Unpreserved ophtalmic formula : PYCLEAR™ Protection fully controlled risk of contamination with common 3 parts eye dropper

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Purpose:International Pharmacopeia specifies that the ophthalmic preparations must comply with sterility criteria. Recent studies have shown that the use of preservatives in the formulation of ophthalmic products can have toxic side effects for patients. All these studies have led to authorities encouraging the use of unpreserved multi-dose dispensers. This study tests new technology to replace preservatives in multi-dose eye drops.

Methods:Antibacterial activities (ISO22196) on plastics surface have been tested. The tests were performed at 36±1°C for 24h with *E.coli* and *S.aureus*. The results highlight an average antibacterial activity of 5-Log for each tested strain. Kinetic measure shows a decrease of 2-Log after 6h contact.
For ophthalmics products, the highest contamination risk is localized in the orifice, as it may come in contact with skin and lacrimal fluid. The dropper tip is more often contaminated (>85%) than the residual solution (Nentwich et al. 2007). Back-contamination tests, using a specific protocol (guidelines CPMP/QWP/159/96), simulating a use being more drastic than conventionally “in-use tests” by deliberately contaminating the tip with test controlled bacterial suspensions on standard eye dropper versus “Pylote added” eye dropper,several times a day for 28 days. Protocol was done with 5 strains of the Ph. Eur. and a sporulate form *B. subtilis*.

Results:Results highlight a complete control of the formulation back-contamination risks against the tested strains. 3 parts “Pylote added” eye dropper does not contaminate while in the same conditions the standard packaging is completely contaminated. Stability tests were performed on formulations filled in the « Pylote added » container. Different tests were conducted. Results show full formula stability.

Conclusions:Our results presents a contamination elimination by direct contact with 99,99+% performance. Tip protection due to unintentional contact with skin and/or lacrimal fluid is assured. Performance to stop back-contamination after use was demonstrated. Stability tests were successful.
Thus, eye drop solution is protected against microbiological contamination during the treatment period and patients will receive clean & pure doses upon each application. This innovation requires no change in patient treatment methods, only the usual droplet application.

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