPRESSO PAP 90 CPC

(Acetaminophen directly compressible granules)

Batch No. : 2002295

Drum No. : 001

Mfg.Dt. : Jun-2020

Tare Wt. : 05.40 Kg

Exp.Dt. : May-2024

Net Wt. : 50.00 Kg

Mfg.Lic.No. : 37/RR/AP/2003/F/R

Gross Wt. : 55.40 Kg

Storage : Preserve in well closed containers, store at room temperature.

Caution : For Manufacturing, Processing or Repacking only.

GIL/PL/036C



Manufactured by:

Granules India Limited

Sy.No.160/A, 161/E, 162, & 174/A, Gagillapur Village,
Dundigal-Gandimaisamma Mandal, Medchal-Maikhajgiri District - 500043,
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