AC 2010-385: INTEGRATION OF PARTICLE TECHNOLOGY WITH PHARMACEUTICAL INDUSTRY APPLICATIONS IN THE CHEMICAL ENGINEERING UNDERGRADUATE CURRICULUM AND K-12 EDUCATION

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Integration of Particle Technology with Pharmaceutical Industry
Applications in the Chemical Engineering Undergraduate Curriculum
and K-12 Education

Abstract

Rowan University, in collaboration with the National Science Foundation (NSF) funded
Engineering Research Center for Structured Organic Particulate Systems (C-SOPS), is
developing teaching modules and problem sets to introduce students to engineering concepts in
the particle and powder technology of pharmaceutical processing and drug delivery systems. The
Center is hosted by Rutgers University and also includes Purdue University, the New Jersey
Institute of Technology, and the University of Puerto Rico, Mayaguez. The goal of the Center is
to become a national focal point for developing structured organic particulate systems used in
pharmaceuticals and their manufacturing processes. Rowan University has partnered as an
outreach/education member institution to develop teaching modules for K-12 and college level
students. Teaching modules for nano-particle manufacturing, V-mixer applications, and general
particulate properties have been developed and implemented. In addition, problem sets
illustrating drug delivery systems and pharmaceutical manufacturing concepts have been
developed. These problem sets and the flexible and interactive teaching modules are excellent
educational vehicles to introduce students to pharmaceutical processing, drug delivery and basic
principles in particle and powder technology. These efforts will also serve to teach engineering
concepts in the context of pharmaceutical industry particle and powder operations. The teaching
modules and problem sets will be used in undergraduate mass and energy balances, fluid
mechanics and transport courses. They will also be used in workshops for middle and high
school students and teachers. The completed educational materials will be incorporated into the
C-SOPS website for use by Center members and faculty at other schools. This work will serve to
expand and strengthen the educational impact of the Center in the region and throughout the
country.

Introduction

The NSF-sponsored Center for Structured Organic Particulate Systems (C-SOPS) is striving to
become a focal point in pharmaceutical processing. The overall goals of the Engineering
Research Center are coordinated through carefully planned thrust areas. The thrust areas include
the major research initiatives of the Center: manufacturing science; composites structuring and
characterization; and particle formation and functionalization. Three test beds based on
programs developed from the thrust areas have been created at the Center. Development
Program I concentrates on the continuous manufacturing of pharmaceutical tablets. Continuous
tablet manufacturing processes offer significant advantages over batch processes. These
advantages include an increase in tablet uniformity and stability, reduced production and labor
costs and simplified scale up from experimental testing to full scale manufacturing. Development
Programs II and III focus on novel methods for drug delivery. Development
Program II focuses on the stabilization of API (active pharmaceutical ingredient) nano-particles
in edible substrates. The higher surface areas of nano-particles results in higher material
bioavailability. Finally, Development Program III includes a drop-on-demand system to layer
API’s on an edible substrate. The system could be portable and compact for use in third world
countries and military applications. Rowan University partnered with the ERC-SOPS Center in 2008 to provide outreach and training components to support the educational mission of the Center. During the first year of the project, Rowan University worked with various constituency groups to implement certain projects that directly impact the Center’s goals. This work has been expanded during the second year and additional modules and course materials have been developed.

This paper describes the progress to date. Our long term goals are to:

- train students who will be effective engineers and leaders in the manufacturing and research operations of the pharmaceutical and allied industries of the center.
- train students for roles in education and in the agencies involved in regulating food and drug manufacturing operations.
- integrate the Center’s research discoveries in engineered organic composite systems to enrich the existing engineering curriculum at both the undergraduate and graduate levels.
- develop educational programs for industrial practitioners and foster alliances with industry in the education and outreach activities of the center.
- design and promote experiential programs and pedagogical material for K-12 outreach recognizing diverse student and teacher backgrounds.
- develop a suite of modular educational units for use by the various center constituents in formats that allow for efficient web-based dissemination.

These goals are important components of the overall center vision and are an integral part of its mission to bring together cutting-edge research, technology transfer and next-generation training of the technical workforce. The outreach modules and educational materials have been developed by a highly qualified College of Engineering faculty team working with undergraduate and graduate students. The following sections provide a summary of the ongoing activities in the various projects under the Rowan University / ERC-SOPS Center partnership umbrella. There are two major sections in this paper. The first section highlights the educational laboratory modules and outreach experiences, and the second section highlights the textbook problems developed as part of this work. More detailed examples of the outreach/educational materials and problems will be presented in the final poster presentation.

**Educational laboratory modules and outreach experiences**

Synthesis of nano-scale particles: A series of laboratory experiments, suitable for high school students, is being developed. These laboratory experiments will introduce students to the importance of nano-scale drug particles. The experiments will demonstrate (i) the enhanced solubility of nano-scale particles which are nominally insoluble (ii) the various methods of achieving nano-scale particles that are relevant to the biotechnology industry. The main goal of this endeavor is to create laboratory experiments with dramatic impact for students under constraints of the limited resources of high schools and other outreach partners. An example of these experiments will be presented in the poster.
Particle properties and powder mixing experiments throughout the curriculum: A V-mixing laboratory experience has been designed for students to investigate the effect of mixing time, particle size and loading configuration in a statistical design. The experiments and data analysis are conducted over multiple class periods, and students are exposed to experimental design strategies. A 5 L constant frequency V-mixer is used for laboratory experiences in courses, projects and research. Figures 1a and b show the mixer and the loading operation for a mixing experiment.

Figures 1  a) 5 L V-mixer                                     b) Loading mixer for experiment

Factorial and response surface Box-Behnken experimental designs are used and students assess the efficacy of experimental design strategies. Variables studied include particle size and particle size difference, mixing time and loading configuration. Figures 2 a and b are qualitative illustrations of three variable factorial and Box-Behnken experimental designs used in this work. The three variables illustrated in Figures 2 a and b are mixing time, particle size difference and loading configuration. The circles indicate experimental conditions and the vertices are the minimum and maximum values of the variables investigated. In the case of loading configuration, the experimental conditions refer to specific configurations (i.e. top/down, side by side).

Figures 2           a) Factorial Design                   b) Box-Behnken Design

A spectrophotometric technique was developed to measure mixing quality for these experiments. Different color silica particles were used so that students could easily distinguish among different mixtures. After the particles were mixed at specific conditions, a sample (2 g) of the particle mixture was placed in 25 ml of hexane. The dye dissolved in the hexane, and a spectrophotometer was used to detect the absorbance of the liquid at the wavelength corresponding to the dye color. Red particles with compounded dye and yellow particles were used (Figure 1b). The red dye was not soluble in hexane, thus only yellow was detected using
the spectrophotometer. Tracking only one color simplified the spectrophotometric analysis since color mixtures did not have to be considered. Statistical analysis of the data for different samples in different locations in the mixer, and the Poole index were used to assess mixing quality. These experiments afford students the opportunity to study particle and powder mixing with pharmaceutical applications. In addition, students are exposed to experimental design and to the statistical measures of mixing quality. Variance calculated using Equation 1 and the Poole index were used to measure mixing quality. Table 1 is a listing of the variances obtained for different experimental conditions.

\[
\sigma^2 = \frac{\sum_{i=1}^{N} (y_i - \bar{y})^2}{N-1}
\]  

(1)

Where \( y \) is a single absorbance measure at specific conditions and \( \bar{y} \) is the average absorbance for the specific experimental condition.

<table>
<thead>
<tr>
<th>Variance</th>
<th>Experimental Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0000858</td>
<td>front-back, 18rev</td>
</tr>
<tr>
<td>0.000313</td>
<td>front-back, 3rev</td>
</tr>
<tr>
<td>0.000317</td>
<td>right-left, 10.5rev</td>
</tr>
<tr>
<td>0.000363</td>
<td>front-back, 10.5rev</td>
</tr>
<tr>
<td>0.000473</td>
<td>right-left, 18rev</td>
</tr>
<tr>
<td>0.000565</td>
<td>top-bottom, 18rev</td>
</tr>
<tr>
<td>0.000821</td>
<td>top-bottom, 10.5rev</td>
</tr>
<tr>
<td>0.00145</td>
<td>top-bottom, 3rev</td>
</tr>
<tr>
<td>0.00347</td>
<td>top-bottom, 3rev</td>
</tr>
<tr>
<td>0.00372</td>
<td>top-bottom, 3rev</td>
</tr>
<tr>
<td>0.00465</td>
<td>top-bottom, 3rev</td>
</tr>
<tr>
<td>0.00487</td>
<td>right-left, 3rev</td>
</tr>
</tbody>
</table>

Results to date indicate that the loading configuration is the most significant variable determining mixing quality at the scale and application used in this work. Figure 3 is a Pareto diagram illustrating this result for experiments testing the effect of loading profile, location in V-mixer and number of revolutions.

![Figure 3: Pareto diagram for V-mixer experiment](image-url)
Hands-on demonstrations of particle properties:
A series of highly visual demonstrations illustrating particle properties has been designed, constructed and used in a course. Figures 4 through 7 illustrate arching in hopper flow, the effect of particle size on segregation, compression forces generated during particle flow and the rise of a large particle in a bed of smaller particles.

These demonstration modules are used and will continue to be expanded and used in courses and as part of outreach efforts in summer programs aimed at middle and high school students and teachers. Student and faculty feedback will be used to improve and enhance the demonstrations. These demonstrations were part of a workshop for high school teachers during the fall 2009 semester and were very well received. All demonstrations can be constructed from a variety of materials and in different sizes. They can be adapted for use in K-12 activities as well as upper level technical courses. Details on these demonstrations and experiments will be provided in the poster presentation.

Particulate systems textbook problems

The development of introductory level textbook problems has been the focus of several projects that undergraduate students take for credit at […] University. Initial work focused on problems for late middle school to college sophomore students. The present work focuses solely on the revision of old problems and development of new problems for students of introductory (freshman or sophomore level) chemical engineering courses. The formatting, layout, style and focus of the problems are based on the work of Felder and Rousseau, a common textbook for material and energy balance courses. Courses taught with a different textbook may still use the
problems developed without inconvenience. Problem sets illustrating pharmaceutical 
manufacturing were developed with a focus on mass and energy balances related to operations 
such as blenders, dryers, and tablet presses. The problem sets developed here expose students to 
practical industrial and research applications relevant to the course topical content. Students are 
also informed regarding the pharmaceutical specialization in chemical engineering as a possible 
career path after graduation. Many of the problem statements are written using second-person 
narrative to encourage students to see themselves involved in the process. Development of 
problems was done solely by members of the student teams. The students examined published 
literature of every description, such as patents, textbooks, handbooks and reference works, on the 
subjects of pharmaceutical design, manufacturing and engineering. Ideas for problems were 
individually developed into problems, and the problems were mapped by concept to specific 
sections of the text by Felder and Rousseau. The problems will be distributed on the 
pharmaHUB website for professors at Rowan University and others to use in their courses. Feedback from these professors and their students will be used to edit and improve the problems. Additional problems will be developed to round out coverage of all chapters in Felder and 
Rousseau. In addition, problem sets will be expanded to include courses such as momentum 
and heat and mass transfer as well. Two example problems are highlighted below.

Problem development in drug delivery - metered-dose inhaler specifications:
Gas-phase behavior and modeling is an important subject in chemical engineering and therefore 
in chemical engineering education; most sophomore-level material and energy courses devote 
significant time to these subjects. This problem was developed to illustrate the use of complex 
quadratic equations of state (EOS), the truncated virial equation of state, in a unique setting. The 
choice of a common and easily understood medical device, the respiratory inhaler, as the system 
illustrates the application of apparently abstract chemical engineering models to familiar, 
concrete objects. The universal knowledge of inhalers among students and professors from 
personal use, use by others and advertisements makes them particularly useful since basic 
knowledge of their operation and function can be assumed. This allows a professor to extend the 
problem with information or demonstrations of his or her own, such as displaying a sample 
inhaler and documentation. The choice of propellant, which comprises the realistic background 
to the problem, references the environmental (“green”) and sustainability issues present in the 
pharmaceutical engineering industry.

Problem statement: In a metered-dose inhaler (MDI), such as those used for asthma medication, 
the medicine is delivered by a pressurized propellant, similar in idea to a can of spray paint. 
When the inhaler is activated, a set amount of the medicine is expelled from the mouthpiece to 
be inhaled. In the past, chlorofluorocarbons (CFCs) were used as propellants; however because 
of their reactivity with the earth’s ozone layer they have been suppressed. The new propellants, 
hydrofluorocarbons (HFCs), are considered “greener” because they do not react with the ozone 
layer.

You are assigned to calculate the amount of substance required to meet specifications of an MDI. 
The original propellant, CFC 12, has been replaced by HFC 227ea. Both inhalers contain 100 mL 
of propellant at 80 psia. The use of the truncated virial equation of state is specified due to the 
pressurization of the cylinder. Because of the increased computational effort required to use the
virial equation of state (You’ll see when you try it), you should test the ideal gas law equation of state to see if it is close enough to use instead.

Problem solution: In setting up the problem, an assumption of temperature must be made. The most logical is standard temperature (25 °C / 298 K) since inhalers are commonly used at room temperature. We then need to look up the values needed for these compounds, specifically critical temperature ($T_c$), critical pressure ($P_c$) and the acentric factor ($\omega$). To do this we consult sources. An expected part of this is the discovery of what CFC 12 and HFC 227ea really are: dichlorodifluoromethane and 1,1,1,2,3,3,3-heptafluoropropane. What reference is chosen is immaterial, since all legitimate references should give very similar values.

Using the 2nd edition of Knovel Critical Tables (available through the AiChE eLibrary) for the critical constants and two papers for the acentric factors:

<table>
<thead>
<tr>
<th></th>
<th>$T_c$ (K)</th>
<th>$P_c$ (atm)</th>
<th>$\omega$</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFC 12</td>
<td>384.95</td>
<td>40.71</td>
<td>0.180</td>
</tr>
<tr>
<td>HFC 227ea</td>
<td>374.83</td>
<td>28.74</td>
<td>0.356</td>
</tr>
</tbody>
</table>

Now the hard part is done and the calculations may be performed. Since, like all advanced equations of state, the constants are obtained from the solution to earlier equations, we should examine the equations to determine the order of the equations and where to start:

$$\text{(Start)} \frac{T}{T_c} - (B_0, B_1) - \beta \rightarrow \hat{\nu}$$

The first step is to calculate the reduced temperature, which we will do for CFC 12:

$$T_r = \frac{T}{T_c} = \frac{298 \text{ K}}{384.95 \text{ K}} = 0.774$$

Substituting this into the equations for $B_0$ and $B_1$:

$$B_0 = 0.083 - \frac{0.422}{T_r^{1.6}} = -0.553$$

$$B_1 = 0.139 - \frac{0.172}{T_r^{4.2}} = -0.365$$

We now substitute these values into the formula for $B$:

$$B = \frac{RTc}{Pc} (B_0 + \omega B_1)$$

$$B = 0.08206 \frac{\text{L atm}}{\text{mol K}} \times 384.95 \text{ K} \times (-0.553 + 0.180 \times (-0.365))$$

$$B = -0.489 \frac{\text{L}}{\text{mol}}$$

Inserting this and other values into the viral equation:

$$\frac{P \hat{\nu}}{RT} = 1 + \frac{B}{\hat{\nu}}$$
There are two solutions (roots) to any quadratic equation. This may be solved with an equation solver, such as Wolfram Mathematica, a spreadsheet “goalseek” function, or the quadratic formula. In any case, two answers are found:
\[ \hat{\nu} = (3.944, 0.546) \text{ L/mol} \]

The obvious question now is how to make a choice. A possible choice is to compare the two values to an already known molar volume, such as a compressed gas in a similar circumstance. An easier and more reasonable way (That is also suggested by the book) is to use the ideal gas law and pick the value that is closer to its solution.

To use the ideal gas law here, we simply rearrange Equation 5.2-2 (Felder and Rousseau):
\[ P \nu = RT \]
\[ \nu = \frac{RT}{P} \]

Substituting and solving:
\[ \hat{\nu} = \frac{0.08206 \text{ L} \cdot \text{atm}}{\text{mol} \cdot \text{K}} \times 298 \text{ K} \times \frac{1}{80 \text{ psi}} \times 14.696 \frac{\text{psi}}{\text{atm}} = 4.50 \text{ L/mol} \]

This suggests that 3.944 L/mol is the correct solution to the quadratic equation of state. Remembering that this is a 40 mL cylinder, we determine the amount of substance:

\[ n = \frac{V}{\hat{\nu}} = \frac{0.100 \text{ L}}{3.944 \text{ L/mol}} \]

\[ n_{\text{CFC}12} = 0.0254 \text{ mol CFC 12} \]

Doing the same thing for HFC 227ea gives us:

\[ n_{\text{HFC 227ea}} = 0.0274 \text{ mol HFC 227ea} \]

To test the ideal gas law, we simply divide 40 mL by the specific molar volume found before:

\[ n = \frac{V}{\hat{\nu}} = \frac{0.100 \text{ L}}{4.50 \text{ L/mol}} = 0.0223 \text{ mol} \]

To calculate the percent error we substitute in:

\[ \varepsilon_{\text{CFC12}} = \left| \frac{0.0254 - 0.0233}{0.0254} \right| \times 100\% \]

\[ \varepsilon_{\text{CFC12}} = 12.2\% \]

\[ \varepsilon_{\text{HFC 227ea}} = 18.7\% \]
The ideal gas law is not completely incorrect, but it noticeably deviates from the virial value. Since this subject concerns medicine, a difference of this magnitude is unacceptable. Students should be warned not to attempt to use the ideal gas law and divide by a correction factor determined from these percent errors instead of using the more accurate EOS. The correct way to save time is to do this all in a spreadsheet that will automatically redo the calculations when any conditions are changed.

In solving the problem, the student is required to perform independent research to discover the necessary physical property constants, understand the use of critical properties, cascading calculations, solution of non-obvious quadratic equations, determination of the root of physical significance, calculation of error, and drawing the requested conclusions from the data.

Problem development in pharmaceutical manufacturing - flow rate from a hopper:
This problem illustrates basic concepts in pharmaceutical technology related to unit conversions and engineering calculations. It is important for chemical engineering students to understand how to convert between the volumetric flow rate and the velocity of a process stream. Current pharmaceutical manufacturing research is developing a process to turn the batch process for manufacturing pharmaceutical tablets into a continuous process. The process uses a hopper to feed the pharmaceutical particles into a continuous mixer. The students will be required to determine the volumetric flow rate of pharmaceutical particles from the hopper based on experimental data. They will then be asked to increase the flow rate out of the hopper by changing the diameter of the hopper outlet. By assuming that the velocity of the particles through the outlet is constant, the students will be able to develop simple calculations to determine the necessary outlet diameter. This problem is appropriate for a sophomore-level engineering course.

Problem statement: Various powder ingredients used to make the final compressed solid tablets, which include the API, binder and fillers, are fed into a hopper which sends them to a continuous pill press. In this particular case, the hopper is being fed with acetaminophen, an active pharmaceutical ingredient used for pain relief, and a binder, Starch 1500. The hopper is placed on an electronic scale to determine the flow rate of pharmaceutical particles leaving the system. As the particles leave the hopper, a flow rate is determined:

\[
\text{Flow Rate} = \frac{|\Delta \text{ mass}|}{(\rho)(\Delta \text{ time})}
\]

where \(\rho\) is the average density of the flowing particles (0.34 g/cm\(^3\)). The flow rate must be consistent for the continuous tablet production process to produce uniform tablets. Table 2 contains data from the hopper operation. The mass listed includes the mass of the empty hopper, which is 50 kg. Determine the average volumetric flow rate of material out of the hopper.
Table 2. Calculated average volumetric flow rates based on the change in hopper weight over time

<table>
<thead>
<tr>
<th>Time</th>
<th>Total Weight</th>
<th>Weight Powder</th>
<th>Flow Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sec</td>
<td>G</td>
<td>g</td>
<td>cm³/s</td>
</tr>
<tr>
<td>0</td>
<td>50725</td>
<td>725</td>
<td>0</td>
</tr>
<tr>
<td>30</td>
<td>50720</td>
<td>720</td>
<td>0.49</td>
</tr>
<tr>
<td>60</td>
<td>50715</td>
<td>715</td>
<td>0.49</td>
</tr>
<tr>
<td>90</td>
<td>50711</td>
<td>711</td>
<td>0.39</td>
</tr>
<tr>
<td>120</td>
<td>50707</td>
<td>707</td>
<td>0.39</td>
</tr>
<tr>
<td>150</td>
<td>50702</td>
<td>702</td>
<td>0.49</td>
</tr>
<tr>
<td>180</td>
<td>50697</td>
<td>697</td>
<td>0.49</td>
</tr>
<tr>
<td>210</td>
<td>50693</td>
<td>693</td>
<td>0.39</td>
</tr>
<tr>
<td>240</td>
<td>50687</td>
<td>687</td>
<td>0.59</td>
</tr>
<tr>
<td>270</td>
<td>50683</td>
<td>683</td>
<td>0.39</td>
</tr>
<tr>
<td></td>
<td><strong>Average Flow Rate</strong></td>
<td></td>
<td><strong>0.46</strong></td>
</tr>
</tbody>
</table>

The operator wishes to increase the volumetric flow rate out of the hopper by 20% by changing the diameter of the hopper outlet. If the diameter of the current outlet is 10 cm, determine the diameter of the outlet that would allow for the increase in flow rate. (Assume that the velocity of particles is constant and independent of the outlet diameter.)

Problem solution: First, students must subtract the tare weight of 50,000 g from the total system weight to determine the weight of the powder at each step. They can then determine the average volumetric flow rate of the powder.

\[
\text{Flow Rate} = \frac{|725 - 720|}{0.34 \cdot \frac{6}{\text{cm}^2} \cdot (30 - 0 \text{ s})} = 0.49 \text{ cm}^3/\text{s}
\]

The results of the calculations are listed in Table 2. The students can then determine the average velocity of the particles through the hopper outlet using the following equation.

\[
v = \frac{\bar{V}}{A_c}
\]

where \( v \) is the velocity of the particles, \( \bar{V} \) is the volumetric flow rate of the particles and \( A_c \) is the cross sectional area of the hopper outlet. By calculating the initial cross sectional area, the students can determine the velocity of the particles. Because the velocity of particles is assumed to be constant, the cross sectional area can then be determined based on the increased volumetric flow rate.
Velocity through Existing Outlet

\[ v = \frac{V}{A_c} = \frac{0.49 \, \text{cm}^3}{78.54 \, \text{m}^2} = 0.0060 \, \text{cm} \, s \]

New Flow Rate through Outlet

\[ v_2 = v_1 + 0.2v_1 \\
\quad = 0.49 \, \text{cm}^3 \, s^{-1} + 0.2(0.49) \, \text{cm}^3 \, s^{-1} = 0.59 \, \text{cm}^3 \, s^{-1} \]

Cross Sectional Area of New Outlet

\[ A_c = \frac{V}{v} = \frac{0.59 \, \text{cm}^3}{0.0060 \, \text{cm} \, s} = 98 \, \text{cm}^2 \]

Diameter of New Outlet

\[ D = \sqrt{\frac{4A_c}{\pi}} = \sqrt{\frac{4(98 \, \text{cm}^2)}{\pi}} = 11 \, \text{cm} \]

**Summary**

The laboratory experiences and the textbook problems described here serve to educate students on the research and technology associated with pharmaceutical processing. The modules will be integrated into the CSOPS website for distribution to faculty within the Center and other schools. The modules will also be used in college level courses and in outreach efforts for middle and high school students and teachers. The problems developed as part of this work are intended for use in sophomore level chemical engineering courses. Each problem introduces topics related to pharmaceutical technology and is directly related to a process, tablet formulation, drug delivery, or pharmaceutical equipment. All of the problem descriptions are based on realistic technology in use or currently under development. Students must use principles of chemical engineering they are learning in their courses to solve the problems. Detailed solutions are provided with each problem. These solutions can be used by faculty to assist in the presentation of the problem, or distributed directly to students. The problems have been reviewed by multiple team members and faculty. They will be distributed to sophomore classes at Rowan University to obtain feedback from students in the type of course where the problems could be used. Feedback on the educational modules will be obtained as well in an effort to continuously enhance and improve the material. The goal is for students to become familiar with pharmaceutical applications of powder and particle technology, and to practice the material they are learning in class in a realistic application of pharmaceutical technology. Students will become familiar with an
important technology in chemical engineering and the impact of the Center will be expanded through increased student interest in pharmaceutical engineering.

Acknowledgements

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Bibliography