



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

Prequalified Medicinal Products



Reference Number: HA561

Date of prequalification: 08 April 2014

Basis of listing: Prequalified by WHO

Status: Active

INN: Emtricitabine/Tenofovir disoproxil fumarate

Therapeutic area: HIV/AIDS

Dosage form & strength: Tablet, Film-coated 200mg/300mg

Storage condition: HDPE bottle: Do not store above 30°C, store in dry place protected from light; Alu/OPA/Alu/PVC blister: Do not store above 25°C, store in dry place protected from light

Shelf life (months): 24

Packaging: Bottle HDPE: 30x1; Alu/cold form laminate of OPA/Alu/PVC: 10x10

Applicant:

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

FPP Manufacturing Site:

Macleods Pharmaceuticals Ltd, Block No. N2, Village Theda, P.O. Lodhi Majra, Tehsil Baddi, District Solan, Himachal Pradesh, 174 101, India

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

API Manufacturing Site:

(Tenofovir disoproxil fumarate) Hetero Labs Limited, Unit 9, Plot 2, Hetero Infrastructure SEZ - Ltd, N Narasapuram Village, Nakkapalli Mandal, Visakhapatnam District, Andhra Pradesh, 531 081, India

(Tenofovir disoproxil fumarate) Mangalam Drugs and Organics Limited, Unit-2, G.I.D.C, 3rd Phase, Plot no. 1203, Vapi, Valsad, Gujarat, 396 195, India

(Tenofovir disoproxil fumarate) Hetero Labs Ltd, Unit 1, Survey No 10 IDA, Gaddapothoram Village, Jinnaram (M), Sangareddy District, Telangana, 502319, India

(Tenofovir disoproxil fumarate) Acebright (India) Pharma Pvt Ltd, 77D & 116/117 KIADB Industrial Area, Jigani, Bangalore, Karnataka, 560 105, India

(Tenofovir disoproxil fumarate) Mangalam Drugs and Organics Ltd, Unit 1, Plot No 187, 2nd Phase GIDC, Vapi, Gujarat, 396 195, India

(Tenofovir disoproxil fumarate) Laurus Labs Ltd, Plot No 21, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam District, Andhra Pradesh, 531 021, India

(Emtricitabine) Hetero Labs Limited, Unit 9, Plot 2, Hetero Infrastructure SEZ - Ltd, N Narasapuram Village, Nakkapalli Mandal, Visakhapatnam District, Andhra Pradesh, 531 081, India

(Emtricitabine) Shijiazhuang Lonzeal Pharmaceuticals Co Ltd, Workshop No.303 and 102, No.16 West Ring Road, Shenze, Shijiazhuang, Hebei, 052560, China (People's Republic of)

(Emtricitabine) Shanghai Desano Chemical Pharmaceutical Co Ltd, 417 Binhai Road, Laogang Town, Pudong New Area, Shanghai, 201302, China (People's Republic of)

(Emtricitabine) Laurus Labs Ltd, Plot No 21, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam District, Andhra Pradesh, 531021, India

(Emtricitabine) Laurus Labs Ltd, Plot No 18, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam District, Andhra Pradesh, 531021, India

(Tenofovir disoproxil fumarate) Laurus Labs Ltd, Plot No 18, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam District, Andhra Pradesh, 531021, India

(Tenofovir disoproxil fumarate) Laurus Labs Limited (Unit-4)

(Emtricitabine) Macleods Pharmaceuticals Ltd, Plot No 2209 GIDC Industrial Area, At and Post Sarigam, Taluka: Umbergaon, Valsad District, Gujarat, 396155, India

(Tenofovir disoproxil fumarate) Macleods Pharmaceuticals Ltd, Plot No 2209 GIDC Industrial Area, At and Post Sarigam, Taluka: Umbergaon, Valsad District, Gujarat, 396155, India

API WHO Public Inspection Reports:

- M **Acebright (India) Pharma Pvt Ltd - (22 - 24 July 2019),**
📍 **Karnataka, India**
- M **Hetero Labs Limited (Unit I) - Desk Review - (02 September - 01 October 2019),**
📍 **Gaddapotharam, India**
- M **Laurus Labs Limited - Desk Assessment - (03 May 2020),**
📍 **Visakhapatnam, India**
- M **Macleods Sarigam (Macleods Pharmaceuticals Ltd) - Desk Assessment - (27 August 2020),**
📍 **Gujarat, India**
- M **Shanghai Desano Chemical Pharmaceutical Co Ltd - (15 - 18 January 2019),**
📍 **Shanghai, China**
- M **Laurus Labs Limited (Unit-4) - Desk Assessment - (10 - 13 August 2020),**
📍 **Hyderabad, India**
- M **Laurus Labs Limited - Desk Assessment - (03 May 2020),**
📍 **Visakhapatnam, India**

WHO Public Assessment Reports

 [Part 1](#),  [Part 2](#),  [Part 3](#),  [Part 4](#),  [Part 5](#),  [Part 6](#),  [Part 7](#),  [Part 8](#)

Part 1 - Abstract

Part 2 - All accepted presentations (including photo)

Part 3 - WHO-PQ recommended patient information leaflet*

Part 4 - WHO-PQ recommended summary of product characteristics*

Part 5 - Label

Part 6 - Discussion (status at the time of prequalification)

Part 7 - Steps before Prequalification

Part 8 - Steps following Prequalification (from 01 March 2014, only changes to the published information are included)

** This summary of product characteristics/patient information leaflet focus on uses of the medicine covered by WHO Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities (term to be revised). The medicine may be authorised for additional or different uses by national medicines regulatory authorities.*

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