

Dermatological Preparations – A Quality Study with the Unguator® Advanced Mixing System

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Abstract

The goal of our latest study was to verify that preparations that met the actual quality criteria established by the United States Pharmacopeia, the Therapeutic Compounding Formulary, and the British Pharmacopoeia could be achieved by using the Unguator® Mixing System. To achieve this goal, the optimal conditions, such as speed, mixing time and order of addition of the components, were determined for each of several representative preparations.

Two different systems were studied, the Unguator® 2000 and the Unguator® e/s and the effectiveness of standard and disposable blades was examined. Formulations prepared during the study were tested for appearance, microscopic appearance and, when judged necessary, uniformity of content. Study results revealed that both models tested were less suitable for preparation of gel bases than for other types of bases. Very positive and reproducible results were obtained with compositions containing a low content of active ingredient in hydrophobic ointment or hydrophilic cream. A hydrophobic drug such as clioquinol can be mixed effectively in a hydrophilic carbomer gel with either model, as quantitative assays of different batches showed perfect homogeneity, and microscopic examination found no large agglomerates. Special conditions were required for a material such as benzoyl peroxide, which consists of large and hard agglomerates. Salicylic acid hydrophobic 10% ointment can be prepared without any difficulty. The Unguator® technology products provide full protection for the operator against dust inhalation, since all preparation steps, with the exception of weighing the ingredients, occur in closed containers.

Introduction

The Unguator® Advanced Mixing System was designed to facilitate the preparation of many pharmaceutical, cosmetic, veterinary and other formulations. Many superior quality

ointments, creams, gels, suspensions, emulsions, and other compounds may be prepared with the system in a fraction of the time and cost associated with conventional methods. The use of the Unguator® Advanced Mixing System offers an entire range of new compounds with consistent quality by replacing many of the traditional tools.

Unguator® mixing machines correspond to the recognized safety standards for laboratory instruments. The machine's access and use are to be limited to authorized personnel only. All Unguator® mixing machines are manufactured with variable speed motors to customize formulations. While speeds generally decrease as viscosities increase, the strength of our motors were selected to keep speed fluctuations to a minimum.

Commercially the Unguator® Advanced Mixing System is available in three models for the preparation of dermatological bases and to mix active pharmaceutical ingredients with semisolid bases such as ointments, creams, gels and pastes. Both models combine vertical with horizontal mixing movements and claim the advantages of high production speed, excellent preparation quality and safety for the operator.

The preparation methods described in most formulary directories make use of conventional equipment such as mortar and pestle and spatula. Use of the Unguator® Advanced Mixing System, however, offers the great advantage of the "one-pot" technology: the preparation is mixed and dispensed in the same jar. The goal of the latest study in 2006 was to verify that preparations that meet the actual quality criteria established by the United States Pharmacopeia (USP), the Therapeutic Compounding Formulary (TCF), and the British Pharmacopoeia (BP) could be achieved when using the Unguator® Advanced Mixing System. To that end, optimal