

Prequalified Medicinal Products



Reference Number: ANDA 208355 USFDA 2

Basis of listing: USFDA

Status: Active

INN: Dolutegravir (Sodium)

Therapeutic area: HIV/AIDS

Dosage form & strength: Tablet 50mg

Packaging: Bottle, HDPE 30x1, 90x1

Applicant:

Aurobindo Pharma Ltd, Plot No 2, Maitrivihar, Ameerpet, Hyderabad, Telangana, 500 038, India

FPP Manufacturing Site:

Aurobindo Pharma Ltd, Unit VII, SEZ, APIIC Plot No SI, Survey No 411, 425, 434, 435 and 458, Green Industrial Park, Village Polepally, Mandal Jedcherla, District Mahaboobnagar, Andhra Pradesh, India
