

Prequalified Medicinal Products



Reference Number: TB159

Date of prequalification: 23 March 2007

Basis of listing: Prequalified by WHO

Status: Active

INN: Pyrazinamide

Therapeutic area: Tuberculosis

Dosage form & strength: Tablet 400mg

Storage condition: Do not store above 30°C, protect from moisture

Shelf life (months): 48

Packaging: Blister Alu/PVC: 10x3, 10x10, 28x3, 28x24, 10x24, 10x28; Alu/PVDC /PVC blister: 10x3, 10x10, 28x3, 28x10, 28x24, HDPE Bottle: 500x1, 1000x1

Applicant:

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

FPP Manufacturing Site:

Oxalis Labs, Vill. Theda, P.O. Iodhimajra, Baddi, Distt. Solan, 174101, 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 **Oxalis Labs - (13 - 16 March 2018),**
📍 Solan, India

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

API Manufacturing Site:

Linaria Chemicals (Thailand) Ltd, 309, Soi6C, Sukhumvit Rd, Bangpoo Industrial Estate, Moo4, Tumbol Phraska, Ampur Muang Samutprakan, Samutprakan, 10280, Thailand
(Pyrazinamide) Calyx Chemicals & Pharmaceuticals Ltd, Plot No-102/91/90, MIDC Industrial Area, Tarapur, Boisar, Maharashtra, 401 506, India
(Pyrazinamide) Anuh Pharma Ltd, E17/3 & 17/4 MIDC, Boisar, Tarapur, Thane District, Maharashtra, 401 506, India
(Pyrazinamide) 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 **Calyx Chemicals & Pharmaceuticals Ltd - (28 January - 01 February 2019),**