

Engineering Drug Delivery

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Capstone Design Project- University of Oklahoma - Spring 2003

EXECUTIVE SUMMARY

The purpose of this project is to consider a timed-release drug delivery system and expound all creative avenues available to the market. The project considers the complete undertaking of developing such a drug, from research and development, to fabrication and marketing of the new system. The type of delivery system that is to be used will be a capsule taken orally, consisting of a semi-permeable membrane, and then making use of osmotic pressure to slowly release the drug over the required time frame, adjusting from short periods up to 24 hours. The drug chosen for use in this experiment was tamsulosin hydrochloride, known commercially in the U.S. as Flomax®. Flomax® is used to treat the symptoms of an enlarged prostate--a condition technically known as benign prostatic hyperplasia or BPH¹. The major symptom associated with BPH is trouble urinating. This drug was selected because it could be purchased, was found to have a sizeable and increasing market size, and had the information available to allow completion of the project. A process flow diagram has been constructed illustrating the fabrication process of this new delivery system. Market research for the project takes into account the economics of each segment of the project including profit opportunities.

It has been determined that a push pull osmotic pump will be the preferable system for delivering the drug tamsulosin hydrochloride in a slow, time released format. This venture, while requiring a large initial investment (\$61, 557, 000), with a pre-production time investment of four years for both construction and the FDA approval process necessary before the product can be presented to the public, has the potential to be highly profitable. Raw materials alone shall have an annual cost of \$75 million. Similarly, the production costs and high standards of quality control lend to a total annual manufacturing cost of \$156 million. Though the investment capital required for this venture is large, the annual income far outweighs the expenses associated with the process. Based on our market strategy, the plant has been design to produce 300 million tablets per year. Current prices obtained from pharmaceutical companies indicate that these tablets can be sold for approximately one dollar per tablet for an annual income around \$300 million before taxes. This profit margin allows the company to repay the capital investment only a year and a half after production begins and gives a margin of safety to investigate risk analysis and worst-case scenarios.

Conservative estimates have the project reaching a financial break-even point in under two years; a good sign that helps reduce the risk of the venture in an unendingly progressing market vulnerable to change with future pharmaceutical advances.