

Development of Colored Hydroalcoholic Solutions of Chlorhexidine for Surgical Field Antisepsis: Preparation Process, Antimicrobial and Coloring Efficiencies and Stability Study

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Guidelines for the prevention of surgical site infection issued by the French Society of Hygiene Hospital¹ and World Health Organization² are recently in favor of a use of the chlorhexidine hydroalcoholic (CHX-OH) solution. The objective of the study was to develop new colored CHX-OH solution enabling skin staining mandatory for efficient pre-operative antisepsis. The stability of CHX-OH solution supplemented with various dyes (sunset yellow, eosin, erythrosin) was examined immediately after mixing ingredients in order to detect the absence of sedimentation, flocculation or discoloration. The most stable colored CHX-OH solution was stored at $25\text{ °C} \pm 2\text{ °C}$, $60\% \pm 5\% \text{ RH}$ and $40\text{ °C} \pm 2\text{ °C}$, $75\% \pm 5\% \text{ RH}$ for 24 months. Pharmaceutical control, in accordance with Good Preparation Practices and European Pharmacopoeia, included the organoleptic characteristics, the dosage of the active ingredients and a microbiological control. The determinations of *In-vitro* antiseptic efficacy according to AFNOR standards (NF EN 1040, NF EN 1275), and the efficacy of the *In-vivo* coloring properties on white and black skin by using a colorimetric skin probe have completed this study. The tests demonstrated a better stability of CHX-OH (0.5 to 2.5% (w/v)) and eosin (0.02 to 0.05% (w/v)) solutions. All controls were satisfactory over 24 months at 25 °C and up to 6 months at 40 °C , but due to a random potential instability, the expiry date was fixed preferentially at 18 months. The antiseptic activity of this solution complied with AFNOR standards. Colorimetric measurements have shown that eosin has the most intense staining property, visible on white and black skin. CHX-OH and eosin solution, having many clinical and technical advantages, has been upgraded by an international patent WO2017021667 (A1)³.

References:

- ¹ Societe française d'hygiene hospitalière. Antisepsie de la peau saine avant un geste invasif chez l'adulte Recommandations pour la pratique Clinique, 2016
- ² World Health Organization. Global guidelines for the prevention of surgical site infection, 2016.
- ³ Hydroalcoholic solutions coloured with chlorhexidine, methods for the production thereof, and uses of same. S. Filali, F. Pirot, L. Tall, C. Pivot. Dépôt de brevet WO2017021667 (A1), FR3039768 (A1), 2015-08-06

Biography:

Samira Filali is a hospital pharmacist specializing in the preparation and control of the drug. His research in the pharmaceutical galenical research and development laboratory focuses on the development of new techniques for the administration of active ingredients.