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Secundum Artem

Current & Practical Compounding Information for the Pharmacist.

INTRODUCING:
The first issue of Secundum Artem

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Paddock Laboratories, Inc.

Dear Pharmacist:

Welcome to the premier issue of Paddock Laboratories, SECUNDUM ARTEM, a newsletter created to improve communications between Paddock Laboratories and you, the practicing pharmacist.

We will attempt to provide you with the most up-to-date information and formulations for extemporaneous compounded prescriptions.

We invite you to submit comments, questions, suggestions, and ideas that you would be willing to share with your fellow professionals for future issues of SECUNDUM ARTEM.

Remember, at Paddock Laboratories, you, the professional pharmacist, always come first.

Sincerely,

Bruce G. Paddock
President

Ointment Compounding: Basic Concepts

By Gary Carlson, RPh., Instructor, University of Minnesota, College of Pharmacy

This article is intended to be a review of basic concepts in the compounding of ointments. Much of the material contained herein can be found in the USP, Remington's Pharmaceutical Sciences, Dispensing of Medication, and Sprowl's American Pharmacy.

The USP defines ointments as "semisolid preparations intended for external application to the skin or mucous membranes." Refer to Table I for a classification of base types.

The incorporation of powders into an ointment base is most readily achieved by simple levigation using a spatula on a clean surface such as a glass or porcelain tile. Crystalline drugs must first be reduced to powder form by grinding them using a morter and pestle. A smooth, lump-free ointment is then prepared by making a thick paste with a small portion of the base and the drug powder. The higher shear forces obtained in levigating the thick paste greatly facilitates the removal of lumps. Indeed, if too much base is used initially, resulting in a paste that is too thin, it is usually easier and cheaper to start over than to try and reduce lumps. The lump-free thick paste is then geometrically diluted with the remaining base to form the finished product. The incorporation of powders by fusion (adding powder to the molton base) does not usually result in an elegant finished product unless high shear mixing can be used to remove the powder lumps. The use of a levigating agent other than a portion of the base itself is sometimes desirable. It may be a matter of personal preference. Points to remember about the use of levigating agents 1) the weight of the levigating agent must be subtracted from the base weight to maintain proper drug concentration. 2) For small quantities (less than 240g) the ointment base itself is the best levigating agent. 3) The levigating agent must be compatible with the base in general; use mineral oil for oleaginous and w/o emulsion and water soluble bases. 4) The levigating agent must be compatible with the drug. The use of fusion in preparing ointments is most efficient with drugs that are 1) soluble in a hydrocarbon base, eg; testosterone propionate in white petrolatium or 2) with drugs that can be dissolved in water and added to molton absorption base, eg; urea in water added to Aquaphor[R] since the ointment must be stirred until the drug is dissolved (1) above) or until it is cool enough for the emulsion to be stable (2) above). The fusion technique is much easier if one has a hot plate with a magnetic stirring apparatus. Do not heat the base above 70°C - the addition of water to very hot molton base may result in an "explosion" due to rapid boiling and possible injury. Never heat alcohol or other flammable liquids due to the possibility of explosion and/or fire.

The addition of water to an absorption base results in the formation of a water-in-oil (w/o) emulsion. Recall that in a w/o emulsion, the water is in the form of very small droplets and is referred to as the internal, discontinuous or dispensed phase. The hydrocarbon (oleaginous) portion forms the external or continuous phase. Because of the structure involved, the volume of water that can be incorporated is limited, in general, to about 50% of the total ointment volume. Attempts to incorporate additional water will, at best, result in the formation of an unstable emulsion where the excess water will soon separate from the base. Eucerin[R] which is an o/w emulsion essentially consisting of 50% water in Aquaphor[R] will accept little, if any, additional water.

Water washable bases are oil-in-water (o/w) emulsions where the oil is in very small droplets and is referred to as the internal, discontinuous or dispersed phase. The water portion forms the external or continuous phase. This type of base is most acceptable to patients because of its non-greasy, "vanishing" characteristics. Because water comprises the external phase, these emulsion bases are easily diluted with water even to the extent that they become pourable and may be more properly termed "lotions". These bases are often called creams even though they are officially defined as ointments. Some of these bases have a soap as the emulsifying agent (Triethanolamine stearate in lubriderm Cream). The soap type emulsifying agents are labile to the effects of acidic drugs such as salicylic acid or phenol which results in breaking of the emulsion. The emulsion may be protected by the addition of a suitable nonionic emulsifying agent such as polysorbate 80 (Tween 80[R]) at a concentration of about 5%.

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The only official water soluble ointment base is Polyethylene Glycol Ointment, USP. Gels for topical use might also be included in this category. A drug-free gel for use in compounding is not available commercially and the preparation of such gels from scratch is beyond the scope of this article.

One may occasionally be faced with the need to compound an ointment using a drug of unknown or uncertain stability. In general, drugs must be in aqueous solution to degrade over a short period of time (1 week, for example). Once you have determined that an alternative ointment of known stability is not suitable, the safest thing to do is to use an anhydrous, oleaginous base such as white petrolatum. Water washable bases are more acceptable to the patient and many topical drugs are more effective in the presence of water. If a drug has low water stability, a water washable base may be better.

A final general rule for preparing ointments containing three or more ingredients: In the absence of evidence to the contrary, each ingredient should be added sequentially to the base as opposed to mixing two or more ingredients together and then adding the mixture to the base. This assures maximum stability of the drugs and gives you the greatest likelihood of pharmaceutically elegant ointment.

Market your Compounding Practice

Assume you made a decision to provide or expand your compounding practice. What do you do next? Make three batches of new formulas? Buy 20 pounds of Rocktobiotone? Purchase a new high-speed mixer or hire additional personnel?

First identify the needs of your current customer and patients, then find out from your fellow medical professionals that you work with daily what compounded preparations they need. Ask your customers or patients if there are any dosage forms they are not satisified with, i.e., a geriatric or pediatric patient that has difficulty swallowing a solid oral dosage form. Ask if a patient is allergic to a particular component of a commercially available product, i.e., a dye, stabilizer, or preservative that may be eliminated if the preparation is extemporaneously compounded. Some drugs not effective by the oral route may be effective when administered by the rectal, vaginal, topical, or buccal route. Listen to patients as they pick up their prescriptions. Have clerks and store personnel keep track of patient medication requests. Ask the nursing staff at the local nursing home if they have special medication requests. Distribute a questionnaire in prescription bags, at the checkout counter, or in monthly billing statements.

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Next, ask physicians if they have requests for preparations that are not presently available through established commercial channels. There are many ways of informing doctors that you possess the expertise, experience, and desire to help their patients, as well as yours. Here are a few suggestions:

Telephone dermatologists, pediatricians, OB-GYN; proctologists, internists and inform them of your service. Write them a letter. Produce a brochure describing your pharmacy services. Make an office visit. Meet the physician for coffee. Participate in local medical meetings. Include a description of your compounding services in your business cards and/or run an ad in your local medical/business journal or newspaper.

Table 1

Base Type	Occlusiveness	Emolliency	Water Washable	Water Absorbancy
Hydrocarbon (oleaginous) eg. white petrolatum	high	high	poor	poor
Absorption Bases 1. without pre-existing water (Hydrophillic petroleatum, Anhydrous lanolin, Aquaphor®)	high	high	medium	high
2. Emulsion Type (Lanolin, cold cream, Eucerin®)	medium to high	medium to high	medium	depends on amount of water in base
Water removable bases (Hydrophilic ointment, Lubriderm cream®)	low	low	high	will thin out to get a lotion
Water soluble bases (Polyethylene Glycol ointment, water base gels)	low	low	high	will thin out to get a lotion

Question: I have received numerous requests for various strength Retinoic Acid Cream. Can you suggest different ways to compound these?

Suggested formula for Retinoic Acid

Cream	0.025%, 60 gms.
Retinoic Acid	15 mg.
BHT	60 mg.
Propylene Glycol	9.0 ml.
Emollient Cream	**51 gm.

Compounding Procedure

Dissolve BHT in Propylene Glycol using heat if necessary followed by Retinoic Acid, then dilute and geometrically mix with Emollient Cream.

Suggested formula for Emollient Cream Base

120 gm.

Anhydrous Ointment Base	40.0 gm.
Polysorbate 80	2.4 gm.
Purified Water	78.0 ml.

Compounding Procedure

Melt Ointment Base at 70°C and add Polysorbate 80.
Heat water up to 70°C and add to base.
Stir with electric mixer without heat until cream thickens and is uniform.

Keep refrigerated after compounding.

Use EITHER 0.02% Sodium Benzoate OR 1/2000 Methylparaben and 1/4000 Propylparaben as preservative.

Examples of Commercially available Emollient Creams **

Cutemol Cream, Summers
Allercrene Ultra Emollient, Owen
Lanolor Cream, Squibb
Keri Creme, Westwood
Shepard's Cream, Dermik
Formula 405 Cream, Doak
Shepard's Hand Cream, Dermik
Purpose Dry Skin Cream, Ortho
Nivea Moisturizing Cream, Beiersdorf

** *Facts and Comparison pp. 610-12, 1987.*