

BECKER DATA

Drug Master Files (FDA)

All active DMFs (FDA) for Aciclovir

Name	Aciclovir	CAS Number	59277-89-3	Originator	Wellcome Foundation (GSK)	Market Status	Launched	Uses	Antiviral			
Active Ingredients	Intermediate	Reaction	RCD	DMF	COS	JDMF	KDMF	Company	SPC	US Paragraph IV	Orange Book	Trial
DMF 23 result(s) Export												
Number	Type	Submission Date	Holder		Subject							
36328	II	29/09/2021	AUREORE LIFE SCIENCES PRIVATE LTD		ACYCLOVIR USP [SITE KHAZIPALLY]							
34516	II	28/01/2020	AUREORE LIFE SCIENCES PRIVATE LTD		ACYCLOVIR USP							
10671	II	10/01/1994	EXCELLA GMBH AND CO KG		ACYCLOVIR							
10945	II	09/06/1994	EXCELLA GMBH AND CO KG		ACYCLOVIR SODIUM							
35112	II	31/08/2020	HAINAN POLY PHARM CO LTD		ACYCLOVIR SODIUM DRUG SUBSTANCE							
25587	II	13/12/2011	HETERO DRUGS LTD		ACYCLOVIR							
24919	II	08/04/2011	HUBEI YITAI PHARMACEUTICAL CO LTD		ACYCLOVIR (NON-STERILE, BULK FORM)							
13277	II	22/10/1998	MYLAN LABORATORIES LTD		ACYCLOVIR USP							
20445	II	05/04/2007	OLON SPA		ACYCLOVIR							
10685	II	12/01/1994	OLON SPA		ACYCLOVIR							
25389	II	29/09/2011	PIRAMAL ENTERPRISES LTD		ACYCLOVIR							
8584	II	25/05/1990	QUIMICA SINTETICA SA		ACYCLOVIR							
10044	II	12/01/1993	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA SPA		ACYCLOVIR							

Name	Aciclovir	CAS Number	59277-89-3	Originator	Wellcome Foundation (GSK)	Market Status	Launched				
Active Ingredients	Intermediate	Reaction	RCD	DMF	COS	JDMF	KDMF	Company	SPC	US Paragraph IV	Orange Book
DMF 23 result(s)											
Number	Type	Submission Date	Holder								
36328	II	29/09/2021	AUREORE LIFE SCIENCES PRIVATE LTD								
34516	II	28/01/2020	AUREORE LIFE SCIENCES PRIVATE LTD								
10671	II	10/01/1994	EXCELLA GMBH AND CO KG								
10945	II	09/06/1994	EXCELLA GMBH AND CO KG								
35112	II	31/08/2020	HAINAN POLY PHARM CO LTD								
25587	II	13/12/2011	HETERO DRUGS LTD								
24919	II	08/04/2011	HUBEI YITAI PHARMACEUTICAL CO LTD								
13277	II	22/10/1998	MYLAN LABORATORIES LTD								
20445	II	05/04/2007	OLON SPA								
10685	II	12/01/1994	OLON SPA								
25389	II	29/09/2011	PIRAMAL ENTERPRISES LTD								
8584	II	25/05/1990	QUIMICA SINTETICA SA								
10044	II	12/01/1993	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA SPA								

FGD

