

PEPFAR and USAID Consolidated List of Approved ARVs

Date: February 11, 2008

Generic Name	Strength	Dosage form	Supplier	Manufacturing Site(s)		Approval
Abacavir	20mg/ml	Oral solution	Aurobindo	Hyderabad	India	FDA (tentative)
Abacavir	300mg	Tablet	Aurobindo	Hyderabad	India	FDA (tentative)
Abacavir	300mg	Tablet	Cipla	Maharashtra	India	FDA (tentative)
Abacavir	300mg	Tablet	Matrix	Malegaon	India	FDA (tentative)
Abacavir	20mg/ml	Syrup	GlaxoSmithKline	Mississauga, Ontario	Canada	USAID
Abacavir	300mg	Tablet	GlaxoSmithKline	Ware, Hertfordshire	UK	USAID
Abacavir/Lamivudine	600mg/300mg	Tablet	GlaxoSmithKline	Ware, Hertfordshire	UK	USAID
Abacavir/Lamivudine/Zidovudine	300mg/150mg/300mg	Tablet	GlaxoSmithKline	Ware, Hertfordshire	UK	USAID
Amprenavir	50mg	Capsule	GlaxoSmithKline	Ware, Hertfordshire	UK	USAID
Amprenavir	75mg/5ml	Oral Solution	GlaxoSmithKline	Mississauga, Ontario	Canada	USAID
Atazanavir	100mg	Capsule	Bristol Myers Squibb	Evansville, IN	USA	FDA
Atazanavir	150mg	Capsule	Bristol Myers Squibb	Evansville, IN	USA	FDA
Atazanavir	200mg	Capsule	Bristol Myers Squibb	Evansville, IN	USA	FDA
Atazanavir	300mg	Capsule	Bristol Myers Squibb	Evansville, IN	USA	FDA
Atazanavir	100mg	Capsule	Emcure	Pune	India	FDA (tentative)
Atazanavir	150mg	Capsule	Emcure	Pune	India	FDA (tentative)
Atazanavir	200mg	Capsule	Emcure	Pune	India	FDA (tentative)
Darunavir	300mg	Tablet	Tibotec	Janssen-Cilag S.p.A., Latina	Italy	USAID
Delavirdine	100mg	Tablet	Pfizer		USA	FDA
Delavirdine	200mg	Tablet	Pfizer		USA	FDA
Didanosine	100mg	Tablet, chewable, dispersible or buffered	Aurobindo	Hyderabad	India	FDA (tentative)
Didanosine	150mg	Tablet, chewable, dispersible or buffered	Aurobindo	Hyderabad	India	FDA (tentative)
Didanosine	200 mg	Tablet, chewable, dispersible or buffered	Aurobindo	Hyderabad	India	FDA (tentative)
Didanosine	200mg	Enteric Capsules	Barr Laboratories	Pomoma, New York	USA	FDA
Didanosine	250mg	Enteric Capsules	Barr Laboratories	Pomoma, New York	USA	FDA
Didanosine	400mg	Enteric Capsules	Barr Laboratories	Pomoma, New York	USA	FDA
Didanosine	25mg	Tablet	Bristol Myers Squibb	Meymac	France	USAID
Didanosine	100mg	Tablet	Bristol Myers Squibb	Meymac	France	USAID
Didanosine	150mg	Tablet	Bristol Myers Squibb	Meymac	France	USAID
Didanosine	200mg	Tablet	Bristol Myers Squibb	Meymac	France	USAID
Didanosine	250mg	Enteric Capsules	Bristol Myers Squibb	Meymac	France	USAID
Didanosine	400mg	Enteric Capsules	Bristol Myers Squibb	Meymac	France	USAID
Didanosine	50 mg	Tablet	Bristol Myers Squibb	Meymac	France	USAID
Didanosine	10mg/ml	Powder for Oral Suspension	Aurobindo	Hyderabad	India	FDA
Didanosine	10mg/ml	Powder for Oral Suspension	Bristol Myers Squibb	Meymac	France	USAID
Efavirenz	600mg	Tablet	Aurobindo	Hyderabad	India	FDA (tentative)
Efavirenz	600mg	Tablet	Cipla	Goa	India	FDA (tentative)

Efavirenz	30mg/ml	Syrup	Merck	Haarlem	Netherlands	USAID
Efavirenz	50 mg	Capsule	Merck	Haarlem	Netherlands	USAID
Efavirenz	50 mg	Capsule	Merck	Midrand	South Africa	USAID
Efavirenz	200mg	Capsule	Merck	Haarlem	Netherlands	USAID
Efavirenz	200mg	Capsule	Merck	Midrand	South Africa	USAID
Efavirenz	50mg	Capsule	Aurobindo	Hyderabad	India	FDA (tentative)
Efavirenz	100mg	Capsule	Aurobindo	Hyderabad	India	FDA (tentative)
Efavirenz	200mg	Capsule	Aurobindo	Hyderabad	India	FDA (tentative)
Efavirenz	600mg	Tablet	Merck	Haarlem	Netherlands	USAID
Efavirenz	600mg	Tablet	Merck	Midrand	South Africa	USAID
Efavirenz	100mg	Capsule	Merck	Haarlem	Netherlands	USAID
Efavirenz	600mg	Tablet	Matrix	Malegaon	India	FDA (tentative)
Efavirenz	600mg	Tablet	Strides Arcolab	Bangalore	India	FDA (tentative)
Efavirenz	600mg	Tablet	Emcure	Pune	India	FDA (tentative)
Emtricitabine	10mg/ml	Oral Solution	Gilead Sciences		USA	FDA
Emtricitabine	200mg	Capsule	Gilead Sciences		USA	FDA
Enfuvirtide Injection	90mg	Vial	Hoffmann-La Roche	Basel	Switzerland	USAID
Etravirine	100mg	Tablet	Tibotec	Janssen-Cilag S.p.A., Latina	Italy	USAID
Fosamprenavir	700mg	Tablet	GlaxoSmithKline	Ware, Hertfordshire	UK	USAID
Fosamprenavir	50mg/ml	Oral Suspension	GlaxoSmithKline	Mississauga, Ontario	Canada	USAID
Indinavir	400mg	Capsule	Merck	Haarlem	Netherlands	USAID
Indinavir	200mg	Capsule	Merck	Haarlem	Netherlands	USAID
Lamivudine	10mg/ml	Oral Solution	Aurobindo	Hyderabad	India	FDA (tentative)
Lamivudine	150mg	Tablet	Aurobindo	Hyderabad	India	FDA (tentative)
Lamivudine	300mg	Tablet	Aurobindo	Hyderabad	India	FDA (tentative)
Lamivudine	10mg/ml	Syrup	GlaxoSmithKline	Mississauga, Ontario	Canada	USAID
Lamivudine	150mg	Tablet	GlaxoSmithKline	Ware, Hertfordshire	UK	USAID
Lamivudine	150mg	Tablet	GlaxoSmithKline	Cape Town	South Africa	USAID
Lamivudine	300mg	Tablet	GlaxoSmithKline	Ware, Hertfordshire	UK	USAID
Lamivudine	150mg	Tablet	Hetero	Hyderabad	India	FDA (tentative)
Lamivudine	300mg	Tablet	Hetero	Hyderabad	India	FDA (tentative)
Lamivudine	150mg	Tablet	Ranbaxy	Paonta Sahib, Pradesh	India	FDA (tentative)
Lamivudine	10mg/ml	Oral solution	Cipla	Goa	India	FDA (tentative)
Lamivudine	150mg	Tablet	Matrix	Malegaon	India	FDA (tentative)
Lamivudine/Stavudine	150mg/40mg	Tablet	Strides Arcolab	Bangalore	India	FDA (tentative)
Lamivudine/Stavudine	150mg/30mg	Tablet	Matrix	Malegaon	India	FDA (tentative)
Lamivudine/Stavudine	150mg/40mg	Tablet	Matrix	Malegaon	India	FDA (tentative)
Lamivudine/Stavudine	150mg/30mg	Tablet	Cipla	Goa	India	FDA (tentative)
Lamivudine/Stavudine	150mg/40mg	Tablet	Cipla	Goa	India	FDA (tentative)
Lamivudine/Stavudine + Efavirenz	150mg/40mg + 600mg	Co-Pack Tablets	Strides Arcolab	Bangalore	India	FDA (tentative)
Lamivudine/Stavudine + Nevirapine	150mg/40mg + 200mg	Co-Pack Tablets	Strides Arcolab	Bangalore	India	FDA (tentative)
Lamivudine/Stavudine/Nevirapine	30mg/6mg/50mg	Dispersible tablets	Cipla	Goa	India	FDA (tentative)
Lamivudine/Stavudine/Nevirapine	60mg/12mg/100mg	Dispersible tablets	Cipla	Goa	India	FDA (tentative)

Lamivudine/Stavudine/Nevirapine	150mg/30mg/200mg	Tablet	Cipla	Goa	India	FDA (tentative)
Lamivudine/Stavudine/Nevirapine	150mg/40mg/200mg	Tablet	Cipla	Goa	India	FDA (tentative)
Lamivudine/Zidovudine	150mg/300mg	Tablet	Cipla	Goa	India	FDA (tentative)
Lamivudine/Zidovudine	150mg/300mg	Tablet	Pharmacare	Port Elizabeth	South Africa	FDA (tentative)
Lamivudine/Zidovudine	150mg/300mg	Tablet	Aurobindo	Hyderabad	India	FDA (tentative)
Lamivudine/Zidovudine	150mg/300mg	Tablet	GlaxoSmithKline	Ware, Hertfordshire	UK	USAID
Lamivudine/Zidovudine	150mg/300mg	Tablet	GlaxoSmithKline	Cape Town	South Africa	USAID
Lamivudine/Zidovudine	150mg/300mg	Tablet	Emcure	Pune	India	FDA (tentative)
Lamivudine/Zidovudine	150mg/300mg	Tablet	Matrix	Malegaon	India	FDA (tentative)
Lamivudine/Zidovudine + Efavirenz	150mg/300mg + 600mg	Co-Pack Tablets	Aurobindo	Hyderabad	India	FDA (tentative)
Lamivudine/Zidovudine + Efavirenz	150mg/300mg + 600mg	Co-Pack Tablets	Strides Arcolab	Bangalore	India	FDA (tentative)
Lamivudine/Zidovudine + Nevirapine	150mg/300mg + 200mg	Co-Pack Tablets	Aspen	Port Elizabeth	South Africa	FDA (tentative)
Lamivudine/Zidovudine + Nevirapine	150mg/300mg + 200mg	Co-Pack Tablets	Strides Arcolab	Bangalore	India	FDA (tentative)
Lamivudine/Zidovudine/ Nevirapine	150mg/300mg/ 200mg	Tablets	Cipla	Goa	India	FDA (tentative)
Lamivudine/Zidovudine/Abacavir	150mg/300mg/300mg	Tablet	Aurobindo	Hyderabad	India	FDA (tentative)
Lamivudine/Zidovudine/Nevirapine	150mg/300mg/200mg	Tablet	Aurobindo	Hyderabad	India	FDA (tentative)
Lopinavir/Ritonavir	80mg/20mg/ml	Oral Solution	Abbott	Abbott Labs, Queensborough	UK	USAID
Lopinavir/Ritonavir	200mg/50mg	Capsule	Abbott	Abbott Ludwigshafen	Germany	USAID
Lopinavir/Ritonavir	100mg/25mg	Capsule	Abbott	Abbott Ludwigshafen	Germany	USAID
Lopinavir/Ritonavir	133mg/33mg	Capsule	Abbott	Rp Scherer, St Petersburg	USA	FDA
Maraviroc	150mg	Tablet	Pfizer		USA	FDA
Maraviroc	300mg	Tablet	Pfizer		USA	FDA
Nelfinavir	250mg	Tablet	Hoffmann-La Roche	Basel	Switzerland	USAID
Nelfinavir	250mg	Tablet	Hoffmann-La Roche	Madrid	Spain	USAID
Nelfinavir	650mg	Tablet	Hoffmann-La Roche	Basel	Switzerland	USAID
Nelfinavir	650mg	Tablet	Hoffmann-La Roche	Madrid	Spain	USAID
Nelfinavir	50mg/g	Oral powder	Hoffmann-La Roche	Switzerland	Switzerland	USAID
Nevirapine	200mg	Tablet	Aurobindo	Hyderabad	India	FDA (tentative)
Nevirapine	50mg/5ml	Oral Suspension	Aurobindo	Hyderabad	India	FDA (tentative)
Nevirapine	200mg	Tablet	Strides Arcolab	Bangalore	India	FDA (tentative)
Nevirapine	200mg	Tablet	Boehringer Ingelheim	Ingelheim	Germany	USAID
Nevirapine	50mg/5ml	Oral Suspension	Boehringer Ingelheim	Ingelheim	Germany	USAID
Nevirapine	50mg/5ml	Oral Suspension	Boehringer Ingelheim	Columbus, Ohio	USA	FDA
Nevirapine	200mg	Tablet	Cipla	Goa	India	FDA (tentative)
Nevirapine	200mg	Tablet	Ranbaxy	Paonta Sahib, Pradesh	India	FDA (tentative)
Nevirapine	200mg	Tablet	Huahai US Inc.	Xunqiao	China	FDA (tentative)
Nevirapine	200mg	Tablet	Hetero	Hyderabad	India	FDA (tentative)
Nevirapine	200mg	Tablet	Emcure	Pune	India	FDA (tentative)
Raltegravir	400mg	Tablet	Merck	Whitehouse Station	USA	FDA
Ritonavir	100mg	Capsule (1x84)	Abbott	Rp Scherer St Petersburg	USA	FDA
Ritonavir	100mg	Capsule (4x84)	Abbott	Rp Scherer, Benheim	France	USAID
Ritonavir	80mg/ml	Oral Solution	Abbott	Abbott Labs, Queensborough	UK	USAID
Saquinavir	200mg	Capsule	Hoffmann-La Roche	Basel	Switzerland	USAID

Saquinavir	500mg	Capsule	Hoffmann-La Roche	Basel	Switzerland	USAID
Stavudine	15mg	Capsule	Aurobindo	Hyderabad	India	FDA (tentative)
Stavudine	20mg	Capsule	Aurobindo	Hyderabad	India	FDA (tentative)
Stavudine	30mg	Capsule	Aurobindo	Hyderabad	India	FDA (tentative)
Stavudine	30mg	Capsule	Strides Arcolab	Bangalore	India	FDA (tentative)
Stavudine	40mg	Capsule	Strides Arcolab	Bangalore	India	FDA (tentative)
Stavudine	40mg	Capsule	Aurobindo	Hyderabad	India	FDA (tentative)
Stavudine	1mg/ml	Powder for Oral Solution	Aurobindo	Hyderabad	India	FDA (tentative)
Stavudine	1mg/ml	Powder for Oral Solution	Cipla	Goa	India	FDA (tentative)
Stavudine	15mg	Capsule	Bristol Myers Squibb	Meymac	France	USAID
Stavudine	20mg	Capsule	Bristol Myers Squibb	Meymac	France	USAID
Stavudine	30mg	Capsule	Bristol Myers Squibb	Meymac	France	USAID
Stavudine	40mg	Capsule	Bristol Myers Squibb	Meymac	France	USAID
Stavudine	1mg/ml	Powder for Oral Suspension	Bristol Myers Squibb	Evansville, IN	USA	FDA
Stavudine	1mg/ml	Powder for Oral Suspension	Bristol Myers Squibb	Meymac	France	USAID
Stavudine	5mg/ml	Powder for Oral Suspension	Bristol Myers Squibb	Evansville, IN	USA	FDA
Stavudine	30mg	Capsule	Matrix	Malegaon	India	FDA (tentative)
Stavudine	40mg	Capsule	Matrix	Malegaon	India	FDA (tentative)
Tenofovir	300mg	Tablet	Gilead Sciences	Altana Pharma, Oranienburg	Germany	USAID
Tenofovir	300mg	Tablet	Gilead Sciences	Pantheon, Inc., Mississauga	Canada	USAID
Tenofovir	300mg	Tablet	Aspen	Port Elizabeth	South Africa	USAID
Tenofovir	300mg	Tablet	Matrix	Malegaon	India	FDA (tentative)
Tenofovir/Emtricitabine	300mg/200mg	Tablet	Gilead Sciences	Altana Pharma, Oranienburg	Germany	USAID
Tenofovir/Emtricitabine	300mg/200mg	Tablet	Gilead Sciences	Pantheon, Inc., Mississauga	Canada	USAID
Tenofovir/Emtricitabine	300mg/200mg	Tablet	Aspen	Port Elizabeth	South Africa	USAID
Tenofovir/Emtricitabine/Efavirenz	300mg/200mg/600mg	Tablet	Merck	Haarlem	Netherlands	USAID
Tipranavir	250mg	Capsule	Boehringer Ingelheim	Columbus, Ohio	USA	FDA
Zalcitabine	0.375mg	Tablet	Hoffmann-La Roche	Basel	Switzerland	USAID
Zalcitabine	0.75mg	Tablet	Hoffmann-La Roche	Basel	Switzerland	USAID
Zidovudine	10mg/ml	Solution for IV infusion	GlaxoSmithKline	Ware, Hertfordshire	UK	USAID
Zidovudine	100mg	Capsule	Cipla	Goa	India	FDA
Zidovudine	100mg	Capsule	Aurobindo	Hyderabad	India	FDA
Zidovudine	300mg	Tablet	Aurobindo	Hyderabad	India	FDA
Zidovudine	50mg/5ml	Oral Solution	Aurobindo	Hyderabad	India	FDA
Zidovudine	100mg	Capsule	GlaxoSmithKline	Crawley, West Sussex	UK	USAID
Zidovudine	250mg	Tablet	GlaxoSmithKline	Ware: Hertfordshire	UK	USAID
Zidovudine	300mg	Tablet	GlaxoSmithKline	Aranda	Spain	USAID
Zidovudine	300mg	Tablet	GlaxoSmithKline	Ware, Hertfordshire	UK	USAID
Zidovudine	50mg/5ml	Syrup	GlaxoSmithKline	Mississauga, Ontario	Canada	USAID
Zidovudine	300mg	Tablet	Ranbaxy	Paonta Sahib, Pradesh	India	FDA
Zidovudine	300mg	Tablet	Roxane Labs	Columbus, Ohio	USA	FDA

FDA = Fully approved by FDA;

FDA (tentative) = Tentatively-approved by FDA

USAID = Approved by USAID under the USAID Blanket ARV Source Waiver (for ARVs of innovator companies manufactured in specific non-US sites)