

2104000009

Granules India Limited	CERTIFICATE OF ANALYSIS	Page 1 of 2
Dept.: Quality Control		

<u>Manufacturing Site:</u> Granules India Limited Plot No.160/A,161/E,162 &174/A Madhapur village, Madhwal-Gandimaisamma Mandal, Medchal-Malkajgiri Dist-500043, Sangana,INDIA Tel. No.: 91-8418-306401 91-8418-306402	<u>Corporate Address:</u> 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 CFC (Acetaminophen Directly compressible Granules)			
No.:	2002466	A.R. No.:	IFP/5140/1220
Date:	DEC'2020	Exp. Date:	NOV'2024
No.:	GGFPS145-R	Rev. No.:	05
Lot Size:	6050.0 kg	Analysis completion date:	\$

TEST	SPECIFICATION	RESULT
Characteristics	White free flowing granules	White free flowing granules
Identification		
1.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	169°C
Bulk density (Tapped) in g/ml	For Information	0.725 g/ml
Sieve Analysis (Particle size distribution) ASTM Mesh No.	% Cumulative retention	% Cumulative retention
#12	NIL	NIL
#20	5.0 - 25.0%	13.9%
#40	30.0 - 60.0%	47.6%
#60	50.0 - 90.0%	74.9%
#100	75.0 - 95.0%	87.1%
#200	85.0 - 100.0%	96.9%
Pan	NMT 15.0%	2.9%

Prepared by QC Sign & Date	Approved by QC Sign & Date	Authorized by QA Sign & Date
<i>R. Pullaji Naidu</i>	<i>18/12/2020</i>	<i>20/12/2020</i>

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

K. Parthi Chowdary
 Asst. Manager - QC

N. Ravi Kumar
 Manager - QA

Granules India Limited		CERTIFICATE OF ANALYSIS		Page 2 of 2
<u>Depot Quality Control</u> <u>Manufacturing Site:</u> Granules India Limited Plot No. 150/A, 161/E, 162 & 174/A Madhapur village, Telangana-Gandimaisamma Mandal, Telangana-Malkajgiri Dist-500043, Telangana, INDIA Tel: 91-8418-306401 Fax: 91-8418-306402		<u>Corporate Address:</u> 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: 91-40-66750000 Fax: 91-40-23115145		
Product Name : COMPRESSO PAP 90 CPC (Acetaminophen Directly compressible Granules)				
No.:	2002466	A.R. No.:	IFP/5140/1220	
Date:	DEC 2020	Exp. Date:	NOV 2024	
Lot No.:	GCFPS145-R	Rev. No.:	05	
Net Weight:	6050.0 kg	Analysis completion date:	§	

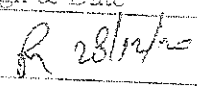
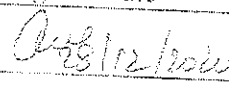
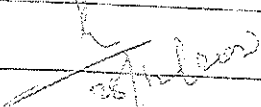
TEST	SPECIFICATION	RESULT
Residual Solvents	Shall meet the requirement as per USP <467>	Not Applicable
<u>Active ingredient</u> Acetaminophen USP 90.00% w/w	<u>B) Excipients</u> 1. Pregelatinised starch USP NF/Ph.Eur -8.40%w/w 2. Povidone (PVPK-30) USP /Ph.Eur -0.60%w/w 3. Stearic Acid USP NF/Ph.Eur - 1.00%w/w	

Test: Product complies with the above specifications.

Stability tests are under progress

Notes: 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>.

Minor 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. Pullaji Naidu Executive QC	 K. Prithvi Chowdary Asst. Manager - QC	 N. Ravi Kumar Manager - QA

Lot No.: GGQC021/F-04-01