

## INSTRUCTIONAL DESIGN AND ASSESSMENT

### Analysis of Compounded Pharmaceutical Products to Teach the Importance of Quality in an Applied Pharmaceutics Laboratory Course

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**Objective.** To assess the effectiveness of a product-analysis laboratory exercise in teaching students the importance of quality in pharmaceutical compounding.

**Design.** Second-year pharmacy students (N=77) participated in a pharmaceutical compounding laboratory exercise and subsequently analyzed their final product using ultraviolet (UV) spectrometry.

**Assessment.** Reflection, survey instruments, and quiz questions were used to measure how well students understood the importance of quality in their compounded products. Product analysis showed that preparations compounded by students had an error range of 0.6% to 140%, with an average error of 23.7%. Students' reflections cited common sources of error, including inaccurate weighing, contamination, and product loss during both the compounding procedure and preparation of the sample for analysis. Ninety percent of students agreed that the exercise improved their understanding of the importance of quality in compounded pharmaceutical products. Most students (85.7%) reported that this exercise inspired them to be more diligent in their preparation of compounded products in their future careers.

**Conclusion.** Integrating an analytical assessment during a pharmaceutical compounding laboratory can enhance students' understanding of quality of compounded pharmaceutical products. It can also provide students a chance to reflect on sources of error to improve their compounding technique in the future.

**Keywords:** compounding, analysis, pharmaceutics, pharmacy practice laboratory

## INTRODUCTION

As the number of patient-specific medicinal therapies increases, pharmaceutical compounding remains a pertinent skill for pharmacists to master. According to the International Academy of Compounding Pharmacists, compounded prescriptions comprise approximately 1% to 3% of the United States' prescription market.<sup>1</sup> Compounding is especially useful for targeting patients who are challenging to treat; specifically pediatric, geriatric, and veterinary patients.<sup>2</sup> Additionally, compounding enables patients to regain access to medications removed from the market because of manufacturer cost burden. Medical professionals and patients rely on pharmacists to compound these products using the highest-quality standards, which are thoroughly outlined in the United States Pharmacopeia/National Formulary (USP/NF), the official

compendia of the United States.<sup>2</sup> In an effort to ensure compounding pharmacies are fulfilling these guidelines, the Pharmacy Compounding Accreditation Board was founded. This organization provides a standardized system for evaluating and validating quality-control techniques performed by compounding pharmacies voluntarily seeking accreditation.<sup>3</sup> Even though resources are available to compounders, errors that have the potential to compromise patient safety still occur. The Federal Drug Administration (FDA) performed a limited survey in 2001 in which compounded products from 12 pharmacies across the United States were evaluated using standard quality testing outlined by the USP. Of the 29 samples evaluated for potency testing, 9 (31%) of the products failed, with concentrations ranging from 59% to 89% of the label claim.<sup>4</sup> In a subsequent 2006 FDA survey, 36 samples from various compounding pharmacies were analyzed for potency of bulk active pharmaceutical ingredient (API) and products containing that active ingredient were compounded. All bulk API samples contained the label claim based on assay results; however, 33% of the compounded products failed potency testing, with drug concentrations ranging from

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67.5% to 268.4% of label claim.<sup>5</sup> Although these studies had small sample sizes and significant limitations, their results raised valid concerns regarding the quality of compounded products being dispensed. High-profile compounding errors publicized in the media have revealed the tragic consequences of improper compounding.<sup>6,7</sup> With the recent compounding errors resulting in numerous deaths from contaminated methylprednisolone acetate steroid injections, and the subsequent Drug Quality and Security Act being proposed into legislation, the importance of pharmacists practicing proper quality-assurance procedures has heightened awareness.<sup>8-12</sup> The foundation for accurate compounding must begin at the pharmacy-education level and resonate with pharmacy students, empowering them to be more cognizant of the proper quality-control procedures and to maintain these high standards throughout their pharmacy careers.

The Accreditation Council of Pharmacy Education Standards requires students to learn the “techniques and principles used to prepare and dispense individual extemporaneous prescriptions.”<sup>13</sup> This topic is also addressed by the Center for Advancement of Pharmaceutical Education Outcomes, which maintains that students must “prepare safe and effective dosage forms and perform in-process quality control.”<sup>14</sup> To fulfill these requirements, pharmacy colleges and schools have full authority regarding the extent of compounding instruction included in the curriculum and the means by which students are evaluated for “quality control.” The boards of pharmacy in Georgia and New York, for example, place a greater emphasis on the art of compounding and require successful completion of a hands-on (wet laboratory) compounding examination for licensure. Both state boards of pharmacy evaluate students based on correctness of calculations, procedure, labeling, visual inspection, and scalar measurements (eg, weight, volume) but do not require analytical testing of the product (A.T. Corigliano, e-mail, January 21, 2013; T.F. Allen, e-mail, November 5, 2012). Interestingly, no state requires students to provide proof that they are able to compound products that fulfill USP standards with respect to potency and purity.<sup>15-17</sup> It is therefore imperative for pharmacy colleges and schools to take initiative to verify that students are preparing pharmaceutically elegant products that fulfill the USP quality standards testing. This goal can be accomplished by incorporating an analytical method in the compounding laboratory.

A survey evaluating the compounding curriculum within pharmacy colleges and schools identified the lack of analytical testing in educational compounding laboratories. Most survey respondents cited direct observation as their primary assessment approach, while only a small percentage (8%) of institutions used a quantitative method

to evaluate student preparations.<sup>18</sup> Although this study was not all-inclusive, it did reflect a trend among pharmacy colleges and schools in the assessment of students’ compounded products. Other concerns identified in the literature include students’ retention of compounding skills and the attenuated role of compounding in academia.<sup>19,20</sup> Some institutions have attempted to implement analytical testing in the laboratory through changes in course design and assessment.<sup>21-27</sup> One study in which the accuracy of pharmaceutical products compounded by pharmacy students was evaluated found that 54% of students prepared the desired potassium permanganate solution within 10% of the intended concentration.<sup>27</sup> Students who were unsuccessful in accurately compounding the solution had concentrations ranging from less than 75% to greater than 200%. In the same study, 78% of student preparations of caffeine citrate solution fell within 10% of the intended concentration, with errors ranging from less than 89% to more than 269% of the required potency. The wide variation in product potency compounded by pharmacy students mirrors the FDA’s findings on a national level.

Incorporating analytical testing of compounded pharmaceutical products into the pharmacy curriculum gives students a sense of accountability for ensuring that their products meet the acceptable quality standards to dispense to a patient. This study describes the design and implementation of a product-analysis laboratory to teach students the importance of quality in compounded products. The laboratory included preparation of a compounded product, subsequent analytical testing, product evaluation, and student reflection. The impact of the exercise on students’ perceptions regarding the importance of quality in compounding was also recorded.

## DESIGN

Beginning in the first year of a 4-year doctor of pharmacy (PharmD) program at St. John Fisher College, Wegmans School of Pharmacy, students were taught foundational principles of physical, chemical, and biological mechanisms involved in drug formulation during the pharmaceuticals course sequence. Students were expected to use this knowledge in a practical setting as part of a 2-semester Applied Pharmaceuticals compounding laboratory sequence, comprising 2 single-credit-hour courses offered during the second year. The courses consisted of a 1-hour prelaboratory lecture in conjunction with a 3-hour laboratory period consisting of 2 sections. Course evaluation comprised of 2 practicals, a cumulative final laboratory practical, 2 quizzes, and an overall professionalism score. Final products were assessed by visual inspection, accuracy of calculations, and completeness of compounding procedure. Individual laboratory sessions were not

graded in order to provide students the opportunity to refine their compounding skills and learn from their errors in a controlled learning environment. Course instructors and teaching assistants were available consistently throughout the laboratory sessions to provide feedback and answer students' questions. Faculty members rotated teaching throughout the semester to provide instructional guidance on their particular dosage-form specialty.

The product-analysis exercise was incorporated during the second-semester laboratory course. At the completion of this laboratory session students were expected to (1) prepare a compounded product with a designated level of precision and accuracy; (2) complete a pharmaceutical analysis of a compounded product; (3) accurately perform calculations related to compounding and dilution; (4) identify sources of error that could have occurred in pharmaceutical compounding and analysis; (5) evaluate assay results of a compounded product to determine if it met the quality standards necessary to dispense for patient use; and (6) comprehend the importance of accuracy and quality in compounded products. These learning outcomes and the corresponding instruments used to assess them are presented in Table 1. The St. John Fisher College Institutional Review Board approved this project as exempt.

Students were provided a packet containing a prescription for methimazole 5% in poloxamer lecithin organogel (PLO), directions for compounding, assay procedure, and reflection questions during the 1-hour prelaboratory class session held 1 week prior to the laboratory exercise.<sup>28,29</sup> (Appendix 1). Students were informed that they would assay their final product to determine potency using UV spectroscopy. Supplying the materials prior to the exercise gave students sufficient time to complete the calculations and familiarize themselves with the product in anticipation of the analytical process. Students were also informed that a bonus point would be added to their next quiz if their product analysis was found to be within an acceptable range.

During the 3-hour laboratory period, students compounded the prescription according to the instructions provided and removed a 0.5-gram sample for the assay. This sample was serially diluted and filtered before being placed in a plastic cuvette and assayed using the UV spectrophotometer at a wavelength of 252 nm. With the absorbance value obtained from the UV spectrophotometer, students calculated the concentration of the sample derived from the product they prepared.

After conducting the assay, students were asked to complete the last page of their laboratory exercise, including a calculation worksheet with reflection questions. Students were instructed to use the Beer-Lambert Law

equation to convert their absorbance value to concentration, perform calculations to determine the concentration of assayed solution after performing serial dilutions, and calculate a percentage of error based on their product versus the target concentration. The reflection portion of the exercise required students to evaluate their assay results by indicating whether their product met an appropriate level of quality required to dispense to their patients. Students were also provided an opportunity to reflect on potential sources of error in their compounding or analytical procedure.

As per standard procedure for the semester laboratory, each student then completed a final "check-out" with a teaching assistant or laboratory instructor to review the prescription write-ups, final products, analysis worksheet, and reflection questions. The teaching assistant/instructor ensured that all aspects of the laboratory were completed, during which time the student also had an opportunity to ask any additional questions before leaving the laboratory.

## **EVALUATION AND ASSESSMENT**

Students' product analysis worksheets were collected and tabulated at the conclusion of the laboratory exercise. Absorbance values were used to determine the final concentration and percentage error for each sample. Of the 77 student products assayed, products ranged in errors from 0.6% to 140%, with an average error of 23.7%. Only 32 (41.6 %) products prepared by students fell within an acceptable 10% error range. An additional 16 (20.8%) samples fell within the 10% to 20% error range, with the remaining 38% having an error rate of more than 20%.

Written responses identifying sources of errors were coded to reveal common themes (Table 2). For a response to be considered a theme, a minimum of 25% of students had to have commented on that specific category. Over 72% of students discussed some form of measurement error as a potential source of deviation from the expected potency. Examples of these errors included improper calibration of balance, measuring more API than required, and measuring an inappropriate amount of gel for the analysis portion. A second theme that more than 61% of students cited involved errors made during the serial dilution process. Many students commented that loss of product could have occurred during the stepwise serial dilution or as a result of inadequate dissolution of the product into the assay solvent. Contamination of either the drug source or glassware, including the plastic cuvette, was discussed by over 25% of students. Twenty-five percent of students reported that their error may have occurred during the compounding of the gel product. Students mentioned improper mixing, loss of product while removing air bubbles, and calculation errors as potential sources of inaccuracy.

Table 1. Learning Outcomes and Methods for Assessment in a Laboratory Exercise on Pharmaceutical Compounding

<b>Learning Outcomes</b>	<b>Method of Assessing Learning Outcome</b>	<b>Questionnaire Statements</b>	<b>Learning (Bloom's Taxonomy)</b>
Prepare compounded products with a level of precision and accuracy.	Product assay	As a result of analyzing my own compounded products in this lab, I believe I will prepare compounded products more accurately in the future.	Application
Complete a pharmaceutical analysis on a compounded product.	Successful completion of laboratory exercise as documented by laboratory instructor and teaching assistants	As a result of this laboratory exercise, I now know how pharmaceutical products can be analyzed for drug content.	Knowledge/ application
Accurately perform calculations related to compounding and dilution	Calculations recorded on laboratory worksheet and assessed by teaching assistants and instructor Calculation question on course quiz	By performing the calculations associated with this laboratory exercise, I now feel more confident about performing calculations related to compounding.	Application
Identify sources of error that can occur in pharmaceutical compounding and analysis.	Reflection question: What sources of error may have occurred in the preparation or analysis of the product?	This laboratory experience helped me to think through the sources of error that may occur while compounding and analyzing compounded products.	Synthesis
		I believe I know where the errors associated with my compounded product may have occurred.	Synthesis
Evaluate assay results of a compounded product to determine if it meets the quality standards necessary to dispense to a patient.	Reflection question: What is the percent error of this product? Based on your analysis, is the product suitable to dispense to a patient?	After completing this laboratory, I am more confident in my ability to evaluate the assay results of a compounded product.	Evaluation
Comprehend the importance of accuracy and quality in compounded products	Open-ended questions on course quiz	The laboratory exercise involving the assay of the methimazole in PLO gel compounded product I prepared helped me to better understand the importance of quality in compounding pharmaceutical products.	Comprehension

Abbreviation: PLO=poloxamer lecithin organogel.

When students were asked to reflect on whether their product was suitable for dispensing based upon the analysis results, a majority (97%) identified less than 10% error as acceptable for dispensing. The remaining 3% indicated an acceptable error of less than 5% and evaluated their results based on this guideline. As part of a 10-question laboratory quiz in the overall course assessment, 2 questions pertained to the analysis laboratory. The first was a calculation, similar to that required for the dilution conducted in the laboratory. Of the 75 students who completed the quiz, 56 (75.7%) responded correctly

to the open-ended question. The second question asked students to explain why accuracy and quality of compounded products is an important aspect of pharmaceutical compounding. Of the 75 students who responded, 100% provided a correct written response, citing either patient safety or medication effectiveness.

To obtain each student's perspective on the laboratory, an optional 8-item questionnaire was distributed to students at the end of the laboratory period. The voluntary survey instrument included 7 Likert-scale questions and 1 open-ended question. Students were instructed to

Table 2. Summary of Themes in Student Reflection in a Laboratory Exercise on Pharmaceutical Compounding: Potential Sources of Error (N=68)

Theme	No. (%)
Errors due to inaccurate weighing or measuring of volume	49 (72.1)
Errors involved during serial dilution	42 (61.8)
Errors due to contamination of drug product, glassware, cuvette	20 (29.4)
Errors involved in compounding procedure	19 (27.9)

complete the survey instrument without any personal identifiers to maintain anonymity and to rank their level of agreement with the statements using a 5-point Likert scale (1=strongly disagree, 2=disagree, 3=neutral, 4=agree and 5=strongly agree) (Appendix 1). The survey instrument questions were designed to match the learning outcomes for the laboratory exercise (Table 1).

Of the 77 second-year pharmacy students who successfully completed the product-analysis laboratory,

71 (92.2%) completed the survey instrument and returned it at the conclusion of the laboratory exercise. The results were reported using descriptive statistics (Table 3). The students responded positively to all 7 questions, indicating that the laboratory exercises were useful in emphasizing the importance of quality in compounded products. Ninety percent (63 of 70) of students agreed or strongly agreed that the exercise helped them understand the importance of quality in compounding pharmaceutical products. Students were also asked an open-ended question to allow them to reflect on any future changes they would make to their compounding technique based on their experience during the exercise. Several responses emphasized taking more care while compounding, cleaning glassware thoroughly prior to compounding, and minimizing product loss while measuring and mixing ingredients.

## DISCUSSION

Pharmaceutical compounding offers a unique niche in the healthcare arena. It not only provides patients with

Table 3. Student Responses to a Survey Regarding Evaluation of Methimazole in PLO Gel Product in a Laboratory Exercise on Pharmaceutical Compounding

Survey Instrument Question	Strongly Disagree, No. (%)	Disagree, No. (%)	Neutral, No. (%)	Agree, No. (%)	Strongly Agree, No. (%)	No Response, No.	Mean (SD)
The laboratory exercise involving the assay of the methimazole in PLO gel compounded product I prepared helped me to better understand the importance of quality in compounding pharmaceutical products.	0	1 (1.4)	6 (8.6)	31 (44.3)	32 (45.7)	1	4.3 (0.7)
As a result of this laboratory exercise, I now know how pharmaceutical products can be analyzed for drug content.	0	2 (2.8)	8 (11.3)	33 (46.5)	28 (39.4)	0	4.2 (0.8)
This laboratory experience helped me to think through the sources of error that may occur while compounding and analyzing compounded products.	0	1 (1.4)	6 (8.6)	39 (55.7)	24 (34.3)	1	4.2 (0.7)
I believe I know where the errors associated with my compounded product may have occurred.	1 (1.4)	3 (4.2)	13 (18.3)	34 (47.9)	20 (28.2)	0	4.0 (0.9)
By performing the calculations associated with this laboratory exercise, I now feel more confident about performing calculations related to compounding.	0	2 (2.8)	10 (14.0)	37 (52.1)	22 (31.0)	0	4.1 (0.8)
After completing this laboratory, I am more confident in my ability to evaluate assay results of a compounded product.	0	2 (2.8)	15 (21.1)	32 (45.1)	22 (31.0)	0	4.0 (0.8)
As a result of analyzing my own compounded products in this lab, I believe I will prepare compounded products more accurately in the future.	0	2 (2.9)	8 (11.4)	36 (51.4)	24 (34.3)	1	4.2 (0.7)

Abbreviations: PLO=poloxamer lecithin organogel.

drug formulations specifically tailored to best suit their needs but also can improve patient compliance and health outcomes. Unfortunately, compounding errors can have deleterious effects that overshadow these benefits and have a lasting impact on the pharmacy profession. It is paramount that pharmacy students realize the responsibility they have to their patients concerning quality of compounded products. One mechanism of executing this academically would be to incorporate an analytical element to the compounding curriculum.

After compiling the students' overall error percentages, only 32 (41.6 %) products were found to be within an acceptable 10% error rate. Error percentages ranged from 0.6% to greater than 140%. This wide range in potency mirrors similar trends seen by the FDA and reported by other academic institutions.<sup>4,5,23,27</sup> Several factors may have contributed to the students' poor analytical performance. Although students were provided a bonus-point incentive, their grade was not greatly affected by the outcome of the product analysis. This may have influenced some students not to put forth their best effort during the exercise. Also, the unique compounding procedure for this product is more complex than other dosage forms, such as solutions or intravenous admixtures that can be easily assayed. This laboratory exercise was purposely designed to include analysis of a complex formulation toward the end of the compounding course as a means of a near-final assessment for the students. Analysis of a simpler formulation would have likely increased the percentage of products that would have been deemed acceptable for dispensing. Additionally, the assay sample preparation required a 2-step dilution in volumetrics. This multiple-step process had the potential to precipitate product loss or contamination when conducted by a student with limited analysis training.

After coding students' reflection responses, many students cited similar rationales for not obtaining a sample within an acceptable potency range. Most of the responses involved errors in measurement, measuring either too little or too much active ingredient. Because this laboratory took place near the end of the compounding sequence, it was expected that students would be proficient in basic tasks, such as accurate measuring. With the analysis having no impact on the students' grade, less care may have been taken during the measurement process. A similar study determined that student performance significantly improved when students were required to remake unacceptable products outside of their scheduled laboratory time.<sup>23</sup> This step may be a valid consideration for future years in an effort to prompt students to use class time meaningfully. Students mentioned that the multiple steps involved for both the compounding and assay preparation

created many opportunities for product loss. This particular laboratory procedure incorporated a novel method for mixing involving 2 syringes attached by a connector as the mixing vessel. Students had never been exposed to this type of compounding method and may have produced better products if had they first mastered the compounding technique. Overall, having students identify their sources of error was an important learning outcome to ensure they could target their weaknesses and correct these errors in subsequent attempts.

Students responded positively on survey items regarding the analytical laboratory component, agreeing that this exercise enhanced their understanding of the importance of quality compounded products and would enable them to better prepare accurate products in the future. A similar trend in student response was observed in previous research involving pharmaceutical laboratory analysis.<sup>24</sup> Most students were able to identify where their errors may have occurred while compounding and responded favorably to the exercise, with increased confidence in compounding-related calculations. An important aspect was the students' ability to identify whether the product was within an acceptable range for dispensing. According to the survey, most students felt better prepared to evaluate their product quality because of the exercise.

This study has several limitations. The laboratory handouts guided students through both the compounding and analytical procedures. Providing students with only the prescription and no other instructional material would simulate a more realistic scenario in which pharmacy students must take initiative to consult the appropriate compounding monograph as a resource. Students were also aware prior to the laboratory that the products were to be assayed. Blinding students to the analysis portion may have achieved different results and potentially a greater impact for students regarding their skill level and the care with which they compounded products. Other institutions might consider implementing an analytical laboratory multiple times throughout the semester to provide a longitudinal method for tracking student progress, taking into account the potential cost and time implications. Because this laboratory exercise was a single assessment of students' ability to prepare quality compounded products, it is unclear whether these attitudes or compounding abilities were maintained beyond this laboratory exercise. Measuring student perceptions by means of a preexercise and postexercise survey instrument might provide a better indication of students' evolution of learning after exposure to an analytical method. Regardless of methodology, pharmacy colleges and schools must design pedagogy that will ensure students' understanding of the importance of quality

in compounded products. Analytical testing of student products combined with subsequent reflection appears to be one way to accomplish this outcome.

From an institutional perspective, implementing an analytical element to a laboratory can be an expensive and time-consuming undertaking. Institutions might consider collaborating with other departments in the college or university for assays requiring more advanced instrumentation. For the purposes of this study, the UV spectrophotometer and bulk materials were relatively inexpensive and already on hand at the institution. Additionally, using assays developed from previous research at the institution may provide an easier transition for classroom implementation. For example, extensive research was previously performed at the Wegmans School of Pharmacy using methimazole in PLO, facilitating the development of the UV assay method and stability of the formulation.<sup>29</sup> Faculty members were familiar with this product and comfortable applying these methods on a larger scale for classroom purposes.

The overarching theme of this laboratory exercise was the importance of quality in compounding. All students enrolled in the course completed an analytical assay and accurately interpreted whether their product was appropriate for dispensing to a patient. Every student effectively identified sources of errors and performed the calculations necessary for compounding and completing the assay. The open-ended quiz question on the survey instrument solidified that students understood that quality is important for patient safety and medication effectiveness. Student questionnaires correlated students' perceptions regarding the measured outcomes. Although some students were unable to accurately prepare this compounded product within the recommended error range, the impact the exercise had on all participants may have been an equally important learning outcome. The exercise caused them to look beyond the pharmaceutically elegant products they had often prepared to evaluate the products for drug content. This important aspect of quality in compounded products is often marginalized by product appearance and elegance. The result of such negligence can potentially be fatal to patients and, thus, should be a motivation for educational institutions to consider the addition of analytical methodology in their compounding laboratories.

## SUMMARY

Implementing product analysis in the pharmacy-compounding curriculum provided students with the opportunity to assess objectively their products for accuracy. Students were receptive to this laboratory exercise and able to identify potential sources of error during their

compounding process. This assessment effectively enabled students to reflect on their compounding skills, understand the importance of compounding quality, and better prepare to compound products more accurately in their future careers.

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Appendix 1. Materials Distributed to Students During the Laboratory Session: (a) Methimazole 0.5% in PLO Procedure; (b) Analysis Procedure for Methimazole 0.5% in PLO; (c) Evaluation of Methimazole in PLO Gel Product Evaluation

**St. John Fisher College  
Wegmans School of Pharmacy  
Applied Pharmaceutics II (PHAR 4212)**

**Veterinary Products**

***Methimazole in PLO Gel:***

Prepare 5 ml of preparation and dispense 3ml in an oral syringe.

Please note: Sorbic Acid has been added to the Lecithin Isopropyl Palmitate Solution as a preservative and the Pluronic 20% Gel has been prepared for you.

Pluronic Lecithin Organogel (PLO) with 5% Active Ingredient

Active Ingredient	0.25 g
Ethyl Alcohol	0.5 ml
Base, Lecithin Isopropyl Palmitate Solution	1.1 ml
Base, Pluronic Gel 20% qs	5.0 ml

1. Using a 12 ml luer-lock syringe, remove the plunger and place a black rubber tip cap on the end of the syringe. Place the syringe in a beaker (as a holder).
2. Draw up 0.5 ml ethanol into a 1ml oral syringe. Place 0.25 ml ethanol into the open end of the 12 ml syringe.
3. Place the drug in the 12 ml syringe, followed by the remaining 0.25 ml of ethanol. Swirl syringe until the powder is wetted.
4. Measure the 1.1 ml of Lecithin Soln and add to barrel of syringe.
5. Replace plunger into the barrel of the syringe, carefully invert the syringe and remove the black tip cap to allow air to escape.
6. Determine the volume of the mixture in the syringe and calculate the quantity of Pluronic 20% gel needed to have a total of 5ml (ie: 5 ml (total) - \_\_\_\_ = \_\_\_\_ ml Pluronic 20% gel
7. Using a separate 12 ml luer lock syringe, draw up the calculated amount of Pluronic 20% gel into the syringe.
8. Attach a RED luer/luer adapter to the syringe containing the gel and purge all the air out of the syringe and adapter.
9. Connect the two 12 ml syringes together. Push the GEL into the syringe containing the Lecithin/Drug and mix back and forth 20 times until a uniform mixture is obtained. – It is important to more the GEL into the DRUG first, so that the adapter does not clog.
10. When thoroughly mixed, move all the mixture into one syringe. Remove the adapter and the empty 12 ml syringe.
11. Place a clear luer/slip adapter on the syringe containing the compound. Purge all the air out of the adapter.
12. Place a 3 ml oral syringe into the slip side of the adapter.
13. Load the syringe with 3 ml, and cap the syringe with a light blue cap.
14. Dispense in a ziplock bag.

**St. John Fisher College  
Wegmans School of Pharmacy  
Applied Pharmaceutics II (PHAR 4212)**

**Methimazole in PLO Gel Assay:**

Pluronic Lecithin Organogel (PLO) with 5% Methimazole	
Methimazole	0.25 g
Ethyl Alcohol	0.5 ml
Base, Lecithin Isopropyl Palmitate Solution	1.1 ml
Base, Pluronic Gel 20%	qs 5.0 ml

**Procedure**

Using a 1 ml syringe, dispense 0.5 ml of the gel product into a 100 ml beaker and add 30 mL of methanol. Dissolve the gel by mixing with a glass rod then transfer the solution to a 500 mL volumetric flask. Add 20 mL of methanol to the beaker, stir, and transfer the solution again to the same 500 mL volumetric flask. Fill the volumetric flask with approximately 300 mL of deionized water and stir/shake well (the solution will turn slightly cloudy). QS to 500 ml with deionized water (be sure to remove any stir bar or glass rod first!) and mix well. Measure out 20.0 mL of this first dilution (try using a 10 mL graduated cylinder rather than a 100 mL graduated cylinder for greater accuracy) and place into a 250 mL volumetric flask. QS to 250 mL with deionized water and mix well. Finally, filter a 5-10 mL aliquot of the mixture into a clean beaker, test tube, or acrylic cuvette.

What is the expected concentration of this final filtered solution? \_\_\_\_\_ mcg/ml

Fill a plastic cuvette two-thirds full with your filtered solution and assay by UV analysis at 252 nm. Compare your results to the standard to calculate the concentration of the drug in your diluted solution.

$$\frac{\text{Abs}_{\text{standard}}}{\text{Conc}_{\text{standard}}} = \frac{\text{Abs}_{\text{sample}}}{\text{Conc}_{\text{sample}}} \quad \text{Abs}_{\text{standard}} = 1.7246 \quad \text{Conc}_{\text{standard}} = 12.5 \text{ mcg/ml}$$

Your Product: Absorbance (Abs): \_\_\_\_\_ Concentration (Conc): \_\_\_\_\_ mcg/ml

What is the percent error of this product? Based on your analysis, is the product suitable to dispense to a patient?

What sources of error may have occurred in the preparation or analysis of the product?

**Evaluation of Methimazole in PLO Gel Product Evaluation**

Please provide a score to the following assessment statements on a scale of 1-5.

1 = SD (Strongly Disagree) 2 = D (Disagree) 3 = N (Neutral) 4 = A (Agree) 5 = SA (Strongly Agree)

1. The laboratory exercise involving the assay of the methimazole in PLO gel compounded product I prepared helped me to better understand the importance of quality in compounding pharmaceutical products.
2. As a result of this laboratory exercise, I now know how pharmaceutical products can be analyzed for drug content.
3. This laboratory experience helped me to think through the sources of error that may occur while compounding and analyzing compounded products.
4. I believe I know where the errors associated with my compounded product may have occurred.
5. By performing the calculations associated with this laboratory exercise, I now feel more confident about performing calculations related to compounding.
6. After completing this laboratory, I am more confident in my ability to evaluate assay results of a compounded product.
7. As a result of analyzing my own compounded products in this lab, I believe I will prepare compounded products more accurately in the future.