

## 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:** Do not store above 30°C, protect from moisture, protect from light

**Shelf life (months):** 24

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

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#### 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

#### FPP WHO Public Inspection Reports:

M **Macleods Pharmaceuticals Ltd (Unit 2) - Desk Review - (22 October 2018),**  
📍 Shanti Nagar, India

M **Macleods (N2 (Unit VI) - Desk Review - (27 August 2018),**  
📍 Village Theda Baddi, India

#### API Manufacturing Site:

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

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

(Emtricitabine) Hetero Drugs 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.101 and 302, 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, 201 302, China (People's Republic of)

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

(Emtricitabine) Macleods Pharmaceuticals Ltd, Plot No 2209 GIDC Industrial Area, At and Post Sarigam, Taluka: Umbergaon, Valsad District, Gujarat, 396 155, India

(Tenofovir disoproxil fumarate) Macleods Pharmaceuticals Ltd, Plot No 2209 GIDC Industrial Area, At and Post Sarigam, Taluka: Umbergaon, Valsad District, Gujarat, 396 155, India

#### API WHO Public Inspection Reports:

- M **Hetero Labs Limited (Unit I) - Desk Review - (02 September - 01 October 2019),**  
📍 Gaddapotharam, India
- M **Laurus Labs Limited (Unit-1 & Unit-3) - (04 - 07 September 2017),**  
📍 Visakhapatnam, India
- M **Macleods Pharmaceuticals Ltd - (08 - 12 August 2016),**  
📍 Gujarat, India
- M **Mangalam Drugs and Organics Ltd, Unit I - (01 - 04 May 2018),**  
📍 Vapi, India
- M **Shanghai Desano Chemical Pharmaceutical Co Ltd - (15 - 18 January 2019),**  
📍 Shanghai, China
- M **Shijiazhuang Lonzeal Pharmaceuticals Co Ltd - (15 - 19 May 2017),**  
📍 Shijiazhuang, China

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## 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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