

2.3 QUALITY OVERALL SUMMARY

INTRODUCTION

- Drug Substance Proprietary name: Travoprost
- Drug Substance Non-proprietary name (INN): Travoprost

Drug Product:

- Drug Product Manufacturer:
.
- Drug Product Dosage Forms: Eyes, drops solution
- Strengths: 40 micrograms/ml
- Route of administration: Topical

Proposed indication:

Travoprost/ Pharmathen 40 micrograms/mL preservative free eye drops, solution in multi dose container decrease the elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.