Bacteria barrier evaluation of MistGo®

Conducted by Danish Technological Institute 2023

EYEGO

Background & Purpose

- Eye drops delivered in a multidose container must maintain sterility of the contents throughout the use period, as microbial keratitis is a risk for users of topical ophthalmic solutions upon accidental contamination of the product.
- Antimicrobial activity is often achieved through the addition of preservatives – the most frequently used benzalkonium chloride (BAK) – which due to toxicity have deleterious effects on the ocular surface.
- Removal of the preservative eliminates preservative-induced complications.
- A preservative free eye medication must be dispensed in a delivery system designed to keep the liquid formulation sterile throughout the treatment period.
- The test examines the possible contamination of the liquid stored in cartridges within MistGo® by bacteria that settle on the nozzle tip during use.

Methods

Moistened swab with bacteria suspension applied directly onto nozzle after daily use. Test temperature 32 ˚C.

- **Preparation**: Sterilized cartridges were aseptically filled with 6mL sterile liquids. MistGo® was assembled under aseptic conditions.
- **Simulated use**: designed to mimic load and release of 2 mists (one per eye) three times daily followed by contamination of the nozzle tip with pseudomonas aeruginosa as test organism. The cap was placed immediately after followed by overnight incubation at 32 ˚C standing in an upright position.
- **Examination**: after 7 days (A: growth media) and 30 days (B: saline) of incubation 2 mL liquid was retracted and evaluated on TSA plates to detect growth or no growth.

MistGo® designed to maintain sterility

- MistGo® is airtight and designed to maintain sterility in following way:
- Integrates a collapsible multilayer cartridge obviating air ventilation. No back flow of (contaminated) air requiring filtering.
- The liquid is sealed off from the environment using nonpermeable materials. Several barriers are established to separate the liquid from the environment, including a one-way valve.
- The system enables pressurized air to both create the mist and completely clean the outlet nozzle chamber after dispensing. The liquid column is broken, and no liquid is left for later microbiocidal contamination.
- An eye interface protects the nozzle from contamination caused by user contact, and a lid helps protect the dosing chamber during storage between use.

MistGo® can be used for eye medications both with and without preservatives

Results and Conclusions

- Both batch A and B showed no contamination with P. aeruginosa during the specified test conditions.
- The obtained results suggest that the sterility of the liquid retained in the cartridges can be maintained despite the nozzle tip being exposed to bacteria during simulated use.
- MistGo® is designed to provide an effective barrier to microbial ingress and is a delivery device suitable for preservative free eye medications.