Compounding in the Pharmacy Curriculum: BEYOND THE BASICS

Introduction

The pharmacist's compounding role has diminished with the increase in commercially available dosage forms. Therefore, student exposure to extemporaneous medication compounding has not been a priority of colleges and schools of pharmacy for many years. Pharmacy educators have evolved their curricula to address advanced disease-state management and have drifted from the compounding origins of the profession.

The resurgence of extemporaneous medication compounding has created a need for skilled compounding pharmacists. With the emergence of new medical information and therapies, it has become evident that not every patient should receive the same medicinal treatment. Pharmaceutical companies produce medicines to treat the most common disease states in the dosage forms that work for the majority of the population. Until recently, patients who could not be adequately treated with commercially available dosage forms were left with few alternatives.

Modern compounding practice requires pharmacists to acquire extra education and training in order to provide quality custom pharmaceutical products. Such courses are intended to develop the student's ability to select and prepare contemporary pharmaceutical dosage forms to deliver drug therapy. Extemporaneous preparations are becoming more sophisticated and numerous, and many pharmacists in practice are intimidated by the formulations they have been receiving. Accordingly, current pharmacy students could benefit from more extensive instruction in the extemporaneous preparation of medications.

During the first two years of their professional education at Purdue University, all pharmacy students receive instruction in the basics of extemporaneous compounding through a series of lectures and laboratories. During this time, the students learn pharmaceutical calculations and gain experience in the preparation of basic compounds (ie, ointments, solutions, suspensions, capsules, emulsions).

In recognition of the increasing demand for customized dosage forms and the growing interest in contemporary compounding among our students, we have developed as an elective an advanced compounding class for professional students enrolled in Purdue University's School of Pharmacy and Pharmacal Sciences. The course, designed for students who have completed at least two years of the professional curriculum, will allow those students interested in advanced compounding to develop their ability to select and prepare contemporary pharmaceutical dosage forms and deliver customized drug therapy. The most current dosage forms seen in practice today are reviewed in lectures and/or discussions, followed by a laboratory experience during which students gain practice in the preparation of representative compounded prescriptions.

The course was designed for a class size of twelve to fourteen students. The smaller class size was chosen to facilitate more one-on-one, student-to-instructor contact during the learning process. The smaller class size was also selected because the first class will be a pilot program; subsequently, the number of students can be increased as demand, human resources, and equipment allow.

As with any advanced course, this elective course will require students to assume a proactive role in the learning process and to work cooperatively with other students to achieve course goals. While this approach may be uncomfortable for some students at first, research has demonstrated that active learning methods are essential when the development of problem-solving skills is a desired outcome of instruction. Further, because interest in contemporary compounding continues to increase

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among members of the public, these skills will be even more critical for effective patient care in the future.

This course is intended for students who want to develop the additional knowledge and skills required to prepare contemporary compounded prescriptions. However, it is not a comprehensive treatment of the topic. Thus, additional instruction will be necessary for students to acquire all of the abilities required for contemporary compounding. To that end, additional elective courses may be developed if demand for such instruction remains strong among our professional students.

Course Activities

The class is scheduled as a one-credit elective course and will meet for 150 minutes once a week for 8 weeks. The first class meeting focuses solely upon general guidelines for contemporary compounding practices. Topics covered during this lecture/discussion include: (1) compounding facilities, (2) resources, (3) equipment, (4) ingredient standards, (5) steps in the compounding process, (6) packaging, (7) storage, (8) labeling, (9) product stability, (10) quality control, and (11) regulatory issues that impact contemporary compounding practices.

The second class meeting also employs the lecture/discussion format and further explores the stability of compounding medications. During this meeting, course instructors demonstrate the significance of product stability by describing an experiment in which identical suspensions were left in environments varying from room temperature to refrigeration. The compounds were monitored for microbial growth and photographed at regular intervals. Photographs depicting different levels of microbial growth show the students that it is important to properly store compounded medications.

The subsequent six class meetings cover a variety of the contemporary dosage forms seen in practice. The first 50 minutes of each meeting employ the lecture format. The lectures outline applications of each dosage form in practice, its preparation, storage, labeling, and stability, as well as the patient counseling information that is unique to the dosage form under consideration. Students then have the opportunity to compound two or three formulations for each dosage form (Table 1).

Prior to each of the last six lectures, students take a quiz that covers the previous week's material. The quizzes are used as a tool to assess the student's progress and to identify any areas of misunderstanding. The short-answer quiz questions cover information provided in the previous lecture about the dosage forms under consideration. For example, questions cover counseling tips, prescription indications, packaging and labeling of the finished product, and storage. The quizzes do not

Table 1. Course Schedule.

Week	*Dosage Form*	*Formulations*
1	Guidelines for compounding practice	N/A
2	Stability of compounded preparations	N/A
3	Flavors, sweeteners, colors and sticks	Acyclovir lip balm
4	Lozenges, suckers and Gummy Bears	Gag tablet lollipops and atropine gelatin Gummy Bears
5	Troches	Phenylpropanolamine hydrochloride troches for dogs and anesthetic troches
6	Gels	Nifedipine vasodilating gel, scopolamine topical gel, clonidine/gabapentin/ketamine PLO gel, and estrogen vaginal gel
7	Suppositories	Migraine headache suppositories and nitrofurantoin urethral inserts
8	Ophthalmic, otic, and nasal preparations	Amphotericin B ophthalmic solution, morphine sulfate nasal spray, and veterinary antibiotic/antifungal/ anti-inflammatory otic drop

entail any calculations pertaining to the formulations prepared in the laboratory.

A two-hour laboratory session follows each of the last six lectures. During each laboratory session, students are asked to prepare the assigned compounds discussed in the lecture, to complete all necessary research, and to complete the calculations applicable to the laboratory before each class session. A prelaboratory assignment is due before the laboratory session begins. The assignment contains questions pertaining to the compounds that are to be prepared in the laboratory, ie, calculations needed for each formulation, and indications and patient counseling information for each compound. However, the students are not required to prepare their compounds based solely upon their own work. Each student's paper is graded and any errors corrected before preparation begins. This ensures that calculations are done properly and that the compound is prepared correctly. The students learn from their errors. After any corrections are made, students are left to prepare the compounds.

Students are also required to package and label completed compounds appropriately. Pharmaceutical elegance in compounding is essential; a properly prepared and packaged compounded prescription shows the patient that a skilled practitioner filled the prescription. Students are required to demonstrate knowledge of this key component in dispensing compounded prescriptions. A post-laboratory inspection takes place after each student has completed the assigned preparations. The instructors evaluate the elegance of preparation, correct packaging and labeling.

Effective and thorough counseling of a patient on such specialized dosage forms is crucial to ensure appropriate therapeutic outcomes. Students are required to counsel an instructor posing as a patient about the prepared compound. The student must demonstrate knowledge about the indicated use of the compounded prescription as well as instructions for administration and storage by the patient. In addition, the students are required to make their patients aware of common side effects as well as those side effects that can indicate toxicity. Finally, the student is required to relate any contraindications to the prepared compound's active and inactive ingredients during the mock counseling session.

Course Grading Policy

The course outlined above is based on a total of 440 available points. Those 440 points have been assigned to the above-mentioned activities as well as attendance at both lecture and laboratory sessions (Table 2). Attendance at any class is important, but a class based upon laboratory experience necessitates strict attendance because the development of any skill, including compounding ability, requires regular practice. Therefore, more than 35% of this course's total points are based on attendance. Grades will be assigned according to a standard percentage-based scale (Table 3).

Table 2. Course Grades.

Lecture attendance = 80 points
Laboratory attendance = 80 points
In-lecture quizzes = 80 points
Pre-laboratory assignment = 80 points
Post-laboratory product inspection and patient counseling = 120 points

Table 3. Grade Distribution.

A = 90% to 100%
B = 80% to 89%
C = 70% to 79%
F = any score less than 70%

Table 4. Student Supply Kit.

Category	*Required Equipment*
Labeling	Sticker labels for each dosage form
Packaging	Suppository foil
	Suppository molds
	Suppository sleeves
	Lip balm tubes
	Troche molds
	Troche sleeves
	Troche paddles
	Gummy Bear molds
	0.22-micron ophthalmic filters
	Otic and ophthalmic bottles
	Nasal spray bottles
	Lollipop sticks
	Lollipop vials

Note: Total cost of supply kit per student = $150.57. Breakdown: materials kit = $65.93; chemical kit = $84.64.

Course Materials

The course manual and required text, *The Art, Science, and Technology of Pharmaceutical Compounding* by Loyd V. Allen Jr., will be available for purchase. Each student will also be required to purchase a compounding supply kit containing materials needed to prepare, label, and package each compound. The kits will be constructed by the Professional Compounding Centers of America (Table 4). Students will be made aware of this additional financial expense before scheduling to attend this class. The hardware used for preparing the compounds is made available in the laboratory (Table 5). The students will be encouraged to bring to class any additional material or information they feel will benefit their learning experience. Such material could include journal articles, books, other formulations or information about new dosage forms.

Table 5. Laboratory Materials.

Note: The laboratory materials are listed according to each formulation.

Migraine Headache Suppositories

For 14 batches of 12 suppositories per batch	
Note: Each suppository's weight was estimated to calculate the base required. The molds will need to be calibrated before this calculation will be accurate.	
Cafergot tablets	336
Metoclopramide 10-mg tablets	168
Fattibase or cocoa butter	336 g
Equipment	
Weigh paper	
Electronic scale	6
Hot plate	14
Glass stirring rod	14
Mortar and pestle	14
Suppository mold	14
Foil wrappers	
Labels	
200-mL beaker	14
Spatula	4

Nitrofurantoin Urethral Inserts

For 14 batches of 3 inserts per batch	
Note: Inert base for this compound was estimated. The actual amount must be based upon the mold being used.	
Nitrofurantoin	42 mg
Lidocaine	700 mg
Inert base	qs
Polyethylene glycol (PEG) 1450 estimated amount 2698.8 mg	95%
PEG 300 estimated amount 142.05 mg	5%
Equipment	
Weigh paper	
Hot plate	14
Electronic scale	6
Glass stirring rod	14
1-cc syringe (possible mold)	42
Foil wrappers	
Labels	
Mortar and pestle	14
200-mL beaker	14
Spatula	14

Acyclovir Lip Balm

For about five 5-g tubes for each of 14 students	
Acyclovir 200-mg capsules	84
Span 80	7 g
Glycerol monostearate	70 g
Hydrocream base	273 g
Aromatic flavors (optional)	
Equipment	
Weigh paper	
Hot plate	14
Electronic scale	6
Glass stirring rod	14
Lip balm mold (5-g size)	70
300-mL beaker	14
Mortar and pestle	14
Spatula	14

Gag Tablet Lollipops

For 72 lollipops	
Note: The lollipop mold needs to be calibrated to calculate the amount of PEG 1450 to be used.	
Sodium chloride	93.12 g
Potassium chloride (KCl)	6.00 g
Calcium lactate	12.24 g
Magnesium citrate	4.08 g
Sodium bicarbonate	44.88 g
Sodium phosphate monobasic	7.68 g
Silica gel	7.20 g
PEG 1450	qs
Colors	
Flavors	
Equipment	
Weigh paper	
Electronic scale	6
Hot plate	14
Lollipop mold (depending upon size desired)	7
Vegetable spray	3
Lollipop stick	80
Wax paper	
Magnetic stir bar	14
300-mL beaker	14
Mortar and pestle	14

Atropine 1 mg Gelatin Troches

For 14 batches of 24 troches per batch	
Atropine sulfate	336 mg
Gelatin base	392 mg
Silica gel	3360 mg
Stevia powder	7000 mg
Acacia powder	5600 mg
Citric flavor	8050 mg
Flavor	

Phenylpropanolamine Hydrochloride 10-mg Chewable Troches for Dogs

For 14 batches of 24 troches per batch	
Phenylpropanolamine hydrochloride	3360 mg
Silica gel	3360 mg
Acacia powder	6720 mg
Peanut butter	201.6 g
Hydrogenated vegetable oil	134.4 g

Dyclonine Hydrochloride 1-mg and Diphenhydramine Hydrochloride 10-mg Anesthetic Troches

For 14 batches of 24 troches per batch	
Dyclonine hydrochloride	336 mg
Diphenhydramine hydrochloride	3360 mg
Aspartame	3360 mg
Acacia powder	6720 mg
PEG 1450	322 g
Flavor oil	3 drops per student for a total of 42 drops
Note: The equipment listed below applies to all troche formulations.	
Equipment	
Water bath	14
Hot plate	14
Electronic scale	6
200-mL beaker	14
Magnetic stir bar	14
Weigh paper	
Mortar and pestle	14
Troche mold	14
Labels	
Spatula	14
Glass stirring rod	14

Summary

The resurgence of extemporaneous medication compounding has created a need for skilled compounding pharmacists. However, the amount of time devoted to the subject in pharmacy curricula has dwindled as the number of commercially available dosage forms has increased. In recognition of the increasing demand for customized dosage forms, the Purdue University School of Pharmacy and Pharmacal Sciences has developed an advanced compounding elective class for pharmacy students and will run a pilot offering of the course during 2004. Results of the pilot will be used to improve the course and to determine whether there are sufficient interest and resources for additional compounding electives.

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Amphotericin B 2-mg/mL Ophthalmic Solution

For 14 solutions	
Amphotericin B	280 mg
Sterile water for injection	140 mL
0.22-micron filters	14
Equipment	
Electronic scale	6
Syringe 5-mL	14
Syringe 10-mL	14
Graduated cylinders (10-, 25-, 100-mL)	14 of each size
Ophthalmic bottle	14

Morphine Sulfate 5-mg/0.1-mL Nasal Spray

For 14 nasal sprays	
Morphine sulfate	70 g
Citric acid	2800 mg
Methylparaben	2800 mg
Propylparaben	280 mg
Sodium hydroxide	140 mL
Purified water	1400 mL
Equipment	
Electronic scale	6
Graduated cylinders (10-, 25-, 100-mL)	14 of each size
Sterile 0.22-micron filter	14

Veterinary Antibiotic/Antifungal/ Anti-Inflammatory Anesthetic Otic Drop

For 14 bottles	
Gentamicin sulfate	4200 mg
Betamethasone valerate	1400 mg
Miconazole nitrate	14 g
Tetracaine hydrochloride	14 g
Propylene glycol	1400 mL
Equipment	
Graduated cylinders (10-, 25-, 100-mL)	14 of each size
Mortar and pestle	14

Nifedipine 20% Vasodilating Gel

For 14 gels	
Nifedipine	280 g
Alcohol 95%	140 mL
Lecithin: Isopropyl palmitate solution	280 g
Pluronic F127 20% gel	980 g
Equipment	
Mortar and pestle	14
Electronic Scale	6
Syringe (1-mL)	140
Graduated cylinders (10-, 25-, 100-mL)	14 of each size

Scopolamine Hydrobromide 0.25-mg/0.1-mL Topical Gel

For 14 gels	
Scopolamine hydrobromide	3500 mg
Soy lecithin: Isopropyl palmitate solution	336 mL
pH 5.0 buffer solution	35 mL
Pluronic F127 20% gel	1120 mL
Equipment	
Mortar and pestle	14
Electronic scale	6
Syringe (1-mL)	140
Graduated cylinders (10-, 25-, 100-mL)	14 of each size
Weigh paper	

Estrogen 0.625-mg/5-g Vaginal Gel

For 14 (one month supply) gels	
Conjugated estrogens	175 mg
Polysorbate 80	28 g
Methylcellulose 25% gel	1358 g
Equipment	
Mortar and pestle	14
Electronic scale	6
Syringes (1-mL)	420
Graduated cylinders (10-, 25-, 100-mL)	14 of each size
Weigh paper	

Clonidine Hydrochloride 0.2%/Gabapentin 6%/Ketamine Hydrochloride 10% in Pluronic Lecithin Organogel (PLO)

For 14 (one month supply) gels	
Clonidine hydrochloride	2800 mg
Gabapentin	84 g
Ketamine hydrochloride	140 g
Propylene glycol	140 mL
Lecithin: Isopropyl palmitate solution	308 mL
Pluronic F127 20% gel	1120 mL
Equipment	
Mortar and pestle	14
Electronic scale	6
Syringe 1-mL	140
Graduated cylinders (10-, 25-, 100-mL)	14 of each size