



Reference Number: TB237

Date of prequalification: 03 October 2012

Basis of listing: Prequalified by WHO

Status: Active

INN: Levofloxacin

Therapeutic area: Tuberculosis

Dosage form & strength: Tablet, Film-coated 250mg

Storage condition: Do not store above 30°C, store in dry condition, protect from light

Shelf life (months): Alu/PVC Blister (36 months), HDPE bottle (24months)

Packaging: Blister Alu/PVC: 10x10; HDPE bottle: 100x1

Applicant:

Micro Labs Ltd, 31 Race Course Road,
Bangalore, Karnataka, 560 001, India

FPP Manufacturing Site:

Micro Labs Ltd, Unit 3, 92 Sipcot Industrial
Complex, Hosur, Tamil Nadu, 635 126, India

FPP WHO Public Inspection Reports:

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**Micro Labs Limited - Unit-3 - (07 - 10
December 2015),**  Hosur, India

API Manufacturing Site:

(Levofloxacin) Shangyu Jingxin Pharmaceutical
Co Ltd, No 31 Weisan Road, Hangzhou Bay,
Shangyu Economic and Technological
Development Are, Shangyu, Zhejiang Province,
312369, China (People's Republic of)
(Levofloxacin) Zhejiang Apelo Kangyu
Pharmaceutical Co Ltd, 333 Jiangnan Road,
Hengdian, Dongyang, Zhejiang Province, 322
118, China (People's Republic of)

API WHO Public Inspection Reports:

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**Zhejiang Apelo Kangyu
Pharmaceutical Co Ltd - Desk
Assessment - (07 - 10 September
2020),**  Zhejiang, China

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**Shangyu Jingxin Pharmaceutical Co
Ltd - (21 - 24 January 2019),**
 Zhejiang Province, China