杜邦药辅 – 助力药品关联审评审批制度改革

杜邦 彭荣

目　录

新杜邦成立历程

2017 → **2019** →

陶氏化学和杜邦公司合并，所有产品线进行整合

合并分拆的目的是创建三家强大的独立公司

April

材料科学

June

农业

June

特种产品

新杜邦业务横跨全球70+国家

32,000+
员工

~200
生产基地

10+
全球研发中心

DUPONT™

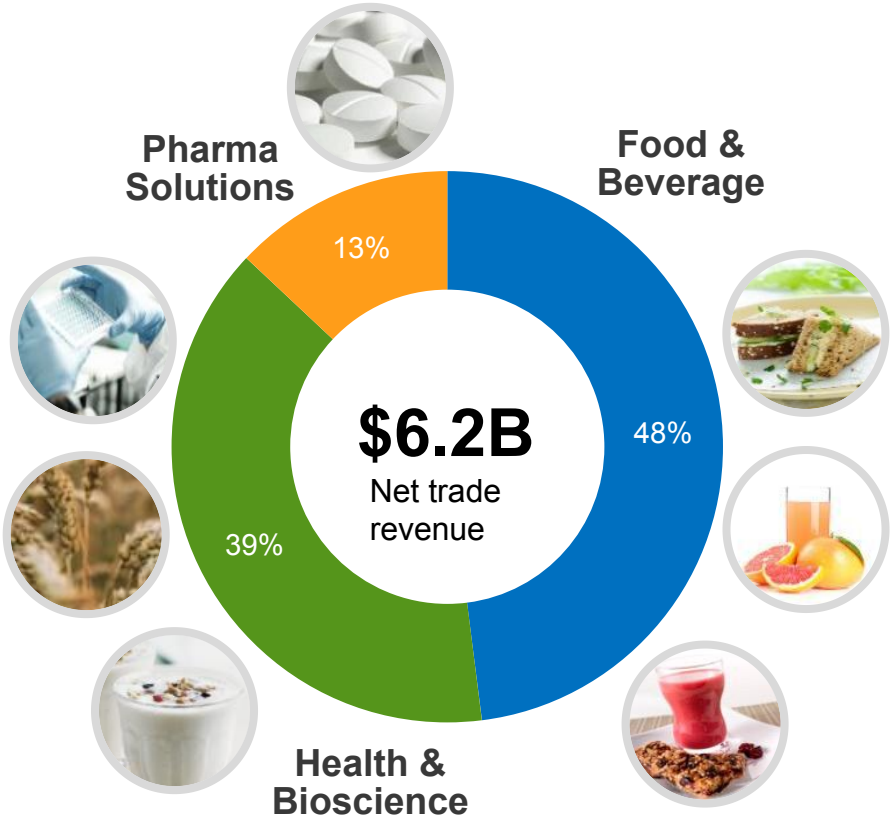
新杜邦业务构成

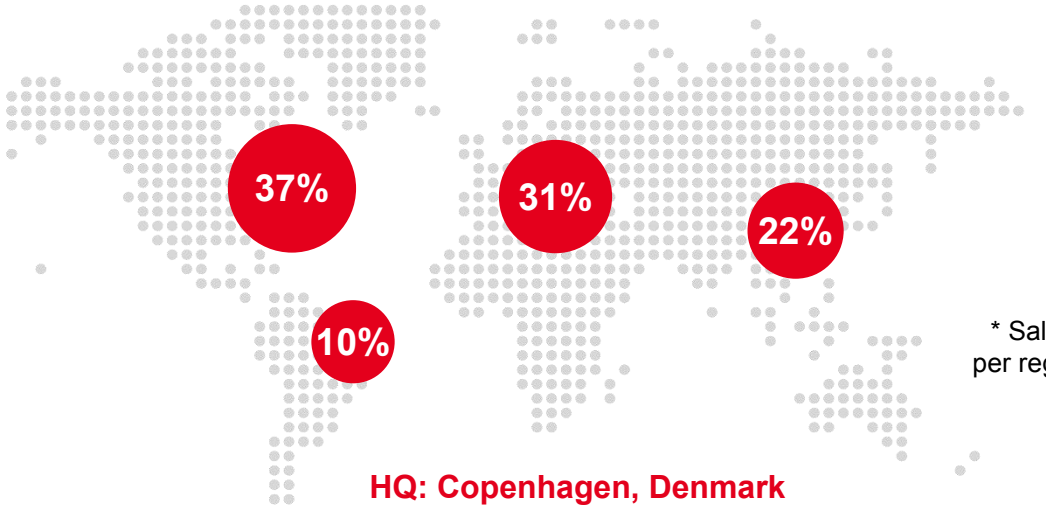
专业解决方案

从高度工程化的产品和天然原料的基本创新来塑造工业和日常生活

营养与生物科技事业部是全球市场的领导者

A unique business with a second-to-none portfolio, focused on serving customers through scientific excellence and essential and sustainable innovations making people thrive





* Sales per region

HQ: Copenhagen, Denmark

>10,000
Colleagues

>70
Manufacturing sites

>25
Technology & Innovation and Application Centers

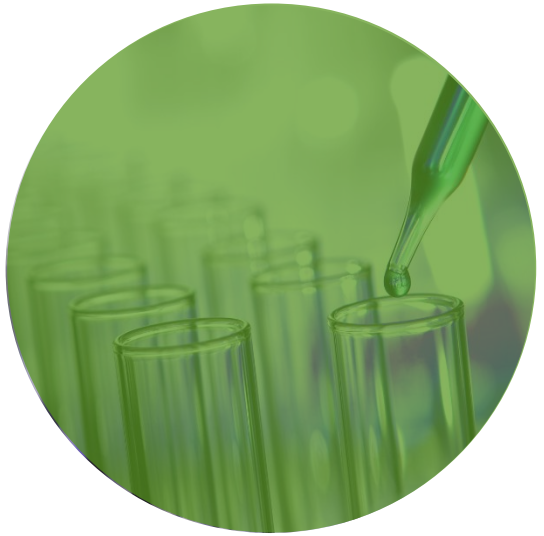
营养与生物科技事业部业务构成

Food & Beverage

› Functional Solutions

› Emulsifiers & Sweeteners

› Protein Solutions



Health & Bioscience

› Probiotics, HMO, Fibers

› Cultures, Food Enzymes, Food Protection

› Animal Nutrition

› Grain Processing

› Household & Personal Care

› Microbial Control

Pharma Solutions

› Pharma Excipients

› Global Specialty Solutions

› Nitrocellulose

DUPONT™

杜邦药用辅料部门
全球领先的原料药及药用辅料解决方案提供商

3个之中的1个

杜邦的材料用于全球在售药片

40亿

每年我们提供的海藻酸钠缓解胃酸反流疾病的病患数

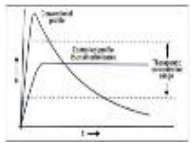
200亿

SeaGel® 技术制造的软胶囊

80亿

帮助到的全球糖尿病病人数量

200亿



为了帮助提高患者的顺应性，而制造的缓释药片及胶囊

500亿

使用我们材料包衣的药片，帮助客户做产品的差异化

Source: market estimates

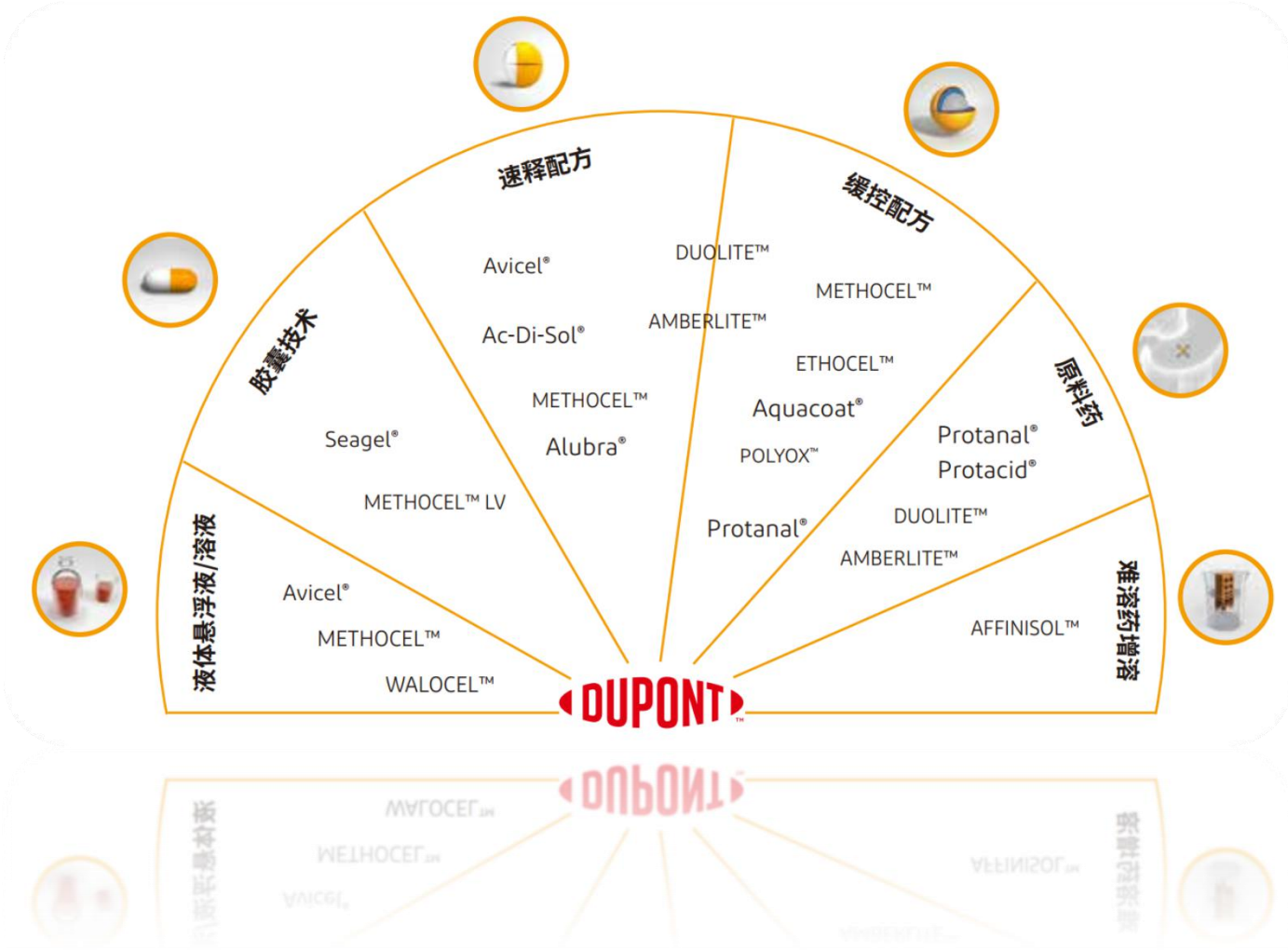
目　录

杜邦药辅部门旗下的药辅产品

Brand

API

Drug Formulation & Delivery



DUPONT

最全面的口服固体剂型产品组合

从API到药用辅料

API	药用辅料			
	控释	缓释	速释	增溶
抗反流 高胆固醇 高血钾	亲水性骨架 多层包衣微粒 渗透泵	肠溶包衣	包衣、粘结剂、胶囊 乳膏、液体、栓剂	热熔挤出 固体干燥分散
海藻酸盐 离子交换树脂	羟丙甲纤维素(HPMC) 乙基纤维素 (EC) 聚氧乙烯(PEO) 海藻酸盐 离子交换树脂(IER)	醋酸羟丙甲纤维素琥珀酸酯(HPMCAS)	羟丙甲纤维素(HPMC) 微晶纤维素(MCC) 交联羧甲基纤维素钠 离子交换树脂(IER) 卡拉胶 硬脂酰富马酸钠	醋酸羟丙甲纤维素琥珀酸酯(HPMCAS) 羟丙甲纤维素（用于热熔挤出）

DUPONT™

What We Offer for API- Hypercholesterolemia高胆固醇

Lowering cholesterol levels starts with a healthy diet and exercise, but when that isn't enough, DuPont's DUOLITE™ Ion Exchange Resins can help with innovative chemistry.

Hypercholesterolemia

DUOLITE™ AP143 resin used as an Active Pharmaceutical Ingredient can help lower a patient's net cholesterol levels by capturing unwanted bile acids and preventing them from being re-absorbed by the body.

DUPONT™

What We Offer for API- Anti-reflux and Endoscopy Care 抗反流

Heartburn/GERD is a growing concern among consumers, and sales of anti-reflux solutions are increasing every year.

Used as APIs, **PROTANAL®®** is DuPont's alginate which is a natural polysaccharide derived from seaweed. It works to relieve the symptoms of acid reflux by forming a physical barrier in the form of a floating gel or raft on top of the stomach contents, preventing the acid from coming back into esophagus.

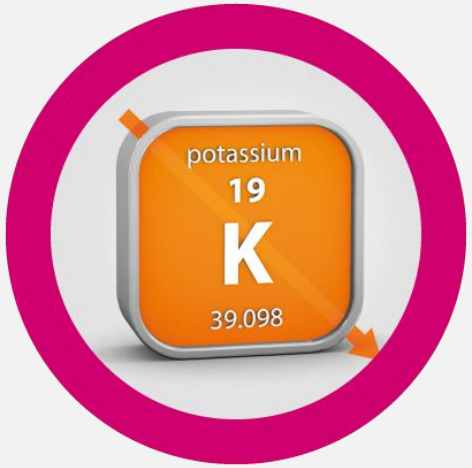
PROTANAL®® offers the following benefits:

- Immediate onset of action
- Longer-lasting effect than antiacids
- Non-systemic physical mode of action
- Safe or use by pregnant women and infants

DUPONT™

What We Offer for API- Hyperkalemia高血钾

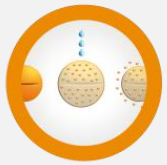
Patients with kidney failure can experience high levels of potassium, a condition that is not well addressed by traditional dialysis. This condition affects the function of both skeletal and smooth muscles, and in extreme cases can result in cardiac arrest. However, DuPont's specially tailored **AMBERLITE™ Ion Exchange Resins** can help.



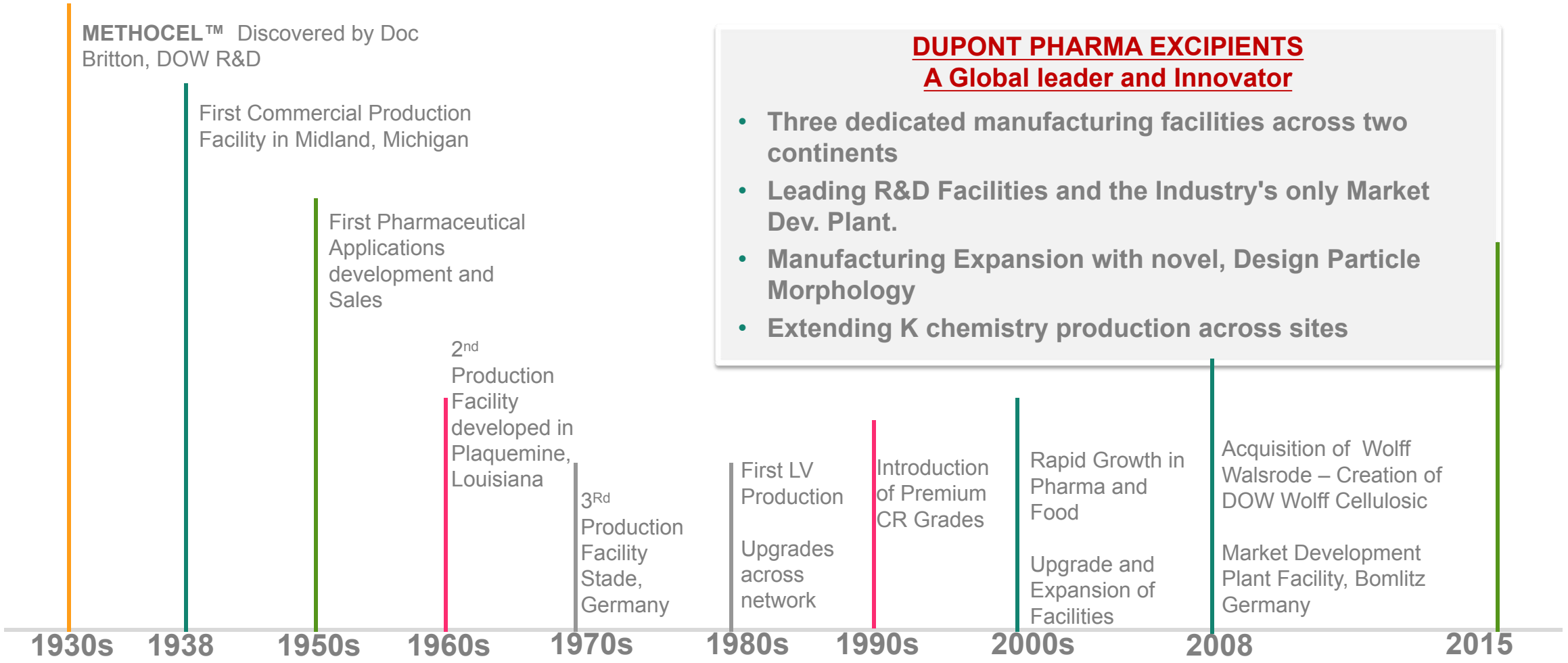
AMBERLITE™ Ion Exchange Resin is ingested and as it passes harmlessly through the body it collects potassium while simultaneously releasing harmless calcium or sodium ions. The result is a unique, safe and effective way to help patients facing elevated potassium levels.

DUPONT™

METHOCEL™: 长达80年的在各类型配方中的应用历史

Applications	The METHOCEL™ Benefits
Vegetable Capsules 胶囊 	METHOCEL™ offers customers a non-animal derived (vegetarian) and sustainable material without sacrificing desired release performance. Additionally, HPMC based capsules provide good mechanical properties enabling a high quality, robust end capsule product. .
Controlled Release Hydr Matrix 控释亲水骨架 	METHOCEL™ Polymers are specially designed to deliver consistent drug-release performance. Their varying molecular weights and chemical substitutions are ideal features to modify and control the release of APIs.
Tablet Coating 片剂包衣 	METHOCEL™ products offer formulators a micro-thin glossy coating that is printable, hypo-allergenic, non-tacky, and compatible with pigments and dyes. METHOCEL™ VLV Premium tablet coatings are also designed to be easily swallowed and minimize overall cycle coating time.
Granulation/Binders 造粒/粘结剂（速释） 	METHOCEL™ Premium LV products offer important binding and adhesive properties during the granulation step of the manufacturing process for immediate release tablets.
Liquids/Topical 液体/局部用药 	The wide variety of viscosity grades of METHOCEL™ helps formulators achieve a broad spectrum of solution viscosities with little risk of drug-polymer interactions. They can be used as a thickening agent to help prevent or minimize suspension settling without altering taste or mouth feel.

METHOCEL™：长达80年的HPMC优良性能证明



DUPONT PHARMA EXCIPIENTS
A Global leader and Innovator

- **Three dedicated manufacturing facilities across two continents**
- **Leading R&D Facilities and the Industry's only Market Dev. Plant.**
- **Manufacturing Expansion with novel, Design Particle Morphology**
- **Extending K chemistry production across sites**

Peace of mind from a proven, established brand!

DUPONT™

ETHOCEL™: 多颗粒和很多其他制药应用的聚合物选择

Applications	The ETHOCEL™ Benefits
Extended release 缓释 multiparticulate coatings 多粒子包衣 	Strong films with good adhesion, providing a versatile diffusion barrier
Micro-encapsulation of actives活性成分微囊化 	Durable rate-modifying barriers which can be compressed without fracturing
Controlled release 控释 hydrophobic matrices 疏水骨架 	Release profile modification of an inert matrix without swelling or dissolving
Solvent and extrusion Granulation溶剂和挤压造粒 	Enables production of strong, low-friability tablets with wide range of dissolution rates.
Tablet binding片剂粘结 	Versatility in drug release rates as well as improvements in processing conditions, producing hard tablets with very low friability.
Taste-masking of bitter APIs掩味 	The water-insoluble nature of ETHOCEL™ prevents immediate dissolution upon ingestion

POLYOX™：高度可膨胀的聚合物，提供不同给药解决方案

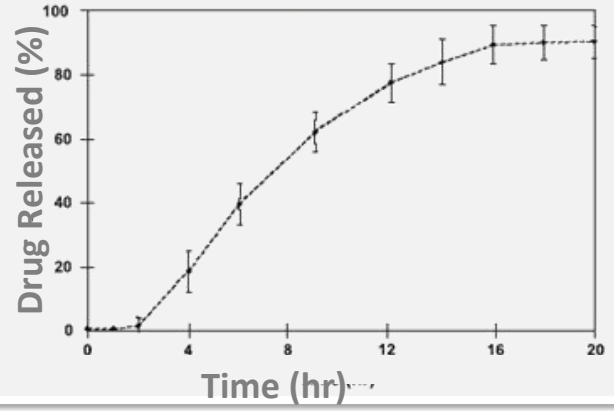
Applications	The POLYOX™ Benefits
Osmotic Pump Technology 渗透泵技术 	POLYOX is the No. 1 choice for osmotic formulations Allows for zero-order release and clinical robustness
Matrix Tablets骨架片 	POLYOX provides a viable alternative to be used in matrices due to its high swelling characteristics
Abuse Deterrence 防止药物滥用 	Its thermoplasticity and gelling behavior make it a successful candidate in discouraging abuse
Gastro-Retentive Systems 胃内滞留 	Fast hydration feature of POLYOX allows this technology to work in keeping the dosage form in the stomach
Mucoadhesive Delivery Systems 粘膜粘附 	Flexibility to penetrate mucus membrane and hydrogen bonding groups make it effective for buccal and oral care
Hot Melt Extrusion 热熔挤出 	Highly thermoplastic in nature, POLYOX extrudes very well

18

POLYOX™：独特的溶胀性能，渗透系统和其他需要长时间释放的配方的理想选择

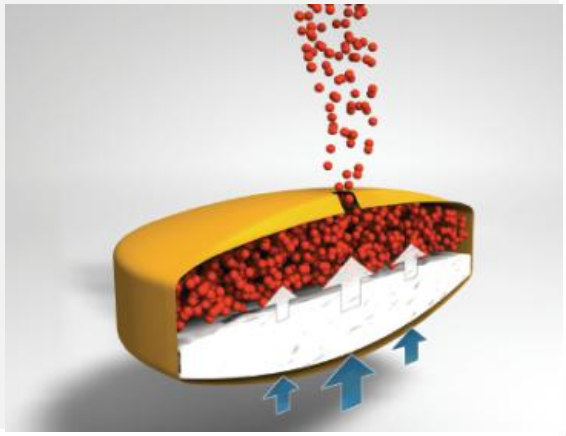
- ✓ Possible zero order release
- ✓ Good in vivo-in vitro correlation
- ✓ Controlled drug delivery for up to 24 hours
- ✓ Can be used with large molecular size APIs

Dissolution Curve with Zero Release Profile



The high molecular weight of this polymer allows for outstanding swelling power…

- POLYOX is **the recommended polymer** for high swelling applications like Osmotic Pump Technology
- Osmotic formulations carry many advantages:
  - ✓ Clinical robustness
  - ✓ Constant, prolonged delivery within the body, up to 24 hours
  - ✓ Zero order release and customized release profiles
  - ✓ Less impact of variables like gastrointestinal motility or food effects



DUPONT™

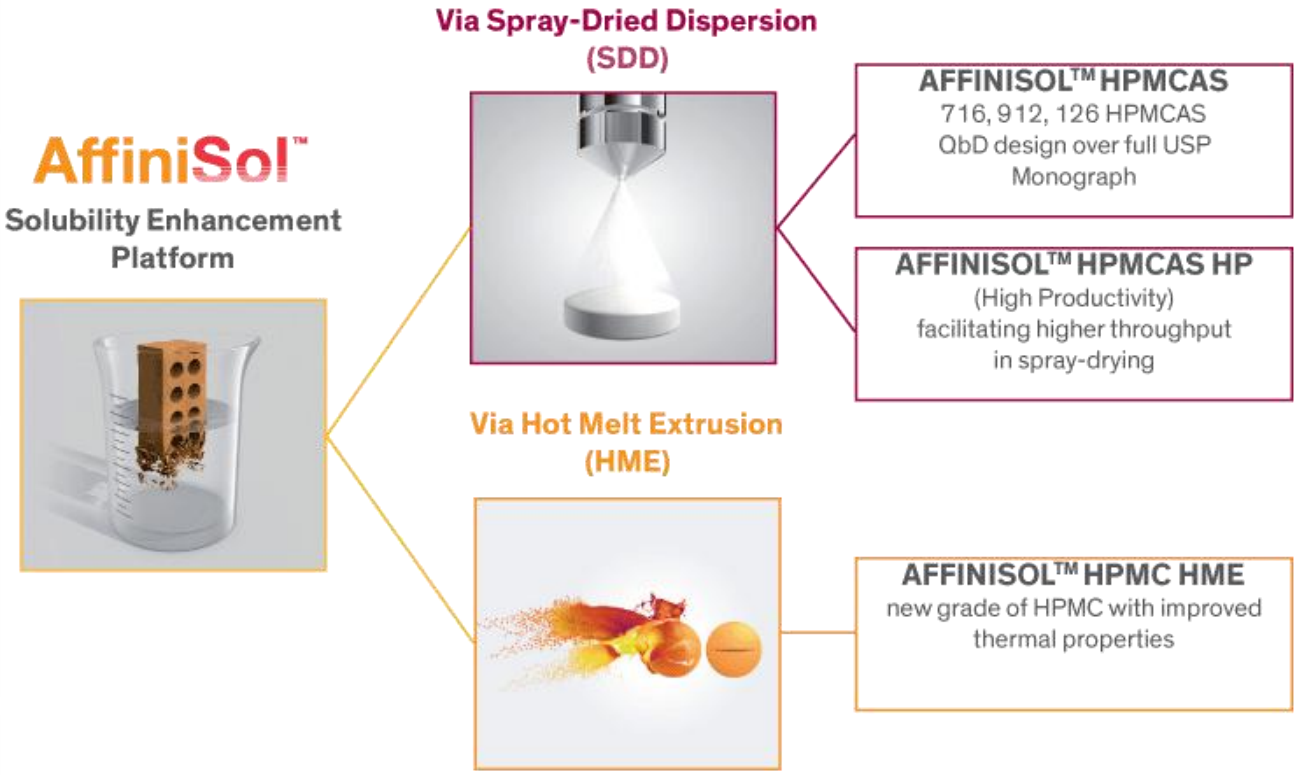
19

AMBERLITE™ & DUOLITE™ 离子交换树脂：更多药品制剂配方的选择

Applications	The AMBERLITE™ & DUOLITE™ Benefits
Extended Release **缓释** 	They offer a distinctive solution to control the release of APIs in liquid suspensions. They can be used in combination with other excipients to provide targeted drug release profiles.
Taste Masking **掩味** 	They prevent bitter active ingredients from releasing in the mouth, leading to increased patient compliance.
Abuse Deterrence **防止药物滥用** 	They bind the API and prevent immediate release even when the formulation is crushed, maintaining the intended rate of absorption.
Hypercholesterolemia **高胆固醇** 	Cholestyramine (**DUOLITE™ AP143**) can help lower a patient's net cholesterol levels by sequestering unwanted bile acids and preventing them from being re-absorbed by the body.
Hyperkalemia **高血钾** 	As Sodium/Calcium Polystyrene Sulfonate (**AMBERLITE™ IRP69 / AMBERLITE™ IRP69Ca)** passes through the body it collects excess of potassium while simultaneously releasing harmless sodium and/or calcium ions.

AFFINISOL™, a breakthrough platform for solubility enhancement

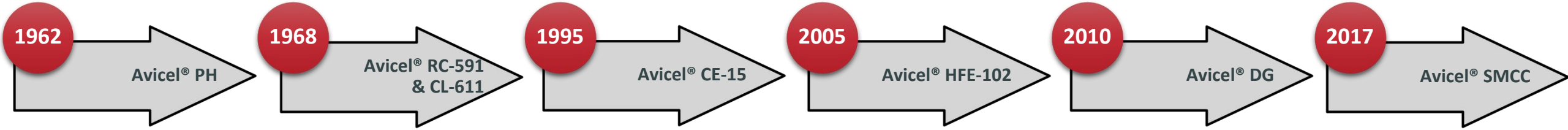
AFFINISOL™	• AFFINISOL™ HPMCAS 716 G, 912 G, 126 G for SDD • AFFINISOL™ HPMC & HPMCAS High Productivity for SDD • AFFINISOL™ HPMC for HME
FEATURES	• Standard and differentiated HPMCAS chemistry • Tailorable Acetate / Succinate content • Full QbD & scale-up support • Extrudable HPMC
BENEFITS	• Formulation of poorly soluble APIs • SDD process optimization • Innovation in HME capability, IR & CR profile flexibility • Compelling science-based dossiers for regulatory approvals
VALUE	• New drug delivery solutions for poorly soluble APIs



DUPONT™

Avicel® - 多功能赋形剂解决配方的关键需求

Continuous improvement of Avicel® offering via co-processing



Colloidal Avicel® RC-591 and CL-611 *Co-processed MCC / CMC (11% respectively 15%)*	**Avicel® CE-15** *Co-processed: MCC / guar gum (15%)*	**Avicel® HFE** *Co-processed: MCC / mannitol (10%)*	**Avicel® DG** *Co-processed: MCC / dicalcium phosphate (25%)*	**Avicel® SMCC** *Co-processed: MCC / colloidal silicon dioxide (2%)*
Functional synergy • Improved suspension power • Higher thixotropy and gel strength • Improved stabilization • Provide consistent pellet property when used as a granulation fluid in E/S process	**Functional synergy** • Increased sensory characteristics • Lessens grittiness • Reduces tooth packing • Minimizes chalkiness • Decreases friability • Imparts creamier mouthfeel • Improved compactibility	**Functional synergy** • Lower lubricant sensitivity • Improved compactibility compared to MCC • Improved flow • Improved texture in chewable tablets	**Functional synergy** • Superior compactibility for direct compression processes • Maintain re-compactibility after roller compaction process • Improved flow	**Functional benefits** • Optimum flow • Superior compactibility • Allows for robust formulations with fewer ingredients • Reduced mfg. costs • Solve complex formulation problems

DUPONT™

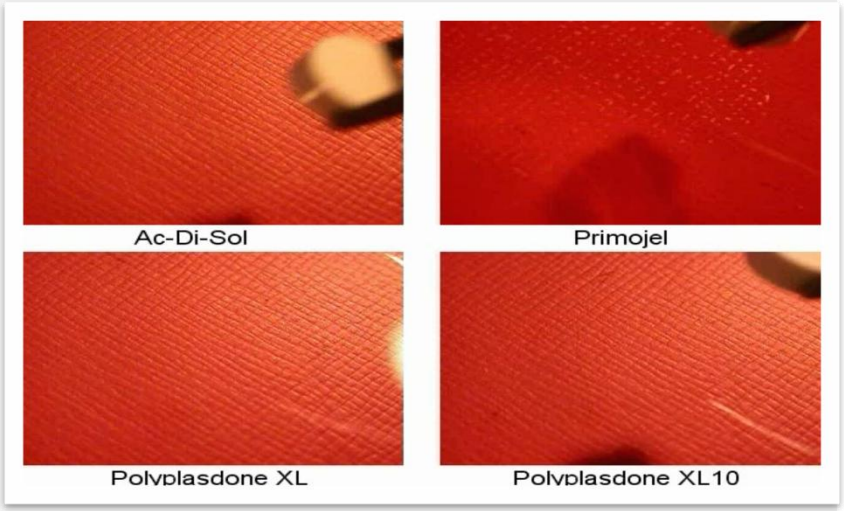
Ac-Di-Sol®：长达30多年的优良品质保证

Ac-Di-Sol® offers super disintegrating properties with

- Superior purity
- Superior water uptake and absorption capacity with low polymer level
- Low moisture and water soluble
- Stable quality and supply

- Superior performance at low concentration of 2-3 % for various process platform
- NON GMO certification for nutraceutical application

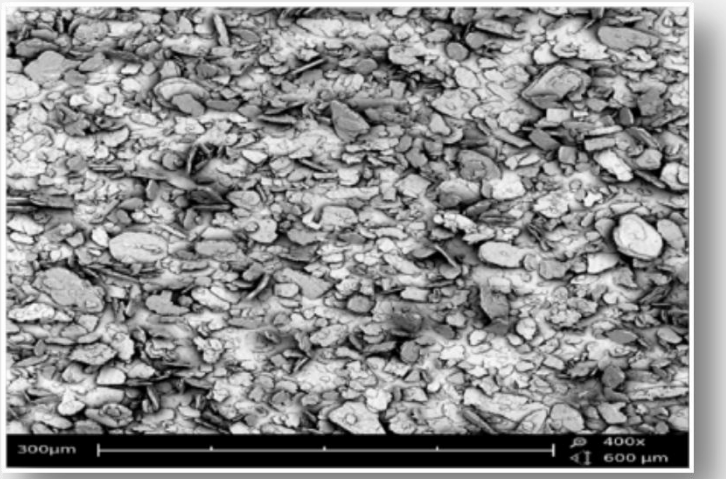
- Ac-Di-Sol SD711: **Premium product with superior functionality**
- Ac-Di-Sol SDW 802:**Non-GMO product from wood pulp**



Alubra®：不溶性API的润滑剂选择

Alubra® is less hydrophobic thus ideal for insoluble API formulation. It Eliminates the risk of over lubrication and blending and improves tablet tensile strength with

- Optimized surface area
- Narrow particle size distribution
- Optimized morphology



- Effective at 0.5-1% concentration in various processing technologies
- Feasibility to use in continuous manufacturing

- Alubra® PG 100: Recommended use level 0.5 -1%

SeaGel®：植物软胶囊，具有非常好的热稳定性和化学稳定性

- SeaGel is patented technology to make vegetable soft capsules. It is eco-friendly and entirely sustainable. It is propriety carrageenan grade targeted for maximum strength and flexibility for vegetable soft capsules. It is a patented soft gel process to achieve competitive yield than gelatin and provide better thermostability. It can be customized and it is colorless.

- Vegetarian clean label soft gel capsule offering
- Significant improved thermal stability
- 50% production efficiency improvement vs. other functional polymers
- Technology roadmap for successful feasibility studies and technical transfer to production facility
- Equipment engineering support for facility modification

- SeaGel® CAP 101 non GMO for pharmaceuticals
- SeaGel® CAP 201/202 of premix blends for easy operation for nutra
- SeaGel® CAP 203 non GMO for nutra

Aquacoat®: 水分散以保证药物释放

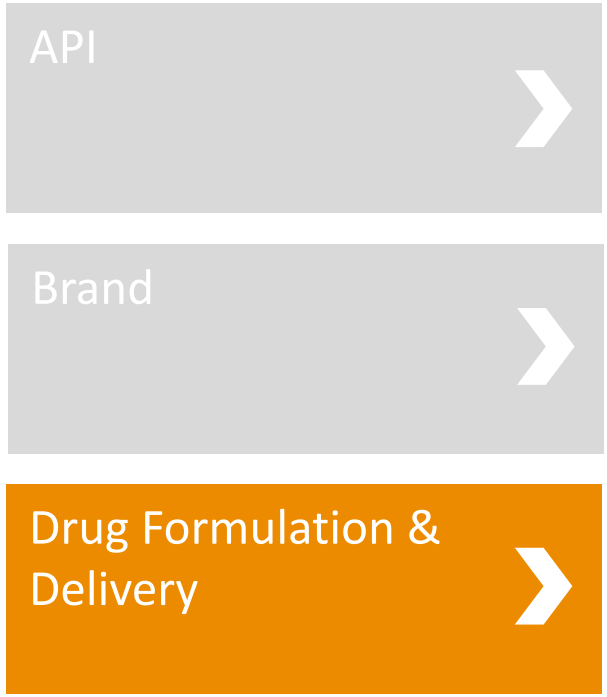
Aquacoat® is DuPont's brands for both aqueous dispersion of ethyl cellulose and aqueous dispersion of cellulose acetate phthalate. It provides good film properties to achieve the pH independent and enteric release.

- Aquacoat ARC: Excipient solution for alcohol dose dumping
- Aquacoat ECS: Easy cure system, formulation approach to eliminate curing

- Aquacoat ECD: Aqueous dispersion of Ethyl cellulose (pH independent coating)
- Aquacoat CPD: Aqueous dispersion of cellulose acetate Phthalate (pH dependent enteric coating)

DUPONT™

Drug Formulation & Delivery

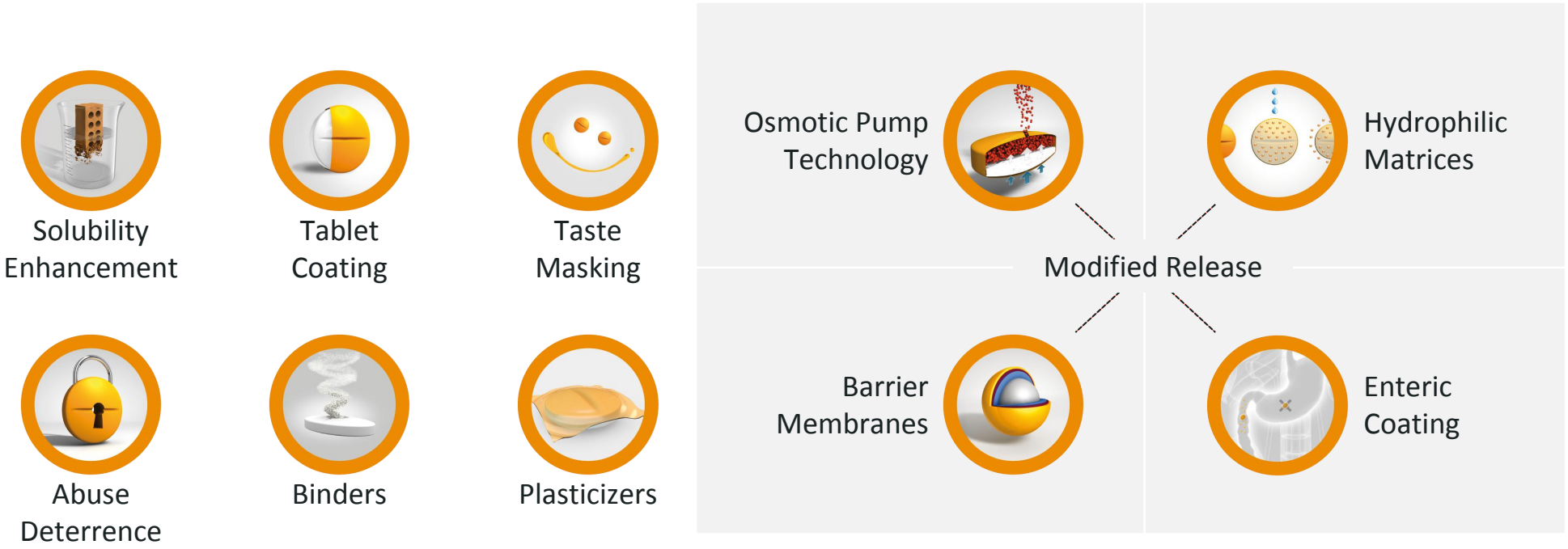


Tablets 片剂	Capsules 胶囊	Oral Liquid Dosages 口服液体制剂
Semi Solid Dosage 半固态制剂	Other Delivery Forms 其他给药方式	Processing Technology 加工工艺改善

Drug Formulation & Delivery - Tablets

About two-thirds of all prescription medication is dispensed in solid dosage forms, and half of these are compressed tablets. Patients like them because they can be sure of dose accuracy, they are compact, portable, bland in taste, and easy to take. Manufacturers like them because they are simple, economic, stable and convenient to handle.

Yet, while they look simple, tablets are really complex mixtures of crystalline or granular materials, combined with binders, modified release polymers, solubility enhancement, coating and taste-masking technology. DuPont offers solutions for these technically challenging needs.



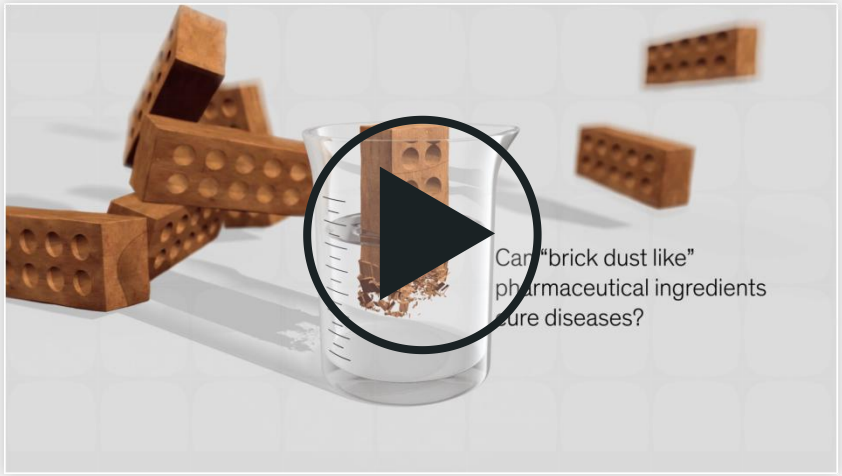
Drug Formulation & Delivery - Tablets

Solubility Enhancement

Need help to bring insoluble APIs to the market?
Solving the Insoluble with DuPont!

Our **AFFINISOL™ polymers** are uniquely tailored to address the solubilization performance requirements of your APIs, whether you have chosen to formulate via Spray-Dried Dispersion or Hot Melt Extrusion.

- Commercial AFFINISOL™ HPMCAS, QbD sample sets and polymer tailoring offered with expanded acetyl & succinyl levels;
- NEW AFFINISOL™ HPMCAS and HPMC High Productivity facilitating higher throughput in spray-drying;
- NEW AFFINISOL™ HPMC HME with improved thermal properties, designed for hot melt extrusion.
- Samples of our new developmental grades are available for evaluation in your drug project/platform.



You've invested a lot into your API.
Why not get the most out of it?

Drug Formulation & Delivery - Tablets

Abuse Deterrence

Abuse Deterrence

Whether intentional or unintentional, the abuse of certain drugs can be life threatening. One of the best known types of deliberate drug abuse is that of opiates. Last year, the FDA ruled that narcotic products without the use of abuse deterrence technologies will no longer be approved in the USA.

DuPont offers a broad range of chemistry for abuse deterrence applications. **POLYOX™,** a high molecular Polyethylene Oxide, is the leading, recognized technology in this space providing tamper resistant properties. It makes tablets extra tough to crush, or help manufacturers create a formula that can turn a pill's powdery contents into a jelly-like substance when water is added to make an injectable solution, not allowing abusers to make an injectable solution. In addition, ion exchange resins, such as **AMBERLITE™ IRP69** bind the active pharmaceutical ingredient (API) and prevent immediate release even when the formulation is crushed, maintaining the intended rate of absorption.

Drug Formulation & Delivery - Capsules

Non-Gelatin Options (Vegetarian)

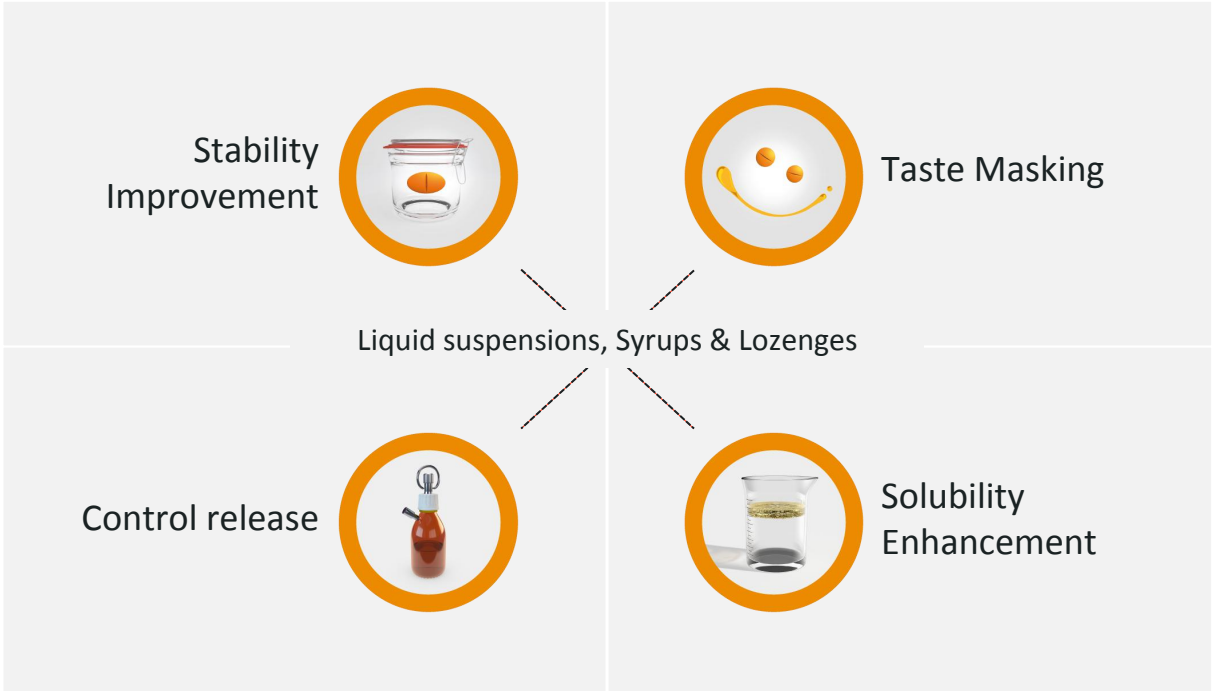
Non-Gelatin Options (Vegetarian)

METHOCEL™ solutions, derived from wood pulp, are increasingly preferred materials over traditional Gelatin (animal) based capsules. METHOCEL™ offers customers a non-animal derived (vegetarian) and sustainable material without sacrificing desired release performance. Additionally, HPMC based capsules provide good mechanical properties enabling a high quality, robust end capsule product.

SeaGel® solutions, derived from seaweed enable you to use the technology in-house to make vegetable soft capsules. SeaGel® is easily adaptable to existing gelatin operation, among others, so it often requires minimum capital investment and equipment to implement.

Drug Formulation & Delivery - Liquid Dosage

DuPont technologies enable the creation of liquid pharmaceutical preparations tailored for specific uses. Better drug design and delivery options will help improve the chances that patients will willingly take their medications as prescribed. DuPont provides thickeners, binders, film-formers products that help with water retention for a broad number of liquid formulations.



Nasal

Drug Formulation & Delivery - Semi Solid Dosage

DuPont technologies help control the release of active ingredients and improve stability of semi-solid dosage forms. They are also used as rheology modifiers to improve emulsion stability, suspend solids, lubricate and retain moisture. Finally, DuPont offers coating solutions to provide elasticity and lubricity of suppositories.

Topical Applications

Rectal Applications

Gums

Drug Formulation & Delivery - Other Delivery Forms

Mucosal Bio-Adhesives

POLYOX™ offers good mucosal bio-adhesives

Owing to the ease of the administration, the oral cavity is an attractive site for the delivery of drugs. Through this route it is possible to realize mucosal (local effect) and trans mucosal (systemic effect) drug administration.

The main obstacles that drugs meet when administered via the buccal route derive from the limited absorption area and the barrier properties of the mucosa. DuPont offers solutions to help overcome those obstacles.

Drug Formulation & Delivery - Processing Technology

Looking to improve manufacturing efficiency?

There is an industry-wide shift from batch to continuous processing to improve efficiency and reduce production costs.

- **Direct compression** is the ideal continuous processing option because all granulation steps would be eliminated, further simplifying the manufacturing process and avoiding degradation of moisture-labile or heat-sensitive APIs.
- **Hot melt extrusion** is gaining popularity in pharma for its continuous processing and the advantages it offers for the formulation of APIs difficult to process and deliver.

Explore DuPont' Solutions including newly designed polymers.

Direct Compression

Hot Melt Extrusion

目　录

登记号	品种名称	企业名称	企业地址	产品来源	包装规格	规格	更新日期	与制剂共同审评审批结果
F20180000913	乙基纤维素	DDP Specialty Electronic Materials US, Inc.;DDP Specialty Electronic Materials US, Inc.:罗门哈斯电子材料（上海）有限公司;	400 Arcola Road, Collegeville, PA 19426, United States of America;Building 298, Midland, MI, 48667, United States:中国（上海）自由贸易试验区富特西一路139号1110室;	进口	22.68kg：聚乙烯内衬纸袋：每袋22.68kg。25kg：聚乙烯内衬纸桶：每桶25公斤。20kg：聚乙烯内衬纸桶：每桶20kg。		2019-08-26	I
F20180001540	醋酸羟丙甲纤维素琥珀酸酯	DDP Specialty Products Germany GmbH & Co. KG;Cambrex Karlskoga AB:罗门哈斯电子材料（上海）有限公司;	August-Wolff-Straβe 13, 29699 Bomlitz, Germany;Bjorkborn Industriomrade, Kalskoga, 69185, Sweden:中国（上海）自由贸易试验区富特西一路139号1110室;	进口	25kg：内衬为聚乙烯（PE）袋的塑料桶：每桶25kg		2019-03-07	I
F20180000502	羟丙甲纤维素（LV）	陶氏化学公司:陶氏化学公司:罗门哈斯电子材料（上海）有限公司;	2030 Dow Center, Midland, MI 48674 USA;21255 Louisiana Highway 1, Plaquemine, Louisiana 70765, USA:中国（上海）自由贸易试验区富特西一路139号1110室;	进口	25kg：聚乙烯内衬纤维桶：每桶25kg。		2018-11-08	A
F20180000422	羟丙甲纤维素（VLV）	DDP Specialty Products Germany GmbH & Co. KG;DDP Specialty Products Germany GmbH & Co. KG:罗门哈斯电子材料（上海）有限公司;	August-Wolff-Straβe 13, 29699 Bomlitz, Germany;August-Wolff-Straβe 13, 29699 Bomlitz, Germany:中国（上海）自由贸易试验区富特西一路139号1110室;	进口	20kg：聚乙烯内衬纸箱：每箱20kg。		2019-04-08	A
F20170000238	羟丙甲纤维素	DDP Specialty Electronic Materials US, Inc.;DDP Specialty Electronic Materials US, Inc.:罗门哈斯电子材料（上海）有限公司;	400 Arcola Road, Collegeville, PA 19426, United States of America;Building 1131, Midland, MI, 48667, United States:中国（上海）自由贸易试验区富特西一路139号1110室;	进口	25kg：聚乙烯内衬纤维桶：每桶25kg。243kg：聚乙烯内衬牛皮纸袋：每袋243kg。	E4M, E10M, F4M, K4M, K15M, K100M, K100, K200M	2019-09-09	I
F20170000039	聚氧乙烯	Specialty Products US, LLC;Specialty Products US, LLC:罗门哈斯电子材料（上海）有限公司;	2211 H. H. Dow Way, Midland Michigan 48674, United States of America;Route 25, Institute, WV, United States:中国（上海）自由贸易试验区富特西一路139号1110室;	进口	63.50 Kg/桶		2019-09-19	I

登记号	品种名称	企业名称	企业地址	产品来源	包装规格	规格	更新日期	与制剂共同审评审批结果
F20180000686	微晶纤维素	DuPont Nutrition USA, Inc.;FMC International Health and Nutrition;杜邦（上海）实业有限公司;	974 Centre Road, Wilmington, DE 19805;Wallingstown, Little Island, Co. Cork, Ireland;中国（上海）自由贸易试验区蔡伦路600号8幢5楼北14单元;	进口	（1）20kg/箱；（2）50kg/桶	（1）PH102；（2）PH105；（3）PH112；（4）PH113；（5）PH301；（6）PH302	2019-08-26	I
F20180000429	交联羧甲基纤维素钠	DuPont Nutrition USA, Inc.;FMC International Health and Nutrition;杜邦（上海）实业有限公司;	974 Centre Road, Wilmington, DE 19805;Wallingstown, Little Island, Co. Cork, Ireland;中国（上海）自由贸易试验区蔡伦路600号8幢5楼北14单元;	进口	50kg/桶		2018-11-26	A
F20180000430	微晶纤维素	DuPont Nutrition USA, Inc.;FMC International Health and Nutrition;杜邦（上海）实业有限公司;	974 Centre Road, Wilmington, DE 19805;Wallingstown, Little Island, Co. Cork, Ireland;中国（上海）自由贸易试验区蔡伦路600号8幢5楼北14单元;	进口	20kg/箱，50kg/桶		2018-11-26	I
F20180000053	交联羧甲基纤维素钠	DuPont Nutrition USA, Inc.;DuPont Nutrition USA, Inc.;杜邦（上海）实业有限公司;	974 Centre Road, Wilmington, DE 19805;1301 Ogletown Road Newark, DE 19711;中国（上海）自由贸易试验区蔡伦路600号8幢5楼北14单元;	进口	50kg：聚乙烯袋/纸板桶：每桶50kg		2018-10-24	A
F20180000179	微晶纤维素	DuPont Nutrition USA, Inc.;DuPont Nutrition USA, Inc.;杜邦（上海）实业有限公司;	974 Centre Road, Wilmington, DE 19805;1301 Ogletown Road Newark, DE 19711;中国（上海）自由贸易试验区蔡伦路600号8幢5楼北14单元;	进口	20kg/箱，50kg/桶		2018-11-26	A

法人变更

所提交资料:

1. 产品变更申请;
2. 登记表（原件、Word电子文件、原件扫描件Word电子文件）。

所附证明材料：

1. 产品所有权人变更与生产企业名称变更说明文件并附翻译文件;
2. 生产企业合法生产与产品所有权人总部地址证明文件及大使馆认证并附翻译文件;
3. 变更后持证商授权代理机构的授权信并附翻译文件。

联系人信息变更

所提交资料:

1. 产品变更申请;
2. 登记表（原件、Word电子文件、原件扫描件Word电子文件）。

所附证明材料：

1. 持证商授权代理机构的授权信并附翻译文件;
2. 代理机构营业执照复印件。

小结

1. 原辅包发生变更时原辅包登记人应主动开展研究，并及时通知相关药品制剂生产企业（药品上市许可持有人），并及时更新登记资料，并在年报中体现。但相应变更申请所需资料和变更流程还未完全明确。目前变更申请可正常进行。
2. 药品关联审评审批制度，是基于药品制剂生命周期全链条的风险管理。
3. 药品关联审评审批制度对于药品制剂生产企业和原辅包生产企业均提出了更高的要求。上下游企业需携手前进、同舟共济。
4. 新制度是挑战也是机遇，有助于行业健康发展。
5. 行业需紧密配合药监部门做好法规研究制定工作，确保法规可落地，且有助于行业发展。