



WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)

Prequalified Medicinal Products



Reference Number: ANDA 214397 USFDA 2

Basis of listing: USFDA

Status: Active

INN: Dolutegravir (Sodium)

Therapeutic area: HIV/AIDS

Dosage form & strength: Tablet, Film-coated 50mg

Packaging: Bottle 30x1, 90x1, 180x1

Applicant:

Macleods Pharmaceuticals Ltd, 304 Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, 400 059, India

FPP Manufacturing Site:

Macleods Pharmaceuticals Ltd, Unit 2, Plot No 25-27, Survey No 366, Premier Industrial Estate, Kachigam, Daman, 396 210, India

<https://www.facebook.com/WHO>