

| 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<br>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<br>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<br>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<br>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 |                        |

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| ANDA 2<br>077464b<br>USFDA 2 | Lamivudine                | HIV/AIDS | Prequalified | USFDA | Tablet<br>360mg        | Blister:10x1;<br>Bottle; Bottle<br>HDPE: 60x1 | Hyderabad, Andhra Pradesh, 500 002, Bachupally, Hyderabad, Telangana, 500 038, India<br>Hyderabad, Andhra Pradesh, 500 072, Rangareddy District, India | Hyderabad, Andhra Pradesh, 500 072, Bachupally, Hyderabad, Telangana, 500 038, India<br>Hyderabad, Andhra Pradesh, 500 072, Rangareddy District, India |
| ANDA<br>077521<br>USFDA 2    | Nevirapine                | HIV/AIDS | Prequalified | USFDA | Tablet<br>200mg        | Blister:10x1;<br>Bottle<br>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<br>077558<br>USFDA 2    | Lamivudine/<br>Zidovudine | HIV/AIDS | Prequalified | USFDA | Tablet 150m<br>g/300mg | Blister:<br>10x1; Bottle<br>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