CAPSTONE EXPERIENCE 2015

Production of Solid-Dosage Malaria Treatment

Jonathon Dance (BE), Kavya Kumar (BE), Coleen Riley (BE), and Hao Ye (BE)

PURDUE UNIVERSITY

Agricultural & Biological ENGINEERING

Our Mission

To design and model a small-scale pharmaceutical manufacturing plant for the production of an Artemisinin-based combination therapy (ACT) for the treatment of *P. Falciparum* malaria in Nigeria.

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[1]. Malaria is a disease caused by parasites that are transmitted through the bites of infected mosquitos. 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.

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[2]

Malaria-related complications are responsible for the following[3]:

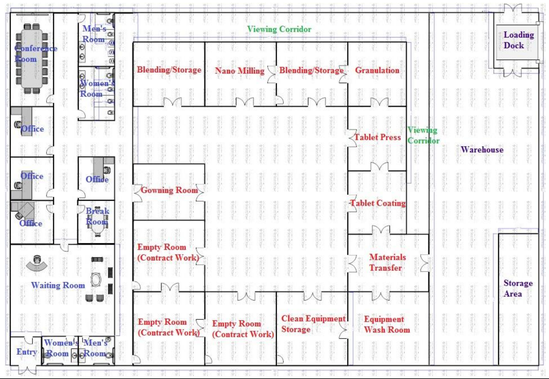
- 60% of outpatient facility visits
- 30% of total childhood deaths
- 25% of total deaths for infants under the age of one year

Purdue Involvement:

- Artemisinin growth & extraction from Purdue Horticulture
- Internships, co-op, & clerkship opportunities for students to gain hands-on experience and knowledge on GMP regulations

Plant Layout

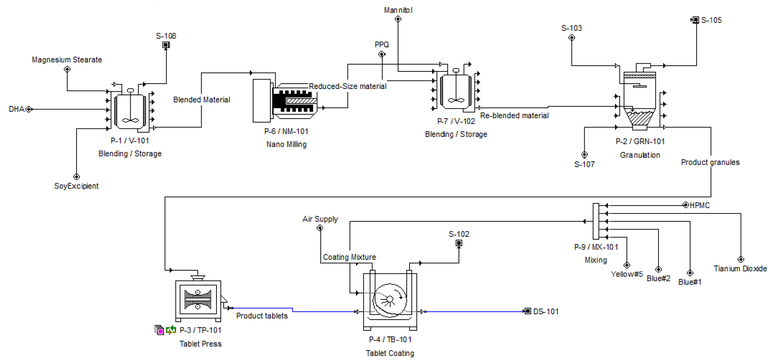
The initial design of the plant is based on The Chao Center, located in Research Park.



Dimensions:
150 ft x 100 ft

- Production area
- Office area
- Viewing area
- Storage & warehouse

Current Design and Formulation



Dosage

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

Component	Mass [mg]	%
Magnesium Stearate	4.8	0.010
Mannitol	52.8	0.109
Soy Excipient	69	0.142
DHA	40	0.082
PPQ	320	0.658

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[4]:

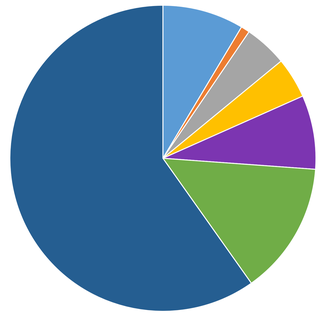
- Naa ational Institute of Health (NIH)
- The Indiana Soybean Alliance
- The World-Health Organization (WHO)
- Unicef

Product will be sold for $0.80 USD per dose

Annual Costs

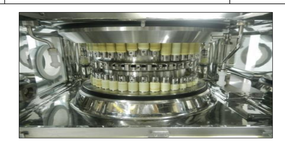
Estimated Revenue: $568,860
Rate of Return: **-33%**

Steam	$72,738
Water	$7,840
Electricity	$38,398
Disposal	$36,389
Labor	$66,150
Utilities	$119,000
Raw Materials	$506,591
Total	**$847,106**



Design Specifications

Unit Operation	Equipment Dimensions	Power Usage/batch (kW)	Cost ($)
Mixing/Blending	500 L	1.5	10,000
Conveying	15 m (total)	431.0	1,500
Cyclone	Height: 1.2 m Diameter: 0.24 m	Included in conveying	2,000
Milling	2 L	3.2	17,000
Fluidized-bed Granulating	Bed height: 0.5 m Bed diameter: 0.3 m	5	150,000
Tablet pressing	Max throughput: 1890	1.1	45,000
Tablet Coating	-	-	50,000



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

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