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## INSTRUCTIONAL DESIGN AND ASSESSMENT

# The Use of Animated Videos to Illustrate Oral Solid Dosage Form Manufacturing in a Pharmaceutics Course

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**Objective.** To evaluate the impact of animated videos of oral solid dosage form manufacturing as visual instructional aids on pharmacy students' perception and learning.
**Design.** Data were obtained using a validated, paper-based survey instrument designed to evaluate the effectiveness, appeal, and efficiency of the animated videos in a pharmaceutics course offered in spring 2014 and 2015. Basic demographic data were also collected and analyzed. Assessment data at the end of pharmaceutics course was collected for 2013 and compared with assessment data from 2014, and 2015.
**Assessment.** Seventy-six percent of the respondents supported the idea of incorporating animated videos as instructional aids for teaching pharmaceutics. Students' performance on the formative assessment in 2014 and 2015 improved significantly compared to the performance of students in 2013 whose lectures did not include animated videos as instructional aids.
**Conclusions.** Implementing animated videos of oral solid dosage form manufacturing as instructional aids resulted in improved student learning and favorable student perceptions about the instructional approach. Therefore, use of animated videos can be incorporated in pharmaceutics teaching to enhance visual learning.

**Keywords:** pharmaceutics, dosage forms, instructional aids, visual learning, animated videos



## INTRODUCTION

Educators in contemporary pharmacy education are facing challenges for the development of effective pedagogical strategies to accommodate the needs of net-savvy Internet generation students.[1] Student pharmacists belonging to this generation are increasingly visually oriented and favor visual learning modalities.[2] There is growing evidence that, as a teaching method, use of visual instructional aids improves students' understanding and retention of topics in complex and information heavy courses such as pharmaceutics and pharmacology.[2-3] One such visual instructional aid is the use of videos for classroom teaching. Examples of successful use of video-type visual aids to improve course effectiveness and increase student appeal exist in the pharmacy education literature.

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Dunham et al used video modules and video clips as instructional aids in a drug assay course and assessed students' perceptions and performance in the course after addition of video-based instructional aids. Students' perception of the course improved significantly after the introduction of the video-based instructional tools.[3] Similarly, Haines et al reported that an Internet-based video casting project, which involved public health information videos, increased pharmacy students' self-esteem, respect for peers, creative and critical-thinking abilities, and enhanced the student perception of the importance of pharmacists providing accurate public health information.[1] Therefore, use of animated videos of the oral solid dosage form (OSD) manufacturing may be helpful in improving the effective delivery of pharmaceutics principles and concepts to pharmacy students.

Pharmaceutics as a subdivision of pharmaceutical sciences commonly involves scientific and technological aspects of the design and manufacture of dosage forms. Knowledge of manufacturing and preparation of dosage forms is important for student pharmacists as it provides them with the ability to understand the influence of manufacturing parameters on the therapeutic efficacy of the dosage forms and assists in the decision-making process for choosing the appropriate dosage forms for patients. The Accreditation Council for Pharmacy Education (ACPE) regards "materials and methods used in preparation and use of dosage forms" as an essential element to the development of pharmacists in Appendix B, Additional Guidance of the Science Foundation for the Curriculum.[4] Furthermore, in the recently approved ACPE 2016 Standards, Appendix 1 lists "physicochemical properties of drugs, excipients, and dosage forms important to the rational design and manufacture of sterile and non-sterile products" as one of the required elements of the didactic doctor of pharmacy (PharmD) curriculum.[5]

The Center for Advancement of the Pharmacy Education (CAPE), in its 2013 Educational Outcomes, emphasized the importance of knowledge of foundational pharmaceutical sciences to solve therapeutic problems and advance patient-centered care.[6] Undoubtedly, a clear understanding of the foundational pharmaceutics concepts that involve dosage forms and processes involved in their manufacturing is of importance to pharmacy education. Incorporation of the ACPE Standards into the learning outcomes of pharmaceutic course framework is a fundamental way to ensure this. Table 1 provides specific learning outcomes listed in the pharmaceutics course taught at the College of Pharmacy, Roseman University of Health Sciences. Table 1 also lists required elements of the didactic PharmD curriculum listed in Appendix 1 of the ACPE Standards 2016[5] that are related to the learning outcomes of the course.

Student pharmacists enrolled in pharmaceutics courses often perceive translation of basic manufacturing principles to practical application as a challenge.[7] This challenge is partly a result of the nature of current pharmaceutics teaching concepts that heavily focus on basic science at the expense of practical application.[8] Therefore, there is an immediate need for developing effective teaching strategies in the field of pharmaceutics. Integration of animated videos of the oral solid dosage form (OSD) manufacturing into didactic pharmaceutics course teaching is an attempt to promote enhanced learning in pharmaceutics education. These videos may generate interest in dosage form manufacturing and enhance the ability of students to translate the basic dosage form knowledge to practical application. For example, the video on tablet compression depicts how tablet weight can be controlled by fill depth of the die cavity of a tablet compression machine. Any mechanical problems with machines involving die cavity would result in tablets with irregular weights and, thus, may result in dose-related adverse effects, particularly in the case of drugs with

Table 1. Learning Outcomes Associated with Corresponding OSD[a] Videos Showed to Students in Pharmaceutics Course

| Animated OSD Video | Learning Outcomes Listed in Syllabus | Required Elements for the Didactic PharmD Curriculum from ACPE[b] Standards 2016 |
|---|---|---|
| Tablet compression | Recognize the methods of preparation and manufacture of conventional solid oral dosage forms<br>Recognize the formulation factors that affect the release of drugs in conventional solid oral dosage forms | Physicochemical properties of drugs, excipients, and dosage forms important to the rational design and manufacture of sterile and nonsterile products |
| Tablet coating | Identify the different types of tablet coating<br>Identify the differences between the various types of tablet coating<br>Identify the differences between aqueous and nonaqueous tablet coating techniques<br>Identify the problems associated with an aqueous film coating<br>Recognize the different components involved in the tablet coating process | Application of physical chemistry and dosage form science to drug stability, delivery, release, disposition, pharmacokinetics, therapeutic effectiveness, and the development of quality standards for drug products |
| Capsule filling | Recognize the advantages and disadvantages of hard and soft gelatin capsules<br>Distinguish the different types of gelatin used in capsule manufacturing<br>Identify the basic characteristics, different sizes, and shapes of hard gelatin capsules | Physicochemical properties of drugs, excipients, and dosage forms important to the rational design and manufacture of sterile and nonsterile products |

[a]Oral solid dosage form, [b]Accreditation Council for Pharmacy Education

narrow therapeutic windows (eg, phenytoin, warfarin sodium, lithium carbonate).

In our study, animated videos that simulate OSD (eg, tablets, capsules, powders) manufacturing were developed, and students' perceptions about use of these videos as visual instructional aids were evaluated. Also, the performance of students in summative assessments at the end of pharmaceutics course in 2014 and 2015 was compared with the performance of students in 2013, where animated videos were not included as instructional aids. We hypothesized that the animated OSD videos would be beneficial to pharmacy students in understanding the concepts of dosage form manufacturing.

## DESIGN

The OSD form manufacturing videos are approximately 15 to 20 minutes long and were developed to involve tablet compression, tablet coating, bulk density testing of powder, and capsule filling. The animated videos were developed using 3D Studio Max graphic design software (Autodesk, Inc., San Rafael, CA). The lighting and polishing, along with the addition of audio to the videos was performed using Adobe Creative Suite (Adobe Systems Inc., San Jose, CA). Previews of the videos are available: (www.productanimations.com/process-videos). Screenshots of animated videos showing tablet compression and tablet coating are presented in Figure 1. The animated videos were integrated into the pharmaceutics course lecture material wherever beneficial and were shown to students as a part of lecture material. Access to videos was also provided to students upon request after completion of the lecture, outside of class. The assessment questions related to the topics presented in OSD videos are provided in Appendix I.

A previously validated survey instrument by Conceicao et al[9] was adapted for use in our study. The survey was conducted in spring 2014 and 2015 during the pharmaceutics course. The survey included a Likert-type scale and was initially piloted with 12 students and subsequently revised.

Validity and reliability testing were performed using factor analysis with varimax rotation. The survey instrument identified three strong constructs: effectiveness, appeal, and efficiency. Effectiveness is how well the instructional aids help students with their learning. Efficiency is defined by the degree of effectiveness of the instruction divided by the instruction time. The appeal is the extent to which learners enjoy using the instructional aids.[9] Items within the construct of the effectiveness factor were loaded from 0.58 to 0.83. Items within the construct of appeal were loaded from 0.52 to 0.85. Items within the construct of efficiency were loaded from 0.63 to 0.84. The reliability of the survey instrument was tested using Cronbach alpha and was determined to be 0.92 and 0.95 for data obtained in 2014 and 2015 surveys, respectively.

The survey instrument was distributed to students in paper format in the classroom after completion of the oral solid dosage forms section of the course. Students were notified in class that all responses would remain confidential, and completion of questionnaire indicated consent for their responses to be included in the study. The survey contained 12 multiple-choice questions and one open-ended question. Demographic factors, including gender, age range, and previous experience in pharmaceutical manufacturing also were collected as a part of the survey instrument.

To assess the influence of animated OSD videos on students' performance, assessment data in 2014 and 2015 were compared with the year 2013 where animated OSD videos were not included as instructional aids in the pharmaceutics course. The assessment questions used in 2013,

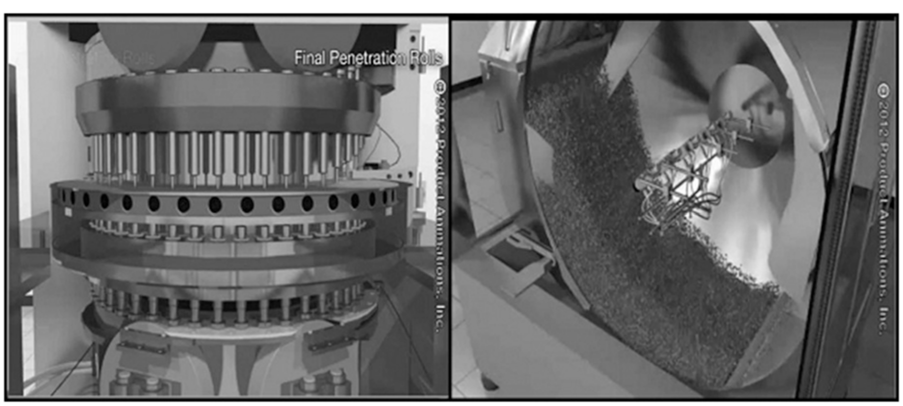


Figure 1. Screenshot of Animated OSD Video Depicting Tablet Compression (left panel) and Tablet Coating (right panel) Process. A preview of the video can be accessed at www.productanimations.com/process-videos.

2014, and 2015 were different but based on the same learning outcomes related to the topics associated with OSD videos. The assessments included 20 (34%) multiple-choice questions related to OSDs, and the rest of the questions covered other topics. Some examples of the questions used in 2013, 2014, and 2015 assessments are provided in Appendix I.

The percentage of students who answered OSD questions correctly was obtained from item analyses of respective assessments and was compared to evaluate students' performance. All percentage values are expressed as mean (SD). The assessments for the pharmaceutics course were paper-based and conducted in spring of 2013, 2014, and 2015 in a proctored setting. The same instructor provided questions for all assessments. Assessments were in a multiple-choice question format, and students who did not watch animated videos but attended assessments were excluded from the data analysis related to students' performance evaluation.

The completed survey instruments were coded and analyzed using the SPSS Statistics, v22 (IBM, Armonk, NY). A series of descriptive analyses were performed on the demographic variables. Chi-square tests were used to analyze survey data, and unpaired *t* tests were used to compare assessment data. A 0.05 probability level was considered significant for all analyses. Verbatim responses to the open-ended question were analyzed using SPSS® Text Analytics, v4.0.1 (IBM, Armonk, NY). The responses to open-ended questions were categorized into themes of interest based on descriptors such as concepts, types, patterns, and category rules obtained from analysis results of SPSS® Text Analytics. The study was reviewed and approved by the Roseman University of Health Sciences Institutional Review Board. Students enrolled in the pharmaceutics course were the first-year PharmD students.

## EVALUATION AND ASSESSMENT

The survey was provided to student pharmacists of the first (P1) year in 2014 and 2015. Seventy-five students completed the survey in 2014 and 77 in 2015 for a total of 152 (response rate 86%). Ethnicity was the only significantly different demographic characteristic between student population of 2014 and 2015 ($p<0.05$). The demographic characteristics of the student pharmacists completing the survey instrument are provided in Table 2.

Survey questions and responses are tabulated in Table 3. Seventy-six percent of student pharmacists agreed or strongly agreed that they would recommend incorporating the animated OSD videos as an instructional aid for teaching pharmaceutics. There was no difference between gender or ethnicity in their perception of the effectiveness, appeal, and efficiency of the videos included in the survey ($p>0.05$ for all questions in the survey). There was no difference between age groups in overall satisfaction with the videos ($p=0.57$) or for recommendation to include the videos as instructional aids ($p=0.33$). However, a significant difference between age groups was seen when student pharmacists were asked about whether the videos helped them understand the processes involved in the manufacturing of oral solid dosage forms ($p=0.048$).

Students between ages 18 to 24 strongly agreed or agreed (83%) that videos helped them in understanding the process involved in the manufacturing of oral solid dosage forms as compared to only 64% of students between ages 35 to 44. A significant difference was also seen between ages when students were asked whether the animated videos improved their perceived performance in the assessment ($p=0.026$). Fifty-two percent of students between ages 18 to 24 strongly agreed or agreed that videos improved their perceived performance in the assessment compared to 64% of students between ages 25 to 34 and 50% of students between ages 35 to 44. Fifty-nine percent either agreed or strongly agreed that the videos improved their perceived performance on the assessment. Student pharmacists with previous experience in either visiting or working in a pharmaceutical manufacturing facility did not have any significant difference in response compared to students with no experience in all aspects of the survey instrument ($p>0.05$ for all questions).

When students were asked whether the videos added meaning to the course material or content taught in the course, 80% of respondents either strongly agreed or agreed. There was no difference between age, gender, or ethnicity regarding this question ($p>0.05$). For questions assessing the appeal of the OSD videos, 80% of students either agreed or strongly agreed that animated OSD videos simulated the environment inside an OSD manufacturing unit of the pharmaceutical industry. Similarly, there was no significant difference between demographic variables age, gender, and ethnicity when students were assessing the appeal of the OSD videos ($p>0.05$). Eighty-four percent of students either agreed or strongly agreed that animated OSD videos conveyed the information clearly and in a logical fashion.

A significant difference between students' age ($p<0.05$) observed for this question, and no significant difference was observed between gender and ethnicity ($p>0.05$). The percentage of students who responded that they either agreed or strongly agreed with this question

Table 2. Demographics of Pharmacy Students Completing a Survey Instrument on Use of Animated OSD Manufacturing Videos as Instructional Aid for a Pharmaceutics Course

| Variable | Respondents 2014 (N=75) no. (%) | Respondents 2015 (N=77) no. (%) |
|---|---|---|
| Gender | | |
| Male | 42 (56) | 28 (36) |
| Female | 33 (44) | 49 (64) |
| Age | | |
| 18 to 24 | 20 (27) | 26 (34) |
| 25 to 34 | 47 (62) | 45 (58) |
| 35 to 44 | 8 (11) | 6 (8) |
| Ethnicity* ( $p<0.05$) | | |
| White | 46 (61) | 21 (27) |
| African American | 2 (3) | 4 (5) |
| Hispanic | 2 (3) | 5 (6) |
| Asian | 22 (29) | 43 (56) |
| Other | 3 (4) | 4 (5) |
| Previous experience in either visiting or working in a pharmaceutical manufacturing facility | | |
| Yes | 8 (11) | 9 (12) |
| No | 67 (89) | 65 (88) |

was 90% for age group 25 to 34 and was 64% for age group 35-44. Finally, 63% of students either agreed or strongly agreed that they were able to learn the information from the OSD videos to a similar degree that they would by visiting a pharmaceutical manufacturing facility. There was no significant difference between demographic variables age, gender, and ethnicity in responses to this question ( $p>0.05$).

Students were also asked to provide suggestions or comments at the end of the survey. There were 39 comments overall. They were categorized into the following themes of interest: beneficial, accessibility, quality of the videos, interactivity, and not beneficial. The theme beneficial was reported most frequently as a comment by students with 20 (51%) responses. The beneficial theme was identified based on how advantageous the OSD videos were to the needs of students' understanding of the material.

Examples of keywords and phrases are perspective, helpful, informative, beneficial, good application, visual, and clearer picture. Accessibility was the next common theme found in student comments with 10 (26%) responses. Accessibility was identified by the keywords and phrases: later time, posting on university portal, access at home, and watch at other times. The quality theme included appeal and content of the OSD videos. Five (13%) respondents mentioned the quality of the videos and was identified by the keywords and phrases: real-life, produced well, and good visual aid. Two (5%) respondents mentioned the interactivity of OSD videos, identified by keywords and phrases: skill-based exposure and prefer to visit the pharmaceutical facility. Finally, two (5%) respondents mentioned that OSD videos were not beneficial in their responses to the open-ended question. The keywords and phrases used to identify this theme were: did not understand, bad video, and slow-moving video.

Comments included statements such as, "The videos helped the students put into perspective some of the equipment and techniques being taught;" "The videos were very beneficial to understand better the processes and requirements in drug manufacturing;" "Videos in class were very helpful. Good visual aid, recommend watching in class;" and, "I learn from pictures explaining rather than just text, so the videos helped me tremendously to put a picture to the words." Some of the comments that suggested improvements in the video included, "They were useful but did not connect the ideas behind the use of certain excipients to the manufacturing process," and, "The video went very quickly and was difficult to keep up at times."

Students averaged 79 % (6), 91% (6), and 97% (6) correct on the OSD questions for 2013, 2014, and 2015, respectively. Descriptive statistics for the assessment data included a comparison of 2013 data with and 2014 and 2015 data independently. An unpaired *t* test yielded significant difference for student performance in 2013 when compared with student performance in 2014 and 2015. The percentage of students who recorded correct responses in 2014 increased by 13% compared to 2013 ( $p<0.05$). Similarly, the percentage of students who recorded correct responses in 2015 increased by 18% compared to 2013 ( $p<0.05$). The demographic data of students enrolled in pharmaceutics course in 2013 was

Table 3. Total Student Survey Results on Use of Animated OSD Videos as Instructional Aids for a Pharmaceutics Course in 2014 and 2015[a]

| | Frequency of responses (%) | | | | | |
|---|---|---|---|---|---|---|
| **Statement** | **Strongly Agree** | **Agree** | **Neutral** | **Disagree** | **Strongly Disagree** | **Mean (SD)[b]** |
| Effectiveness | | | | | | |
| The animated OSD manufacturing videos helped me in understanding the processes involved in the manufacturing of oral solid dosage forms. | 53 (35) | 79 (52) | 16 (11) | 4 (3) | 0 (0) | 4.2 (0.7) |
| The animated OSD videos put meaning to the course material (content) taught in Pharmaceutics course PHAR 430. | 48 (32) | 73 (48) | 26 (17) | 5 (3) | 0 (0) | 4.0 (0.8) |
| The animated OSD videos helped me in understanding the influence of manufacturing process variables on the bioavailability of oral solid dosage forms. | 40 (26) | 69 (45) | 33 (22) | 9 (6) | 1 (1) | 3.9 (0.9) |
| Appeal | | | | | | |
| The animated oral solid dosage form (OSD) manufacturing videos simulated the environment inside an OSD manufacturing unit of the pharmaceutical industry. | 44 (29) | 77 (51) | 27 (18) | 4 (3) | 0 (0) | 4.1 (0.8) |
| The animated OSD videos were able to convey the information clearly and in a logical fashion. | 56 (37) | 71 (47) | 22 (14) | 3 (2) | 0 (0) | 4.2 (0.8) |
| Efficiency | | | | | | |
| I would recommend using animated videos simulating manufacturing environment as an instructional aid for all topics of the Pharmaceutics course. | 55 (36) | 61 (40) | 28 (18) | 6 (4) | 2 (1) | 4.1 (0.9) |
| The animated OSD videos improved my performance in the assessment, especially for the questions related to the topics shown in the videos. | 36 (24) | 54 (36) | 46 (29) | 10 (7) | 6 (4) | 3.7 (1.0) |
| General Satisfaction | | | | | | |
| Overall I feel I was able to learn the information from the animated OSD manufacturing videos as well as I would have in a visit to a pharmaceutical manufacturing facility. | 29 (19) | 67 (44) | 32 (21) | 19 (13) | 5 (3) | 3.6 (1.0) |

[a]The survey instrument was administered to pharmacy students on February 20, 2014 and March 19, 2015. N=75 for 2014 and N=77 for 2015
[b]based on a 5-point Likert scale anchored at 5 = strongly Agree, 4 = Agree, 3 = Neutral, 2 = Disagree, and 1 = Strongly Disagree

similar to those of students enrolled in 2014 and 2015 (data not shown).

## DISCUSSION

Seventy-six percent of students recommended the incorporation of animated OSD videos as an instructional aid for teaching pharmaceutics, and assessment results showed that the videos helped students get good scores on the course assessment and end-of-year assessment. The survey response rate of 86% was likely a result of the adoption of a paper-based survey format in place of an online survey and of the time permitted for students to complete the survey during class. Even though an online survey format provides advantages such as ease of administration, avoiding the need to administer surveys in class, ease of data entry, etc., literature strongly suggests that online surveys are much less likely to achieve response rates as high as surveys administered on paper.[10,11]

Further evidence of students' satisfaction related to their ability to learn information from the videos in a similar fashion as they would if visiting a pharmaceutical manufacturing facility. The most common theme reported by students in open-ended questions indicated that OSD videos were beneficial to students as instructional aids. These data suggest that animated OSD videos can be useful pedagogical tools for teaching pharmaceutics.

In 2014 and 2015 a significantly higher number of students answered the assessment questions correctly than in 2013. While we believe that the improvement in student performance was the result of using OSD animated videos as instructional aids, further research is needed to discern if this improvement in student performance was an anomaly. Variables such as different instructors, the difficulty level of questions, and class size may have played a role in the difference in student performance and must be taken into consideration in future studies.

The survey results showed no significant difference between male and female students in the perception of animated OSD videos. This finding is different from previous findings published by Scott et al; according to their report, male students were more comfortable than female students with technology such as electronic slides and audio recordings.[12] This difference may be attributed to the fact that the OSD videos did not require students to use extensive technology. The videos were provided to students as part of the lecture. Interestingly, the concept of using animated OSD videos as an instructional aid was supported by students of all ages. However, students in the age group 35 to 44 indicated less than other groups that animated OSD videos helped them understand the manufacturing process of OSDs compared with students in the age group 18 to 24. This result is consistent with the observation that students of the "Net Generation" have grown up with technology and are typically fascinated by new technologies.[13] Romanelli et al reviewed various learning styles and reported that younger students, particularly in industrialized nations, are accustomed to enhanced visual images associated with computer- and television-based games and game systems.[14] Moreover, students of that generation are intuitive visual communicators and perhaps, because of their expertise with games, they can integrate the virtual and physical world efficiently.[13]

Obtaining data from students with previous experience visiting or working in a pharmaceutical facility helped evaluate whether they had a different opinion about the effectiveness, appeal, and efficiency of the animated videos as instructional aids compared with students without any such experience. There was no difference in opinion between students with previous experience and without previous experience in OSD manufacturing. However, the sample size of the students with previous experience in OSD manufacturing was low and could be a limitation to validating this conclusion.

Use of instructional aids in adult education and online education as teaching tools to help students understand concepts is increasing.[15] However, the successful use of instructional aids for learning incorporates the constructs of effectiveness, efficiency, and appeal.[16] Students in our study were satisfied with using animated OSD videos in all three aspects measured. Students either agreed or strongly agreed at higher percentages with questions that related to the appeal construct compared to effectiveness or efficiency.

A limitation of the study is that videos were used only for part of the pharmaceutics course involving OSD form manufacturing. It would be interesting to evaluate the use of animated videos for all topics of the course. Future studies may involve development and evaluation of animated videos as instructional aids for all topics of the course, evaluation of students' performance before and after use of OSD videos as instructional aids, and effect of OSD videos on the outcome of long-term retention in standardized examination\s like the ePharmacy Curriculum Outcomes Assessment (PCOA) and in the second-year (P2) and third-year (P3) courses. Another limitation is that the study was conducted in classes of pharmacy students at only one college. Obtaining data from multiple colleges of pharmacy would help validate the research idea and would provide a better understanding of student perception on the use of animated videos as an instructional aid.

Based on the findings of this study, animated OSD videos can be beneficial for future use as visual instructional aids for teaching pharmaceutics courses. Pharmaceutics is a complex subject that involves a combination of various concepts involving physical chemistry, pharmacotherapy, formulation, etc. Therefore, it is often considered a "dry" subject for faculty members to teach and for students to learn.[2] Incorporating animated videos as instructional aids in pharmaceutics course curriculum will help bridge the gap between understanding the concept of dosage form manufacturing process variables and their influence on the bioavailability and therapeutic efficacy of drugs.

## CONCLUSIONS

Animated OSD manufacturing videos were developed, and student perceptions on the use of animated videos as instructional aids for teaching a pharmaceutics course and their effect on students' performance in the assessment were evaluated. The majority of students supported the use of videos as instructional aids, and also positively rated aspects of evaluation of instructional aids, namely: effectiveness, appeal, and efficiency. Students' performance improved in the assessments where OSD videos were used as instructional aids when compared to previous assessments that did not include OSD videos. The instructional strategy described in this project can be easily adopted by other faculty members involved in the teaching of pharmaceutics to enhance students' understanding of and interest in dosage form manufacturing. Future directions of this research include a comparison of effective of OSD videos with other modes of learning such as lecture material, books, primary literature, etc.

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Appendix 1. Assessment Questions Related to Topics Presented in Animated OSD Videos (*indicates correct answer choice)

1. Which of the following tablet excipients is added to prevent the adhesion of tablet material to the surface of the dies and punches of tableting machine?
   a) Magnesium stearate*
   b) Colloidal silicon dioxide
   c) Gelatin
   d) Lactose

2. Which of the following tablet coating defects is characterized by two tablets sticking together?
   a) Orange-peel effect
   b) Erosion
   c) Chipping
   d) Twinning*

3. Which of the following polymers is widely used for enteric coating?
   a) Cellulose acetate phthalate*
   b) Gelatin
   c) Zein
   d) Aminoalkyl methacrylate copolymer

4. Which of the following statements is TRUE about soft gelatin capsules?
   a) Soft gelatin capsules do not contain a plasticizer
   b) Soft gelatin capsules have higher bloom strength than hard gelatin capsules
   c) Soft gelatin capsules are well-suited for formulating volatile drugs*
   d) Drugs subject to oxidative or hydrolytic degradation cannot be formulated in soft gelatin capsules

5. Microcrystalline cellulose (Avicel) is most commonly used as:
   a) Diluent/filler*
   b) Binder
   c) Disintegrating agent
   d) Lubricant

6. RJ is a 24-year old female who presents to her primary care physician complaining about her bloating, gas, pain or cramps in the lower belly and diarrhea. RJ has recently started taking fluoxetine tablets manufactured by XY, Inc. RJ mentioned that her symptoms of GI distress started developing after she started taking fluoxetine tablets of XY, brand. She also informed that she never had any problems with fluoxetine tablets manufactured by AB, Inc, which she was taking before. RJ's physician asked her pharmacist to change her medication to AB brand fluoxetine tablets, prescribed some simethicone suspension and asked her to follow-up after two-weeks. In her two-week follow-up visit, RJ mentioned that she is feeling well and do not have any bloating, gas, pain or cramps in the stomach and diarrhea. Which of the following is most likely the reason for RJ's GI symptoms seen while taking fluoxetine tablets manufactured by XY Inc.?
   a) Fluoxetine tablets by AB, Inc. have magnesium stearate as a lubricant, whereas tablets by XY, Inc. have no lubricant.
   b) Fluoxetine tablets by AB, Inc. are branded formulation while by XY, Inc. are generic.
   c) The dissolution rate of fluoxetine tablets by AB, Inc. is higher than the dissolution rate of fluoxetine tablets by XY, Inc.
   d) Fluoxetine tablets by AB Inc. have microcrystalline cellulose as diluent, whereas tablets by XY Inc. has lactose as diluent*

7. AB Pharma is a pharmaceutical company involved in the large-scale manufacture of generic tablets of Atenolol. Recently, their atenolol tablet batches were failing the USP dissolution test due to inadequate dissolution. Which of the following is a possible reason for the decreased dissolution of atenolol tablets?
   A. Use of high concentration of magnesium stearate as lubricant*
   B. Use of lactose as diluent
   C. Use of gelatin as binder
   D. Decreasing the granule size

8. Croscarmellose is commonly used in tablet manufacturing as:
   A. Diluent
   B. Lubricant
   C. Glidant
   D. Super disintegrant*

9. Given below are in vitro dissolution profiles of four tablet formulations of methotrexate manufactured by MR Pharma. Based on the dissolution profiles predict the formulation with the highest bioavailability?
   A. MX4
   B. MX3
   C. MX1*
   D. MX2

10. Capping and lamination, a common tablet manufacturing defect are mainly because of:
    A. Uneven distribution of color
    B. Air entrapment in tablet material*
    C. Too much drying of granules
    D. Excess of binder

11. Which of the following tablet excipients improves the flow properties of the tablet material?
    A. Lactose
    B. Hypromellose
    C. Colloidal silicon dioxide*
    D. Mannitol

12. Which of the following excipient makes the shell of a soft gelatin capsule elastic and pliable?
    A. Sodium lauryl sulfate
    B. Lactose
    C. Glycerol*
    D. Magnesium stearate

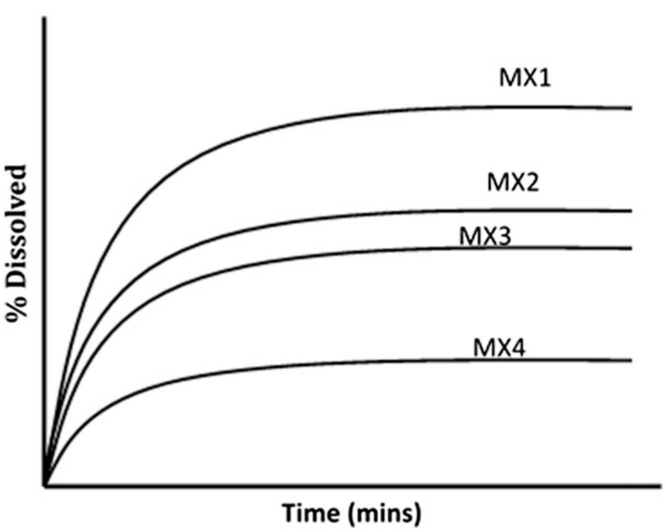


Figure 1. xxx.