

**ACETAMINOPHEN RAPID RELEASE- acetaminophen capsule, gelatin coated
Granules India Limited**

Acetaminophen Rapid Release Gelcaps

ACETAMINOPHEN RAPID RELEASE GELCAPS 500 MG

**Each rapid release gelcap contains
Acetaminophen USP 500 mg**

Batch No.:	XXX	No. of Units	5 x 5000 Gelcaps
Mfg. Dt.:	MMM/YYYY	Gross Wt.:	0.00 kg
Exp. Dt.:	MMM/YYYY	Tare Wt.:	0.00 kg
Mfg. Lic. No.:	37/RR/AP/2003/F/R	Net Wt.:	0.00 kg
NDC No.	XXXXX-XXX-XX	Box number:	000
Storage:	Store at 20 - 25C (68 - 77F); excursions permitted to 15 - 30 C (59 - 86F); Preserve in tightly closed containers.		
Caution	For Repacking only.		

Manufactured in India by:
Granules India Limited
Plot No. 160/A, 161/E, Gagillapur Village
Qutbullapur Mandal, Ranga Reddy Dt - 500 043, AP.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

ACETAMINOPHEN RAPID RELEASE GELCAPS 500 mg

Each rapid release gelcap contains
Acetaminophen USP 500 mg

Batch No. : XXXXXXX

No. of Units : 5000 Gelcaps

Mfg.Dt. : MM/YYYY

Exp.Dt. : MM/YYYY

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

NDC No. : 62207-167-31

Country of Origin: INDIA

Storage : Store at controlled room temperature [store at 20°-25°C (68°- 77°F);
excursions permitted to 15°-30°C (59°-86°F); preserve in tightly closed containers.]

Caution :For repacking only.

Product code : 700000000309

GIL/PL/041C



Manufactured by:

Granules India Limited

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

Sujani
Pillapalem

Digitally signed by
Sujani Pillapalem
Date: 2018.12.19
15:23:52 +05'30'

ACETAMINOPHEN RAPID RELEASE GELCAPS 500 mg

Each rapid release gelcap contains
Acetaminophen USP 500 mg

Batch No. : XXXXXXX

No. of Units : 25,000 (5 x 5,000)

Mfg.Dt. : MM/YYYY

Gross Wt. : 00.000 Kg

Exp.Dt. : MM/YYYY

Tare Wt. : 00.000 Kg

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

Net Wt. : 00.000 Kg

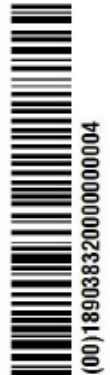
NDC No. : 62207-167-35

Box number : 000

Storage : Store at controlled room temperature [store at 20°-25°C (68°- 77°F);
excursions permitted to 15°-30°C (59°-86°F); preserve in tightly closed containers.]

Caution :For repacking only.

Country of Origin: INDIA



(01)50362207167357(17)000000(10)XXXXXXX

GIL/PL/041C



Manufactured by:

Granules India Limited

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

Sujani
Pillapalem

Digitally signed by
Sujani Pillapalem
Date: 2018.12.19
15:25:35 +05'30'

Product code : 700000000309

Acetaminophen Rapid Release Gelcaps 500mg (Gray)

Each rapid release gelcaps contains
Acetaminophen USP 500 mg

Batch No. : XXXXXXX	Pack Size : 40,000 no's
Mfg. Dt. : MM/YYYY	Gross Wt. : 00.000 Kg
Exp. Dt. : MM/YYYY	Tare Wt. : 00.000 Kg
Mfg.Lic.No. : 37/RR/AP/2003/F/R	Net Wt. : 00.000 Kg
NDC No. : 62207-167-11	Drum No. : 000

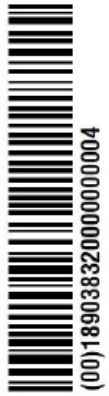
Storage : Store at controlled room temperature [store at 20°-25°C (68°- 77°F);
excursions permitted to 15°-30°C (59°-86°F)]; preserve in tightly closed containers.

Caution : For repacking only.



(01)50362207167111(17)000000(10)XXXXXX

Country of Origin: INDIA



(00)189038320000000004

FG Code : 700000003248

ACETAMINOPHEN RAPID RELEASE

acetaminophen capsule, gelatin coated

Product Information

Product Type	BULK INGREDIENT	Item Code (Source)	NDC:62207-167
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	499.5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
GELATIN (UNII: 2G86QN327L)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
FD&C RED NO. 40 (UNII: WZB9127XOA)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)
D&C RED NO. 33 (UNII: 9DBA0SBB0L)
ISOPROPYL ALCOHOL (UNII: ND2M416302)
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
AMMONIA (UNII: 5138Q19F1X)
ALCOHOL (UNII: 3K9958V90M)

Product Characteristics

Color	red, blue (blue-gray)	Score	no score
Shape	CAPSULE (banded two-part capsule)	Size	19mm
Flavor		Imprint Code	G;1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-167-21	5000 in 1 BOX	10/29/2013	
2	NDC:62207-167-22	25000 in 1 BOX	10/29/2013	
3	NDC:62207-167-31	5000 in 1 POUCH	10/29/2013	
4	NDC:62207-167-32	10000 in 1 POUCH	10/29/2013	
5	NDC:62207-167-33	25000 in 1 POUCH	10/29/2013	
6	NDC:62207-167-35	25000 in 1 BOX	10/29/2013	
7	NDC:62207-167-11	39806 in 1 DRUM	05/30/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		10/29/2013	

Labeler - Granules India Limited (915000087)

Registrant - Granules India Limited (915000087)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Limited		918609236	manufacture(62207-167) , analysis(62207-167)

