

## **2.3 QUALITY OVERALL SUMMARY**

### **INTRODUCTION**

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

#### Drug Product:

- Drug Product Manufacturer: PHARMATHEN S.A., JADRAN - GALENSKI LABORATORIJ d.d.
- Drug Product Dosage Forms: Eyes, drops solution
- Strengths: 40 micrograms/ml Travoprost + 5 mg/ml Timolol
- 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.