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Excipients

US Industry Study with Forecasts for **2011 & 2016**

Study #2280 | January 2008 | \$4500 | 291 pages

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Although gains will lag increases in pharmaceutical shipments due to excipients' commodity status, growth opportunities will extend to a broad range of compounds and applications.

US demand to grow 4.5% annually through 2011

US demand for excipients will advance 4.5 percent annually to \$2.9 billion in 2011. Based on advances in material quality and processing safety, gelatin will remain the leading compound for drug encapsulation, warding off challenges from more expensive cellulosic ethers and carrageenan derivatives. Due to the breadth of existing and potential applications in drug formulations and delivery systems, cellulose derivatives will eventually evolve into the top-selling group of pharmaceutical excipients. These compounds will command especially strong growth opportunities as fillers, controlled release agents and enteric coatings.

Cellulose, minerals, starch among best opportunities

Ongoing efforts to improve the bioavailability and safety of parenteral and inhalation drugs will boost demand for specialty polymer excipients, especially compounds with sustained-release and targeting properties. In addition, multi-functional synthetic polymers, such as povidone and methacrylates, will broaden applications in high value-added oral medicines, including disintegrating tablets and sustained-release drug delivery systems. Through 2011, minerals will command the fastest growth among major groups of pharmaceutical excipients based on a favorable mix of cost and performance properties. Calcium phosphate and calcium carbon-

US Excipient Demand, 2011 (\$2.9 billion)

Gelatin 19%
Cellulose 18%
Synthetic Polymers 12%
Minerals 9%
Other Types 42%



ate as tablet fillers, titanium dioxide as a tablet coating ingredient, and petrolatum and mineral oils in topical drug suspensions will fare particularly well in the marketplace.

Cost and quality advantages will extend market opportunities for starch-based pharmaceutical excipients, with pregelatinized starch fillers and binders and sodium starch glycolate disintegrants realizing the best sales growth. Based on ease of processing advantages and good compacting and compression properties, lactose will retain widespread usage as a tablet filler and diluent. Sorbitol and mannitol will see the strongest demand growth among polyol excipients, the former from uses as a

liquid drug diluent, the latter from applications as a diluent in parenteral preparations.

Among other pharmaceutical excipients, sterile water, surfactants and FD&C colors will amass the largest sales. Demand for sterile water will increase with upward trends in the development and production of parenteral drugs, especially recombinant DNA and monoclonal antibody preparations. Efforts to reduce drug dispensing errors and strengthen drug anti-counterfeiting safeguards will prompt pharmaceutical manufacturers to expand the use of FD&C colors as well as specialty ink excipients.

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Sample Text, Table & Chart

PRODUCTS

Sodium Starch Glycolate

Competing against croscarmellose sodium and croscarmellose sodium starch glycolate (SSG) serves as a super disintegrant to break up drug and dietary supplement tablets and capsules. SSG has also been investigated as a potential suspending agent for liquid medication, but is not expected to penetrate this market in the near term due to the well-established effectiveness of hydroxypropyl methylcellulose, cellulose and, to a lesser extent, gelatin. Based on widespread use as a super disintegrant, SSG demand as a pharmaceutical excipient is forecast to increase annually to \$1.2 billion in 2011, representing

SAMPLE TEXT

SSG is the sodium salt of starch ether of starch. The compound is supplied as a fine, off-white free-flowing powder. SSG is odourless and soluble in water and most organic solvents. The compound is used in both wet and dry tablet and capsule granulation processes. As a super disintegrant, only a small quantity of SSG -- typically two- to eight-percent of the drug or dietary supplement formulation -- is required for effectiveness. The compound exerts its disintegrating action through a rapid, extensive swelling. The performance of SSG as a disintegrant is not impaired by other excipients such as hydrophobic lubricants, and remains consistent irrespective of the level of tableting (or capsule granule) compacting pressure.

Large-selling drugs that contain sodium starch glycolate disintegrants include ALLEGRA ODT, AMBIEN CR, ARMIDEX, ASACOL, AVANDIA, DETROL, EFFEXOR, LAMICTAL, LAMISIL, LOTREL, MICARDIS, NORVASC, SEROQUEL, SUSTIVA, TARCEVA, TOPAMAX, ZOLOFT and ZYVOX. US suppliers of these pharmaceutical excipients include Generichem, Mutchler and Roquette. Generichem's primary SSG offering, known as PRIMOJEL, is manufactured by DMV Fonterra Excipients (Campina BV). Mutchler sells the compound under

111

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TABLE III-3

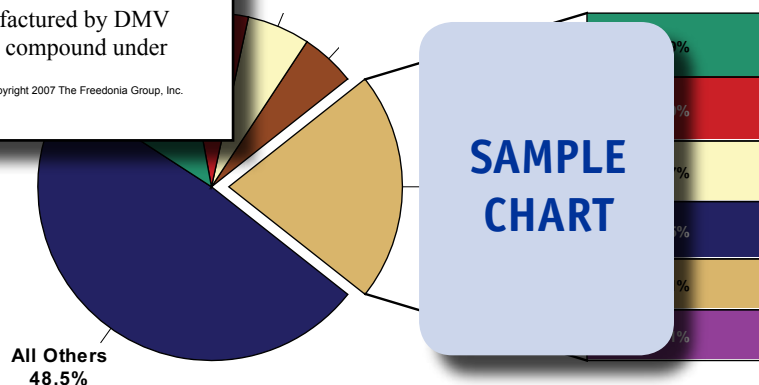
CELLULOSE EXCIPIENT DEMAND BY TYPE
(million dollars)

Item	1996	2001	2006	2011	2016
Oral Pharmaceutical Shpts (bil \$)					
\$ cellulose excipients/000\$ shpts					
Cellulose Excipient Demand					
Microcrystalline Cellulose					
Hydroxypropyl Methylcellulose					
Ethyl Cellulose					
Methyl Cellulose					
Carboxymethylcellulose					
Croscarmellose Sodium					
Other Cellulose Excipients					
\$/lb					
Cellulose Excipients (mil lbs)					

SAMPLE TABLE

CHART V-1

US MARKET SHARE BY COMPANY, 2006
(\$2.3 billion)

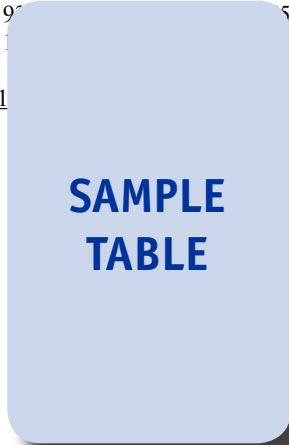


SAMPLE CHART

Sample Profile, Table & Forecast

TABLE IV-1
PHARMACEUTICAL EXCIPIENT DEMAND BY APPLICATION
 (million dollars)

Item	1996	2001	2006	2011	2016
Pharmaceutical Shipments (bil \$)	97	100	105	110	115
\$ excipients/000\$ shipments	1.1	1.1	1.1	1.1	1.1
Pharm Excipient Applications	1.1	1.1	1.1	1.1	1.1
Fillers/Diluents				22	22
Capsules				30	30
Binders				10	10
Drug Delivery Agents				33	33
Suspension/Viscosity Agents				36	36
Coatings				36	36
Flavoring Agents				33	33
Disintegrants				36	36
Colorants				71	71
Preservatives				46	46
Lubricants				10	10
Glidants				7	7



COMPANY PROFILES

Innophos Incorporated
 259 Prospect Plains Road
 Cranbury, NJ 08512
 609-495-7000
<http://www.innophos.com>

Sales: \$1.1 billion (2006)
 US Sales: \$0.8 billion (2006)
 Research & Development: \$0.1 billion (2006)
 Employees: 1,000 (2006)

Key Products: Specialty phosphates, pharmaceutical-grade calcium phosphates, DI-TAB dicalcium phosphate dihydrate, TRI-TAB tricalcium phosphate, INNOCAL WG, INNOCAL W, INNOCAL H, INNOCAL L, INNOCAL M, INNOCAL N, INNOCAL O, INNOCAL P, INNOCAL Q, INNOCAL R, INNOCAL S, INNOCAL T, INNOCAL U, INNOCAL V, INNOCAL W, INNOCAL X, INNOCAL Y, INNOCAL Z.

Innophos is a leading North American manufacturer of specialty phosphates. These products are employed in a wide variety of food and beverages, personal care products, pharmaceuticals and industrial applications. The Company operates in three product groups: Specialty Salts and Specialty Acids, Purified Phosphoric Acid, and STPP and Other. In November 2006, Innophos' parent company, Innophos Holdings Incorporated, held an initial public offering.

Innophos is active in the excipients industry through the Specialty Salts and Specialty Acids group, which accounted for \$277 million of the Company's sales in 2006. Among the various specialty phosphates offered in this product range are several pharmaceutical-grade calcium phosphates. Specific products in this range include Innophos' A-TAB dicalcium phosphate, DI-TAB dicalcium phosphate dihydrate and TRI-TAB tricalcium phosphate. These anhydrous, granular solids, which are manufactured to meet US Pharmacopeia (USP) or National Formulary standards, are typically used as direct compression excipients in tablet manufacturing operations. Related offerings include TRI-CAL WG, a granular tricalcium phosphate product that can serve as a wet



"Capsules are the second-leading drug delivery system for solid oral drugs as well as a widely employed format for producing certain liquid and oil-based medicines. Demand for excipients in capsule manufacturing is forecast to reach \$496 million in 2011, up 4.1 percent annually from 2006. Ongoing advances in tablet formulations will moderate faster growth."

--Section IV, pg. 172

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OTHER STUDIES

Dental Products & Materials

The US dental product and material industry is analyzed in this study. It presents historical demand data (1997, 2002, 2007) and forecasts for 2012 and 2017 by product (e.g., prosthetics, fillings, orthodontic appliances, veneers, whiteners, adhesives and cements, sealants, toothpastes, mouthwash/dental rinses, dental gum); and raw material (metals, chemicals, ceramics, silica, polymers). The study also considers market environment factors, evaluates company market share and profiles leading industry competitors.

#2313 03/2008..... \$4500

Drug Delivery Systems

The US drug delivery system industry is analyzed in this study. It presents historical (1997, 2002, 2007) demand data and forecasts for 2012 and 2017 for pharmaceuticals and biologicals adapted to drug delivery systems (oral, parenteral, inhalation, topical, implantable); and drug delivery devices (e.g., prefillable syringes, metered dose and dry powder inhalers, IV container systems). The study also considers market environment factors, evaluates company market share and profiles leading producers.

#2294 03/2008..... \$4500

Pet Health: Products & Services

This study covers the US pet health industry. It presents historical demand data for 1996, 2001 and 2006 and forecasts for 2011 and 2016 by product (systemic agents, antibiotics, vaccines, parasiticides, diagnostics, disinfectants, supplements); service (veterinary care, testing laboratories, pet insurance); condition (heart disease, cancer, renal disease, arthritis, diabetes) and animal (e.g., dogs, cats). The study also considers market environment factors, evaluates company market share and profiles leading providers.

#2289 02/2008..... \$4500

Medical & Dental Adhesives & Sealants

US demand for medical and dental adhesives and sealants will rise 7.6% annually through 2011, driven by continuing new product development and increasing acceptance in surgical and consumer settings. Opportunities are expected for cyanoacrylate, polyethylene glycol and various plasma and protein types. This study analyzes the US market for medical adhesives and sealants, with forecasts for 2011 and 2016 presented by product and market. It also evaluates company market share and profiles major suppliers.

#2201 05/2007..... \$4400

In Vitro Diagnostics

US demand for in vitro diagnostic (IVD) products will grow 5.1% annually through 2011. Clinical chemistry and immunoassay methods will remain the top two IVD sciences, while nucleic acid testing products will continue to generate the fastest gains. Hospital labs will stay the largest market while home health care will grow the fastest. This study analyzes the \$15.2 billion US IVD industry to 2011 and 2016 by product, application and market. It also evaluates company market share and profiles major players.

#2175 04/2007..... \$4500

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