Production of Soy Pharmaceutical Tablets

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Background Information
Microcrystalline cellulose (MCC) is the most widely used pharmaceutical binding/filling excipient. Previous research within the ABE department has been done on the possibility of using soy protein derivatives as an alternative binder/filler. The studies have shown that soy protein isolates (SPI) have weak binding abilities, resulting in tablets with low tensile strengths.

Objectives
• Develop tablet formula that uses SPI as the main binder/filler
• Determine the effect of using soy powders with nonzero oil content
• Explore the effects of SPI extrusion on final tablet tensile strength
• Design and scale up a process for manufacturing tablets that use SPI as the main binder/filler

Laboratory Results
• Small scale experiments showed:
  – Lower oil content led to higher tensile strength
  – Extrusion of SPI led to higher tensile strength
  – Extruded SPI yielded lower tensile strength than MCC
• Future work should include:
  – Further experimentation with extrusion shear rate
  – Further experimentation with extrusion temperature control

Process and Plant Design

Alternative Solutions
• Wet granulation
• Alternative equipment options
  – Roller compacter → granulator
  – Dryer → spray dryer
• Develop continuous process

Economic Analysis

<table>
<thead>
<tr>
<th>Summary</th>
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<tbody>
<tr>
<td>Total Capital Investment</td>
<td>$7,163,385</td>
</tr>
<tr>
<td>Revenue Per Year</td>
<td>$9,295,658</td>
</tr>
<tr>
<td>Operating Cost Per Year</td>
<td>$6,994,109</td>
</tr>
<tr>
<td>Return on Investment</td>
<td>20%</td>
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<tr>
<td>Breakeven Point</td>
<td>5 years</td>
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</table>

<table>
<thead>
<tr>
<th>Annual Raw Material Cost</th>
<th>Material</th>
<th>Amount (kg)</th>
<th>Total Cost ($)</th>
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<tbody>
<tr>
<td></td>
<td>APAP</td>
<td>327,846</td>
<td>224,615</td>
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<td></td>
<td>SPI</td>
<td>578,250</td>
<td>44,923</td>
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<td></td>
<td>HPMC</td>
<td>23,253</td>
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<td>Mg Stearate</td>
<td>357</td>
<td>10,210</td>
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<td></td>
<td>SiO2</td>
<td>893</td>
<td>102,098</td>
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</tbody>
</table>

Sustainability
• North central Indiana plant
  – Reduce raw material shipping footprint
  – Reduction of distribution costs across U.S.
• Recycling exit air stream from first dryer
  – Recycle hot air to second tray dryer
  – Recycle water into initial extruder feed
  – Reduces energy used to heat air
  – Reduces amount of water needed

Acknowledgements:

Dr. Martin Okos
Amudhan Ponrajan
Venecia Wilson
Purdue IPPH Department

Sponsor:
Indiana Soybean Association