2.6 Nonclinical Summary

As Latanoprost is not a new chemical entity, this application is for a generic product claiming essential similarity to Xalatan®. A comparative study concerning the physicochemical properties between the two products showed that they are essentially similar. Comparison of physicochemical parameters in test and reference formulations demonstrated essential similarity in pH, viscosity, osmolality, buffering capacity and average drop volumes.
The above similarity demonstrate that Latanoprost/Pharmathen 50micrograms/mL preservative free Eye drops, solution should not lead to any different systemic absorption as compared to the reference product.
Moreover, the pharmacokinetics of Latanoprost have also been evaluated in an *in-vitro* comparative ocular study following administration of Latanoprost in the form of test and reference formulations in rabbits (male New Zealand Whites). The study concluded that Latanoprost acid exhibited similar exposure between test and reference except in Iris where it was likely higher in reference than test.
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 latanoprost please refer to Module 4 of this application.