M Medicines

Prequalified Medicinal Products

Reference Number: HA722

Date of prequalification: 22 February 2021

Basis of listing: Prequalified by WHO

Status: Active

INN: Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate

Therapeutic area: HIV/AIDS

Dosage form & strength: Tablet, Film-coated 50mg/300mg/300mg

Storage condition: Do not store above 30°C

Shelf life (months): 36

Packaging: Bottle, HDPE 30x1, 90x1

Applicant:
Emcure Pharmaceuticals Ltd, T-184, M.I.D.C., Bhosari, Pune, 411026, India

FPP Manufacturing Site:
Emcure Pharmaceuticals Ltd, Plot No P-2, ITBT Park, Phase II MIDC, Hinjwadi, Pune, Maharashtra, 411057, India

FPP WHO Public Inspection Reports:

API Manufacturing Site:
(Lamivudine) Laurus Labs Ltd, Plot No 18, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam District, Andhra Pradesh, 531 021, India
(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
(Dolutegravir (sodium)) Laurus Labs Ltd, Plot No 21, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam District, Andhra Pradesh, 531 021, 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 **Laurus Labs Limited (Unit-1 & Unit-3) - (04 - 07 September 2017),**
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.*