

2.6 Nonclinical Summary

As Bimatoprost and Timolol are not new chemical entities, this application is related to a medicinal product claiming essential similarity Ganfort® (Allergan Ltd, Buckinghamshire, UK) eye drops solution in single dose container. Furthermore, a comparative study concerning the physicochemical properties between the two products showed that they are essentially similar. The physicochemical parameters compared were appearance, pH, viscosity, specific gravity and osmolality. Moreover the surface tension and the average drop volumes were found similar. The above demonstrate that Bimatoprost-Timolol/Pharmathen (0.3/ml + 5 mg/ml) preservative free Eye drops, solution will not lead to any different systemic absorption as compared to the reference product.

Additionally, guideline CPMP/EWP/239/95 final states: '*Generally safety and local tolerance may be guaranteed by knowledge of the active substance and the choice of known inactive ingredients*'. Therefore, tolerability study is not necessary and as no new additional studies have been provided within the documentation, Non-Clinical Summaries are not mandatory.

For a bibliographical research report on all studies carried out on Bimatoprost and Timolol please refer to *Module 4* of this application.