

WHO Reference Number	International nonproprietary name	Therapeutic Area	Date of prequalification	Status	Basis of Listing	Dosage form & strength	Storage Condition	Shelf life (months)	Packaging	Applicant	FPP Manufacturing Site	API Manufacturing Site
ANDA 0091611b USFDA 2	Zidovudine (sulfate)	HIV/AIDS		Prequalified	USFDA	Capsules, hard 300mg			Bottle, HDPE 30x1	Mylan Laboratories Ltd, Plot No.564/A/22, Road No. 92, Jubilee Hills, Hyderabad, Telangana, 500096, India	Mylan Laboratories Ltd, F4 & F12, Malegaon MIDC, Sinnar, Nashik District, Maharashtra, 422 113, India	
ANDA 077267 USFDA 1	Zidovudine	HIV/AIDS		Prequalified	USFDA	Tablet 300mg			Bottle HDPE:60x1; Blister:10x1	Aurobindo Pharma Ltd, Plot No 2, Maitrivihar, Ameerpet, Hyderabad, Telangana, 500 038, India	Aurobindo Pharma Ltd, Unit 3, Survey No 313, Bachupally, Hyderabad, Quthubllaur (M), Rangareddy District, Andhra Pradesh, 500 072, India	
ANDA 077268 USFDA 1	Zidovudine	HIV/AIDS		Prequalified	USFDA	Solution, Oral 10mg/ml			Bottle HDPE: 240ml	Aurobindo Pharma Ltd, Plot No 2, Maitrivihar, Ameerpet, Hyderabad, Telangana, 500 038, India	Aurobindo Pharma Ltd, Unit 3, Survey No 313, Bachupally, Hyderabad, Quthubllaur (M), Rangareddy District, Andhra Pradesh, 500 072, India	
ANDA 077275b USFDA 2	Didanosine	HIV/AIDS		Prequalified	USFDA	Tablets, Chewable 100mg			Bottle HDPE: 60x1	Aurobindo Pharma Ltd, Plot No 2, Maitrivihar, Ameerpet, Hyderabad, Telangana, 500 038, India	Aurobindo Pharma Ltd, Unit 3, Survey No 313, Bachupally, Hyderabad, Quthubllaur (M), Rangareddy District, Andhra Pradesh, 500 072, India	
ANDA 077275c	Didanosine	HIV/AIDS		Prequalified	USFDA	Tablets, Chewable			Bottle HDPE: 60x1	Aurobindo Pharma Ltd, Plot No 2, Maitrivihar, Ameerpet, Hyderabad, Telangana, 500 038, India	Aurobindo Pharma Ltd, Unit 3, Survey No 313, Bachupally, Hyderabad, Quthubllaur (M), Rangareddy District, Andhra Pradesh, 500 072, India	

ANDA 2 077464b USFDA 2	Lamivudine	HIV/AIDS	Prequalified	USFDA	Tablet 360mg	Blister:10x1; Bottle; Bottle HDPE: 60x1	Hyderabad, Andhra Pradesh, 500 002, Bachupally, Hyderabad, Telangana, 500 038, India Hyderabad, Andhra Pradesh, 500 072, Rangareddy District, India	Hyderabad, Andhra Pradesh, 500 072, Bachupally, Hyderabad, Telangana, 500 038, India Hyderabad, Andhra Pradesh, 500 072, Rangareddy District, India
ANDA 077521 USFDA 2	Nevirapine	HIV/AIDS	Prequalified	USFDA	Tablet 200mg	Blister:10x1; Bottle HDPE: 60x1	Aurobindo Pharma Ltd, Plot No 2, Maitrivihar, Ameerpet, Hyderabad, Telangana, 500 038, India	Aurobindo Pharma Ltd, Unit 3, Survey No 313, Bachupally, Hyderabad, Quthubllaur (M), Rangareddy District, Andhra Pradesh, 500 072, India
ANDA 077558 USFDA 2	Lamivudine/ Zidovudine	HIV/AIDS	Prequalified	USFDA	Tablet 150m g/300mg	Blister: 10x1; Bottle HDPE: 60x1	Aurobindo Pharma Ltd, Plot No 2, Maitrivihar, Ameerpet, Hyderabad, Telangana, 500 038, India	Aurobindo Pharma Ltd, Unit 3, Survey No 313, Bachupally, Hyderabad, Quthubllaur (M), Rangareddy

District,
Andhra
Pradesh,
500 072,
India