

1603000155

Manufacturing Site

Granules India Limited
Survey No.160/A,161/E,162,
163/A, &174/A

Gagillapur village
Qutbullapur mandal
Ranga Reddy Dist. 500C43
TELANGANA State
Ph. No.: 08418 306601
Fax: 08418-306600

**Corporate Office**

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

Certificate of Analysis**Product Name: COMPRESSO PAP 90 CPC****Generic Name: ACETAMINOPHEN GRANULES DC 90%**

Batch No	:	2001449	Mfg. Dt.	:	DEC' 2015
A.R. No.	:	FP/1941/1215	Exp. Dt.	:	NOV' 2019
Batch Size	:	6010.00 Kg	Spec. No	:	GGFPS010-R Rev. No : 03

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 b. UV-Absorption in Methanolic Solution. c. Melting Point II. Starch	Shall develop Blue-violet colour Maxima at about 249 nm About 169°C Shall develop Deep Blue colour	Developed Blue-violet colour. Maxima at 248 nm 169°C Developed Deep Blue colour
3.	Test for Purity I. Related Substance by TLC a. 4- Chloroacetanilide b. Other impurities II. 4-Aminophenol	NMT 0.001% NMT 0.05% NMT 0.004%	Not Applicable
4.	Moisture content (by K.F Method)	1.0% – 1.5% w/w	1.1% w/w
5.	Acetaminophen Content (by UV Method) (On as is basis)	87.50 to 92.50% w/w	89.37% w/w
6.	Bulk density (Tapped)	For Information	0.793 g/ml
7.	Angle of Repose in degrees(°)	For information	24.90°

Prepared by / Date D. Vijaya Executive - QC	Approved by Q.C / Date M. Srikanth Reddy Dy. Manager-QC	Released by Q.A / Date N. Sreedhar Gupta Asst. Manager-QA
---	---	---

Manufacturing Site

Granules India Limited
Survey No. 160/A, 161/E, 162,
163/A, & 174/A
Gagillapur village
Qutbullapur mandal
Ranga Reddy Dist. 500043
TELANGANA State
Ph. No : 08418 306601
Fax: 08418-306600

**Corporate Office**

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

Certificate of Analysis**Product Name: COMPRESSO PAP 90 CPC****Generic Name: ACETAMINOPHEN GRANULES DC 90%**

Batch No.	:	2001449	Mfg. Dt.	:	DEC' 2015
A.R. No.	:	FP/1941/1215	Exp. Dt	:	NOV' 2019
Batch Size	:	6010.00 Kg	Spec. No	:	GGFPS010-R Rev. No : 03

S.No.	TEST	SPECIFICATION	RESULT
8.	Sieve Analysis (Particle size distribution) ASTM Mesh No. #12 #20 #40 #60 #100 #200 Pan	% Cumulative retention NIL 5.0 - 25.0% 40.0 - 70.0% 60.0 - 90.0% 75.0 - 95.0% 85.0 - 100.0% NMT 15.0%	% Cumulative retention NIL 16.9 % 49.7% 68.5% 84.0% 97.7% 2.3 %
9.	Heavy metals	NMT 20 ppm	Less than 20ppm
10.	Sulphated Ash	NMT 0.14% w/w	0.05% w/w
11.	Iron	NMT 50 ppm	Less than 50ppm
*12.	Residual Solvents	Shall meet the requirement as per USP <467>	Complies
\$13.	Related Substances (by HPLC Method) i) Impurity J (4-Chloroacetanilide) ii) Impurity K (4-Aminophenol) iii) Impurity F (4-Nitrophenol) iv) Any other impurity v) Total other impurities	NMT 10 ppm NMT 50 ppm NMT 0.05% NMT 0.05% NMT 0.1%.	Not detected 3 ppm Not detected Below disregard limit Below disregard limit

Report: The product conforms to the above specifications.

*Remarks: The following solvents are likely to be present: Formic acid and Acetic Acid, as they are present in the ingredients used in the manufacturing Process of Compresso PAP 90 CPC. Please refer to the Residual solvents declaration for the established limits. No solvents are used in the manufacturing process of Compresso PAP 90 CPC.

\$. This Related substances test is monitored by HPLC method instead of TLC method.

Prepared by / Date 14/12/15	Approved by Q.C / Date 14/12/15	Released by Q.A / Date 15/12/15
--------------------------------	------------------------------------	------------------------------------

D. Vijaya
Executive - QC

M. Srikanth Reddy
Q.C. Manager-QC

N. Sreedhar Gupta
Asst. Manager-QA
Page 2 of 2