



**CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride powder  
Granules India Limited**

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**Cetirizine Hydrochloride, USP**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

<b>CETIRIZINE HYDROCHLORIDE USP</b>			
Batch No. :	Container No. :		
Mfg. Dt. :	Gross Wt. :		Kg.
Exp. Dt.:	Tare Wt. :		Kg.
Mfg. Lic.no. : 26/VP/AP/2007/B/CC/R	Net Wt. :		Kg.
NDC No. : 62207-001-02			
Storage conditions: Preserve in tight containers, protected from light and moisture store at room temperature. store at 20°C-25°C (68°F-77°F); Excursions permitted between 15°C-30°C(59°F-86°F)[See USP controlled room temperature]. Caution: For manufacturing, processing or repacking, "Rx" Only.			
Impurity Procedure: Procedure-2, This drug substance meets USP monograph requirements with regard to cetirizine N-Oxide, cetirizine methyl ester, Des-chlorocetirizine, 2-chlorocetirizine, 3-chlorocetirizine and 4-chlorobenzophenone contents if tested.			
 <b>GRANULES</b>		Country of Origin: India Manufactured by: <b>GRANULES INDIA LIMITED, Unit-IV</b> Plot No.08, Jawaharlal Nehru Pharma City, Tadi Village, Parawada Mandal, Anakapalli District-531019, Andhra Pradesh, India (IND)	

# CETIRIZINE HYDROCHLORIDE, USP

Batch No. : Container No. :  
Mfg. Dt. : Gross Wt. : Kg.  
Expiry Dt. : Tare Wt. : Kg.  
Mfg. Lic. no. : 26/NP/API/2007/B/CC Net Wt. : Kg.  
NDC No : 62207-001-11  
Storage : Preserve in tight containers, protected from light and moisture.  
Store at 20°C-25°C (68°F-77°F); excursions permitted between  
15°C-30°C (59°F-86°F) [See USP Controlled Room Temperature].  
Caution : For manufacturing, processing or repacking  
Impurity procedure : Procedure 2



GRANULES

Country of origin: India  
Manufactured by :  
GRANULES INDIA LIMITED  
Unit-IV, Plot No. 8, JN Pharma City, Tadi Village,  
Parawada Mandal, Visakhapatnam,  
Andhra Pradesh 531019, India (IND).

## CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride powder

### Product Information

Product Type	BULK INGREDIENT	Item Code (Source)	NDC:62207-001
Route of Administration	NOT APPLICABLE		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE HYDROCHLORIDE - UNII:64O047KTOA)	CETIRIZINE HYDROCHLORIDE	25 kg

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-001-11	25 in 1 DRUM	12/06/2016	05/20/2024
2	NDC:62207-001-02	25 in 1 DRUM	12/06/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		12/06/2016	

**Labeler** - Granules India Limited (915000087)

### Establishment

Name	Address	ID/FEI	Business Operations
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Granules India  
Limited

650376275

api manufacture(62207-001) , analysis(62207-001) , label(62207-001) ,  
pack(62207-001)

Revised: 4/2024

Granules India Limited