Implementation of a Pharmaceutics Course in a Large Class through Active Learning Using Quick-Thinks and Case-Based Learning[1]

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This manuscript describes active learning techniques implemented in a pharmaceutics course, taught in the first professional year, with a class size of 114 students. The main objective of this course was to produce learning in a pharmaceutics course using active learning strategies with enhanced student outcomes. The learning was facilitated by active learning strategies including quick-thinks (QTs) and case-based learning (CBL). QTs are active thinking tasks focusing on cognitive skills such as processing of content, application, analysis and evaluation. They are inserted into lectures in such a manner that a student is given an opportunity to think and process the lecture material as the lesson unfolds. During lectures, QTs are presented every 15 minutes with follow-up discussions. For CBL, cases with specific learning objectives were developed and provided to students who were divided into several groups of four members, each member having a defined role. Student groups reviewed the cases, identified and internalized pertinent learning issues, acquired information, formulated group consensus on optimum solution, and prepared reports for class presentations. The outcome measures included a pre-, during, and end-point assessments. Active learning was successfully implemented in a large class where students actively engaged in problem solving, assuming responsibility for their own learning. Enhanced student learning was evident from the assessment data.

INTRODUCTION

The basic science courses of the pharmacy curriculum including pharmaceutics are generally taught in traditional lecture format, with or without the use of case studies or problem sets. Many active leaning methods used in other fields, and in more clinical areas of the pharmacy curriculum(1,2), have traditionally not been considered suitable for the basic sciences(3). The descriptive nature of some basic science courses including physical pharmaceutics and dosage form design may not lend themselves readily to active-learning methods compared to courses in the clinical areas of the pharmacy curriculum. Pharmaceutics I (homogeneous systems) is a required course at the School of Pharmacy at the University of Louisiana at Monroe (ULM). It is offered to first year professional entry-level pharmacy students during the fall semester. The course deals with physical, chemical and biologic principles used in the preparation, preservation and utilization of pharmaceutical

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liquid homogeneous dosage forms. Over the past many years, the course has been primarily offered through traditional lecture format with little or no active learning. Such an approach has a number of inherent problems including passive learning, difficulty in extending the concepts learned in the course to apply to real life problems, inability to relate the information to patient/product scenarios, difficulty in relating the information to pharmaceutical care, and little or no responsibility of students for their self learning. Further, science education is in the process of shifting from mastery of a large body of factual information to an emphasis on the development of reasoning skills and the solving of practical problems(4). Facts alone cannot be correlated with practical application, and the process of how to use the facts is essential part of the study and practice of pharmacy and medicine(5). In lieu of these issues, new approaches to teaching pharmaceutics courses including active learning were sought.

Active Learning

Many institutions, including colleges of pharmacy have adopted curricular changes with an emphasis on producing learning. It is based upon the faculty creating an environment in which learning can be produced rather than in which knowledge is taught (6,7). This learning paradigm involves actively engaging the student in the learning process with shared responsibility for learning(5,8). Many outcomes may be inculcated into students across the curriculum through a variety of active learning (AL) strategies. It has been noted that AL is an attitude, not a method(9). Promotion of AL requires sympathetic teachers, willing students, and an institution that is committed not only to promote interactions between them but also to provide an environment conducive to optimal student learning(9).

Many AL approaches across various curricula have been reported. Some of these include problem-based learning, cooperative and service learning, integrated learning, role-playing and simulations, and interactive web based instruction(10-17). A shift from teacher-centered paradigm to a student-centered paradigm is increasingly evident in many fields of education including pharmaceutical education. The paradigm change in pharmaceutical education across the board has challenged the faculty to develop instructional strategies that transform students from passive listeners to active learners. Active learning methods primarily entailing case study based formats have been described for many courses in the pharmacy curriculum including medicinal chemistry(18,19), pharmaceutics(3,20,21), pharmacokinetics(22), and therapeutics(23). Use of classical problem-based learning (PBL) model(10) has shown some evidence for an improved retention of knowledge compared to more didactic approaches(24,25). Application of PBL model to pharmaceutics has been described by Duncan-Hewitt(26). Brandt *et al.* reported a modified PBL format which included case studies written from the perspective of a pharmacist practicing pharmaceutical care(27). The main challenge for faculty in successfully employing any active learning strategy, however, is to create an environment that is not only conducive to active learning, but also demonstrates enhanced student outcomes. Incorporation of such strategies into the daily routine of classroom instruction, however, must focus on producing student learning.

Perceived drawbacks in implementing pharmaceutics course through active learning (AL) include: (*i*) large class size making it difficult to incorporate any form of AL by an individual instructor; (*ii*) amount of material that needed to be incorporated into the learning experiences; (*iii*) physical facilities to carry out small group activities; (*iv*) committing students to learning; (*v*) possible increase in instructor time demands; (*vi*) fear of losing control in the classroom; and (*vii*) anxiety amongst many students as they try to deal with a new approach(3-5,12,28). Some of these concerns, especially the first one, are real at many schools including the ULM School of Pharmacy. Students often commented that they did not have adequate opportunity to interact with each other or with the course instructor. With these concerns in mind, the pharmaceutics course was redesigned to engage students actively in knowledge acquisition and problem solving, with no significant changes in course content and with no additional costs for course implementation. The present paper examines the implementation of a case-based AL approach in a pharmaceutics course through the use of active learning methods that focus on student-centered learning. The AL methods used in the course replaced the traditional lecture format that was used in previous years.

COURSE OBJECTIVES

The objectives of this redesigned course were to: (*i*) produce learning by actively engaging students in a large class; (*ii*) foster critical thinking abilities to solve real-life patient/product problems as they relate to pharmaceutics and to pharmaceutical care; (*iii*) increase student-instructor and student-student interactions; and (*iv*) enhance course and instructor ratings by students. The overall goal of this course was to help students acquire a learning style that may be applied life-long.

DESCRIPTION OF METHODS

The pharmaceutics course is a three-credit unit, with three scheduled class meetings per week (for 14 weeks). A detailed course schedule with specific topics and learning issues was provided as a hardcopy to all students. In addition, a course schedule and other course related materials were posted on the School's website under the respective course link. Students were able to access this site either from the Computer Center located in the School that housed 22 PC compatible terminals or from remote locations using their own computers. The course outline and the recommended textbooks are listed in Appendix A. A total of 114 students were enrolled in the course. The learning of the course material was facilitated by a variety of active-learning methodologies including quick-thinks (QTs) and case-based learning (CBL).

Quick-Thinks (QTs)

A major portion (approximately 67 percent) of the course content was presented to students in a didactic format that included QTs. QTs are active thinking tasks that are designed and inserted into lectures in such a manner that a student is given an opportunity to think and process the lecture material as the lesson unfolds. QTs are therefore integral part of lectures, which serve to promote critical thinking in large classroom instruction. The procedure involved two lecture blocks per 50-minute class with an instructor-posed discussion question (active-thinking task) after every 15-minutes of lecture. Students were advised to bring a few 3" x 5" index cards, which were labeled on the top with their names and student ID numbers, to all class meetings. Students wrote their individual responses to QTs on these index cards in less than two minutes and handed them over to the instructor. From this pool, the instructor randomly selected a few responses (usually two), prompted the students who wrote those responses to elaborate on their answers, facilitated appropriate discussion, and provided feedback to the entire class. This format was followed in two of the three class meetings per week.

The different types of quick-thinks used over the length of the course included: (*i*) selecting the best response from given choices; (*ii*) correcting the error; (*iii*) supporting the statement; (*iv*) filling in the blanks, (*v*) reordering the steps; and (*vi*) solving a problem based on the information provided. A total of 52 QTs were incorporated into the course. These active thinking tasks focused on recall, comprehension, processing of content, synthesis and analysis, and application. A selected list of QTs is presented in Appendix B.

Case-Based Learning (CBL)

The classroom activities for the remainder (approximately 33 percent) of time were conducted through case-based learning (CBL) where students worked in small groups to maximize their learning. The goals of the CBL were to promote group-learning activities and foster critical thinking abilities, as well as problem solving experiences pertaining to homogeneous dosage forms. For CBL activities, students were divided into several working groups, each consisting of four members. Amongst its members, each group elected a leader, a resource manager, a recorder, and a spokesperson(29). The specific roles and responsibilities of different members of the group are summarized in Appendix C. Within each group, these roles were rotated for different case assignments over the semester. Students were directed to wear lab coats with their name badges for all the CBL sessions, which were scheduled in a different room that had the provisions and facilities for small group activities.

Over the semester(14 weeks), each group worked on six case studies. All the case assignments were provided to students at the beginning of the semester. A representative case study is presented in Appendix D. The cases were designed objectively to contain the specific and relevant learning issues. The cases included a brief overview or descriptive information that both established a context for the problem and identified major decisions that must be made. The cases integrated concepts covered in the didactic portion of the course with their application to pharmaceutical care and were scheduled about the same time when students were receiving the information in lectures.

Each assignment lasted for two weeks. In the first meeting on each assignment, students reviewed the case, identified associated learning issues, discussed the accompanying questions, brainstormed possible solutions, delineated appropriate resources, and divided the responsibilities among the group members. The instructor facilitated this process by providing ready access to relevant resource materials on-site. This task was accomplished by providing resource materials including books, journal articles, and other relevant informational resources on a mobile cart. Most information was derived from the recommended references, multiple copies of which were placed on the cart. Students were encouraged to share information freely with group members; not only to acquire new information, but also to resolve potential conflicts and dilemmas. The group leaders were encouraged to interact with the instructor by electronic mail. All the groups pursued the cases outside of the classroom by meeting at mutually convenient times as needed. Once the students had acquired additional information, they met again to share new information in an attempt to seek a reasonable solution to the problems at hand.

During the second week, each group synthesized information, discussed issues relevant to the outcome, and formulated a group consensus on optimum solutions to the problem set. At this time, a few groups were randomly selected to give a verbal presentation of their findings to the entire class. In general, the spokesperson for each group was responsible for these presentations when called upon. In addition, each group submitted a hand-written or typewritten (preferred) summary report on each case to the instructor, which was returned to the group recorders the following week with appropriate feedback.

Table I. Results of student assessments

	Average percent score ± SD	
	Traditional lecture-based[a]	**AL (with QTs and CBL)**[b]
Preassessment test	14.4 ± 3.7	13.9 ± 5.3
Midterm examination	79.9 ± 16.3	90.3 ± 10.9
Final examination	80.5 ± 15.3	92.6 ± 13.7

aData from previous two years.

bData from this year.

Assessments

Two examinations, a midterm and a final, were administered during the semester. Each examination accounted for 45 percent of the final course grade. Attendance and participation in all learning activities accounted for the remaining (*i.e.*, 10 percent) grade. The standards of the examinations for this year with regard to the difficulty level and the material covered were considered comparable to those in the previous years (where instructor used traditional lecture-based instruction only). A majority of the questions over these years were comparable, if not identical. Average scores from these examinations were compared and the significance of difference was determined by the Student's *t*-test. The values are considered significant at $P<0.05$. In addition, a pre-assessment examination was also conducted approximately one week after the beginning of the semester. The performance in pre-assessment test versus the performance in midterm and final examinations was used to monitor the learning progression of students.

Student Evaluations

At the end of the semester, students were asked to complete (in an anonymous manner) two forms: (*i*) a standardized instructor/course appraisal form; and (*ii*) a specially designed course content/delivery methods evaluation form. The instructor/course appraisal form is a standard evaluation instrument used at ULM consisting of 20 core questions. The University, College, Department, and the individual faculty member- each contributed five questions to this evaluative instrument. The course content/delivery methods evaluation form was designed by the instructor and was comprised of 15 questions. Both evaluation instruments used a five-point ordinal response scale of Strongly Agree (5), Agree (4), Neutral (3), Disagree (2), and Strongly Disagree (1). Student responses to standardized instructor/course appraisal form for this year (where instructor used AL methods) were compared to responses from previous years (where instructor used traditional lecture-based format), hi the content/delivery methods evaluation form, in addition to the 15 questions, students were asked to provide written comments on the following:

1. Which aspects of the course did you like the best?
2. Which aspects of the course did you like the least?
3. What changes would you like to make in the course to improve it for the next year?
4. Please make additional comments concerning the course and/or the instructor.

The frequency count for common comments was determined

Table II. Instructor and course appraisal

Item	Traditional (Median[a,b] ± SD)	AL (Median[c] ± SD)
My instructor displays enthusiasm when teaching.	4.5 ± 0.9	4.6 ± 0.7
My instructor emphasizes conceptual understanding of material.	4.4 ± 0.4	4.5 ± 0.6
Difficult topics are structured in easily understood ways.	4.2 ± 0.3	4.7 ± 1.0
My instructor holds the attention of the class.	3.9 ± 0.7	4.9 ± 0.9
My instructor helps me to apply theory to solve problems.	4.1 ± 0.9	4.8 ± 0.7
My instructor suggests specific ways I can improve.	3.9 ± 0.6	4.6 ± 0.5
My instructor has an effective style of presentation.	4.3 ± 0.5	4.8 ± 0.9
My instructor provides prompt feedback to benefit me.	3.9 ± 0.6	4.8 ± 0.6
My instructor readily maintains rapport with this class.	4.6 ± 0.9	4.5 ± 1.0
My instructor creates an atmosphere highly conducive to learning.	4.0 ± 0.8	4.9 ± 0.8
My instructor has stimulated my thinking.	3.9 ± 0.5	4.7 ± 1.1
This class material is pertinent to my professional training.	4.5 ± 1.0	4.4 ± 0.9
I can apply information /skills learned in this course.	3.9 ± 0.4	4.9 ± 0.7
My technical skills were improved as a result of this course.	4.0 ± 0.6	4.6 ± 0.5
There is sufficient time in class for questions and discussions.	4.5 ± 0.7	4.5 ± 0.5
I like the way instructor conducts this course.	4.3 ± 0.7	4.8 ± 0.7
I feel free to ask questions in class.	4.6 ± 0.8	4.6 ± 0.8
My instructor is receptive and willing to assist students.	4.3 ± 0.6	4.6 ± 1.0
My instructor sets high standards for student performance.	4.6 ± 0.9	4.7 ± 0.9
Overall, I feel I have learned a great deal in this course.	4.1 ± 0.5	4.9 ± 0.6

[a] Average from two years.
[b] Number of responses varied from 115-128.
[c] 111 responses.

Table III. Course content/delivery methods evaluation

Question	Mean ± SD
Ratings on Course, Contents, and Methods of Delivery	
1. Course objectives/competencies were clearly communicated.	4.67 ± 0.49
2. Quick-Thinks enhanced my learning.	4.85 ± 0.51
3. Case-Based Learning enhanced my learning.	4.91 ± 0.51
4. This course integrated the learning issues and concepts into case studies.	4.67 ± 0.49
5. This course actively involved me in the learning process.	4.86 ± 0.67
6. The information/concepts/principles in the course prepared me to identify/solve problems.	4.76 ± 0.67
7. The assessment methods (tests, case-reports, case-presentations, etc.) accurately evaluated the contents in the course.	4.25 ± 0.62
8. This course challenged me to think critically to solve problems.	4.90 ± 0.50
9. This course challenged me to learn more.	4.25 ± 0.62
Instructor's Rating	
10. The instructor is an excellent teacher.	4.67 ± 0.49
11. This instructor treats students with respect.	4.83 ± 0.39
12. This instructor encourages questions.	4.75 ± 0.62
13. This instructor provided me with adequate feedback to help me direct my learning.	4.90 ± 0.40
14. This instructor was willing to help students outside the class.	4.61 ± 0.33
15. This instructor was impartial in assessing students.	4.52 ± 0.40

Scale: Strongly Disagree (1), Disagree (2), Neutral (3), Agree (4), Strongly Agree (5).
N = 111 responses.

and all the repeated ones (>10 percent) are reported.

RESULTS

Student grades (average percentage scores together with their standard deviations) are summarized in Table I. Students who were enrolled in the present course with active learning format scored 10.8 and 11.7 percent higher in the midterm and final examinations, respectively, than those in traditional lecture format. The difference was statistically significant at $P<0.005$. The average scores between midterm and final examinations in traditional format were similar. The final examination scores in the AL format were slightly (2.3 percent) higher than midterm scores, however, the differences were statistically insignificant. The scores from the pre-assessment tests over the years were comparable and statistically insignificant ($P<0.025$).

The student responses to the standardized instructor/course evaluation forms are summarized in Table II. The data indicated better reception of active learning by students over traditional lecture format. Student responses to many items were extremely positive. Student ratings were significantly ($P<0.05$) higher for AL as compared to traditional lectures on many items including: (*i*) my instructor holds the attention of the class; (*ii*) my instructor provides prompt feedback to benefit me; (*iii*) my instructor creates an atmosphere highly conducive to learning; (*iv*) I can apply information/skills learned in this course; and (*v*) overall, I feel I learned a great deal in this course. The average

Table IV. Student written responses: Item (percent frequency)

1. Which aspects of the course did you like the best?
   a. Not sitting in lectures and taking notes passively (64%)
   b. Actively engaging in learning activities (57%)
   c. Quick-thinks (52%)
   d. Group discussions on cases (38%)
   e. Quicker feedback from the instructor (27%)
   f. Challenging (16%)
2. Which aspects of the course did you like the least?
   a. Inadequate physical facilities for group activities (44%)
   b. Inadequate computer facilities (33%)
   c. More work for students (19%)
   d. Feeling challenged and stressed at times (17%)
3. What changes would you like to make in the course to improve it for the next year?
   a. Provide more computer facilities (37%)
   b. Around-the-clock computer access to students (21%)
   c. Conduct CBL in larger room (physical facilities) 16%
   d. Provide training in class presentations (11%)
4. Please make additional comments concerning the course and/or the instructor.
   For the last questions, students expressed a profound satisfaction with the overall handling of the course. Some common comments were (a) great course, (b) I felt I learned a lot in this course, (c) I feel confident of my knowledge and skills, and (d) I enjoyed the focus on student-centered learning.

score increased on this 20-item evaluation form from 4.23 ± 0.65 to 4.69 ± 0.71, demonstrating students' overall acceptance and enhanced ratings. The student response to the survey on Course Contents/Methods Delivery is summarized in Table III. The response of students to the course content and the delivery methods, in general, was very positive. The mean value of student responses for all the 15 questions ranged from 4.25 to 4.91 (where 5 = strongly agree). The highest student ratings (> 4.85) were obtained for questions including: course format (with QTs and CBL) enhance student learning (Questions 2 and 3), active student involvement in the learning process (Question 5), challenging students to think critically and to solve problems (Question 8), and instructor feedback to help students learn (Question 13). Student written responses with their frequency percentage counts were reported in Table IV. While the written responses were generally supportive of AL methods used in the course, physical and computer facilities were identified as inadequate in meeting students' needs. A number of changes were suggested to improve the course for next year; however, none relate to the course contents or the delivery methods. Students expressed a profound satisfaction with the learning that took place in the course. Overall, the data were very supportive of active learning paradigm with improved student outcomes.

DISCUSSION

There is a tremendous need for creative approaches to instruction, which actively engage students in the learning process with enhanced student outcomes. In the overall learning process, students must assume some responsibility for their own learning. Faculty members should facilitate the learning process and help students develop and practice critical thinking and problem solving skills. The AL format must allow students to inquire freely, develop hypothesis, generate multiple hypotheses where possible, and acquire information on their own. While the faculty member(s) should alleviate the conflict of information/discrepancies or ethical dilemmas, they must challenge students to learn more. The learning process must allow students to think critically through each of the hypothesis they generated for an optimal outcome. After each new learning experience, students need time to "process" the information(3,8,10,12).

Most models of active learning are geared toward small group (less than 15 students) settings in which interactions between students and instructor are optimized(4,12). However, many basic courses in the pharmacy curriculum including pharmaceutics are required to meet in large classes in which it is more difficult to utilize active learning methods. Duncan-Hewitt reported using PBL approach to teach pharmaceutics(20). Brazeau *et al.* used problem based discussion format in a dosage forms course which included self and peer-review process(30). While the outcomes in these courses are supportive of AL methods, the need for more than one instructor (facilitator) is clearly evident. The large class size and limited resources to support more facilitators prompted many educators to seek alternatives. One such alternative is the use of tutorless cooperative learning format. However, the drawbacks of such an approach include the possibility of unsupervised students becoming angered, overwhelmed, and/or less motivated to participate in the learning process(26). Unsupervised students can get off track and become committed to wrong problem solutions, incorrect "facts", etc., and this typically is difficult to undo(31). QTs and CBL offer effective means of promoting an active learning experience in large class settings by a single instructor. QTs and CBL sessions force students to actively participate in the learning process. The approach of this AL model with QTs and CBL was built upon the premise that traditional lectures using standard databases are necessary but inadequate for students' early development as pharmacy practitioners, as they marginalize essential areas of discourse and restricts students' critical thinking and problem solving ability. QTs allowed the instructor to stop at critical points to present an opportunity for active thinking in order to minimize passivity and increase the chances of student understanding and retention. Further, QTs allowed students to seek clarifications on important concepts of the lecture as the lesson unfolds.

For CBL, cases with specific learning objectives were developed which were structured enough to lead the students to the important learning issues without the tutor or facilitator, but designed in such a way to allow students to assume some responsibility for self learning (see Appendix A for a sample case study). A set of questions was provided with each case study to allow them to think critically in order to arrive at an optimal solution to the problem on hand. Solutions to problems usually required retrieval of information from the class lectures and other resources. In essence, CBL provided opportunities for students for formally integrating previous knowledge areas to the problem on hand, developing problem-solving skills, and identifying new areas of knowledge acquisition. When students were actively engaged instead of passively recording information, they stayed more focused and were able to check their own understanding.

In any learner-centered environment, faculty become facilitators of learning, and students become active participants, engaging in a dialogue with their colleagues and with the instructor(32). In creation of a successful AL environment, both faculty and students must make adjustments to their respective "traditional" roles in the classroom(32). The key to the successful implementation of a given AL method depends largely on its acceptance by students. The student evaluations and course appraisals are very useful tools in the assessment of student acceptance of AL methods. Further, they provide a mechanism to improve the instructional methods on a continuous basis for optimal student outcomes. The student assessment and evaluative data clearly indicated enhanced student learning and student acceptance of AL methods used in this course. The data from standardized instructor and course appraisal form were very supportive of AL methods used. The format used in the course provided ample opportunities for students to interact among themselves and with the instructor, which was perceived favorably by the students. Further, the provision of prompt feedback by the instructor and a forum to seek clarifications by the students in the follow-up discussions after QTs and CBL were found to be conducive to student participation and learning. In addition to standardized course evaluations, it is important that each faculty member conduct his/her own course and teacher evaluation to assess whether his/her delivery methods and technique is affecting\enhancing student learning. The results of such evaluative data are very useful in making necessary adjustments to the instructional strategies for enhanced student outcomes.

EVIDENCE OF STUDENT LEARNING AND PERSONAL REFLECTIONS

Student learning and knowledge synthesis was demonstrated in many ways. While improved performance in standardized exams serves as a direct measure of student learning, it was also evident by many indirect, subjective observations as well. Student confidence in problem solving was evident in the group discussions/presentations. By working in groups, students learned to cooperate, as evidenced by group consensus case reports. Groups were informed that they would be randomly called upon to present their reports to the entire class. Due to this practice, students were well prepared and confident in their case study presentations. Additionally, by having the students present in front of the class, their public speaking skills and comfort in front of others was visibly enhanced. The present course format allowed the instructor to provide immediate feedback to students on their responses (for QTs) and case presentations (for CBL sessions). The author's experience in teaching the same course by traditional lecture-based format as well as active learning methods convinced him of the importance of active, student-centered learning. Perceived setbacks of implementing active learning in large classes can be minimized by careful planning, effective utilization of time and available resources. The AL methods not only fostered critical thinking abilities but also achieved enhanced student outcomes in a pharmaceutics course.

CONCLUSION

The goal of this pharmaceutics course was to implement active learning in a large class and to produce learning with enhanced student outcomes. Based on the experiences with this course, QTs and CBL represent simple and effective methods of AL in large classes. While these methods require thorough planning, effective utilization of time and good execution, no additional funds are required for implementation. Active learning in a pharmaceutics course established the value and feasibility of active, ability-based and student-centered learning in a large class. Further, the overwhelmingly positive responses of students and overall success of this course lead to some educational rethinking among faculty in other basic science courses of pharmacy. The outcome measures clearly indicated improved/enhanced learning by the students in AL setting compared to traditional lecture-based format.

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APPENDIX A. COURSE OUTLINE AND RECOMMENDED TEXTS

Course Outline:

Introduction to Drugs, Dosage Forms, Pharmaceutics, Pharmaceutical Care, Drug Classification, OTC, Legend, Controlled Substances, Official Compendia, Sources of Information, Pharmacist's Responsibility

Development of New Drugs, Bioavailability, Drug Dosage, Factors Affecting Dose, Routes of Administration

Dosage Form Design, Pharmaceutical Ingredients, Preformulation

Pharmaceutical Solutions- Definitions, Solubility, Factors Affecting Solubility and Dissolution, Solvents for Oral Preparations, Preparation of Solutions

Types of Products and Definitions, Syrups and Elixirs, Official Preparations, Tinctures, Fluid Extracts, Aromatic Waters, Spirits

Pharmaceutical Aerosols- Definitions, Advantages, Components, Principles of Operation, Inhalations, Inhalants, Sprays

Ophthalmic Solutions, Ocular Availability, Formulation Considerations- Sterility, Preservation, Isotonicity, pH and Buffers, Viscosity, Administration, Contact Lens Care Solutions

Other Topical Products; Otic Solutions- Vehicles, Ingredients, Administration, Nasal Solutions, Additives and Formulation

Ionic Equilibria, Modern Theories of Acids and Bases, pH, pOH, hydronium ion concentrations, Dissociation of Weak Acids, Bases and Water, Buffers, Buffer Capacity and Buffered Isotonic Solutions

Kinetics, Rates and Orders of Reactions, Pathways of Degradation, Mechanism of Degradation, Rate Equations, Reaction Orders, Half-life, Shelf-life, Arrhenius Equation, Accelerated Stability Analysis

Biotechnology Derived Solutions, Definitions, Special Considerations, Product Handling

Recommended Texts:
Pharmaceutical Dosage Forms and Delivery Systems, 6th Edition, by Howard C. Ansel and Nicholas G. Popovich, Lee & Febiger, Philadelphia

Remington's Pharmaceutical Sciences, 17th Ed., Mack Publishing Company

Physical Pharmacy, 4th Edition, by A. N. Martin, J. Swarbrick and A. Camarata, Lee & Febiger, Philadelphia

APPENDIX B. SELECTED EXAMPLES OF QUICK-THINKS (ACTIVE THINKING TASKS)

1. Is the following statement True or False?
   All biological equivalents are pharmaceutical equivalents but not all pharmaceutical equivalents are biological equivalents.
2. Which of the following statement(s) is correct pertaining to ophthalmic formulations?
   a. Drugs may be administered orally to treat ocular pathologies.
   b. Smaller the volume (less then 50 mL) instilled into the eye for ocular medications, better the ocular availability.
   c. Drugs that are extremely lipophilic (log p > 4) have excellent ocular availability.
   d. Applying a slight pressure at the root of the nose may increase ocular availability by decreasing nasolacrimal drainage.
3. If a sterilization procedure destroyed 98% of all bacterial population in a parenteral product, would you consider this product sterile?
4. If a drug suspension (125 mg/mL) degrades by zero-order kinetics with a rate constant for degradation, k, of 0.5 mg/mL/hr, how would you know the concentration remaining after 3 days?

APPENDIX C. ROLES AND RESPONSIBILITIES OF EACH GROUP MEMBER

Leader
- Leads the group and facilitates the task
- Articulates a group plan and provides direction
- Ensures that all members participate and work productively
- Resolves potential conflicts among team members
- Substitutes for any absent member

Recorder
- Records names/roles and maintains activity sheet
- Lists learning activities
- Records group responses for the case-based questions
- Prepares final group report
- Ensures that the activity is complete

Spokesperson
- Makes sure everyone understands answers/ideas to be shared
- Present group report to the class when called upon
- Shares the information with the group
- Reports any potential conflicts/dilemmas back to the group

Resource Manager
- Identifies and manages resources to be used
- Collects the information needed
- Shares the collected information with the group
- Keeps contacts and shares information with resource managers of other groups as and when needed

APPENDIX D. A CASE STUDY ON STABILITY KINETICS

Ms. Julie Connaly is working as a clinical Pharmacist at St. Francis Medical Center at Monroe, LA. She received a prescription that requires 1 g of cefazolin sodium to be administered to the patient in 100 mL of NS. Cefazolin is an antibiotic, which may be administered by slow infusion into the vein (IV infusion). Cefazolin is a weak acid (MW = 455; pKa = 2.10) and is poorly soluble in aqueous IV infusion solutions such as 5% dextrose (D5W) or 0.9% saline (NS). Recognizing the solubility problem with cefazolin, Ms. Connaly prepared the formulation using the sodium salt of cefazolin (MW = 477). When Ms. Connaly referred AHFS Drug Information to check the stability of the two marketed formulations of cefazolin sodium, Ancef® and Kefzol®, she learned that these solutions are stable for 10 days when refrigerated. Suspecting the stability of sodium cefazolin in aqueous solution at room temperature, Ms. Connaly sent her formulation to ULM School of Pharmacy for stability assessment. When assayed approximately 75 hours after the formulation has been prepared, the concentration was found to be 8.4 mg/mL. The drug was reported to undergo first-order degradation with a half-life of 12 days.

Questions:

1. a) What would be the pH when 1 g of sodium cefazolin is dissolved and made up to a liter with purified water?
   b) Do you expect that the pH of an admixture prepared in D5W or NS would be any different than the above aqueous preparation?
2. What is the rate constant for the first-order reaction, k?
3. What is the concentration remaining after 24 and 72 days?
4. What should be the expiration date on the label?
5. What fraction of drug will be remaining after 5 half-lives?
6. If the drug undergoes zero-order degradation with the same rate constant, what will be the half-life?
7. Does the pH of the formulation change when the concentration is dropped to 8.4 mg/mL
8. What is "accelerated stability analysis?" Explain how it is done.