

Influence of relative humidity on water loss from eye drop bottles with silicone rubber teats

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(Received May 7th, 1979)

(Accepted May 17th, 1979)

The British Pharmaceutical Codex (1973) recommends the use of silicone rubber teats on eye drop bottles containing benzalkonium chloride-preserved solutions. However, because silicone rubber is permeable to water vapour the British Pharmaceutical Codex Supplement (1976) recommends that storage of such preparations should be limited to three months. There is some controversy concerning the rate at which water is lost from solutions of eye drops in such containers. For instance, Shaw et al. (1972) reported that eye drop bottles containing 10 ml water sealed with silicone rubber teats showed 4.92% loss of weight in 12 weeks at room temperature, while Lynch and Lund (1977) reported a 2.5% loss under similar conditions. In none of the reports was there any control of environmental humidity. Since moisture loss is a reflection of the water permeability of silicone elastomers, the rate of movement of water through the polymer will be influenced by any difference in water vapour concentration on either side of the silicone film. Therefore, the influence of the relative humidity of the air surrounding the container on the rates of moisture loss was assessed.

Hexagonal 10 ml eye drop bottles (British Standard 1679 Part 5, 1965) were

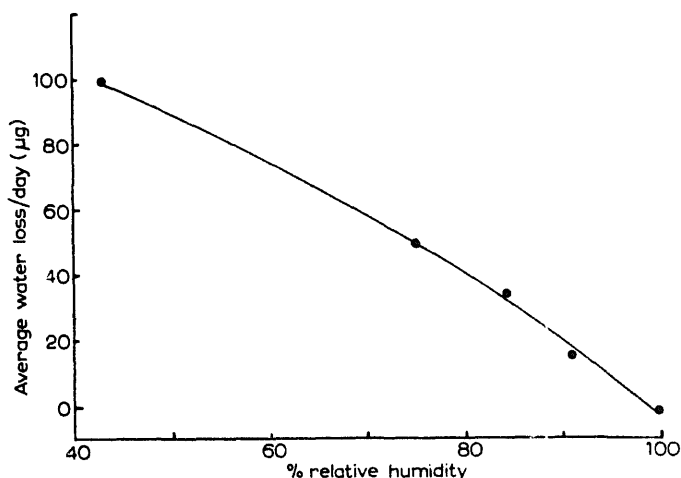


Fig. 1. The effect of relative humidity on the rate of loss of water vapour from eye drop bottles sealed with silicone rubber teats.

assembled using silicone rubber teats (W. Freeman and Co. Ltd., Subaseal Works, Staincross, Barnsley, Yorks., England). Ten ml distilled water was measured into each bottle, the assembled containers autoclaved at 115°C for 30 min, allowed to cool and then weighed. Three containers were placed in each desiccator, the relative humidity being controlled by saturated salts solutions, and the desiccators maintained at 32°C in an incubator. Each bottle was reweighed at suitable intervals.

The rate of loss of moisture occurred at a constant rate over a 4 month period and increased in direct proportion to the reduction in relative humidity, as shown in Fig. 1. Losses ranged from 2.2% at 91% R.H. to 10.1% at 43% R.H. over a 4 month period. It can be concluded that loss of water through silicone rubber teats is influenced by the relative humidity of the storage conditions, the rate constant at 32°C is $-0.00167 \text{ mg\% R.H.}^{-1} \text{ days}^{-1}$. Similar bottles stored in a desiccator humidified with water in fact showed no loss of contents during the 4 month period. Solutions of 0.9% w/v sodium chloride showed similar losses during storage. Therefore, the maintenance of eye drops in bottles sealed with silicone teats in conditions of high humidity can prevent appreciable water loss, and thus minimize potentially dangerous increases in the concentration of the active constituents of the preparation.

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