

EXCIPIENTS FOR PHARMACEUTICALS

The Wikipedia defines excipients as:

“**An excipient** is an inactive substance used as a carrier for the active ingredients of a medication. In addition excipients can be used to aid the process by which a product is manufactured. In general, the active substances (such as aspirin) may not be easily administered and absorbed by the human body; they need to be put in some appropriate form. In such cases, the active substance is dissolved or mixed with an excipient. Excipients are also sometimes used to bulk up formulations with very potent active ingredients, to allow for convenient and accurate dosage”

Some excipients:

Starch and modified starches like Starch IP, Sodium Starch Glycolate, Pregelatinised Starch. Mainly used as binders in tablets. They also help in quick disintegration.

Preservatives based on Para Hydroxy Benzoic Acid - Methyl Paraben, Propyl Paraben, Butyl Paraben

Products based in micro crystalline cellulose - Microcrystalline Cellulose Powder (MCCP), Ethyl Cellulose, Cross Carmellose carboxy methyl cellulose), Sodium carmellose, Hydroxy propyl cellulose These are also used as binders. They also influence the release of active ingredients

Metallic Stearates like Calcium stearate, Magnesium stearate Used as binders

Zinc Citrate, Magnesium Citrate, Di-Sodium Hydrogen Citrate, Sodium citrate, Potassium Citrate, Calcium Citrate. Used as preservatives

Lactose: Used as binder and diluent

Shellac: Used for coating

Bronopol: Preservative

Kyron (Taste masking polymers)

Methacrylic Acid co-polymer Type-A, B, C: Coating to influence slow release / timed release

Colorants for film forming polymers

Proposal:

Pharmaceutical industry is one of the fast growing industries in India. The industry is modernizing and changing to meet GMP requirements and international standards. There is need for consistent quality excipients. Many of the formulators are depending on imports. A project for excipients manufacture meeting GMP requirements has good prospects.

Product mix:

Starch based excipients	3000 tons per year
MCCP based excipients	3000 tons per year
Preservatives	1500 tons per year

Market:

Indian pharmaceutical market is currently valued at Rs. 40,000 crores. Excipients market in this is about 10 %. The market is expected to grow at 10 % per year. This indicates additional market of Rs. 400 crores per year. These excipients are also used in cosmetics. That is another Rs. 10000 crore market, also growing at 10 % per year.

Manufacturing process:

Starch based excipients: Commercial grade starch is available from starch plants. Adding chemicals or physical treatment can modify this. Pre gelatinized starch is made by cooking the starch with water under controlled conditions

MCCP based excipients: Commercial grade microcrystalline cellulose is available from cellulose powder manufacturers. Adding chemicals can modify this.

Technology:

The technology involved is simple. Main features are accurate control of process conditions. The particle size of the finished product also makes a difference to the formulator. Another feature is manufacturing under GMP conditions.

Most of the excipients are branded products. It would be advantageous to collaborate with a foreign company having established brands.

Plant and Machinery:

Plant and machinery consist of Blenders, Fluid bed / Spray dryers, milling equipment, boiler etc.

Quality control equipment is a major component of the plant.

Raw materials:

Starch, microcrystalline cellulose powder, ethylene oxide, Propylene oxide, chloroacetic acid etc are the raw materials required

Utilities:

Power and steam are the utilities required

Project cost:

Rs. 5 crores

Turnover and profitability

Annual turnover of Rs. 20 crores with net profit margin of 10 % is possible.

Suggested location:

Around Hyderabad

Entrepreneur profile:

Technocrat with exposure to Pharma Industry.

Apitco's consultancy:

1. Market survey
2. Project planning
3. Technology tie-up