BIORICH GROUP

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INSIGHTS

PHARMACEUTICAL INGREDIENTS, HEALTH SOLUTIONS & INNOVATION

SOFTGEL FORMULATION TECHNOLOGY

FROM CAPSULE SHELL STRUCTURE TO FORMULATION DESIGN

Discover softgel capsule structure, the role of plasticizers, and the pharmaceutical ingredients used in formulation design



STRUCTURE & TECHNOLOGY
An overview of softgel capsule structure and manufacturing processes.

PLASTICIZERS
Their role and impact on capsule shell properties.

INGREDIENTS & FORMULATION
Properties and applications of pharmaceutical ingredients.

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Delivering in-depth expertise on raw materials and solutions for the pharmaceutical industry.

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OVERVIEW OF SOFTGELS

DEVELOPMENT JOURNEY, STRUCTURE & PRODUCTION TECHNOLOGY



DEVELOPMENT HISTORY OF SOFTGELS

1500 BCE



ANCIENT PRECURSORS

Starch cakes made from wheat flour and starch paste were first documented in the Ebers Papyrus of Ancient Egypt.



1730



THE FIRST OBLATE WAFERS

Pharmacist de Pauli of Vienna invented the starch wafers to conceal the bitter taste of pine resin.



1833



THE FIRST PATENT

François Mothes and Joseph Dublanc (France) were granted a patent for the production of gelatin capsules.

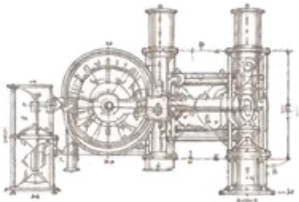


1844 - 1860



DEVELOPING PRODUCTION METHODS

- **1844–1846:** Capsule molding methods and grooved roller devices.
- **1860:** The dripping method laid the foundation for seamless capsule technology.



1933 & 1970s



INDUSTRIALIZATION AND ELASTIC CAPSULE SHELLS

- **1933:** Robert P. Scherer developed the rotary die process, bringing softgels into mass production.
- **1970s:** Addition of glycerin to produce softgels, elastic capsule shells.



1 STRUCTURE OF SOFTGELS

Softgels comprise a softgel shell and softgel fill, designed to protect and contain the active pharmaceutical ingredient in an appropriate formulation.

SOFTGEL SHELL

It consists of gelatin, a plasticizer, water, and several other excipients.



SOFTGEL FILL

Contains APIs in the form of a solution or suspension along with suitable excipients.

SOFTGEL SHELL

The softgel shell consists of three primary components: gelatin, plasticizers, and water. Additionally, preservatives, colorants, opacifiers, flavorings, and organic acids may be incorporated.



GELATIN
Forms the film and establishes capsule shell structure

PLASTICIZERS
Enhance shell flexibility and elasticity

WATER
Dissolves gelatin and maintains shell softness

FUNDAMENTAL COMPONENTS



Gelatin
- The primary ingredient is derived from animal collagen.
- Two types: Type A (hydrolyzed by acid) and Type B (hydrolyzed by alkali).



Plasticizers
- Helps improve the flexibility and elasticity of the softgel shell.
- Glycerin and sorbitol are commonly used plasticizers.

ADDITIONAL COMPONENTS



Coloring and opacity agents
- Provides color, opacity, and visual product identification; must meet organoleptic requirements and prevent oxidation-induced discoloration or spotting caused by metallic impurities.



Flavoring agents & sweeteners
- Helps improve organoleptic properties, mask unpleasant tastes and odors, and establish product distinction.



Organic acids
- Organic acids help inhibit gelatin cross-linking, with Glycine and Lysine being commonly used.

SOFTGEL FILL

In typical softgel fill, the active pharmaceutical ingredient is usually present as a solution or suspension.



SOLUTION
The APIs dissolved in a lipophilic or hydrophilic solvent



SUSPENSION
The APIs is typically dispersed in a lipophilic solvent

COMPONENTS IN SOFTGEL FILL



APIs
- Most inorganic and organic **solid APIs** can be formulated in **softgels as suspensions**.
- APIs with **strongly acidic/ basic** properties, **ammonium salts**, **high water solubility**, and moisture sensitivity are generally unsuitable for softgel formulations.



Solvent
- **Lipophilic solvents:** soybean, sesame, castor, or paraffin oil.
- **Hydrophilic solvents:** PEG 400 and PEG 600.



Viscosity-enhancing agent

It helps prevent solid particles from settling during formulation and encapsulation.
- **Lipophilic:** white beeswax, solid paraffin, stearate derivatives, ...
- **Hydrophilic**: PEG 4000, PEG 6000, solid glycol esters, ...



Other excipients
- **Antioxidants** and **pH adjusters** help improve the stability of the active pharmaceutical ingredient (API) throughout storage

QUALITY REQUIREMENTS FOR GELATIN USED IN SOFTGEL SHELLS



Gel Durability (Bloom)

100 – 200 Bloom

Indicates the gelling capacity and firmness of gelatin. The higher the Bloom value, the stronger and firmer the gelatin gel, which consequently affects the mechanical strength of the capsule shell.



Microbiological limits
- Total aerobic microorganisms: **≤ 10^3 CFU/g**
- Total yeast and mold count: **≤ 10^2 CFU/g**
- Absence of *Escherichia coli.*
- Absence of *Salmonella spp.*



Iron Limit

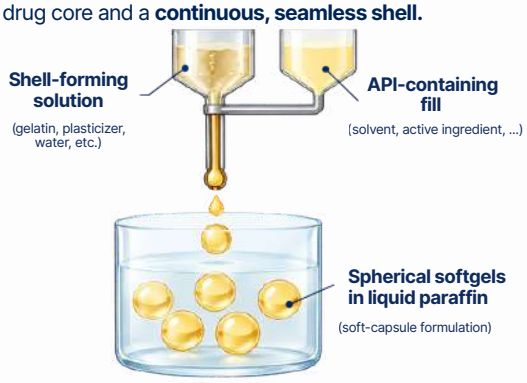
≤30 ppm

However, levels of **≤15 ppm** are generally preferred to minimize oxidative catalysis and softgel shell discoloration.

2 METHODS FOR PRODUCING SOFTGELS

A Seamless process

The softgel fill is pumped through the inner nozzle, while a stream of gelatin simultaneously surrounds it from the outer nozzle. Interfacial tension facilitates the **formation of spherical droplets** containing a drug core and a **continuous, seamless shell.**



Advantages

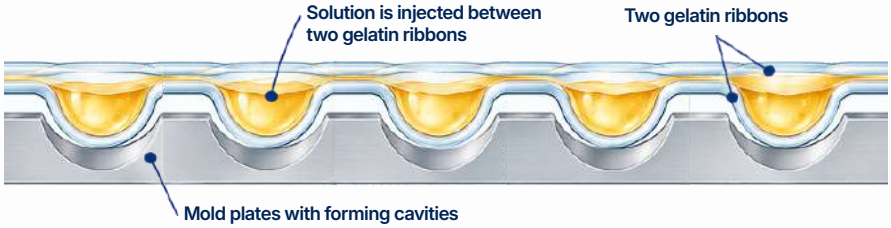
- Produces spherical capsules with a monolithic, seamless shell.
- Relatively simple equipment that is easy to clean and assemble.
- Minimal gelatin wastage

Disadvantages

- Shape is limited primarily to spheres, with capsule weight not exceeding 750 mg.
- Requires strict control of dual-phase flow rates, interfacial tension, and shell solidification
- Encapsulated fills are limited to low-viscosity (1 – 130 cPs) lipophilic solutions.

B Plate process

Two symmetrical metal mold plates containing forming cavities corresponding to half-capsules are coated with a hot gelatin solution at approximately 45 – 50 °C and dried to form thin films. The drug solution or suspension is filled into the cavities of the lower mold, after which the two mold plates are tightly pressed together to seal and form the softgel capsules.



Advantage

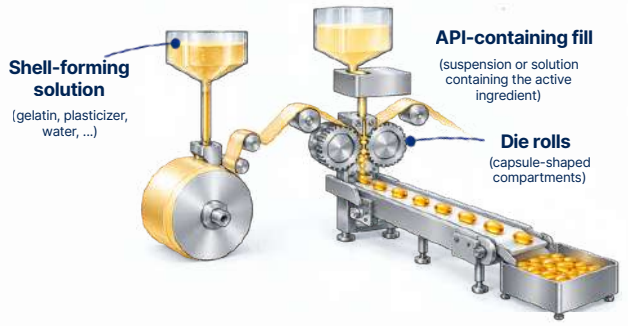
- Simple operating principle, easy manual adjustment.
- Suitable for experimental use or small-scale batches in research settings.

Disadvantages

- Low productivity, highly manual operation; capsules typically feature one flat side.
- High weight variation of the fill mass can reach 20 – 40%.
- Substantial material loss of 15 – 20%.

C Rotary die process

Two continuous gelatin ribbons are formed and fed between two counter-rotating die rolls. The fill material is injected between the two ribbons, while the dies simultaneously shape, seal, and cut out the softgels.



Advantage

- High productivity, suitable for industrial-scale manufacturing.
- Good weight uniformity when the process is well-controlled.
- Wide variety of capsule shapes and sizes.

Disadvantages

- High equipment capital and maintenance costs
- Strict control is required over ribbon thickness, temperature, fill rate, and sealing.
- Visible seam joining the two shell halves.

3 QUALITY REQUIREMENTS FOR SOFTGELS



1 Appearance
Accurate and complete description of the shape, color, and size of the softgel capsules.

2 Identification, Assay, Dissolution
As specified in the individual monograph.

3 Content Uniformity
Applicable to softgels containing less than 2 mg or less than 2% (w/w) of the APIs.

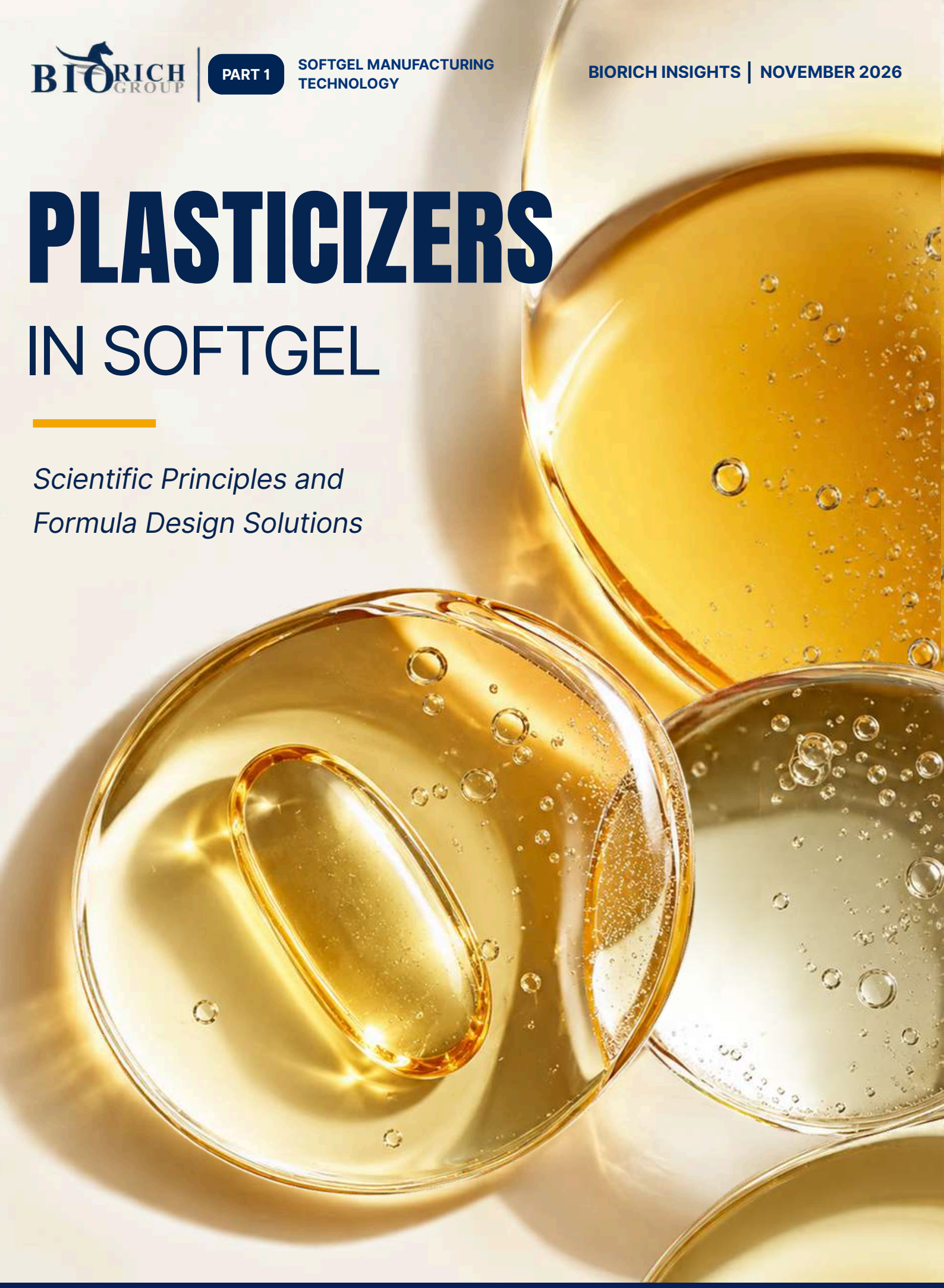
4 Uniformity of Mass

Average capsule mass	Percentage deviation from average mass (%)
Less than 300 mg	± 10%
300 mg or more	± 7,5%

5 Disintegration
< 30 minutes.

PLASTICIZERS IN SOFTGEL

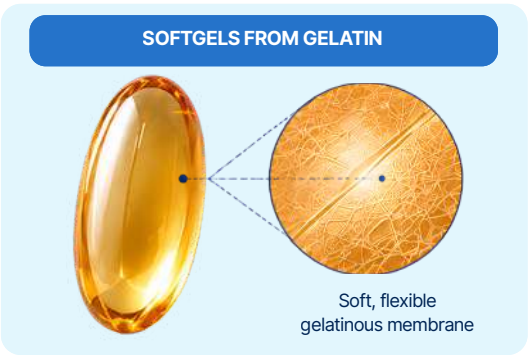
Scientific Principles and Formula Design Solutions



1 THE ROLE OF PLASTICIZERS IN SOFTGELS

Gelatin is a naturally occurring biopolymer produced through the partial hydrolysis of animal collagen, with protein as its primary component. However, **pure gelatin does not possess the optimal mechanical properties required for film formation and for maintaining the flexibility of softgel capsules.**

To overcome this limitation, plasticizers are incorporated into the formulation to modify the mechanical properties of the gelatin film. They increase its flexibility and deformability while reducing stiffness and brittleness. Consequently, the capsule shells adapt more effectively to various production processes, reducing the risk of deformation-related breakage and helping preserve shell integrity during storage.



SPECIAL PLASTICIZERS

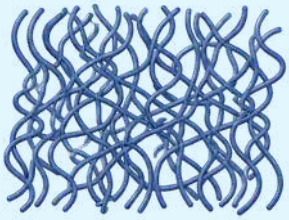
WATER – Fundamental factor in softgels / Volatile plasticizer
Water is essential for gelatin structure formation, viscosity adjustment, and initial film flexibility. Since its content decreases during drying, it must be combined with non-volatile plasticizers to maintain the elasticity and toughness of the capsule shell.

2 MECHANISM

When incorporated into the formula, **plasticizers insert themselves between gelatin polymer chains**, **increasing free volume** and **facilitating relatively easier movement of the molecular chains**. Consequently, they modify the mechanical and thermal properties of the capsule shell

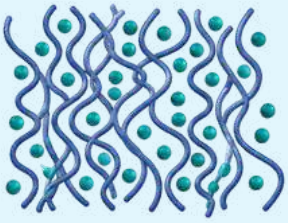
MECHANISM OF GELATIN FILM PLASTICIZATION

01 Gelatin network (before plasticizer addition)



Tightly bound gelatin polymer chains

02 After plasticizer addition



Plasticizers insert between gelatin chains, increasing free volume

EFFECTS ON CAPSULE SHELL PROPERTIES

INCREASE

- Flexibility and pliability
- Elongation at Break (EAB)
- Water-holding capacity
- Permeability to water vapor, oxygen, and dissolved volatile substances.

REDUCE

- Melt viscosity
- Tensile strength (TS)
- Elastic modulus (E mod)
- Glass transition temperature (Tg)

3 PLASTICIZERS USED IN SOFTGELS

Plasticizers utilized in softgel shell formulations exhibit distinct characteristics and mechanisms, directly influencing the mechanical properties, stability, and quality of the finished product.

PLASTICIZERS	EXCEPTIONAL BENEFITS	LIMIT	IMPACT ON MECHANICAL PROPERTIES
 **Glycerin**	• **Standard plasticizer** that interacts directly with gelatin	• High **hygroscopicity** can cause capsule sticking during storage • **Increases permeability** to oxygen and **volatile** components.	↑ **EAB** increases as concentration increases ↓ **PSt, TS, E mod** decrease as concentration increases
 **Sorbitol**	• **Indirect plasticizer** (acts as a humectant). Reduces migration of PEG and volatile substances into the shell.	• **Lower plasticizing efficiency than glycerin.** • **Prone to crystallization**, causing shell blooming/hazing and brittleness.	↓ **PSt** Decreases as concentration increases.
 **Propylene glycol**	• **Higher plasticizing efficiency** than both glycerin and sorbitol.	• Causes shell stickiness, hindering ribbon formation. • High volatility reduces mechanical strength during storage.	↔ **PSt** (virtually unchanged) as concentration increases
 **Citrate derivatives**	• **Imparts flexibility** to the capsule shell.	• Poor compatibility, prone to phase separation during drying and shell opacification. • Requires addition of emulsifiers (e.g., lecithin).	↓ **TS** Decreases as concentration increases.

PARAMETER GLOSSARY

EAB
Elongation at break
Indicates the ductility and flexibility of the capsule shell.

PSt
Puncture force
Maximum force required to tear or puncture the capsule shell.

TS
Tensile strength
Resistance of the film to breaking under tension.

E mod
Elastic module
Measure of a material's resistance to elastic deformation.

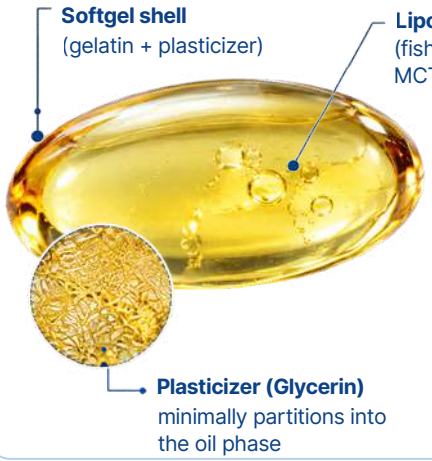
4 IMPACT OF SOFTGEL FILL ON SOFTGEL SHELL STABILITY

01 LIPOPHILIC FILL

(Fish oil, oil-soluble vitamins, MCT)

Maintains plasticizers within the shell

Because plasticizers (such as Glycerin) are **completely insoluble in the oil phase**, they rarely partition into the fill, allowing the plasticizer to remain stable within the polymer network. Consequently, the shell does not undergo plasticizer extraction/leaching, enabling a **Gelatin : Plasticizer ratio of 1 : 0.3 – 1 : 0.5 (dry weight)** to achieve a firm, mechanically robust, and impact-resistant capsule shell.



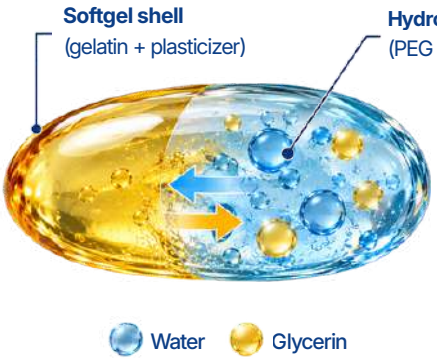
- Maintains plasticizers within the softgel shell
- Firm, mechanically robust capsule shell
- Minimizes cracking caused by deformation

02 HYDROPHILIC FILL

(PEG 400, co-solvents, SNEDDS)

Risk of component migration between phases

Polar softgel fills act as a "sink" that draws **Glycerin and water out of the capsule shell**. As Glycerin is depleted from the shell, the glass transition temperature (Tg) of the shell increases, transitioning the gelatin film from a flexible state to a **brittle state, causing shrinkage and shell cracking (leaking)**. Conversely, Glycerin migrating into the fill alters viscosity and reduces API solubility, leading to the risk of **API recrystallization and directly increasing disintegration time or causing dissolution failure.**



- Plasticizer is depleted from the capsule shell
- Increased Tg, brittle shell, prone to cracking (leaking)
- Risk of API crystallization

5 STRATEGIES FOR SOFTGEL SHELL FORMULATIONS WITH HYDROPHILIC FILLS

01 INCREASING PLASTICIZER RATIO IN THE SHELL

- For hydrophilic fills, the **Gelatin : Plasticizer ratio needs to be increased to 1 : 0.6 – 1 : 0.8** to pre-compensate for the expected migration of plasticizer into the fill matrix.



Standard rate 1 : 0.3 – 1 : 0.5

Increased ratio for hydrophilic fills 1 : 0.6 – 1 : 0.8

02 INITIAL CHEMICAL SATURATION

- Incorporate **5 – 10% Glycerin** directly into the PEG 400 fill solution during fill compounding.
- This **equilibrates the osmotic pressure and chemical potential of Glycerin** across both sides of the shell membrane at the moment of encapsulation, inhibiting the driving force for diffusion from the shell into the fill.



Reduces chemical potential gradient, limiting Glycerin diffusion

03 APPLICATION OF SORBITOL SORBITAN SOLUTION

- **Replace Glycerin partially or completely** with **Sorbitol Sorbitan Solution**.
- Because Sorbitol is insoluble in PEG and possesses a larger molecular size, it creates steric hindrance, significantly reducing the diffusion coefficient of the plasticizer into the fill and enabling the capsule shell to maintain its film structure.



Water | Glycerin | Sorbitol/Sorbitan (large molecular size)

SORBITOL SORBITAN SOLUTION

Plasticizers used in soft capsules



1 GENERAL INTRODUCTION



GLYCERIN

Widely used plasticizers

Glycerin is commonly used in softgels because of its **superior flexibility-enhancing properties** compared with other plasticizers. However, plasticizer selection also depends on the characteristics of the encapsulated liquid. **In formulations containing polyethylene glycol, glycerin may migrate from the capsule shell into the liquid**, altering the plasticizer composition and affecting the shell's properties during storage.



SORBITOL–SORBITAN SOLUTION

Alternatives to Glycerin

Sorbitol–sorbitan solution can serve as an alternative to, or be used in combination with, glycerin to **limit plasticizer migration.** Owing to its lower hygroscopicity and insolubility in polyethylene glycol, this excipient system helps preserve the mechanical properties and stability of the capsule shell. Moreover, selecting an appropriate sorbitol–sorbitan system can **help minimize crystallization on the capsule shell surface**.



2 PLASTICIZERS PROPERTIES AND MECHANISMS

INGREDIENTS AND THEIR PROPERTIES

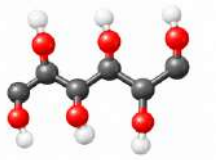
Sorbitol–Sorbitan Solution

- D-sorbitol
- 1,4-sorbitan
- Other sugars, polyhydric alcohols, and hexitol anhydrides

D-sorbitol

≥ 25,0%

$C_6H_{14}O_6$

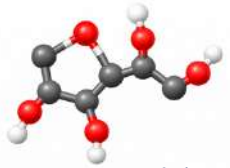


Sorbitol is a polyol containing multiple hydroxyl groups that functions as **an indirect plasticizer.**

1,4-sorbitan

≥15,0%

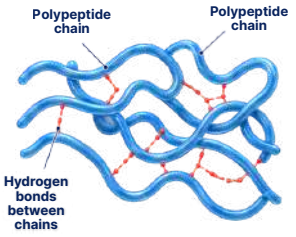
$C_6H_{14}O_5$



1,4-Sorbitan is a cyclic polyol capable of **directly interacting with the gelatin chain.**

MECHANISM OF PLASTICIZATION

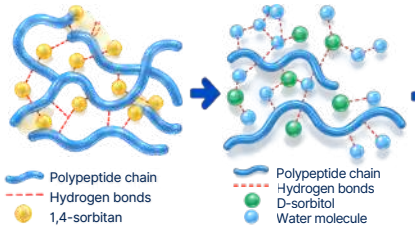
Gelatin forms a polymeric network.



Polypeptide chains bond and interact with one another to form the membrane structure, while ordered regions contribute to stabilizing the network.

Plasticizing systems modulate molecular interactions

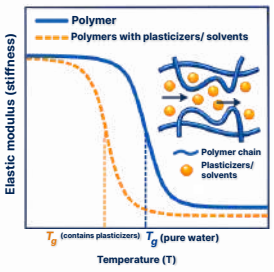
Direct 1,4-sorbitan | **Indirect D-sorbitol**



Directly interacts with the gelatin network, enhancing membrane flexibility.

Maintains flexibility indirectly by retaining bound water within the membrane.

Modulating network flexibility



The addition of a plasticizer lowers the gelatin film's Tg, causing the capsule shell to transition from a rigid, brittle state to an elastic, pliable state at storage temperature.

Optimizing softgel shell properties



Sorbitol–Sorbitan solution helps prevent plasticizer migration into the fill (particularly PEG 400) and sorbitol crystallization that causes shell opacity.

3 ADVANTAGES OF SORBITOL–SORBITAN SOLUTION

Resistance to plasticizer migration

Limits plasticizer migration into the fill, maintaining shell flexibility and preventing hardening during storage.

Anti-crystallization & hazing prevention

Prevents sorbitol crystallization at low humidity, ensuring shell transparency and stable appearance.

Low hygroscopicity & anti tack

Provides high moisture resistance, reduces capsule tackiness under fluctuating conditions, and lowers oxygen permeability.

Reduce production drying time

It reduces capsule shell drying time by 10% to 20%, thereby lowering energy consumption and labor costs.

Excellent compatibility with PEG fill

Highly compatible with PEG 400/600 fills, minimizing adverse shell–fill interactions.

4 APPLICATIONS AND PRODUCTS AVAILABLE ON THE MARKET

METHYL SALICYLATE–CONTAINING PREPARATIONS



Advil

Ibuprofen 200 mg



Aleve

Naproxen sodium 220 mg



Zyrtec Allergy

Cetirizine HCl 10 mg

WHITE BEESWAX

Daily Wax

Structure-forming excipients in emulsions and suspensions



DEVELOP STRUCTURE

Refine consistency and texture

CLASSIFY

Stabilize emulsions and suspensions

STABLE

Preserve physical properties





FROM NATURE TO PHARMACEUTICAL FORMULATIONS

1 INTRODUCE

White beeswax (Cera Alba) is obtained through the refining and bleaching of natural beeswax. Composed primarily of fatty acid esters and long-chain alcohols, the raw material is hydrophobic with characteristic melting and solidification profiles, providing a foundational basis for applications in various pharmaceutical excipient systems.

In pharmaceutical formulations, White Beeswax is used to adjust the **consistency and structure** of excipient bases **in oil-based emulsions and suspensions.** In softgel capsules, it can be incorporated into the oil phase to modify viscosity and support fill stability, depending on the formulation composition and concentration. This helps control the physical properties of the fill to meet specific formulation requirements.



COMPARISON OF YELLOW BEESWAX AND WHITE BEESWAX



Yellow Beeswax

Cera flava

- Natural beeswax ranges in color from yellow to yellowish brown.
- Contains propolis impurities that may cause dermatitis in topical preparations.



White beeswax

Cera Alba

- The propolis has undergone a purification process to remove impurities.
- Refined beeswax is produced by refining and decolorizing natural beeswax.

2 PROPERTIES OF WHITE BEESWAX

Natural origin.

It consists of a mixture of:
- Long-chain fatty acid esters and alcohols (70 – 75%)
- Free fatty acids (~14%)
- Saturated hydrocarbons (~12%)

Under normal conditions, White Beeswax appears as white to pale yellow flakes, pieces, or pellets with a faint characteristic odor.

Soluble in ether, chloroform, and oil-based solvents; slightly soluble in ethanol (95%); insoluble in water.

PHYSICOCHEMICAL PARAMETERS

Characteristic	Value
Melting point	62 – 66°C
Drop point	61 – 66°C
Acid value	17 – 24 mg KOH/g
Ester value	70 – 80 mg KOH/g
Saponification value	87 – 104 mg KOH/g



3 APPLICATIONS OF WHITE BEESWAX

A STRUCTURING THE SEMI-SOLID SYSTEM

In ointments and creams, white beeswax serves as a **thickening agent, viscosity enhancer, and physical modifier** of the excipient base. It combines with the oil phase to form a lipid-fiber network upon cooling, helping retain oil, **limit separation, and improve the preparation's physical stability.**

Ointment **Cream**

- **Limit oil separation**
- **Enhance physical stability**



B ADJUSTS OIL SUSPENSION VISCOSITY

In solid drug dispersion systems based on oil media, white beeswax can be incorporated to **increase viscosity and regulate the continuous phase's rheological properties**. Higher viscosity may reduce particle settling, **helping maintain system homogeneity during storage and use**. However, its effectiveness depends on the wax concentration, particle characteristics, and oil-matrix composition. Viscosity must therefore be controlled to prevent interference with mixing and filling processes.



Higher viscosity, reduced sedimentation

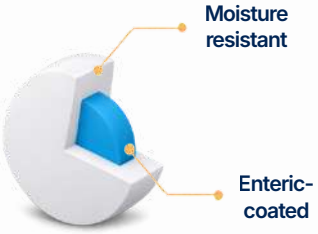
Lower viscosity, prone to settling

C APPLICATIONS IN TABLET COATING

White beeswax may be used to **polish sugar-coated tablets** or combined with polymers or lipids such as ethylcellulose, cetyl palmitate, and alginate gum for applications including **enteric-coated films and moisture-resistant** coatings for core tablets containing moisture-sensitive pharmaceutical substances. However, it should be combined with harder waxes to enhance heat resistance during storage.



Coated or sugar-coated tablets



Film-coated tablets

D FLEXIBILITY IN PHARMACEUTICAL DESIGN

White beeswax may be used in pharmaceutical 3D printing because of its **low melting point, hydrophobicity, and ability to form a solid structure upon cooling**. These properties enable it to create a **lipid matrix for drug delivery** and help regulate **drug-release rates.**



Pharmaceutical 3D printing

POTENTIAL APPLICATION AREAS

- Lipid-based systems
- Specialized dosage form design
- Controlled drug release
- Personalized medicine

4 MARKETED PRODUCTS

White beeswax is used in various commercial pharmaceutical preparations, including softgels, coated tablets, and ointments. The following are typical products containing white beeswax:

SOFT CAPSULES	FILM-COATED TABLETS	OINTMENT
Accutane®	Advil®	Elocon®
		
Active ingredient: Isotretinoin 40 mg	Active ingredient: Ibuprofen 200 mg	Active ingredient: Mometasone furoate 0.1%

CASTOR OIL

The role of excipients in Pharmaceutical formulation





1 GENERAL INTRODUCTION

Vegetable-derived fatty oils comprise a group of ingredients of interest in pharmaceutical formulation because of their versatility across a wide range of formulations.

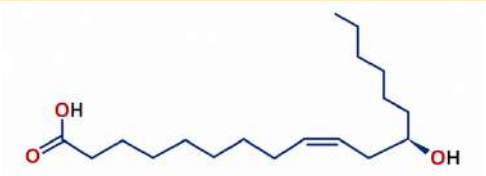
Castor oil, derived from the seeds of ***Ricinus communis L.***, is a notable ingredient in this group. In addition to its industrial applications, it is used in pharmaceuticals, where research investigates its properties for formulation design and drug-delivery systems.

2 CHEMICAL COMPOSITION & PHYSICOCHEMICAL PROPERTIES OF CASTOR OIL

CHEMICAL COMPOSITION

Castor oil is a mixture of triglycerides formed from glycerol and fatty acids. **Ricinoleic acid is the characteristic component** responsible for differences in the oil's chemical structure and physicochemical properties.

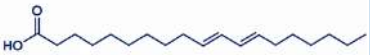
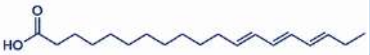
85–92% ricinoleic acid



$C_{18}H_{34}O_3$

Unlike most fatty acids found in other vegetable oils, **ricinoleic acid contains a hydroxyl group (-OH)** adjacent to its double bond, giving castor oil its distinctive physical and chemical properties.

8–15% remaining fatty acid mixture

Palmitic acid < 2.0% ($C_{16}H_{32}O_2$)	
Stearic acid < 2.5% ($C_{18}H_{36}O_2$)	
Oleic acid 2.5 – 6.0% ($C_{18}H_{34}O_2$)	
Linoleic acid 2.5 – 7.0% ($C_{18}H_{32}O_2$)	
Linolenic acid < 1.0% ($C_{18}H_{30}O_2$)	

PHYSICAL AND CHEMICAL PROPERTIES

High hydroxyl value

≥ 160 mg KOH/g

This indicates the presence of hydroxyl groups within the triglyceride structure.

Very high viscosity

900 – 1000 mPa·s (at 20°C)

10 – 20 times higher than conventional vegetable oils.

Unique solubility

Soluble in ethanol

It is soluble in ethanol and can dissolve certain poorly soluble pharmaceutical compounds.

Resistance to oxidation

Minimizes peroxide impurities

The hydroxyl group (–OH) in ricinoleic acid helps limit peroxide formation, giving castor oil greater oxidative stability than other unsaturated fatty oils.

COMPARISON OF CASTOR OIL WITH OTHER VEGETABLE OILS

Characteristic	 **Castor oil** **Castor Oil**	 **Soybean oil (Soybean Oil)**	 **Sesame oil** **Sesame Oil**
Composition	**Acid ricinoleic** 85 – 92%	**Acid linoleic** 50 – 57% Acid oleic 17 – 26% Acid linolenic 5 – 10% Acid palmitic 9 – 13%	**Acid linoleic** 40% Acid oleic 45%
Hydroxyl value	**≥ 160 mg KOH/g**	Very low	Very low
Viscosity	**900 – 1000 mPa·s**	50 – 60 mPa·s	~ 43 mPa·s
Solubility	**Soluble in ethanol**	Insoluble in ethanol	Insoluble in ethanol
Typical applications	Oil phase in self-emulsifying systems, creams & topical ointments	Oil-based excipients in certain appropriate oral or injectable preparations	Oily excipient in selected oral and injectable formulations

3 APPLICATIONS OF CASTOR OIL

IN PHARMACEUTICALS



01 Solvent for injectables & eye drops

Castor oil dissolves various lipophilic and moderately polar pharmaceutical substances.



02 Solvents for topical formulations

It dissolves certain oil-soluble components, while Castor Oil's high viscosity helps adjust the formula's physical properties and consistency.



03 Emollients for topical preparations

It forms a lipid film on the skin's surface, helping to soften the skin and reduce water loss.



04 Plasticizing excipient used in tablet coating

It can serve as a plasticizer in certain coating-film formulations, helping adjust flexibility and reduce brittleness and cracking.



05 Raw materials used in surfactant production

Due to the hydroxyl groups in its triglyceride structure, castor oil can be ethoxylated to produce derivatives such as Polyoxyl 35 Castor Oil.

IN COSMETICS



01 Skin-softening and conditioning agent

It helps soften the skin, forms a protective film on its surface, and reduces water loss.



02 Cosmetic products

Used in lipsticks and cosmetics for viscosity, emolliency, pigment dispersion, gloss, and adhesion.



03 Personal care products

It is used in various formulations of creams, lotions, soaps, and hair care products.

DERIVED FROM CASTOR OIL



Polyoxyl Castor Oil

Ethoxylated castor oil derivatives are used as surfactants and solubilizers in various pharmaceutical and cosmetic preparations.

COMMERCIAL PRODUCTS CONTAINING CASTOR OIL



DUREZOL

Difluprednate
0,5 mg/mL

Ophthalmic drops



RESTASIS

Cyclosporine
0,5 mg/mL

Ophthalmic drops



XONATRIX-120

Fexofenadine hydrochloride
120 mg

Film-coated tablets

MEGLUMINE

POTENTIAL EXCIPIENTS

IMPROVING THE SOLUBILITY OF THE ACTIVE INGREDIENT





The low water solubility of pharmaceutical compounds presents a significant challenge in drug development, prompting research into strategies to enhance solubility.

1 CHALLENGES IN PHARMACEUTICAL DEVELOPMENT



Poor drug solubility remains a major challenge in pharmaceutical development. Statistics show that **approximately 40% of marketed active pharmaceutical ingredients** (APIs) exhibit poor solubility according to the Biopharmaceutics Classification System (BCS), while this figure rises to **nearly 90% for APIs under development**.

This highlights the need for effective solubility-enhancement strategies. Depending on the API's physicochemical properties and formulation requirements, these approaches may involve selecting solubilizing excipients or modifying the formulation environment to improve drug solubility and support optimal formulation development.

01 CYCLODEXTRIN COMPLEXATION



Mechanism

Forms host–guest inclusion complexes with suitable APIs, increasing apparent solubility and potentially improving dissolution rate.

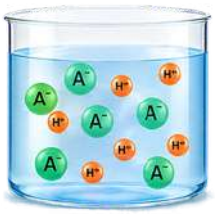
02 CO-SOLVENTS AND SOLUBILIZING EXCIPIENTS



Mechanism

Modifies the solvent environment or interactions between the API and formulation components to enhance solubility.

03 pH ADJUSTMENT & SALT FORMATION



Mechanism

Adjusting pH alters the degree of API ionization, and/or forming salts with appropriate counterions modifies the API's solubility profile.

04 SOLID DISPERSION SYSTEM



Mechanism

Disperses the API within a carrier matrix to reduce crystallinity or convert the drug into an amorphous state, thereby improving solubility.

*Among solubility enhancement strategies, **pH adjustment and salt formation** represent effective approaches for **weakly acidic or weakly basic APIs. Meglumine** is an organic base that can **modulate formulation pH and act as a counterion to form salts with certain acidic APIs**, thereby improving the dissolution profile of the active substance.*

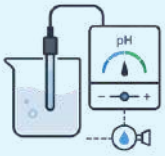
2 SOLUBILITY ENHANCEMENT WITH MEGLUMINE

CHALLENGE



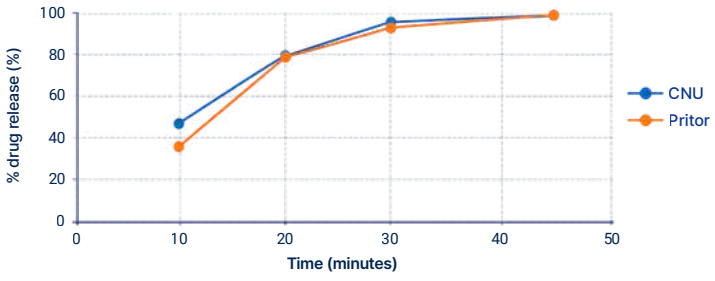
Telmisartan is a Class II BCS drug with good absorption but **extremely low solubility at pH 3 – 8, (< 1 µg/mL).**

SOLUTION



Because **Telmisartan is soluble in strongly alkaline media**, a rational approach involves **microenvironmental pH modulation** using alkalizing agents such as **Meglumine and NaOH**. This strategy can be implemented via formulation processes such as wet granulation, co-grinding, or spray drying in the presence of basic excipients.

Comparison of CNU and Pritor solubility under pH 7.5 conditions (USP Test 1)



***Source:** Comparative Study of Telmisartan Tablets Prepared via Wet Granulation Method and Pritor™ Prepared Using the Spray-Drying Method.*

PritorTM



Pritor™ tablets contain 80 mg of Telmisartan.

CNU



Telmisartan 80 mg tablets use **NaOH and Meglumine** to create an alkaline microenvironment and enhance solubility.

3 ADVANTAGES OF MEGLUMINE

SALT FORMATION WITH ACIDIC APIs

Meglumine is a proton-accepting organic base capable of acting as a counterion to form salts with acidic active pharmaceutical ingredients (APIs). This strategy enhances the solubility and dissolution rate of poorly soluble APIs such as Telmisartan, Meloxicam, and Delafloxacin.



SOLUBILITY MODULATION THROUGH pH AND IONIZATION CONTROL

For weakly acidic APIs, adding Meglumine shifts environmental pH and ionization equilibrium, thereby influencing apparent solubility. This approach can be synergistically combined with salt formation, particularly in liquid formulations.



SYNERGY WITH OTHER SOLUBILIZATION TECHNOLOGIES

In numerous studies, Meglumine is co-formulated with Hydroxypropyl-β-cyclodextrin (HP-β-CD) or integrated into solid dispersion systems to substantially improve API solubility and inhibit recrystallization during dissolution.



4 USES OF MEGLUMINE

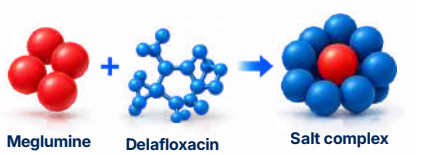
In fact, meglumine is present in pharmaceutical formulations not only as a salt of the active pharmaceutical ingredient but also as an alkalizing excipient. This distinction creates two notable application avenues: counterion selection in salt-formulation design and modulation of the formulation environment.

SEVERAL PRODUCTS ON THE MARKET CONTAIN MEGLUMINE.

BAXDELA



Delafloxacin—300 mg
In the form of delafloxacin meglumine salt



Meglumine forms a salt with delafloxacin, enhancing the active ingredient's solubility.

XIFYRM



Meloxicam 30 mg/mL

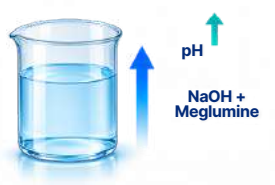


Meglumine contributes to pH adjustment and may form a salt with meloxicam; it also combines with hydroxypropyl betadex to enhance meloxicam's solubility.

PRITOR™



Telmisartan 80 mg



Meglumine and NaOH establish a pH environment that enhances the solubility of telmisartan.

MAGNESIUM OXIDE



Applications in active ingredients, excipients, and dietary supplements.

Magnesium oxide (MgO) is an inorganic compound of magnesium. In pharmaceuticals, it serves two primary functions: as an active ingredient in products such as antacids and as an excipient in certain drug formulations. MgO is also used as a magnesium supplement in health-food products. Its diverse applications require selecting raw-material grades appropriate to the intended use and the characteristics of each formulation.

FORMULA	MOLECULAR WEIGHT	CAS	APPEARANCE
MgO	40.30 g/mol	1309-48-4	White powder or granules



THE ACTIVE INGREDIENT IN THE PHARMACEUTICAL FORMULATION

Antacid; osmotic laxative



EXCIPIENTS IN PHARMACEUTICAL FORMULATIONS

Alkalinizing excipients that adjust the microenvironmental pH



APPLICATIONS IN HEALTH FOODS

Magnesium supplement

1 TECHNICAL SPECIFICATIONS

In industrial production, **Magnesium oxide** is typically manufactured through two primary processes, **Aman and Pattinson**, to produce high-purity synthetic MgO. In pharmaceutical applications, the raw material's physical properties are as important as its purity.

Characteristic	Recommended information
Chemical formula	MgO
Molecular weight	40.30 g/mol
CAS number	1309-48-4
Appearance	White powder or granules with a **porous or relatively dense structure**
Solubility	Soluble in dilute acids and ammonium salt solutions; slightly soluble in pure water; practically insoluble in 95% ethanol.
pH	**10.3** (saturated solution)

In the market, MgO is generally classified into two grades: **Magnesium Oxide Light** and **Magnesium Oxide Heavy**. The difference in apparent density determines the appropriate raw material for each formulation's requirements.

Heavy Magnesium Oxide



Bulk density
0.1 – 0.125 g/ml

Light Magnesium Oxide



Bulk density
0.25 – 0.50 g/ml

2 PHARMACEUTICAL INCOMPATIBILITIES AND STORAGE PRECAUTIONS

01 CHELATE COMPLEX FORMATION INVOLVING ANTIBIOTICS



Magnesium ions can form synergistic complexes with **tetracyclines and fluoroquinolones** in the gastrointestinal tract, reducing antibiotic absorption when taken concurrently. This interaction also **lowers bioavailability** and may compromise **therapeutic efficacy**.

02 PROMOTING THE MAILLARD REACTION



MgO raises the pH of the microenvironment, facilitating the Maillard reaction between the amino groups of the pharmaceutical substance and reducing sugars such as lactose, thereby increasing the risk of discoloration and degradation-product formation during storage.

03 RAW MATERIAL CHANGES DURING STORAGE



MgO absorbs water and CO_2 from the air, forming **magnesium hydroxide** and **magnesium carbonate**. This transformation can alter the material's properties; therefore, careful storage conditions and appropriate packaging are essential.

3 APPLICATIONS OF MAGNESIUM OXIDE

01 API IN THE FORMULATION

ANTACIDS

Magnesium oxide can neutralize stomach acid, alleviating symptoms associated with excess acidity.

OSMOTIC LAXATIVE

At high doses, unabsorbed magnesium retains water in the intestines, softening stool and stimulating bowel movements, thereby helping relieve constipation.



02 EXCIPIENTS IN PHARMACEUTICAL FORMULATIONS

ALKALIZING EXCIPIENTS

Adjusting the pH microenvironment in solid and oral suspension formulations can improve the stability of acid-sensitive pharmaceuticals. "This approach can be used in formulations containing drugs such as omeprazole to enhance chemical stability and minimize adverse interactions between the drug and other formulation components."



03 HEALTH FOOD PRODUCTS

MAGNESIUM SUPPLEMENT

It provides a high concentration of elemental magnesium (approximately 60.3% theoretically); however, its oral absorption rate is relatively low.



4 MARKETED PRODUCTS CONTAIN MAGNESIUM OXIDE

ANTACID



Antacids are preparations that neutralize stomach acid and alleviate the discomfort caused by excess acid.

ALKALIZING EXCIPIENTS



pH-adjusting excipients in solid and oral suspension formulations, particularly those containing acid-sensitive active ingredients.

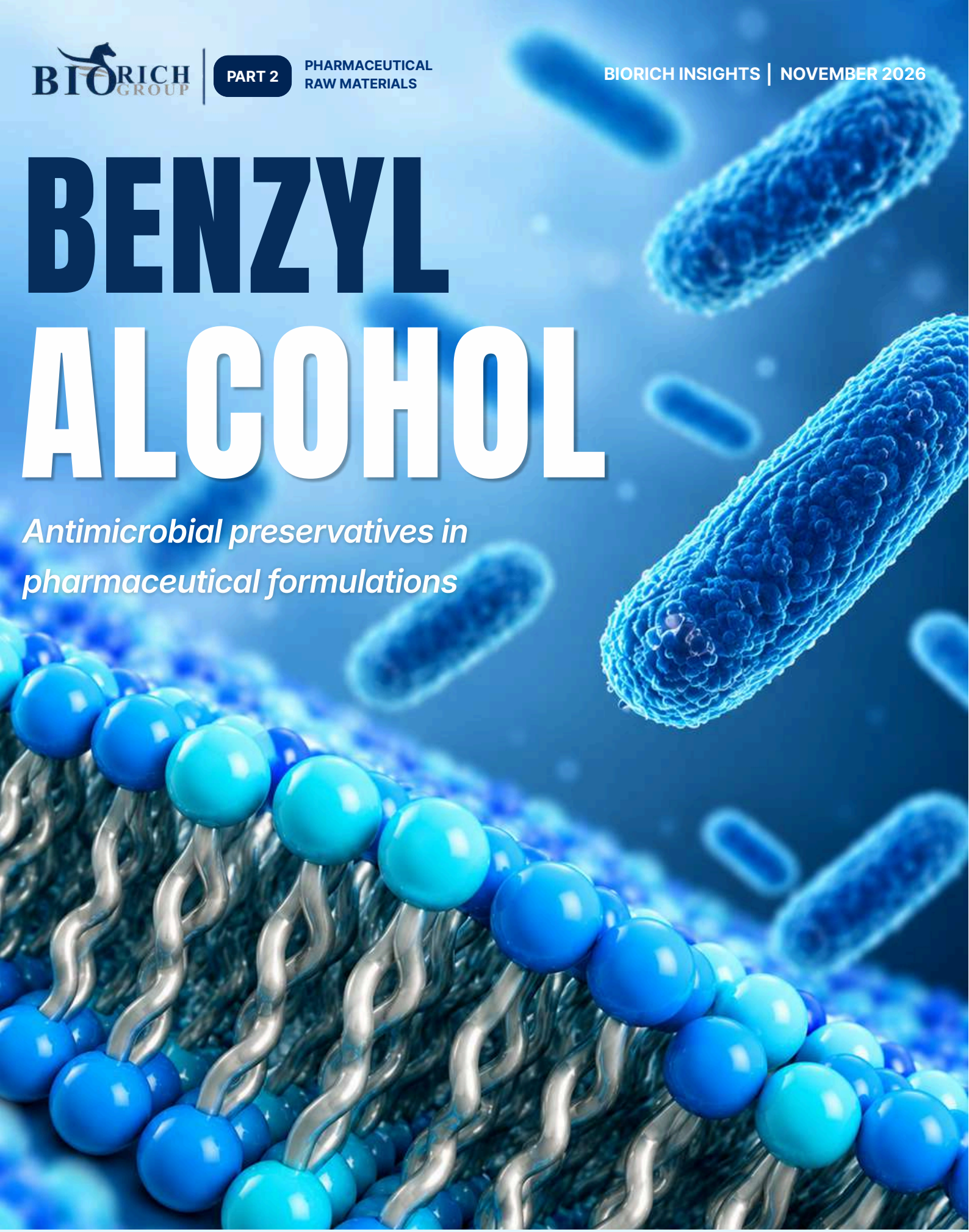
HEALTH FOOD



Magnesium supplements support bone, muscle, and nervous system health.

BENZYL ALCOHOL

Antimicrobial preservatives in pharmaceutical formulations



C7H8O | CAS: 100-51-6 | Molecular weight: 108.13 g/mol

- Injections
- Ophthalmic preparations
- Biologics
- Topical preparations
- Oral dosage forms

1 WHY ARE PRESERVATIVES NECESSARY IN PHARMACEUTICAL PRODUCTS?

Multidose preparations face the **risk of microbial contamination during use** due to repeated opening of the container. This poses a challenge in maintaining product quality, **driving the need for suitable preservative excipients in formulation design**.

To address this challenge, **antimicrobial preservatives are incorporated into certain pharmaceutical preparations as a microbial control solution**, inhibiting the proliferation of microorganisms that may be introduced during storage and administration. Selecting an appropriate preservative therefore plays a critical role in maintaining product quality throughout its in-use shelf life.



Multidose preparations require antimicrobial preservatives



Multidose injections



Ophthalmic and nasal preparations



Oral liquid preparations

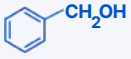


Topical emulsions



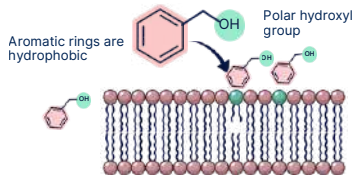
Topical semisolid preparations

2 BENZYL ALCOHOL: PROPERTIES, MECHANISM AND ANTIBACTERIAL SPECTRUM

CHARACTERISTIC	VALUE
Chemical formula	C_2H_5O
Molecular formula	 This structure enables benzyl alcohol to interact flexibly with both polar and nonpolar solvents.
CAS number	100–51–6
Molecular weight	108.13 g/mol
Appearance	Under normal conditions, benzyl alcohol is a clear, colorless liquid with moderate viscosity, low volatility, and a mild, balsamic odor.
Solubility	Soluble in water (~40 mg/mL) and miscible with numerous solvents, including ethanol, fatty oils, essential oils, ether, and chloroform.

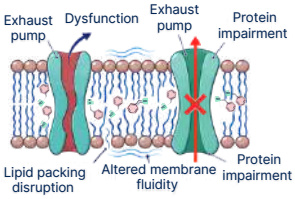
MECHANISM

Interaction with cellular membranes



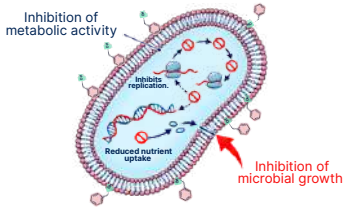
The aromatic ring is relatively hydrophobic, facilitating Benzyl Alcohol's interaction with the lipid bilayer of microbial cell membranes.

Modifying the membrane's structure and function



Affects membrane fluidity and membrane protein function, including efflux pump systems.

Microbial inhibition



Impaired membrane function compromises microbial viability and growth.

ANTIBACTERIAL SPECTRUM



Gram-positive bacteria

It demonstrates strong antibacterial activity against most Gram-positive bacterial strains.



Gram-negative bacteria

Antibacterial activity against Gram-negative bacteria (e.g., Pseudomonas aeruginosa) is weaker than against Gram-positive bacteria. Therefore, co-preservation agents such as EDTA are often added to enhance efficacy against Gram-negative bacteria.



Yeast, mold

Demonstrates pronounced preservative and antifungal efficacy at an MIC of 3 – 5 mg/mL.

3 PHARMACEUTICAL APPLICATIONS OF BENZYL ALCOHOL

Benzyl alcohol is widely used in various pharmaceutical formulations for multiple roles, ranging from antimicrobial preservative, local anesthetic, and protein stabilizer to active pharmaceutical ingredient for topical treatment.

01 ANTIMICROBIAL PRESERVATIVE

- Commonly used in multidose vials, vaccines, intravenous and intramuscular infusions, eye drops and nasal sprays, and topical liquid or cream formulations, with typical preservative concentrations ranging from **0.5% to 2.0% w/v.**



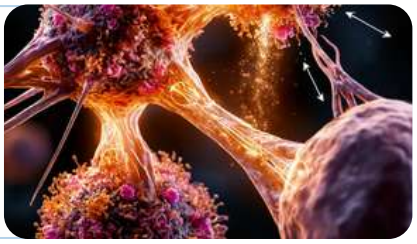
02 LOCAL ANESTHETIC TO REDUCE INJECTION PAIN

- Owing to its mild local anesthetic property, Benzyl alcohol is incorporated into intramuscular or subcutaneous injection formulations such as antibiotics and anti-inflammatory analgesics to reduce stinging pain for patients at the injection site.



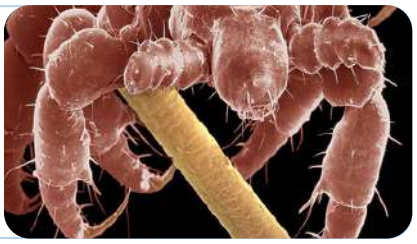
03 PROTEIN AND BIOLOGIC STABILIZER

- In biological drug formulations (proteins, peptides, monoclonal antibodies), Benzyl alcohol at concentrations of **1.0% – 2.0%** interacts with hydrophobic patches on the protein surface, preventing misfolding, denaturation, and thermal aggregation.



04 ACTIVE INGREDIENTS IN TOPICAL TREATMENTS

- Used **at a 5%** concentration in lotion or emulsion preparations to treat lice by mechanically paralyzing their respiratory systems and causing suffocation.



4 PRODUCTS CURRENTLY AVAILABLE ON THE MARKET

Benzyl alcohol is used in a wide range of pharmaceutical preparations. Below are several representative products on the market that contain benzyl alcohol.

KENALOG 10



Triamcinolone acetonide 10 mg/mL

Dosage Form
Injectable suspension



The Role of Benzyl Alcohol
Antimicrobial preservatives

REXALL



Hydrocortisone 1%

Dosage Form
Cream



The Role of Benzyl Alcohol
Antimicrobial preservatives

KOVANZE



Tetracaine Hydrochloride 30 mg/mL; Oxymetazoline Hydrochloride 0.5 mg/mL

Dosage Form
Nasal spray



The Role of Benzyl Alcohol
Antimicrobial preservatives

BIORICH GROUP

NOVEMBER
11
2026

BIORICH
INSIGHTS

PHARMACEUTICAL INGREDIENTS, HEALTH SOLUTIONS & INNOVATION



NEW GENERATION EXCIPIENTS

Improve efficiency, optimize formulas

PHARMACEUTICAL SOLUTIONS

Advanced technology for superior performance

SUPERIOR QUALITY

Complies with stringent international standards

COLLABORATION & CONSULTING

Partnering for sustainable development

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