Evaluation of Barex® Copolymer as a Suitable Packaging Material for Parenteral Pharmaceutical Products
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Purpose
To evaluate Barex® copolymer as an alternative to USP Type I glass and polypropylene for packaging of parenteral pharmaceutical products.

Methods
Commercial preparations of rapid acting insulin (insulin aspart), long acting insulin (insulin glargine) and short acting insulin (human insulin) were transferred to similar sized Barex®, polypropylene and USP type 1 glass containers. Packaged products were stored under accelerated (40°C / 75% RH), long term (25°C / 60% RH) and refrigerated (5°C) conditions, as per ICH guidelines. Samples were analysed periodically to evaluate active and preservative concentrations using an optimised stability-indicating RP-HPLC method. The level of related substances and degradants was also monitored.

The resistance of Barex® to oxygen permeability, in comparison to polypropylene, was investigated by monitoring the level of oxidation of 4-aminophenol in aqueous solutions in the presence and absence of an antioxidant (sodium metabisulphite), via UV-Vis spectroscopy after 14 days storage.

Results
Stability analysis of insulin products stored in Barex® containers demonstrated comparable performance to Type 1 glass and polypropylene after 6 months storage under refrigerated conditions. Under long term and accelerated conditions products stored in Barex® containers remained comparable to those stored in Type 1 glass and demonstrated increased stability when compared to polypropylene.

Aqueous solutions of 4-aminophenol stored in Barex® containers demonstrated an increased resistance to oxidation when compared to equivalent solutions stored in polypropylene, at each ICH stability condition. The addition of 0.1% w/v antioxidant improved stability for each container type and solutions in Barex® without antioxidant demonstrated equivalent stability to antioxidant containing solutions stored in polypropylene.

Conclusion
Commercial insulin products stored in Barex® copolymer containers demonstrated comparable stability to USP Type 1 glass after 6 months storage under refrigerated, long term and accelerated stability conditions. Barex® containers demonstrated an increased resistance to oxidation of 4-aminophenol when compared to polypropylene in the presence and absence of an antioxidant.

These results suggest that Barex® may be a suitable, non-fragile alternative to glass for the packaging of parenteral pharmaceutical preparations.

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