Production of Solid-Dosage Malaria Treatment

Current Design and Formulation

Dosage
- Modeled for children ranging from 15-35 kg, two pills per day

<table>
<thead>
<tr>
<th>Component</th>
<th>Mass [mg]</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium Stearate</td>
<td>4.8</td>
<td>0.010</td>
</tr>
<tr>
<td>Mannitol</td>
<td>52.8</td>
<td>0.109</td>
</tr>
<tr>
<td>Soy Excipient</td>
<td>69</td>
<td>0.142</td>
</tr>
<tr>
<td>DHA</td>
<td>40</td>
<td>0.082</td>
</tr>
<tr>
<td>PPQ</td>
<td>320</td>
<td>0.658</td>
</tr>
</tbody>
</table>

Number of pills per batch: 1000

Economic Analysis

Orphan Drugs are not produced for a profit, therefore we will seek funding from the following sources:
- Naa national Institute of Health (NIH)
- The Indiana Soybean Alliance
- The World-Health Organization (WHO)
- Unicef

Product will be sold for $0.80 USD per dose

Annual Costs
- Estimated Revenue: $568,860
- Rate of Return: -33%

<table>
<thead>
<tr>
<th>Utility</th>
<th>Cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>$72,738</td>
</tr>
<tr>
<td>Water</td>
<td>$7,840</td>
</tr>
<tr>
<td>Electricity</td>
<td>$38,398</td>
</tr>
<tr>
<td>Disposal</td>
<td>$36,389</td>
</tr>
<tr>
<td>Labor</td>
<td>$66,150</td>
</tr>
<tr>
<td>Utilities</td>
<td>$847,106</td>
</tr>
<tr>
<td>Raw Materials</td>
<td>$506,591</td>
</tr>
<tr>
<td>Total</td>
<td>$847,106</td>
</tr>
</tbody>
</table>

Alternative Designs and Considerations
- Ribbon blenders and high shear granulation
- Solvent-aided mixing and grinding
- Manual transport instead of pneumatic conveying to reduce cost
- Optimize scheduling of CIP & SIP
- Packaging, labeling, and quality assurance in-house to increase profit

Future Work
- Conduct benchtop experiments to further understand how soy-based excipients affect product solubility, friability, and stability
- Properly design and model the extraction of DHA from A. annua
- Partner with a company in industry to ensure stable funding
- Model how the facility would conduct private contract work

Plant Layout

The initial design of the plant is based on The Chao Center, located in Research Park.

Global & Societal Market: Why Nigeria?
- Target market: Nigeria
- Nigeria is considered a more developed country, thus the distribution of medicine will be easier
- More than 90% of the population in Nigeria is at risk for malaria
- Estimated 100 million malaria cases with > 300,000 deaths/year
- Malaria-related complications are responsible for the following:
  - 60% of outpatient facility visits
  - 30% of total childhood deaths
  - 25% of total deaths for infants under the age of one year
- Pandemic Involvement:
  - Artemisinin growth & extraction from Purdue Horticulture
  - Internships, co-op, & clerkship opportunities for students to gain hands-on experience and knowledge on GMP regulations

Background: Orphan Drugs & Malaria
An orphan drug is a product developed to treat extremely rare, but usually life-threatening diseases; patient numbers are so small in developed countries that these diseases are not adopted by the commercial pharmaceutical industry. Malaria is a disease caused by parasites that are transmitted through the bites of infected mosquitoes. Despite the extremely high death rate, it is easily treatable if promptly diagnosed. ACTs are the most efficient method of treatment for uncomplicated *P. falciparum* malaria.

References

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