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# Excipients

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US Industry Study with Forecasts for **2015 & 2020**

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Study #2736 | May 2011 | \$4800 | 281 pages

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*As drug makers seek to counter intensifying generic competition and rising production costs, they are using excipients to not only carry their active ingredients, but to add value to them.*

## US demand to rise 3.9% annually through 2015

US demand for excipients will advance 3.9 percent annually to \$1.9 billion in 2015, driven by continued growth in US pharmaceutical production and the increasing importance of functional excipients in drug formulation. As pharmaceutical manufacturers seek to offset the impact of intensifying generic competition and increasing production costs, excipients -- once viewed as simple carriers for active ingredients -- are increasingly being called upon to add value to pharmaceutical products. Excipients can be used to extend shelf life and stability, to improve manufacturing efficiency, and to control the release of medicine in alternative dosing formats such as orally disintegrating tablets (ODTs) and inhalants. Nevertheless, growth will lag that of pharmaceutical output as most excipients are commodity substances with limited pricing flexibility.

## Fillers, binders, disintegrants applications among best opportunities

One of the most important developments in the excipient industry is the preparation of special excipient blends that provide manufacturers with ready-made combinations of fillers, binders, disintegrants, lubricants and other products, reducing manufacturing time and standardizing materials to be combined with active ingredients. Some of these

## US Excipient Demand, 2010 (\$1.5 billion)

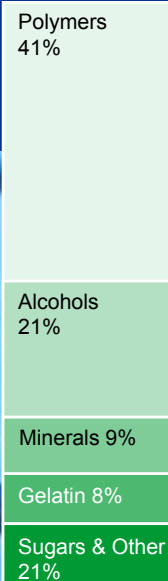


photo: Roquette Pharma

blends are specially formulated for use in direct compression, a method of tablet formulation that eliminates several processing steps used in wet and dry granulation. The direct compression excipient market is rapidly expanding, especially for polymer products such as microcrystalline cellulose and povidone.

Orally disintegrating tablets (ODT) are one of the fastest growing drug delivery formats. ODT formulations can be taken without water and are designed to dissolve on the tongue, rather than be swallowed. Excipients benefiting from growth in ODTs include superdisintegrants such as croscopovidone, croscarmellose or sodium starch glycolate, and bulking agents such as mannitol.

Excipients will also benefit from expanded use of controlled-release formulations. Typically, medicines are given in a specified dose, and repeated several hours or days later. This has produced problematic side effects, and reduces patient compliance with medical regimens. Manufacturers are giving increased attention to methods of providing drugs continuously in a controlled fashion over a prolonged time. Water insoluble polymers are crucial to this process. A range of polymers -- in particular, cellulose ethers -- will benefit from increasing use of controlled- and extended-release formulations.

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## Sample Text, Table & Chart

### APPLICATIONS

#### Binders

Binders are adhesive compounds that hold together active medicinal ingredients in tablets and capsules. They typically up about ten percent of a solid oral drug formulation and are used in both wet and dry granulation processes. Total demand for binders in the US is estimated at \$1.5 billion in 2010, with a forecast of \$1.8 billion in 2015 and \$2.1 billion in 2020. The development of new binders is driven by the need for improved formulation performance, such as enhanced stability and reduced friability. In wet granulation, binders are used directly in the formulation and facilitate the agglomeration of particles into uniform, free-flowing granules. In dry granulation, they are typically blended with pharmaceutical ingredients to achieve desired compaction, hardness, size, shape and mass properties. Some products, such as microcrystalline cellulose (MCC), are adaptable to both wet and dry processing. When added to tablets and capsule powders, the compound increases hardness while reducing friability.

Water-soluble natural and synthetic polymers, including povidone, hydroxypropyl methylcellulose (HPMC) and methyl cellulose, are also among other binder materials that realize strong demand. These compounds are employed primarily in wet granulation processes where they provide excellent film-forming properties. Pregelatinized starch serves as a less expensive substitute for MCC in direct tablet compaction. It provides a favorable mix of cost and performance advantage based on native starches, along with natural gums, gelatin and other natural gums are among other available tablet and capsule binding components. However, demand for these compounds is decelerating due to substitution from better performing cellulose and synthetic polymer binders which are capturing most opportunities in new and modified formulations.

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**SAMPLE TEXT**

TABLE IV-1

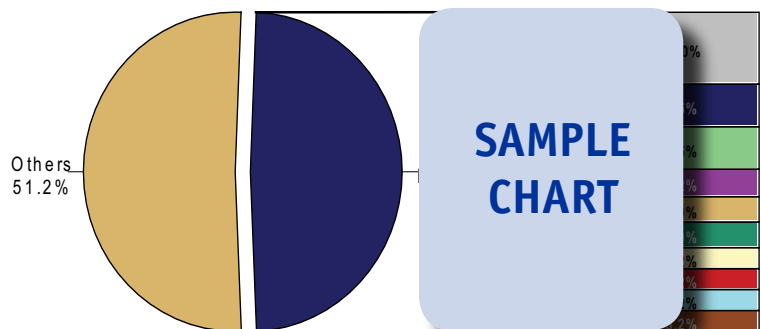
PHARMACEUTICAL EXCIPIENT DEMAND BY APPLICATION  
 (million dollars)

Item	2000	2005	2010	2015	2020
Pharmaceutical Shipments (bil \$)	100	110	120	130	140
\$ excipients/000\$ pharmaceuticals	0.8	0.8	0.8	0.8	0.8
Pharmaceutical Excipient Demand	80	88	96	104	112
Fillers & Diluents	45	48	51	54	57
Binders	15	16	17	18	19
Suspension & Viscosity Agents	4	4	4	4	4
Coatings	1	1	1	1	1
Solvents	3	3	3	3	3
Flavoring Agents	1	1	1	1	1
Capsules	4	4	4	4	4
Disintegrants	7	7	7	7	7
Colorants	0	0	0	0	0
Lubricants & Glidants	9	9	9	9	9
Preservatives	7	7	7	7	7
Other Applications	0	0	0	0	0

**SAMPLE TABLE**

CHART V-1

US EXCIPIENT MARKET SHARE BY COMPANY  
 (\$1.5 billion, 2010)

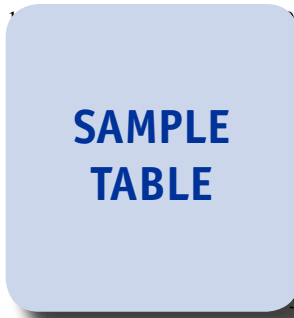


**SAMPLE CHART**

## Sample Profile, Table & Forecast

**TABLE III-19**  
**ALCOHOL EXCIPIENT DEMAND BY TYPE**  
 (million dollars)

Item	2000	2005	2010	2015	2020
Pharmaceutical Shipments					0.0
\$ alcohol/000\$ pharmaceuticals					74
Alcohol Excipient Demand					5.0
Glycerin					5.0
Propylene Glycol					5.0
Sorbitol					0.0
Other Alcohols					4.0
\$/lb					14
Alcohol Excipient Demand (mil lbs)					81



**COMPANY PROFILES**

**Innophos Incorporated**  
 259 Prospect Plains Road  
 Cranbury, NJ 08512  
 609-495-2405  
 http://www.innophos.com

Sales: \$  
 US Sales: \$  
 Research & Development: \$ million (2010)  
 Employees:   
 Key Products:

**SAMPLE PROFILE**

Innophos is a leading North American manufacturer of specialty phosphates. These products are employed in a wide variety of foods and beverages, personal care products, pharmaceuticals and industrial applications. The Company operates in three segments: Specialty Phosphates - US/Canada, Specialty Phosphates - Mexico, and GTSP and Other.

The Company participates in the US excipients industry through the Specialty Phosphates - US/Canada segment, which reported 2010 revenues of \$495 million. The segment encompasses Innophos' production and sale of specialty ingredients; food-, technical- and detergent-grade purified phosphoric acid; and technical sodium tripolyphosphate for the US and Canadian markets. Specialty ingredients, which accounted for \$451 million of the Company's total revenues in 2010, include pharmaceutical-grade calcium phosphate excipients.

Innophos' pharmaceutical excipients are typically manufactured to meet US Pharmacopeia, National Formulary or other compendia specifications. Specific products include TRI-TAB tribasic calcium

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"Alcohols used as pharmaceutical excipients include glycerin, propylene glycol, sorbitol, and other products such as mannitol, ethanol, benzyl alcohol and other polyols. Alcohol excipient demand is expected to reach \$376 million in 2015, growing 2.9 percent annually and representing 351 million pounds. Growth in demand for alcohols will be tempered by reductions in unit price for glycerin and the leveling off of unit price for sorbitol."

--Section III, pg. 83



**OTHER STUDIES**

**Biologics**

This study analyzes the US biologics industry. It presents historical demand data (2000, 2005, 2010) and forecasts to 2015 and 2020 by product (monoclonal antibodies, vaccines, blood and blood derivatives, hormones, enzymes, interferons, colony stimulating factors), and by application (therapeutic, preventive, diagnostic, industrial, research). The study also examines the market environment, details industry structure, evaluates company market share and profiles industry competitors.

#2792 ..... August 2011 ..... \$4900

**Infection Prevention Products & Services**

This study analyzes the US infection prevention industry. It presents historical demand data for the years 2000, 2005 and 2010, and forecasts for 2015 and 2020 by product (e.g., protective apparel and textiles, safety-enhanced devices, disinfectants, sterilization supplies and equipment, medical waste disposal supplies), service (medical waste disposal, contract sterilization) and market. The study also considers market environment factors, details industry structure, evaluates company market share and profiles industry players.

#2783 ..... July 2011 ..... \$4900

**World In Vitro Diagnostic Products**

Global demand for *in vitro* diagnostic (IVD) products will increase 7.1 percent annually through 2015. The US, Western Europe and Japan will remain the dominant markets, while developing world demand grows the fastest. Molecular diagnostics, cellular analysis and pathology products will be the fastest growing technologies. This study analyzes the \$43.8 billion world IVD product industry, with forecasts for 2015 and 2020 by product, application, world region and for 14 countries. The study also evaluates company market share and profiles 25 industry participants.

#2724 ..... March 2011 ..... \$6100

**Vaccines**

US demand for vaccines will advance 5.6 percent annually through 2014, driven by the development of new vaccines to treat complex human diseases, such as cancer. Public health recommendations for adult and adolescent immunization will produce continued strong sales in this segment, which has reached the level of pediatric vaccines sales. This study analyzes the \$10.8 billion US vaccines industry, with forecasts for 2014 and 2019 by product. It also evaluates company market share and profiles US industry competitors.

#2667 ..... August 2010 ..... \$4700

**Nanotechnology in Health Care**

US demand for nanosized medical products will grow 17.1 percent yearly through 2014. Cancer and central nervous system disorders will be the fastest growing applications. Nanomedicines will provide the best opportunities, while nanotech medical supplies and devices grow the fastest from a small base. This study analyzes the \$34.2 billion US nanotechnology medical product industry, with forecasts for 2014 and 2019 by product and application. It also evaluates company market share and profiles industry participants.

#2622 ..... June 2010 ..... \$4800

**About The Freedonia Group**

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