**Development of a Stable Nystatin Oral Suspension to Overcome Shortages of the Commercial Medicine**

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Background Nystatin is often used in the treatment of cutaneous, vaginal, mucosal and oesophageal Candida infections. It’s widely employed in cancer and immunocompromised patients suffering from mucositis. The unobtainability of the commercial oral suspension from July 2011 to February 2012 caused difficulties in the provision of the medicine for these types of inpatients and outpatients.

**Purpose** With the aim of ensuring a safe continuity of treatment, liquid formulations of nystatin 100,000 IU/ml were developed as oral suspensions, due to the insolubility of the drug in water. The suspensions obtained were studied to assess their chemical-physical stability to find the most suitable formulation.

**Materials and Methods** Nystatin was dispersed in water containing preservative using carboxymethyl cellulose (CMC) or tragacanth gum as suspending agents. The aqueous vehicles used were sucrose syrup or sorbitol syrup (for the treatment of diabetic or paediatric patients) flavoured with raspberry flavour. The final pH was adjusted to 4 to 20%, which are usually unavailable, has been reported for microvascular surgery (4 to 20%), which are usually unavailable, has been reported for microvascular surgery (4 to 20%) that are transplanted to the flap and promotes thrombosis in the anastomotic site. The wide availability and rapid effect of topically applied lidocaine is used by many surgeons to prevent and correct vasospasm.

**Conclusion** The development of a stable nystatin suspension was crucial to ensure continuity of care for patients with oral mucositis previously treated with a commercial formulation, whose temporary lack offered new formulation challenges to the hospital pharmacists.

No conflict of interest.

**Development of a Topical Lidocaine Sterile Formulation 20% (w/v)**

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**Background** The topical use of concentrated solutions of lidocaine (4 to 20%), which are usually unavailable, has been reported for microvascular surgery. Vasospasm is known to have an adverse effect on the survival of free tissue transfers. Prolonged vasocstriction decreases blood flow to the flap and promotes thrombosis at the anastomotic site. The wide availability and rapid effect of topically applied lidocaine is used by many surgeons to prevent and correct vasospasm.

**Purpose** To compound a sterile 20% (w/v) lidocaine solution physicochemically and microbiologically stable for topical application during surgery.

**Materials and Methods** Three batches of a 20% (w/v) sterile lidocaine solution were prepared using two sterilisation steps: autoclaving followed by filtration (0.22 μm) inside a horizontal laminar flow hood. Packaging in 10 ml dropping containers prevents intravenous administration and ensures a maximum safe dose (2 g). For physico-chemical and microbiological stability studies, samples were stored in the dark at 5 ± 3°C and 22 ± 3°C, for 15 days. Sterility tests and bacterial endotoxins assays were performed (Ph. Eur.). Samples were collected and characterised on days 0 (T0), 7 (T7) and 15 (T15). Colour, odour, appearance, pH, osmolarity, density and lidocaine hydrochloride content were analysed.

**Results** Throughout the study, the 20% (w/v) lidocaine hydrochloride solutions remained clear, colourless, limp and odourless. The pH of the solutions stored at 5 ± 3°C was 3.6 ± 0.04 (T0), 3.8 ± 0.08 (T7), 3.9 ± 0.02 (T15), and 3.6 ± 0.04 (T0), 3.9 ± 0.02 (T7), 4.0 ± 0.03 (T15) for the solutions maintained at 22 ± 3°C. The HPLC analyses showed that the lidocaine hydrochloride content was maintained (90–110%) after 15 days in all conditions tested. Density and osmolarity remained constant, i.e. 1.0049 ± 0.0036 g/cm³ and 1175.3 ± 20.2 mOsm/kg, respectively (n = 3). The three batches proved to be sterile and endotoxins-free during the study.

**Conclusions** The lidocaine hydrochloride solution proved to be physicochemically and microbiologically stable for 15 days stored in the dark.

No conflict of interest.