

2.3 Quality Overall Summary

INTRODUCTION

Drug Substance Bimatoprost

- Drug Substance Proprietary name: Bimatoprost
- Drug Substance Non-proprietary name (INN): Bimatoprost
- Drug Substance Common name: Bimatoprost

Drug Substance Timolol Maleate

- Drug Substance Proprietary name: Timolol Maleate
- Drug Substance Non-proprietary name (INN): Timolol Maleate
- Drug Substance Common name: Timolol

Drug Product

- Drug Product Manufacturer: EXCELVISION.
- Drug Product Dosage Forms: Preservative free Eyes, drops solution
- Strengths: Bimatoprost 0.3 mg/mL Timolol 5 mg/mL
- Route of administration: Topical
- Proposed indication: Reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues.