BIORICH GROUP

MAY
05
2026

BIORICH
INSIGHTS

PHARMACEUTICAL INGREDIENTS
INNOVATION & HEALTH SOLUTIONS

QUALITY INGREDIENTS IMPROVED RESULTS

High-quality excipients that enhance innovation, ensure quality, and improve patient outcomes.

SCIENCE BACKED
Evidence-based ingredients

INNOVATION-FOCUSED
Innovative solutions for the future

QUALITY GUARANTEED
Reliable global standards

138 Robinson Road, #24-01
Oxley Tower, Singapore 068906

www.biorichgroup.com

+84 834 560 500

director@biorichgroup.com

SCIENCE FOR HEALTH AND QUALITY OF LIFE

BIORICH GROUP We are a company engaged in the supply of raw materials and biotechnology solutions across multiple industries. Our product offerings include a wide array of items such as active pharmaceutical ingredients (APIs), excipients, enzymes, vitamins, and other biological components, catering to the pharmaceutical, nutrition, healthcare, cosmetics, agriculture, and environmental sectors.

HIGH-QUALITY

We are committed to maintaining strict quality and safety standards for all products.

SCIENCE-BASED SOLUTION

Driven by science and innovation to support pharmaceutical, nutraceutical, and cosmetic formulations for businesses.

YOUR RELIABLE PARTNER

Building sustainable value through superior and reliable raw material products.

TABLET OF CONTENTS

SCIENCE

Research and innovation are the core foundation

QUALITY

Commitment to global quality standards

GLOBAL

Establishing reliable partnerships worldwide

SUSTAINABLE

Collaborating for health and sustainable future

TYPES OF SUPERDISINTEGRANTS

MECHANISM AND APPLICATIONS IN PHARMACEUTICAL FORMULATION

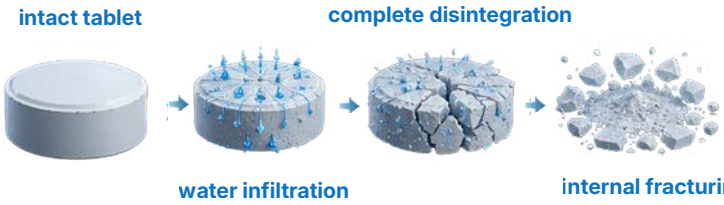
www.biorichgroup.com | +84 834 560 500 | director@biorichgroup.com

1 GENERAL OVERVIEW OF SUPERDISINTEGRANTS

Superdisintegrants are essential components in solid dosage forms, playing important roles in:

- Improving tablet disintegration: helping break down the tablet structure upon contact with gastrointestinal fluids
- Enhancing dissolution, solubility, and bioavailability of active ingredients: particularly for poorly soluble APIs

To effectively perform these functions, superdisintegrants should possess the following properties, depending on the dosage form, active ingredient characteristics, and manufacturing process used:



- Rapid disintegration performance at low use concentrations
- Good flowability (especially for tablets manufactured by direct compression)
- Good compressibility, enabling the production of tablets with high hardness and low friability
- Good wettability toward the dissolution medium Compatibility with ionic compounds
- No adverse impact on the drug release profile
- Maintains water uptake and swelling properties across different pH conditions

2 MECHANISM OF TABLET DISINTEGRATION OF SUPERDISINTEGRANTS

Superdisintegrants generally function through three main mechanisms: swelling, wicking, and shape recovery.

01 SWELLING

When the excipient interacts with water, it expands and disrupts the tablet's structure from within

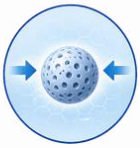
Appropriate when the tablets include components that are not soluble in water (MCC, DCP, inorganic salts, etc.)

02 WICKING

Excipient facilitating capillary water penetration and internal tablet disintegration

Appropriate when the tablets include components that dissolve effectively in water (lactose, mannitol, sugar, polyols)

03 RECOVERY



Upon water contact, excipient particles tend to recover their pre-compression shape, thereby disrupting tablet structure and promoting disintegration

Suitable for most applications, particularly for tablets with poor disintegration properties

Most modern superdisintegrants combine the above mechanisms to varying degrees

3 COMMON SUPERDISINTEGRANTS

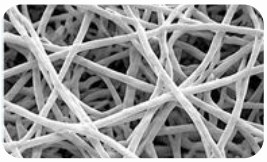
A SODIUM STARCH GLYCOLATE

- High swelling capacity, particularly potato starch-based grades (up to 200× original volume)
- Suitable for poorly water-soluble APIs
- Gel formation upon swelling; usage above 8% may affect tablet disintegration and drug release
- Recommended use level: **2–8%**

B CROSCARMELLOSE SODIUM

- Combines both swelling and wicking mechanisms
- Suitable for tablets containing either water-soluble or water-insoluble ingredients
- Recommended use level: **1–4%**

C CROSPOVIDONE (PVPP)



- Triple-action disintegration mechanism
- Non-ionic, low incompatibility risk
- No gel formation up to 10%
- pH-independent water uptake
- Available in XL & XL-10 grades
- Recommended use level: **1–4%**

D POLACRILLIN POTASSIUM

- Triple-action disintegration: swelling, wicking, and shape recovery
- High swelling capacity without gel formation
- Non-ionic superdisintegrant with low incompatibility risk toward ionic APIs
- Disintegrates into fine particles, enhancing dissolution and bioavailability of APIs

POVIDONE (PVP)

Multifunctional excipients in contemporary pharmaceutical formulation

Povidone (polyvinylpyrrolidone, PVP) is a synthetic compound derived from 1-vinyl-2-pyrrolidone ($C_8H_8NO_3$). It is classified as a non-ionized polymer and is extensively utilized in the pharmaceutical industry for its effective binding capabilities, ability to enhance solubility, and film-forming characteristics.

1 GENERAL OVERVIEW OF THE POVIDONE FAMILY

Product range	Value of K	# Molecular Weight
Povidone K12	10.2-13.8	3,000-7,000
Povidone K15	12.75-17.25	8,000-12,000
Povidone K17	15.3-18.36	10,000-16,000
Povidone K25	22.5-27	30,000-40,000
Povidone K30	27-32.4	45,000-58,000
Povidone K60	54-64.8	270,000-400,000
Povidone K90	81-97.2	1,000,000-1,500,000
Povidone VA 64	Also known as Copovidone, a copolymer composed of 1-vinyl-2-pyrrolidinone (C6H9NO) and vinyl acetate ($C_4H_6O_2$)	
Povidone I	Polyvinylpyrrolidone-iodine complex	

Povidone, also known as PVP (polyvinylpyrrolidone), is the polymerization product of 1-vinyl-2-pyrrolidinone (C_6H_9NO). This non-ionized polymer is extensively utilized in the pharmaceutical industry. Povidone is available in multiple forms, each with varying molecular weights and viscosities, which are defined by its K value.

2 APPLICATIONS OF POVIDONE

Povidone is commonly utilized in a range of dosage forms, including tablets, soft capsules, sustained-release tablets, suspensions, syrups, eye drops and topical drugs.

Tablets

- Used as a binder in tablet formulations, different grades of Povidone offer versatile applications across various manufacturing processes, including wet & dry granulation, direct compression
- An effective binder for high drug-load tablet formulations, helping improve the compressibility of powder blends
- Balances binding capacity, tablet hardness, and disintegration performance, enabling high tablet hardness and low friability while maintaining optimal disintegration time and API dissolution

Film-coated tablets

Component in film-coating solutions, helping reduce the viscosity of HPMC without affecting film-forming properties or the moisture permeability of the film coating

Solid dispersion system

Enhance solubility and reduce recrystallization of the APIs

Sustained-release tablets

A matrix-forming agent for controlled drug release

Topical treatments and liquid formulations

(suspension, syrup, ophthalmic solution, nasal solution, injection)

- Improves the solubility of poorly soluble APIs
- Thickener and suspending agent for liquid and topical drugs
- Taste masking for APIs in oral liquid dosage forms by creating non-bitter complexes
- Prevents the recrystallization of the APIs, thereby stabilizing the APIs in liquid dosage forms and softgel capsules

3 COMMON PRODUCT LINES OF POVIDONE

Povidone K25/K30	Povidone K90	Povidone K17	Povidone VA 64
• The most widely used binder • Suitable for wet granulation and direct compression process • Used as a component in film-coating solutions • Forms taste-masking complexes with certain APIs such as Paracetamol and Guaifenesin • Applied in solid dispersion systems	• Used as a matrix-forming agent for sustained-release tablet • Functions as a binder for formulations with poor compressibility or high drug loading	• Forms low-viscosity solutions, minimizing discomfort during ophthalmic or nasal administration • Its low molecular weight reduces the risk of accumulation in the body, providing improved safety for parenteral formulations	• Binder for the dry granulation process, appropriate for moisture-sensitive APIs.
			

In addition to being a widely used binder, Povidone is also broadly applied in various roles across different dosage forms. The selection of the appropriate Povidone grade and concentration should be carefully considered based on excipient viscosity, API properties, manufacturing process, and the desired characteristics of the final product.

POLYVINYL ALCOHOL (PVA)

EFFECTIVENESS OF FILM COATING

Moisture-resistant

POLYVINYL ALCOHOL (PVA) AND ITS EFFECTIVENESS IN MOISTURE BARRIER FILM COATING TABLETS

1 GENERAL OVERVIEW OF THE FILM COATED TABLET

Tablets are solid pharmaceutical dosage forms with defined shapes, each containing an accurate amount of one or more APIs. They are produced by compressing powder or granules, with or without excipients, using a tablet compression machine. Tablets are among the most widely used dosage forms, accounting for nearly two-thirds of pharmaceutical products available on the market. Their popularity is mainly attributed to their suitability for formulation development, manufacturing, transportation, storage, and patient convenience.

Film coating, also known as thin-film coating, is the process of applying a very thin layer of coating material onto the surface of tablet cores. The composition of a film-coating layer typically includes film-forming agents (polymers), solvents, plasticizers, opacifiers, colorants, and other excipients depending on the intended purpose.

Film coatings are applied to solid dosage forms for various purposes, including maintaining the physical and chemical integrity of APIs. One of the key functions is enhancing drug stability by creating a physical barrier against environmental storage conditions such as light, oxygen, and moisture.

THE FILM COATING PROVIDES SEVERAL KEY ADVANTAGES

PROTECT

Protection against moisture, light, oxygen, and environmental factors

STABLE

Maintains the physical and chemical integrity of the API

CONVENIENT

Conceals odors, easy to ingest, improves appearance

THE ROLE OF POLYMERS IN MOISTURE-BARRIER FILM COATINGS

Polymers are the primary components responsible for the structure and functionality of film coatings. Forming a moisture-protective film around solid tablet cores is a common approach to protect hygroscopic active ingredients from exposure to environmental moisture.

The use of moisture-barrier polymer coatings offers several advantages, including rapid manufacturing processes, strong automation potential, favorable mechanical film properties, minimal increase in tablet size or weight, and the flexibility to customize formulations for different coating purposes.

2 SOME COMMONLY USED MOISTURE BARRIER POLYMERS

Depending on their physicochemical properties, different polymers provide varying levels of moisture-barrier protection. In moisture-barrier film coating systems, the type of polymer and its concentration are selected based on the water-resistant properties of the polymer as well as the hygroscopic nature of the active ingredient used.

Below is a summary table of commonly used polymers in moisture-barrier film coatings along with their typical usage levels.

POLYMER CLASSIFICATION TABLE

POLYMER TYPE	COMMONLY USED POLYMERS
Water-soluble polymers	• HPMC (Hydroxypropyl methylcellulose hoặc Hypromellose) • HPC (Hydroxypropyl Cellulose) • PVP (Polyvinyl Pyrrolidone) • PVA (Polyvinyl Alcohol) • PVA–PEG copolymer
Water insoluble polymers	• Polyvinyl acetate • Ammonio methacrylate • EC (Ethyl cellulose)
Enteric polymers	• Shellac • Methacrylic acid copolymer

POLYMER TYPE	USAGE LEVELS IN FILM COATING FORMULATIONS	SOLVENT
HPMC	**2 – 20%**	Ethanol/Water
HPC	**approximately 5%**	Ethanol/Water
PVP	**0,5 – 5%**	Ethanol/Water
PVA	**20 – 55%**	Water

POLYMER USAGE IN MOISTURE BARRIER FILMS

For moisture barrier film coating, film thickness or theoretical weight gain must be experimentally determined to ensure adequate moisture protection performance. Film thickness remains a critical factor influencing the moisture barrier properties of the coating.

The typical weight gain for moisture barrier film coating is approximately 5%.

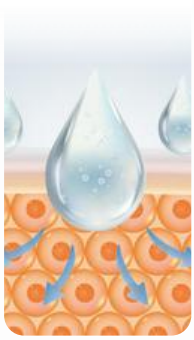
3 PVA AND THE PROCESS OF FORMING A MOISTURE-BARRIER FILM COATING

One of the most commonly used polymers for moisture barrier film coatings is PVA. PVA is a water-soluble synthetic polymer with a molecular weight ranging from 40,000 to 600,000 Daltons. It is considered a non-toxic and thermally stable polymer. The typical concentration of PVA used in coating formulations ranges from 25% to 55% of the total solid content in the coating solution.

THE MOISTURE-RESISTANT MECHANISM OF PVA

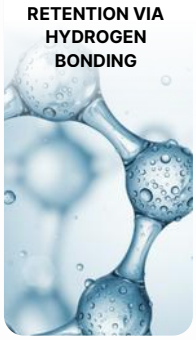
STEP 1

WATER UPTAKE



STEP 2

WATER RETENTION VIA HYDROGEN BONDING



STEP 3

PREVENT WATER PENETRATION

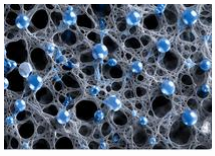
4 A COMPARISON OF PVA WITH VARIOUS OTHER MOISTURE-BARRIER FILM POLYMERS

When comparing the moisture-barrier film-forming performance among three commonly used polymers/polymer blends: HPMC, HPMC combined with HPC, and PVA:

1. HPMC exhibits higher water vapor permeability because water molecules can interact with the hydrophilic groups within the film and act as plasticizers. As a result, moisture can penetrate more deeply into the tablet core.
2. Combining HPMC with HPC helps improve the adhesion of the coating film to the tablet core and reduces the gaps between the core and the coating layer, thereby limiting moisture penetration into the inner tablet core.
3. PVA provides better adhesion and potential advantages in film strength as well as moisture-barrier performance, due to its higher degree of crystallinity compared with HPMC, which helps hinder the diffusion of water molecules.

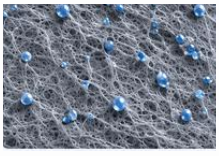
COMPARISON OF MOISTURE-BARRIER COATING UNDER MICROSCOPY

HPMC



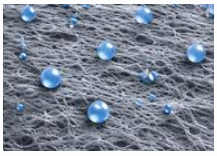
Large pores facilitates moisture ingress

HPMC + HPC



Reduced pores, fewer moisture penetration pathways

PVA



Homogeneous, dense structure, effectively blocking moisture penetration

PVA forms a film coating with an effective moisture-barrier mechanism, making it suitable for protecting moisture-sensitive APIs such as aspirin, clavulanic acid, acetylsalicylic acid, ranitidine, vitamin C, enalapril, and herbal extracts. In addition, PVA film coatings provide good mechanical strength, high stability, and do not adversely affect drug release profiles.

DILUENTS IN DIRECT COMPRESSION

Role, properties, and applications in tablet formulation

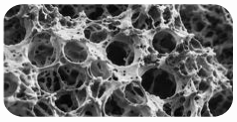
IMPROVE
COMPRESSIBILITY

OPTIMIZE
FLOWABILITY

ENSURE
TABLET PROPERTIES

TYPES OF DILUENTS IN DIRECT COMPRESSION

A MCC

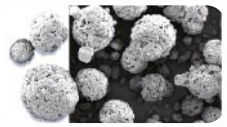




- It is produced through the acid hydrolysis of cellulose under high temperature and pressure
- There are various types differing in particle size and bulk density, among which MCC 102 is the most commonly used grade for direct compression, with a particle size of ~ 130 µm, providing good flowability
- Excellent compressibility with plastic deformation upon compression; therefore, it is also considered a binder that helps to consolidate the components within the powder blend
- Good disintegration due to the inherent water absorption and swelling properties of cellulose
- With low density, MCC can be used at high levels in formulations, thereby improving the overall properties of the powder blend
- Currently, MCC is one of the most widely used and preferred excipients for direct compression

MCC

- VARIATION IN PARTICLE SIZE
- OUTSTANDING COMPRESSIBILITY

B LACTOSE



- A disaccharide composed of galactose and glucose, a by-product of the dairy industry, isolated from cow's milk
- Lactose monohydrate typically has a small particle size, providing good compressibility but poor flowability, making it unsuitable for direct compression
- Spray-dried lactose: the spray-drying process increases particle size, thereby improving flowability for direct compression
- Exhibits brittle fracture behavior, which may increase tablet friability; however, it reduces the sensitivity of the powder blend to lubricants
- Due to the presence of an aldehyde group, lactose can undergo the Maillard reaction with APIs containing amine groups, leading to yellow discoloration of tablets during storage

Lactose can undergo Maillard reaction with APIs containing amine groups, leading to yellow discoloration of tablets during storage

C DCP (DICALCIUM PHOSPHATE)


- Less hygroscopic and stable at room temperature
- Poorer compressibility than MCC but better than lactose
- Exhibits brittle fracture behavior, which may increase tablet friability; however, it reduces sensitivity to lubricants
- Suitable for bilayer tablets, as the formation of new surfaces during compression enhances interlayer bonding during the second compression stage
- Poor solubility, not recommended at high concentrations in tablets containing poorly soluble APIs
- It can also be used as a calcium supplement in formulations

Medium Compressibility | Excellent Flowability | Low Moisture

D PREGELATINIZED STARCH


- Consists of intact starch granules and partially hydrolyzed starch fragments that have been re-aggregated
- Meets the requirements for both compressibility and flowability
- Exhibits elastic deformation; therefore, it is less stable during tableting compared to other direct compression diluents
- It is more sensitive to lubricants

High Compressibility | Excellent Flowability | High Moisture

E SUGAR AND POLYOLS



- Includes sucrose, dextrose, sorbitol, and mannitol
- These are often manufactured by spray-drying to ensure good flowability and compressibility for direct compression
- Exhibit good compressibility and can produce tablets with high hardness
- Hygroscopic, so tablets may become soft during storage
- Mannitol has the lowest moisture content and does not undergo Maillard reactions with amine-containing APIs
- Exhibit brittle fracture behavior, increasing tablet friability; however, they reduce sensitivity to lubricants

Medium Compressibility | Excellent Flowability | Low Moisture

COMPARISON OF FLOWABILITY AND COMPRESSIBILITY

			Flowability	Compressibility
Water soluble	Sugar	Lactose, milled	-	+
		Lactose, DC-grade	+	+
		Dextrate	+	+
		Glucose	+	-
		Saccharose	-	+
	Polyol	Sorbitol	+	+
		Mannitol	+	+
		Xylitol	+	+
		Isomalt	+	+
Water insoluble	Cellulose	Powdered Cellulose, fine	-	+
		Powdered Cellulose, coarse	+	-
		Microcrystalline Cellulose, fine	-	++
		Microcrystalline Cellulose, DC	+	+
		Silicified Microcrystalline Cellulose	+	++
	Calcium salts	Dibasic Calcium Phosphate	++	o
		Calcium sulphate		Commonly used as a diluent, with poor to moderate binding properties

+ + : Very good + : Good o : Medium - : Poor

ION EXCHANGE RESINS

TASTE MASKING APPLICATIONS FOR BITTER APIS

An effective solution for masking bitter taste, stabilizing APIs, and optimizing patient experience

1 INTRODUCTION OF ION EXCHANGE RESINS

Ion exchange resins (IERs) are insoluble high-molecular-weight polymers, typically consisting of a polystyrene matrix cross-linked with divinylbenzene, containing charged functional groups.

Cationic resins

Contain strong acidic functional groups (SO_3^{2-}) or weak acidic functional groups ($COOH^-$), commonly used for taste masking of bitter APIs with positive charge (weak bases).

Anionic resins

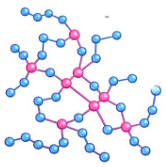
Contain basic functional group (quaternary amines), commonly used for taste masking of bitter APIs with negative charge (weak acids).

Ion exchange resins are widely used in pharmaceutical formulations for taste masking and API stabilization through ion exchange processes.

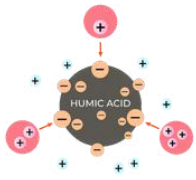
CHARACTERISTICS OF ION-EXCHANGE RESINS

ION EXCHANGE RESIN

CROSS-LINKING STRUCTURE



ELECTRICALLY CHARGED FUNCTIONAL GROUP



MAIN MECHANISM

- Ion exchange
- Form complexes with API
- Bitter taste masking
- Decomplexation in the stomach

2 MECHANISM OF MASKING BITTER TASTE

When ion exchange resins and bitter APIs are mixed together, an ion exchange reaction occurs at a specific pH. This is a reversible reaction:

R-COOH (ion exchange resin) + API (bitter) ⇄ API-COOH (non-bitter drug–resin complex)

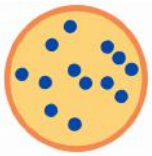
The resulting complex is insoluble at the salivary pH in the oral cavity; therefore, it does not interact with the bitter taste receptors on the tongue.

When this complex reaches the pH environment of the stomach or small intestine, dissociation occurs, allowing the active ingredient to be released and absorbed:

API-COOH ⇄ API + R-COOH (ion exchange resin)

The ion exchange resin is subsequently excreted without affecting the pharmacokinetics of the APIs.

1 COMPLEX FORMATION

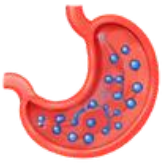


The bitter API binds to the functional groups of the ion exchange resin, forming a non-bitter complex

2 STABLE IN THE ORAL CAVITY

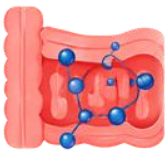
The complex is insoluble at salivary pH and therefore does not interact with bitter taste receptors

3 DECOMPLEXATION IN THE STOMACH



The acidic medium of the stomach causes dissociation of the complex, resulting in the release of the API

4 ABSORPTION



The API is absorbed intact in the small intestine into the systemic circulation

3 ADVANTAGES OF ION-EXCHANGE RESINS

- High taste-masking efficiency, high specificity
- Simple process, does not need complicated equipment
- Overnight incubation (2-8 hours) is not necessary
- Rapid decomplexation
- Without affecting the bioavailability of the API
- Safe elimination, no adverse side effects
- Enables high drug loading
- Facilitates the drug disintegration
- High compatible
- Safe, non-toxic, and does not need to use organic solvents

4 APPLICATIONS IN DRUG FORMULATION

Oral suspension

Syrup

Powders, granules

DT / ODT / Chewable tablets

LIPID BASED EXCIPIENTS

AND APPLICATIONS IN THE PHARMACEUTICAL FORMULATION

1 AN OVERVIEW OF LIPID EXCIPIENTS AND THEIR USES

Lipid excipients are a group of excipients derived from fats, including oils, waxes, phospholipids, and other lipid derivatives.

These excipients are widely used in pharmaceutical formulation and manufacturing for various applications.

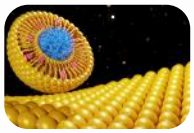
APPLICATIONS OF LIPID-BASED EXCIPIENTS

A. SOLID DOSAGE FORM

- Lubricant

- Sustained-release matrix forming

- Taste-masking agent



- Suppository bases

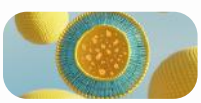
B. LIQUID DOSAGE FORM

- Oily carrier

- Self-emulsifying system

- Nanostructure

- Liposome



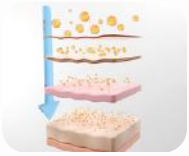
- Enhance solubility and bioavailability

- Thickening, suspending, and stabilizing the API

C. SEMI-SOLID DOSAGE FORM

- Carrier for the oily phase

- Enhance skin permeability



- Enhancing bioavailability for APIs with low solubility, low permeability

- Thickening, suspending, and stabilizing the API

2 COMMON LIPID-BASED EXCIPIENTS

Application	Lipid excipients	Advantages
1 **Lubricant** 	• Glyceryl dibehenate • Glyceryl monostearate • Hydrogenated castor oil	✓ Provides an elegant glossy appearance to tablets ✓ Overcomes the incompatibility issues and metallic taste of Magnesium stearate
2 **Sustained release matrix forming** 	• Glyceryl dibehenate • Cetyl alcohol • Stearyl alcohol	✓ Forms a matrix system that controls drug release through a diffusion mechanism without swelling or erosion ✓ Minimizes the risk of dose dumping
3 **Taste masking agent** 	• Glyceryl dibehenate • Glyceryl monostearate	✓ Provides effective taste masking and can be used with various APIs without requiring specific interactions
4 **Oily carrier** 	• MCT oil • Soybean oil • Castor oil	✓ Enhances solubility and bioavailability ✓ Supports nutritional supplementation in formulations (MCT oil)
5 **Thickerner, suspending agent** 	• Hydrogenated castor oil • Cetyl alcohol • Stearyl alcohol • Cetostearyl alcohol • Glyceryl monostearate • Waxes	✓ Increases viscosity, helping to modify the consistency of liquid and semi-solid dosage forms, while providing thickening, suspending, and improved stabilization of APIs
6 **Solubility and bioavailability enhancement** 	• MCT oil • PEG hydrated castor oil • Glycerol esters • PEG esters	✓ Enhance the solubility and bioavailability of APIs with low solubility ✓ Used in the formulation of targeted drug delivery systems to reduce side effects

Note: The lipid excipients listed in the table above are common examples provided for reference purposes and do not represent the complete range of available lipid excipients. In practice, lipid excipients can be used for a wide variety of applications depending on the formulation requirements and product characteristics defined by the manufacturer.

MATRIX STRUCTURE IN SUSTAINED RELEASE TABLETS

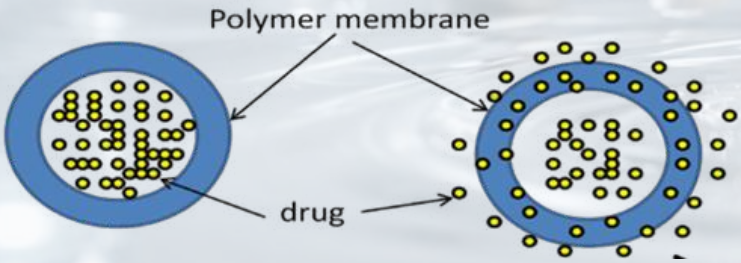
MECHANISMS, INFLUENCING FACTORS, AND APPLICATIONS IN **PHARMACEUTICAL FORMULATION**

SWELLING
The matrix system absorbs water and swells

DIFFUSION
Allowing the drug to diffuse through the capillary network

EROSION
The matrix gradually erodes over time

SUSTAINED-RELEASE SYSTEM



Resevoir system | Matrix system

> ***SCIENCE OF STRUCTURAL VALUE CREATION FOR ENHANCED TREATMENT***

SUSTAINED-RELEASE MATRIX SYSTEM

Roles, properties, and applications in tablet formulation

1 INTRODUCTION OF SUSTAINED-RELEASE MATRIX SYSTEMS

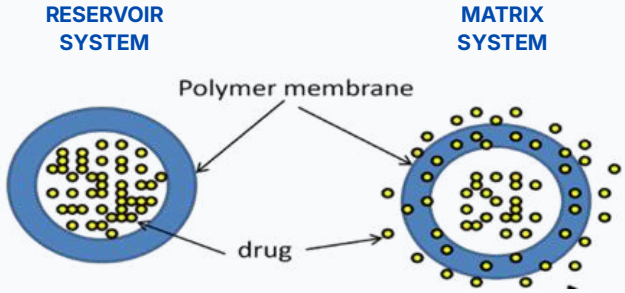
In sustained-release tablet formulations, the two most commonly used systems for controlling drug release are the reservoir system and the matrix system:

The reservoir system: is characterized by a "core–shell" structure, in which the drug serves as the reservoir core and is completely surrounded by a polymeric membrane that acts as a barrier controlling the drug release rate

Matrix system: a structure in which the drug is uniformly dispersed as molecules or solid particles within a matrix network, forming a single solid system

Compared with reservoir systems, matrix systems offer advantages in terms of safety and drug release control. In some cases, when the tablet is damaged or broken, the sustained-release properties of a matrix system are only partially affected rather than being completely lost as in reservoir systems. The use of matrix systems also helps minimize the risk of dose dumping and potential overdose caused by mechanical cracking or breakage of the tablet.

ANALYZE THE TWO SYSTEMS



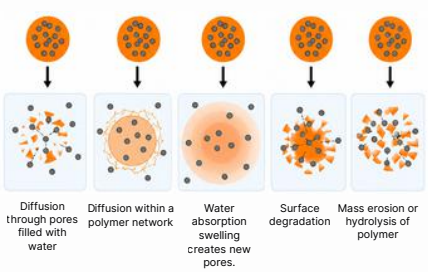
- Core - shell structure
- The API is uniformly dispersed throughout the matrix system
- Release-controlling membrane
- Three-dimensional porous structure
- Drug release depends on the coating membrane
- Drug release through diffusion within the network

2 MECHANISM OF SUSTAINED DRUG RELEASE

The release of APIs from a matrix system occurs via three distinct mechanisms depending on the nature of the polymer used:

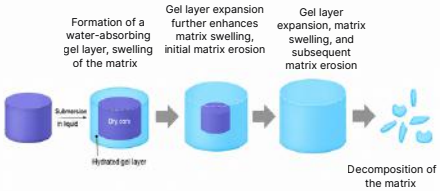
HYDROPHOBIC MATRIX SYSTEM

The tablet maintains its original shape and size throughout the dissolution process. The drug is released entirely by slow diffusion through the porous capillary network within the matrix system



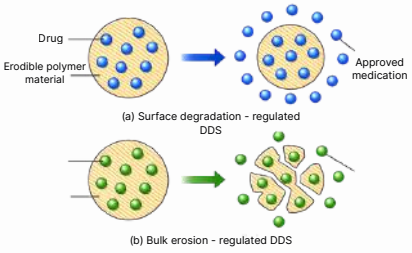
SWELLABLE MATRIX SYSTEM

Upon contact with gastrointestinal fluids, the tablet surface hydrates and swells, forming a viscous gel layer. This gel layer acts as a controlling barrier, through which the drug must diffuse to be released into the surrounding medium

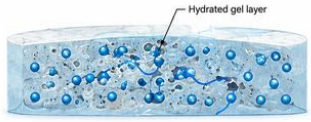
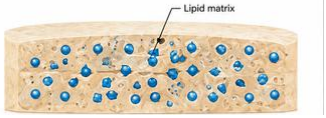
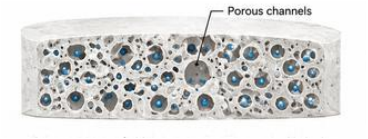


ERODIBLE MATRIX SYSTEM

The tablet size gradually decreases over time due to erosion or dissolution of the excipient matrix. The drug release rate is directly dependent on the erosion rate of the matrix system



3 A VARIETY OF EXCIPIENTS USED TO FORM SUSTAINED-RELEASE MATRIX SYSTEMS

Classification	Typical Excipients	Characteristics & Release Mechanism	Advantages	Limitations
HYDROPHILIC MATRIX SYSTEM	• **HPMC** • **Xanthan gum** • **Sodium alginate** • **PVP K90**	 Hydrates and swells to form a viscous gel barrier upon contact with gastric fluid. The drug is released through diffusion and erosion of the gel layer	• High biocompatibility and safety • Easy modulation of drug release rate through adjustment of polymer viscosity • Simple manufacturing process	• Gel network susceptible to premature rupture from food or intestinal motility • Natural polymers may undergo microbial degradation in the colon
LIPID MATRIX SYSTEM	• **Glyceryl dibehenate** • **Hydrogenated castor oil** • **Carnauba wax** • **Beeswax**	 Forms a hydrophobic, porous, insoluble matrix. Drug release occurs through diffusion and/or matrix erosion under the influence of enzymes and pH	• Highly effective in retarding the release of highly water-soluble drugs • Mechanically stable matrices • Some excipients can additionally function as lubricants	• The release rate may vary due to the effects of lipase enzymes or high-fat meals • Requires more complex manufacturing process (solid dispersion, hot-melt granulation, and hot-melt extrusion)
INSOLUBLE INERT MATRIX SYSTEM	• **Ethyl Cellulose** • **PVC** • **Eudragit RS/RL**	 Does not swell or disintegrate and retains its original shape. Drug release occurs entirely through diffusion via the porous capillary network within the matrix	• Provides constant and predictable release kinetics • Not affected by variations in pH or digestive enzymes	• Non-biodegradable (matrices excreted in feces may cause concern to patients) • Poorly soluble drugs may become trapped in the deep capillary core, resulting in incomplete drug release

4 LIPID MATRIX STRUCTURE

- Some lipid matrix-forming excipients are non-swelling and non-erodible, thereby maintaining a diffusion-controlled release mechanism and minimizing the risk of dose dumping during the first 60 minutes or upon tablet rupture
- Applicable to various processes: direct compression, wet granulation, hot-melt extrusion, and solid dispersion
- No requirement for organic solvents, avoiding explosion hazards and alcohol-induced alterations in drug release
- Stable under physiological conditions, including digestive enzymes and pH variations, reducing interpatient variability
- Chemically inert and compatible with a wide range of APIs and excipients
- Drug release is minimally affected during scale-up manufacturing

NON-SWELLING	**NON-ERODIBLE**
STABLE DIFFUSION	**SOLVENT FREE**
ROBUST	**CHEMICALLY INACTIVE**
SCALE-UP CONVENIENCE	


glyceryl dibehenate


hydrogenated castor oil


cetyl alcohol


stearyl alcohol


cetostearyl alcohol


stearic acid


glyceryl monostearate

GLYCERYL DIBEHENATE

MATRIX-FORMING AGENTS

CONTROL THE DRUG RELEASE RATE

Lipid matrix systems can produce stable and versatile sustained-release tablets with effective control of the drug release rate.

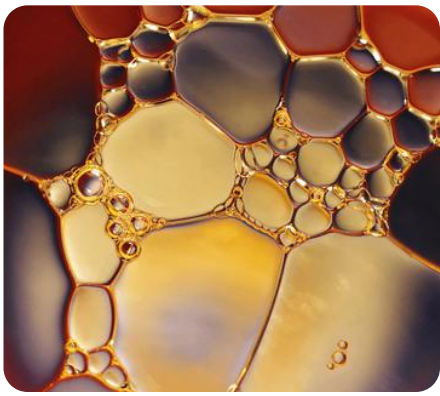
Stable Diffusion
Stable diffusion

Lipid Matrix
Hydrophobic matrices are non-swelling and non-erodible

Controlled Release
Effective control of the drug release rate

Dose Dumping
Minimizes the risk of dose dumping

1 INTRODUCTION OF GLYCERYL DIBEHENATE



Lipid matrix systems for sustained-release tablets have become an increasingly popular trend in the pharmaceutical manufacturing industry due to their ease of release control, stability, and flexibility across various formulation processes.

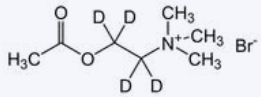
A wide range of lipid excipients has been employed as matrix-forming agents to control drug release rates, including glyceryl dibehenate, hydrogenated castor oil, cetyl alcohol, stearyl alcohol, earyl alcohol, stearic acid, and glyceryl monostearate. Among these, glyceryl dibehenate is one of the most commonly used excipients in sustained-release formulations, providing effective control of drug release rate.

Glyceryl dibehenate is a blend of mono-, di-, and triglyceride esters derived from behenic acid (docosanoic acid). This excipient is frequently utilized in pharmaceuticals for various applications:

- ***Lipid matrix-forming agent for controlling drug release rates in sustained-release tablets***
- ***Lubricant and glidant excipient with good compatibility and improved tablet appearance***

CHEMICAL NATURE

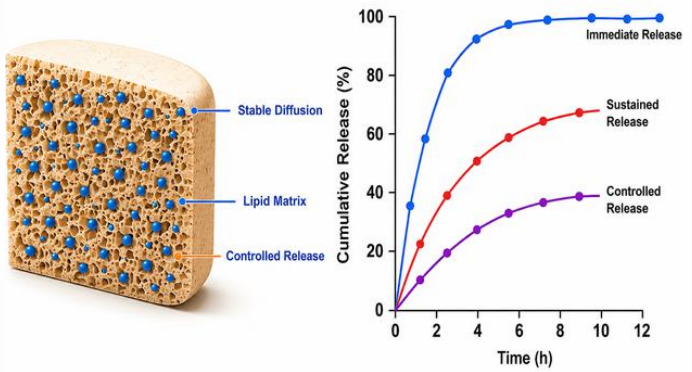
Glyceryl dibehenate consists of a combination of mono-, di-, and triglyceride esters derived from behenic acid.



PRIMARY APPLICATIONS

A LIPID MATRIX STRUCTURE

CONTROL DRUG RELEASE RATE

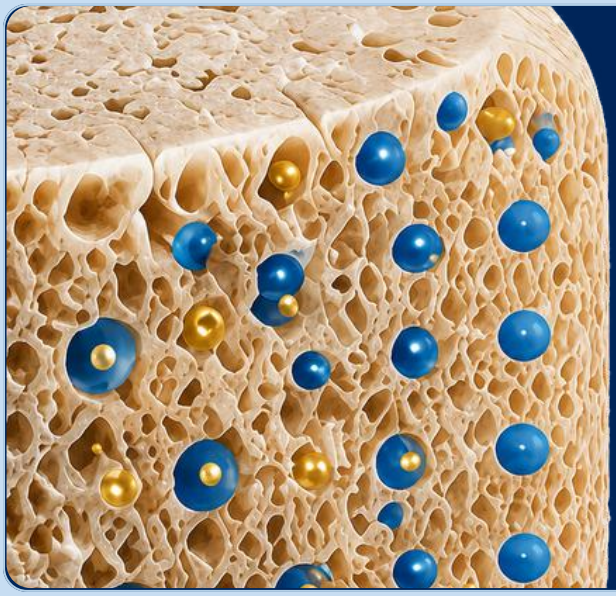


- **Lipid matrix forming agent**
- **Control drug release rate**
- **Mechanical stability**
- **Minimize burst-out release**

B LUBRICANT

- **Lubricant**
- **No incompatibility**
- **Enhance tablet aesthetics**

2 APPLICATIONS IN SUSTAINED-RELEASE TABLETS



Glyceryl dibehenate forms a hydrophobic lipid matrix and is typically used at 15–50% of the tablet weight, depending on the formulation and the API's hydrophilicity. Advantages of glyceryl dibehenate in SR tablets:

- Non-swelling and non-erodible, thereby maintaining a diffusion-controlled release mechanism and minimizing the risk of dose dumping during the first 60 minutes or upon tablet rupture
- Applicable to various processes, including direct compression, wet granulation, hot-melt extrusion, and solid dispersion
- Stable under physiological conditions, including digestive enzymes and pH variations, thus reducing interpatient variability in drug release
- No requirement for organic solvents, avoiding explosion hazards and preventing alcohol-induced alterations in drug release
- Chemically inert, compatible with a wide range of APIs and excipients
- Drug release is minimally affected during scale-up manufacturing

APPLICABLE TO VARIOUS MANUFACTURING PROCESSES

DIRECT COMPRESSION

WET GRANULATION

MELT EXTRUSION

SOLID DISPERSION

REFERENCE FORMULA FOR SODIUM DICLOFENAC 75MG SUSTAINED-RELEASE TABLETS

INGREDIENT	CONTENT
Diclofenac sodium	75 mg
Glyceryl dibehenate	40 mg
Microcrystalline cellulose	80 mg
Lactose monohydrate	50 mg
Colloidal Silicon Dioxide	1 mg
Magnesium stearate	2 mg
Total	**250 mg**

APPLICATIONS AS A LUBRICANT

- Hydrophobic lubricant provides a smooth and glossy tablet surface while reducing ejection force → prolonging punch and die lifespan
- Typically used at 1–3% in tablet, added during external blending
- Non-reactive lubricant, suitable for APIs incompatible with Magnesium stearate
- Does not impart a metallic taste
- Stable and minimally influenced by fluctuating mixing conditions on tablet characteristics
- Possesses good binding properties, which help improve tablet cohesion and overcome hardness limitations commonly associated with lubricants
- Convenient for scale-up manufacturing

BIORICH GROUP

MAY
05
2026

FORMULATION COLLABORATOR

MATERIAL SOLUTIONS FOR PREMIUM PHARMACEUTICALS

Biorich offers sophisticated raw material solutions that facilitate optimal formulation, improve efficacy, and guarantee the quality of your pharmaceutical products

CUSTOMERS REQUIREMENT

- Material samples
- COA / Specification
- R&D support
- Technical documentation
- Suitale excipient solution
- Detailed quotation

CONTACT BIORICH

- Sending samples for testing
- Providing COA / technical documentation
- Excipient formulation consultation
- Support formulation and process optimization

We are dedicated to collaborating with businesses to create high-quality pharmaceutical products

CLEAR ORIGIN	CONSISTENT QUALITY	TECHNICAL SUPPORT	WORLDWIDE NETWORK
Complies with international standards	Adhering to rigorous GMP requirements	Dedicated technical consultation	Connects with reputable global manufacturers

BIORICH GROUP

MAY
05
2026

BIORICH
INSIGHTS

PHARMACEUTICAL INGREDIENTS
INNOVATIVE HEALTH SOLUTIONS

NEXT-GENERATION EXCIPIENTS
Enhancing efficacy
optimizing formulation

FORMULATION SOLUTIONS
Advanced Technology for
Superior Performance

PREMIUM QUALITY
Meeting Stringent
International Standards

PARTNERSHIP & CONSULTATION
Empowering Partners for
Sustainable Growth

CONTACT US
for samples and technical documentation

+84 834 560 500

director@biorichgroup.com