The purpose of this proposed study is to provide a global view of the pharmaceutical excipient sector. It describes the market trends and growth prospects, the supply and level of competition, as well as possible new entrants. On the market, excipients are currently used for tablets, pre-compression, granulation, liquids, caps, and inhalation products.

<table>
<thead>
<tr>
<th>PRODUCTS</th>
<th>APPLICATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUGARS</td>
<td>CHEWABLE TABLETS</td>
</tr>
<tr>
<td>LACTOSE</td>
<td>EFFERVESCENT TABLETS</td>
</tr>
<tr>
<td>MALTOSE</td>
<td>pMDI (Inhalers)</td>
</tr>
<tr>
<td>MCC</td>
<td>SOFT GELS</td>
</tr>
<tr>
<td>STARCH</td>
<td></td>
</tr>
<tr>
<td>ALCOHOLS</td>
<td></td>
</tr>
<tr>
<td>SORBITOL</td>
<td></td>
</tr>
<tr>
<td>MALTITOL</td>
<td></td>
</tr>
<tr>
<td>XILITOL</td>
<td></td>
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<tr>
<td>MINERALS</td>
<td></td>
</tr>
<tr>
<td>CALCIUM PHOSPHATES</td>
<td></td>
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<tr>
<td>CALCIUM CARBONATES</td>
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<tr>
<td>MAGNESIUM STEARATES</td>
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<table>
<thead>
<tr>
<th>FORMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>WET GRANULATION</td>
</tr>
<tr>
<td>DIRECT COMPRESSION</td>
</tr>
<tr>
<td>DRY POWDER INHALATION</td>
</tr>
</tbody>
</table>
Drug products contain both active pharmaceutical ingredient or API and excipients.

Excipients are sub-divided into various functional classifications, depending on the role that they are intended to play in the resultant formulation:

- **Filler & Diluent:** Lactose, MCC, Calcium Carbonate
- **Disintegrants:** Sodium Starch Glycolate, crosscarmellose sodium
- **Binders & Adhesives:** PVP, HPMC
- **Lubricants:** Magnesium stearate, Stearic acid
- **Glidants:** Talc, Colloidal SiO2

Excipients play a wide variety of functional roles in pharmaceutical dosage form, including:
- Modulating solubility & bioavailability of APIs,
- Increasing the stability of active ingredients in dosage forms,
- Helping active ingredients maintain preferred polymorphic forms or conformations,
- Maintaining the pH and/or osmolarity of the liquid formulations,
- Acting as antioxidants, emulsifying agents, aerosol propellants, tablet binders, and tablet disintegrants,
- Preventing aggregation or dissociation (e.g. of protein and polysaccharide actives),
- Modulating immunogenic responses of active ingredients (e.g. adjuvants), and more.

Excipients, in certain cases, interact with the active ingredient in the final formulated dosage form or may provide a matrix that affects the critical quality attributes of the active ingredients like stability and bioavailability.

**ISSUES WITH EXCIPIENTS**

Solubility: almost 10% of current marketed drugs are poorly soluble and almost 40% of new chemical entities (NCE) are dropped due to solubility issues. Low solubility of drug candidates can translate into poor (and varying) bioavailability.

Excipients play a significant role in bioavailability. However, excipients can have a profound effect on GI physiology. They can change the GI motility or even change the permeability of the membrane. For instance, excipients like sorbitol or mannitol affect intestinal transit time. This can create some problems with low permeability drugs.

Sodium pyrophosphate is a cathartic laxative, had a significant effect on ranitidine and bioavailability, reducing it by half.

Oleic acid-bile salts can change the absorption mechanism of propranolol. It is not a widely used excipient, except for maybe polysorbate 80.
INNOVATION IN PHARMACEUTICAL EXCIPIENTS

In general, there are three types of new excipients and the development process of these varies significantly:

- **Product development of new excipients has three main goals:**
  - To demonstrate the advantage over existing materials for the target application
  - To establish a reliable manufacturing process that leads to the desired product characteristics
  - To demonstrate the appropriate stability of the new grade.

- **Modified Excipients**
  - Well known excipients with established quality standards can be modified with regard to their impurity profile or their physical properties. The development for modified excipients time is relatively short with a low R&D investment and a low associated risk.

- **Co-Processed Excipients**
  - Two or more excipients are formulated without chemical changes in order to achieve new performance characteristics which cannot be achieved by simple physical mixing. The development of a co-processed excipient is more complex.

- **Novel Excipients**
  - It is used for the first time in a drug product or a new route of administration. Novel excipient's development is substantially similar to the non-clinical development of a new active ingredient: A high R&D investment and a long development time.
  - As a consequence, only very few manufacturers are willing to invest in the development of a novel excipient.

Couple of new chemical materials has been introduced, less than 10 new functional excipients have been approved in the past 15 years. Only a few drug manufacturers have formulated drug products containing novel excipients in recent years.

**Examples:**
- A new class of alkylsaccharide excipients
- New polymeric carriers such as hypromellose acetate succinate (HPMCAS), copolymers based on dimethylenoethyl methacrylate, butyl methacrylate, and methyl methacrylate, polyvinylpyrrolidone-vinyl acetate (PVP-VA), lauroyl macrogolglycerides (polyoxyglycerides)
- Ultra-pure grades of crospovidone with the lower levels of peroxides
- New grades of HPMC for direct compression
OBJECTIVES

MARKET

Users and expectations
Market size
New applications
Key players
Prices

MANUFACTURERS

Producers and range
Sales and market position
Strengths and weaknesses
Prices

RESEARCH

New researches and new developments

BIOAVAILIBILITY

Bioavailability is a measurement of the extent of a therapeutically active medicine that reaches the systemic circulation and is therefore available at the site of action. Many drugs are effective, but not readily bioavailable.

ISSUES

How to effectively decouple the low intrinsic solubility of the active in the GI tract from the often resulting poor bioavailability?

- The crystal lattice of the drug substance needs to be disrupted at the formulation stage.

SOLUTIONS

Several technologies to disrupt the crystal lattice of drug candidates have been described:

- Self Emulsifying Drug Delivery Systems
- Nanocrystal Formulations
- Media Milling w/ polymeric excipients
- Dissolution and Spray Drying w/ polymeric excipients
- Hot Melt Extrusion w/ polymeric excipients
- Solid Dispersions

Most water soluble drugs, as long as their permeability and metabolic inertness is sufficient, can penetrate biological membranes during the passage of the GI tract and ultimately become bioavailable.

Insoluble drugs generally will not become bioavailable after oral ingestion, and low solubility drugs, like those belonging to Biopharmaceutical Classification System (BCS) class II, will typically show poor and in cases varying bioavailability.
SOLID EXCIPIENTS AFFECTING BIOAVAILABILITY

In addition to enhancing the solubility of drug products, Excipients can impact the consistency and control of drug bioavailability and serve other functions, including improved physiochemical stability and manufacturability. Excipients can also affect the pH of the GI fluid and/or microenvironmental pH of the dosage form—both of which can affect drug release.

- **Povidone, Carboxymethyl cellulose, Pectin, and Gelatin:**
  Viscosity-inducing hydrophilic macromolecular excipients, can minimize polymorphic conversion of a drug in the dosage form.

- **Cyclodextrins:**
  Can complicate the drug, resulting in altered physicochemical and biopharmaceutical properties.

- **Surfactants and polymers:**
  Can also impact the metabolizing cytochrome p-450 enzymes or the P-glycoprotein multi-specific efflux transporter.

- **Mannitol and PEG 400:**
  Have effects on gastro-intestinal motility and it is often due to concentration and a possible overlap of multiple mechanistic pathways of the excipient’s influence on drug absorption.

INTERVIEW

**Aim of the interview**
Knowing the perspectives of leading excipient manufacturing companies on the role excipients play in formulating and manufacturing drugs for improved bioavailability, what has and can be done differently, and how they see the industry and their specific part of the ecosystem evolving.

**Contributing companies are:**
- Ashland Inc. Speciality Ingredients
- Croda Inc
- BASF Corporation
- EMD Millipore
- Shin-Estu Chemical Co., Ltd
EXCIPIENT MANUFACTURING

This process involves processing the drug substance with excipients using a “slugging” or “compaction” technique followed by “granulation sizing” and final blending with additional excipients prior to tablet compression, or capsule shell filling.

Dry Granulation

This process involves processing the drug substance with excipients and a solvent in which a binder may be dissolved to produce a granulation. The granulation is subsequently dried, sized and blended with additional excipients prior to tablet compression or capsule shell filling.

Wet Granulation

It requires fewer processing steps, offers simplified validation, eliminates heat and moisture from the process and improves drug stability. All these advantages translate into economical gains. However, excipients need to possess – good flowability, compressibility, low moisture sensitivity and low lubricant sensitivity - to be successfully used in the DC process.

Direct compression

The trends in manufacturing processes are a shift towards direct compression and the introduction of high speed manufacturing machinery.

- A shift towards direct compression
- The introduction of high speed manufacturing machinery. Machines which are capable of producing 0.1 to 0.2 million tablets per hour. Increased machine speed with faster feed rates and shorter dwell times in the compression stage, have exposed the excipients to a totally new set of challenges. Coprocessing offers a suitable alternative in this regard. By overcoming the above-mentioned limitations of physically mixed excipients, the single-bodied coprocessed product provides ready-to-use excipient with predefined multifunctionality.

TRENDS IN MANUFACTURING PROCESSES

- Process weight variation due to poor flow properties
- Content nonuniformity during mixing due to wide differences in density
- Loss of excipient compressibility due to wet granulation and repeated compaction cycles in dry granulation, or excessive usage of lubricants and poorly compressible ingredients in the formulation
- Poor disintegration of product due to excessive usage of binders

INGREDIENTS USED IN THE PHARMACEUTICAL EXCIPIENTS MARKET

OBJECTIVES

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Users and expectations
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Based on recent market study data, the total market for excipients is estimated at US$ 4.5 billion in 2013, with an average annual growth of 7% to 8% in volume and 4% to 5% in value. That is, the global excipient market is approximately 0.4-0.5% of the global pharma market, which is evaluated at US$ 850 billion. North America and Europe, as the main pharmaceutical producing areas, consume approximately 70% of excipient output. Japan takes another estimated 15% and India, Brazil and China have become major single markets in recent years.

There are currently 1,200 or so excipients on the market and they fulfil the needs of the majority of finished pharmaceutical products. There is no unmet need in immediate-release dosage forms for new excipients, although the big exception here is for modified-release dosage forms.

In general, there is an increased recognition of the role of excipients in the drug delivery process coupled with an increased research on the impact of excipients to enhance the bioavailability of active ingredients.

Thus, there is also an understandable resistance from pharmaceutical companies to double their risk by using a novel excipient. This is also true for excipient manufacturers. At the same time, developing a novel excipient is long and expensive (€ 30 mio).

Usually, the market is segmented by type of process: granulation, direct compression and inhalation.

It is also sub-segmented by markets:
- Generics, which globally represent 50% of the market, and ethicals
- Nutraceuticals and OTC.

Generic products also use edible (i.e. not USP Grade) lactose for cost reasons.
**Objectives**

**Market**
- Users and expectations
- Market size
- New applications
- Key players
- Prices

**Manufacturers**
- Producers and range
- Sales and market position
- Strengths and weaknesses
- Prices

**Research**
- New researches and new developments

**Market Overview**

The market for galenicals, 2013

<table>
<thead>
<tr>
<th>Country</th>
<th>Market share in %</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S.</td>
<td>SAMPLE</td>
</tr>
<tr>
<td>EU</td>
<td></td>
</tr>
<tr>
<td>Japan</td>
<td></td>
</tr>
<tr>
<td>Others</td>
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</tr>
</tbody>
</table>

The main excipients used, 2013

<table>
<thead>
<tr>
<th>Excipient</th>
<th>Number of medicinal products</th>
<th>Market volume</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>lactose</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MCC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stearic acid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carboxymethyl starch</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Excipients used in different drug delivery forms, 2013

<table>
<thead>
<tr>
<th>Form</th>
<th>Excipients</th>
<th>Function</th>
<th>Market size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chewable tablets</td>
<td>Amorphous</td>
<td>50% of the market, common</td>
<td></td>
</tr>
<tr>
<td>Effervescent tablets</td>
<td>Crystal</td>
<td>10% of the market, innovative</td>
<td></td>
</tr>
<tr>
<td>pMDI (inhalers)</td>
<td>Mechanical</td>
<td>20% of the market, common</td>
<td></td>
</tr>
<tr>
<td>Soft gels</td>
<td>Amorphous</td>
<td>10% of the market, rare</td>
<td></td>
</tr>
</tbody>
</table>

ubic@ubic-consulting.com  www.ubic-consulting.com
NEW DEVELOPMENT OF EXCIPIENTS

Development of new excipients

The possible three routes by which new excipients can be developed for the pharmaceutical industry are:

1. New chemical entities as excipients
2. New grades of existing excipients
3. New combinations of existing excipients

New developments have focused on:
- new grades of existing excipients: e.g. pre-gelatinised starches
- new combination of excipients. This is the most followed pathway of research.

Emerging Excipients in Parenteral Medications

Emerging excipients are increasingly becoming integral parts of sophisticated drug delivery systems rather than functioning as “stand-alone” chemical entities. Such systems require complex manufacturing methodologies and precise chemical/engineering protocols to achieve the desired morphology of the drug–excipient recipe.

Higher concentrations of a chemical entity may cause a pharmacological response whereas lower concentrations are incapable of doing so. A range of such excipients are discussed in the present study.

Preclinical testing for a new excipient

The testing strategies proposed by IPEC and the FDA offer a useful starting point for preclinical excipient testing. IPEC has proposed guidance from both a European and a U.S. perspective, reflecting single or limited human exposure, limited or repeated human exposure, and long-term human exposure for a new excipient. The FDA has divided testing requirements into those needed to support short-term, intermediate and long-term use.

New excipients are being developed to improve and make formulations more economic and alter bioavailability and as specific drug delivery materials.

Various toxicology studies performed are discussed in this study.

Novel excipients for reduced protein aggregation

Several excipients included in reconstitution media have been found to result in a significant reduction of protein aggregation. These include sulfated polysaccharides, polyphosphates, amino acids and various surfactants.

A new class of alkylsaccharide excipients was found to be highly effective in preventing protein aggregation. These excipients stabilize and reduce aggregation proteins in therapeutically useful formulations, and they may provide solutions for aggregation-related manufacturing or formulation problems and/or unwanted immunogenicity.
### Objectives

- Users and expectations
- Market size
- New applications
- Key players
- Prices

### Market

- Interviews of excipient suppliers to describe:
  - Interviews with producers to collect information on their pharmaceutical product range, production and capacities, sales and market trends. This will detail their opinion of the sector's evolution, and new market applications.

<table>
<thead>
<tr>
<th>Excipient Suppliers</th>
<th>EU - USA - OCEANIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVANTOR</td>
<td>AQUALON</td>
</tr>
<tr>
<td>BIOLAC</td>
<td>BASF</td>
</tr>
<tr>
<td>DFE</td>
<td>CYDEX</td>
</tr>
<tr>
<td>KERRY</td>
<td>CRODA</td>
</tr>
<tr>
<td>FMC</td>
<td>CARGILL</td>
</tr>
<tr>
<td>FOREMOST</td>
<td>SPI</td>
</tr>
<tr>
<td>MEGGLE</td>
<td>JRS PHARMA</td>
</tr>
<tr>
<td>MEGGLE</td>
<td>ROQUETTE</td>
</tr>
</tbody>
</table>

### Manufacturers

- Interviews of Pharmaceutical companies and contract manufacturers
  - Interviews with users to collect information on their needs, and market trends.

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>ABBOTT LABS</td>
</tr>
<tr>
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</tr>
<tr>
<td>ASTRA ZENECA</td>
</tr>
<tr>
<td>BAYER CORP PHARMACEUTICAL DIVISION</td>
</tr>
<tr>
<td>BIOGAIA AB</td>
</tr>
<tr>
<td>BOEHRINGER INGELHEIM</td>
</tr>
<tr>
<td>BOIRON</td>
</tr>
<tr>
<td>BRISTOL MYERS SQUIBBB</td>
</tr>
<tr>
<td>ELI LILLY</td>
</tr>
<tr>
<td>FRESENIUS KABI</td>
</tr>
<tr>
<td>GLAXO SMITHKLINE</td>
</tr>
<tr>
<td>GENENTECH</td>
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<tr>
<td>IPSEN BIOTECH</td>
</tr>
<tr>
<td>JOHNSON &amp; JOHNSON MEDICAL</td>
</tr>
<tr>
<td>LABORATOIRES DOLISOS</td>
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<tr>
<td>MERCK PHARMACEUTICALS</td>
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<tr>
<td>NOVO NORDISK</td>
</tr>
<tr>
<td>PASTEUR MERIEUX</td>
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<td>PFIZER USA</td>
</tr>
<tr>
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- New researches and new developments
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Study purchase includes one year update available on-line on UBIC’s Extranet

Assistance is also available for specific questions

COMPANY ______________________________________________________________________
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