



SOURCES, QUALITY AND PRICES OF ACTIVE PHARMACEUTICAL INGREDIENTS OF ANTIRETROVIRAL DRUGS

Results of a 2012 WHO survey

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SOURCES, QUALITY AND PRICES OF ACTIVE PHARMACEUTICAL INGREDIENTS OF ANTIRETROVIRAL DRUGS

Results of a 2012 WHO survey

This document reports on a survey by WHO on the market for Active Pharmaceutical Ingredients (API) of antiretroviral (ARV) drugs, conducted in the first quarter of 2012. The information requested from the manufacturers included whether they produce ARV APIs, what is their API price, the regulatory status and pharmacopoeia standard of their products, their production capacity, storage conditions and whether they have an APIMF (API Master File) available or not. Thirteen manufacturers responded. The information they provided is shown in the tables below, which are arranged in alphabetical order by the International Non-proprietary Name of their products. The manufacturers contact information can be found in Appendix 1.

Disclaimer: *All data and information available in the Sources, Quality and Prices of Active Pharmaceutical Ingredients (API) for antiretroviral medicines has been provided by the manufacturers and has not been verified. WHO makes no representations or warranties, either expressed or implied, as to their accuracy, completeness or fitness for a particular purpose. Neither does WHO accept any responsibility or liability with regard to the reliance on, or use of, such data and information.*

WHO has made every effort to ensure the accuracy of the information presented, but the readers should realize that manufacturing and production capacity are a highly dynamic area, and that data can therefore never be complete. The data and information contained herein are being provided as is.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO, in preference to others of a similar nature that are not mentioned. However, some products on this list have been pre-qualified for procurement by the WHO pre-qualification pilot project, and have been endorsed by the Organization. This is the only endorsement WHO gives to pharmaceutical products. The list of WHO pre qualified API is available at <http://mednet3.who.int/prequal/>.

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ABACAVIR							
Manufacturer Company Name	API Price US\$/kg	Address of Production Facility	Regulatory authorities that certified GMP compliance	Pharmacopeia Standard	Storage Conditions	Production Capacity kg/Year (per API)	APIMF available (Yes / No)
Aurobindo Pharma Limited	700	Unit 11, Survey Nos. 61-66, Industrial Development Area, Pydibhimavaram, Ranasthalam Mandal, Srikakulam District, Andhra Pradesh.	India, USFDA	In-House	Store in a Well closed container at Controlled Room Temperature	24,000	Yes
Cipla Limited	1,150	Cipla Kurkumbh	US-FDA, TGA, WHO-Geneva	USP, EP, IP			Yes
Matrix Laboratories Ltd.	850	Unit VIII	USFDA/WHO/India	USP		30	Yes

ACYCLOVIR							
Manufacturer Company Name	API Price US\$/kg	Address of Production Facility	Regulatory authorities that certified GMP compliance	Pharmacopeia Standard	Storage Conditions	Production Capacity kg/Year (per API)	APIMF available (Yes / No)
Matrix Laboratories Ltd.	55	Unit VII	USFDA	USP/BP		200	Yes

A M P R E N A V I R							
Manufacturer Company Name	API Price US\$/kg	Address of Production Facility	Regulatory authorities that certified GMP compliance	Pharmacopeia Standard	Storage Conditions	Production Capacity kg/Year (per API)	APIMF available (Yes / No)
APIchem Chemical Technolgy Co.,Ltd	9000	Rm 15 C202.No 300 Chuantu Rd. Pudong Area. Shanghai 201202'	No	in House		0.1	No

A T A Z A N A V I R							
Manufacturer Company Name	API Price US\$/kg	Address of Production Facility	Regulatory authorities that certified GMP compliance	Pharmacopeia Standard	Storage Conditions	Production Capacity kg/Year (per API)	APIMF available (Yes / No)
APIchem Chemical Technolgy Co.,Ltd	1400	Rm 15 C202.No 300 Chuantu Rd. Pudong Area. Shanghai 201202 China	No	in House		5	No
Emcure Pharmaceuticals Ltd	2000	Emcure Pharmaceuticals Limited, Kurkumbh, India	USFDA				
Matrix Laboratories Ltd.	1400	Unit I	Filed	in House		6	Filed
Shanghai Desano Chemical Pharmaceutical Co., Ltd.	-	Shanghai	US			R&D	Tech pack

DARUNAVIR							
Manufacturer Company Name	API Price US\$/kg	Address of Production Facility	Regulatory authorities that certified GMP compliance	Pharmacopeia Standard	Storage Conditions	Production Capacity kg/Year (per API)	APIMF available (Yes / No)
APIchem Chemical Technolgoy Co.,Ltd	9000	Rm 15 C202.No 300 Chuantu Rd. Pudong Area. Shanghai 201202 China	No	in House		0.1	No

DIDANOSINE							
Manufacturer Company Name	API Price US\$/kg	Address of Production Facility	Regulatory authorities that certified GMP compliance	Pharmacopeia Standard	Storage Conditions	Production Capacity kg/Year (per API)	APIMF available (Yes / No)
Aurobindo Pharma Limited	600	Unit 11,Survey Nos. 61-66,Industrial Development Area, Pydibhimavaram,Ranasth alam Mandal,Srikakulam District,Andhra Pradesh.	India, USFDA	In-House	Store in a Well closed container at Controlled Room Temp.	12,000	Yes
Shanghai Desano Chemical Pharmaceutical Co., Ltd.	-	Shanghai	-			Campaign	Tech pack

E F A V I R E N Z							
Manufacturer Company Name	API Price US\$/kg	Address of Production Facility	Regulatory authorities that certified GMP compliance	Pharmacopeia Standard	Storage Conditions	Production Capacity kg/Year (per API)	APIMF available (Yes / No)
Arch Pharmalabs Ltd.	250	1) Arch Pharmalabs Limited Survey No. 10, Plot No. 3-72, Gaddapotharam, Jinnaram Mandal, Medak Dt. 502 319 (A.P) India	India local FDA	USP	Store in well closed container. Store at 25°C, excursions permitted between 15°C and 30°C	5 tonnes/10 tonnes per campaign. Lead time of 3 months for ordering.	yes
Aurobindo Pharma Limited	200	Unit 8, Survey No.13, Gaddapotharam Village, Jinnaram Mandal, Medak District, Andhra Pradesh.	India, USFDA	In-House	20-25°C [controlled room temperature in a well closed container]	120,000	Yes
Cipla Limited	600	Cipla Kurkumbh	US-FDA, TGA, WHO-Geneva	USP, EP, IP			Yes
Emcure Pharmaceuticals Ltd	450	Emcure Pharmaceuticals Limited, Kurkumbh, India	USFDA				
Matrix Laboratories Ltd.	325	Unit VIII	WHO/India	in House		225	yes
Matrix Laboratories Ltd.	450	Unit VIII	USFDA/WHO/India	in House		36	yes
Matrix Laboratories Ltd.	450	Unit III	USFDA/WHO/India	in House			yes
Shanghai Desano Chemical Pharmaceutical Co., Ltd.		Shanghai	US	IP		150000	Yes

EMTRICITABINE							
Manufacturer Company Name	API Price US\$/kg	Address of Production Facility	Regulatory authorities that certified GMP compliance	Pharmacopeia Standard	Storage Conditions	Production Capacity kg/Year (per API)	APIMF available (Yes / No)
Aurobindo Pharma Limited	420	Unit 11, Survey Nos. 61-66, Industrial Development Area, Pydibhimavaram, Ranasthalam Mandal, Srikakulam District, Andhra Pradesh.	India, USFDA	In-House	Store in a Well closed container at Controlled Room Temp.	20,000	Yes
Cipla Limited	1,100	Cipla Kurkumbh	US-FDA, TGA, WHO-Geneva	USP, EP, IP			Yes
Emcure Pharmaceuticals Ltd		Emcure Pharmaceuticals Limited, Kurkumbh, India	USFDA				
Lonzeal Pharmaceuticals Co., Ltd.	500	No. 16 West Ring Road, Shenze, Shijiazhuang City, Hebei Province 052560 China	N/A	Ph.Int., USP		20,000	Yes
Matrix Laboratories Ltd.	650	Unit III	USFDA/India	in House		24	Yes
Shanghai Desano Chemical Pharmaceutical Co., Ltd.		Shanghai	US			Campaign	Yes

ETRAVIRINE

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