BIORICH GROUP

JULY
07
2026

BIORICH

INSIGHTS

PHARMACEUTICAL INGREDIENTS, HEALTH SOLUTIONS & INNOVATION

PHARMACEUTICAL FORMULATION DESIGN

FROM FUNDAMENTAL RAW MATERIALS TO SOPHISTICATED PHARMACEUTICAL DOSAGE FORMS.

Explore how ingredients enhance formulation performance

SAFETY AND QUALITY
Complies with international standards. Guarantees user safety.

EXCEPTIONAL PERFORMANCE
Optimizing formulations to enhance bioavailability and therapeutic efficacy.

QUALITY AND SAFETY ASSURANCE
Sophisticated solutions to facilitate product development and augment capabilities.

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

www.biorichgroup.com

+84 834 560 500

director@biorichgroup.com

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UNDERSTANDING FOR IMPROVED WELL-BEING

Delivering comprehensive insights into raw materials and solutions for the pharmaceutical sector.

SCIENCE FOR HEALTH
QUALITY FOR LIFE

BIORICH GROUP is a business operating in the field of supplying raw materials and biotechnology solutions to various industries.

We offer a wide range of products such as **Active pharmaceutical ingredients (APIs), excipients, enzymes, vitamins, and other biological components**, serving the pharmaceutical, nutritional, healthcare, cosmetic, agricultural, and environmental industries.

PREMIUM QUALITY

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

SCIENCE-BASED SOLUTIONS

Driven by science and innovation to support pharmaceutical/food/cosmetic formulation for your business.

YOUR TRUSTED PARTNER

Building sustainable value through superior and reliable raw material products.

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INJECTABLE EXCIPIENTS

Injectable pharmaceuticals are sterile dosage forms administered into the body by injection, infusion, or implantation, designed to deliver the active pharmaceutical ingredient directly into the systemic circulation or targeted tissues. Compared with oral dosage forms, injectable drugs offer several advantages, including high bioavailability, rapid onset of action, and the circumvention of gastrointestinal absorption and first-pass metabolism in the liver.

However, due to injectable drugs are administered directly into the body, they must adhere to rigorous quality standards. In addition to the active pharmaceutical ingredient (API), the excipient system plays a critical role in ensuring the stability, safety, and therapeutic efficacy of injectable drugs. Consequently, excipient selection is one of the key factors in the research, development, and manufacturing of injectable drugs.

ADVANTAGE

1. high bioavailability
2. rapid onset of action
3. Avoids first-pass hepatic metabolism
4. Direct delivery of the drug to the site of action

1 CLASSIFICATION OF INJECTABLE PHARMACEUTICALS

TYPES OF INJECTABLES

LIQUID INJECTIONS

SOLUTION FOR INJECTION

SUSPENSION FOR INJECTION

EMULSION FOR INJECTION

SOLID INJECTIONS

POWDER FOR INJECTION

SOLVENTS FOR INJECTION

2 COMPONENTS OF INJECTABLE PHARMACEUTICALS

Injectable pharmaceuticals comprise four primary components: the active pharmaceutical ingredients, the solvents, excipients, and primary packaging materials that directly contacts the APIs.

A ACTIVE PHARMACEUTICAL INGREDIENTS

- Sterility
- Pharmaceutical grade purity
- Does not include pyrogens
- Endotoxin limits
- Batch-wise packaging

B SOLVENT FOR INJECTION

WATER FOR INJECTION

- pH 5 to 7
- Colorless
- Pyrogen-Free
- Endotoxin limits
- Heavy metal limits

WATER-MISCIBLE SOLVENTS

Enhance the solubility and stability of the APIs

WATER-IMMISCIBLE SOLVENTS

Used for oil-soluble APIs

C COMMON EXCIPIENT CATEGORIES USED IN INJECTABLE PHARMACEUTICALS

EXCIPIENTS CATEGORY	ILLUSTRATION	FUNCTION	COMMON EXCIPIENT
1 Solubilizing agent		• Enhance the solubility of the APIs	• Propylene glycol • PEG 400 • Glycerin • Ethanol • N,N-Dimethylacetamide (DMA) • N-Methyl-2-pyrrolidone (NMP)
2 Surfactants		• Enhance the solubility of solution for injection • Improve the stability of suspensions for injection	• Polysorbate 20 (Tween 20) • Polysorbate 80 (Tween 80) • Lecithin • Poloxamer 188 • Cremophor EL
3 Tonicity agent		• Adjust osmotic pressure	• Sodium chloride (NaCl) • Dextrose (Glucose) • Glycerin • Sorbitol • Mannitol
4 Buffering agent		• Adjust and maintain pH	• Phosphate Buffer • Citrate Buffer (Citric Acid, Sodium Citrate) • Acetate Buffer (Acetic Acid, Sodium Acetate) • Histidine–HCl
5 Preservatives		• Inhibit microbial growth	• Benzyl Alcohol • Phenol • Phenoxyethanol • m-Cresol • Chlorobutanol
6 Antioxidants		• Prevent oxidation	• Sodium metabisulfite • Sodium sulfite • Sodium bisulfite • Vitamin C • Methionine • α-Tocopherol

D INJECTABLE PHARMACEUTICAL PACKAGING

Clear glass vial | Amber glass vial | Glass ampoule | Rubber stopper | Aluminum crimp cap | BFS container

PACKAGING FOR INJECTABLE PRODUCTS MUST MEET THE FOLLOWING STANDARDS:

- *No impact on drug product composition*
- *Contact surfaces remain unchanged after sterilization*
- *Protect light-sensitive APIs*
- *Allow visual inspection of drug product quality*
- *Materials remain unchanged after sterilization*

COMMON PACKAGING MATERIALS

- Glass
- Plastic

3 QUALITY REQUIREMENTS FOR INJECTABLE PHARMACEUTICALS

A APPEARANCE

COLORLESS	INJECTABLE SOLUTION	INJECTABLE SUSPENSION	INJECTABLE EMULSION	POWDER FOR INJECTABLE
	Clear	Uniform suspension after shaking	No phase separation	Rapid reconstitution
				
The injection must be colorless	The solution for injection must be clear and free from visible foreign particles.	Sedimentation may occur but should be readily redispersed upon shaking	No phase separation is allowed.	Must rapidly reconstitute to form a clear solution or a uniform suspension upon addition of the solvents

B IDENTIFICATION & ASSAY

Adhere to the guidelines outlined in the current Pharmacopoeia.

C VOLUME/ MASS

VOLUME

The fill volume must exceed the volume specified on the label.

100 – 115 %

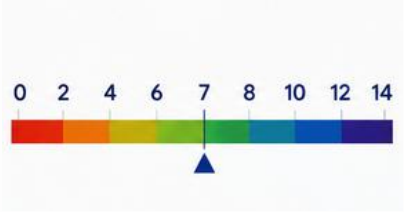
depending on the volume and types of injectable product

MASS

Complies with uniformity of mass

D pH

Complies with the pH limit specified by the Pharmacopoeia.



E STERILITY

Injectable pharmaceuticals must be sterile.

F PYROGEN (PYROGENIC SUBSTANCE)

Parenteral infusions, intravenous injections with a dose exceeding 15 mL, as well as intrathecal, intraocular, and intra-articular injections must be pyrogen-free.

Infusion or IV > 15 mL | **Intrathecal injection** | **Intraocular injection** | **Intra-articular injection**

H ISOTONICITY

Aqueous injection solutions must be isotonic with cellular fluid to ensure optimal tolerability and reduce the injection site pain.

HYPERTONIC	ISOTONIC	HYPOTONIC
		
Cell shrinkage	Intact cell	Cell swelling

Osmotic agents such as NaCl, Dextrose, and Mannitol...e.g. may be added to adjust tonicity.

GENERAL OBSERVATIONS

- All quality standards must be tested before batch release.
- Comply with current Pharmacopoeial requirements and GMP guidelines.
- Ensure full traceability for each batch of product.

CROSS-LINKING IN SOFT GELATIN CAPSULES

Causes and Corrective Actions

Soft gelatin capsules (**Softgel**) are a widely used solid dosage form, consisting of two main components: **the capsule shell** and **fill formulation**.

- **The capsule shell** is primarily composed of gelatin, plasticizers (such as glycerin or sorbitol), a suitable solvent (typically water), flavoring agents, and coloring agents.
- **Fill formulation** is a liquid or semi-solid system and, depending on the formulation, may contain components that form a hydrophilic system (e.g., PEG-based systems), a lipophilic system (various oil-based systems), a suspension, or an emulsion.

CAPSULE SHELL

Composed primarily of gelatin, it provides strength, flexibility, and protects the inner fill material

PLASTICIZER

Glycerin or sorbitol to keep the capsule shell soft, elastic, and resistant to brittleness and cracking

FILL FORMULATION (CAPSULE FILL)

The fill formulation contains the APIs in a liquid or semi-solid state and may be formulated as a solution, suspension, or emulsion system.

SOFTGEL COMPOSITION

CAPSULE SHELL

- Gelatin
- Plasticizers
- Solvent (aqua)
- Flavoring agents
- Coloring agents

+

FILL FORMULATION

- Solution system
- Suspension system
- Emulsion system
- APIs

→

SOFTGEL

- Easy administration, easy swallowing, and taste masking
- API protection

1 ADVANTAGES OF DOSAGE FORMS

SOFT GELATIN CAPSULE

TASTE MASKING
Converts liquid formulations into easy-to-swallow capsules with masked taste.

HIGH BIOAVAILABILITY
Enhanced absorption of APIs compared with many solid dosage forms.

PRECISE DOSING
Uniformity of content across units and production batches.

HIGH DRUG LOADING CAPACITY
Can accommodate nearly 100% liquid fill formulation.

COMMERCIAL VALUE
Various colors and shapes to enhance brand recognition.

EASY TO USE
Convenient for patients and easy to swallow

DISADVANTAGES OF SOFTGELS

01 Complex equipment and strict process control

02 Strict manufacturing conditions (temperature and low humidity).

03 Packaging must be selected to meet storage requirements

04 Some APIs may not be suitable for soft gelatin capsules.

COMMON ISSUES IN THE SOFT GELATIN CAPSULES

POTENTIAL API HYDROLYSIS

CAPSULE SHELL HYDROLYSIS BY STRONG ACID/BASE APIs

API MIGRATION INTO CAPSULE SHELL

CAPSULE SHELL HARDENING

CAPSULE SHELL SOFTENING AND LEAKAGE

CROSS-LINKING

KEY TECHNICAL NOTES

GELATIN COMPATIBILITY
Selection of gelatin type compatible with the formulation

WATER MIGRATION
Control of water migration during storage

CROSS-LINKING CONTROL
Control of cross-linking to maintain capsule quality.

PACKAGING STABILITY
Moisture & oxygen protection

2 CROSS-LINKING

WHAT IS CROSS-LINKING?

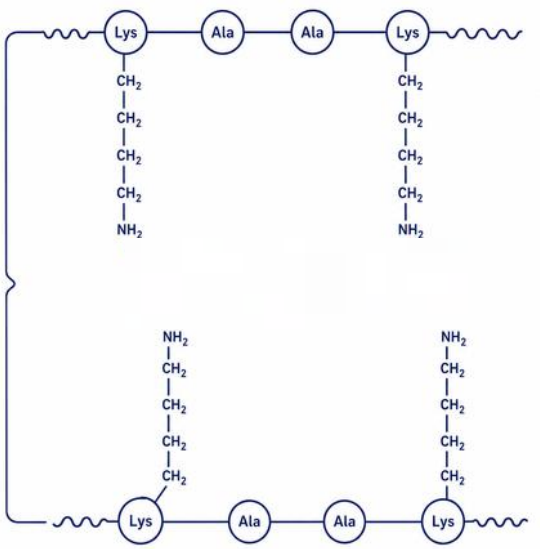
Cross-linking is the formation of **covalent bonds between gelatin polypeptide chains**. This is an irreversible reaction catalyzed by various chemical factors present in the formulation or by external environmental agents.

NOTE

- Polypeptide chain (gelatin backbone)
- New covalent bonds (cross-links)
- Light — Amino acid lysine (Lys)
- Land — Amino acid alanine (Ala)

STANDARD GELATIN

Flexible, unattached polypeptide chains

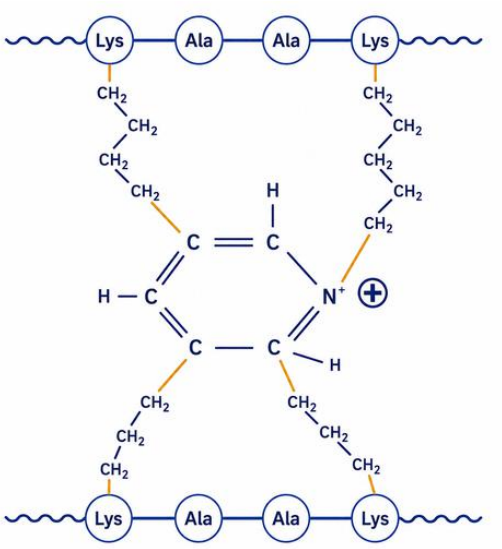


AGENT

- pH — pH acidity/alkalinity
- Elevated temperature
- O_2 Oxygen — Oxidation
- Humidity
- Formulation components
- Unsuitable packaging

CROSS-LINKED GELATIN

The polypeptide chains are covalently bonded, creating a stable three-dimensional network.



CONSEQUENCES OF CROSS-LINKING IN GELATIN CAPSULE SHELLS

- Reduced gelatin solubility and swelling capacity
- Increased shell hardness and reduced elasticity
- Delayed disintegration in aqueous media and gastric acid
- Reduced dissolution and slower drug release

Cross-linking is an irreversible reaction.
Once formed, covalent bonds alter the gelatin network structure and are irreversible.

3 CAUSES OF CROSSLINKING

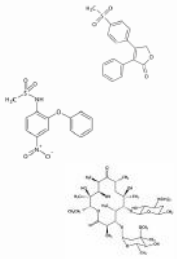
A ALDEHYDES/KETONES AND CARBONYL-CONTAINING API

Aldehyde **Ketone**

- Acts as a cross-linking agent between amino groups on the same or different gelatin chains.
- The degree of cross-linking increases markedly at 60–70% RH.

Examples of API featuring a carbonyl group:

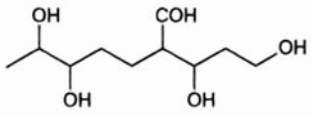
- Rofecoxid
- Nimesulide
- Macrolide antibiotics



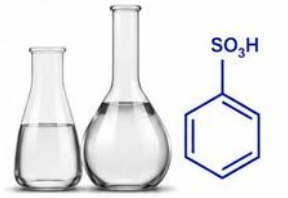
B METAL IONS

- It facilitates the oxidation process.
- Establish cross-links among gelatin chains.

C POLYOLS & OTHER COMPOUNDS



- Polyol (Sorbitol, Mannitol, Glycerin, etc.)
- Peroxide / Exposide
- Benzen
- Sulfonic acid
- Guanidine hydrochloride
- ...



D STORAGE & ENVIRONMENTAL FACTORS

High temperature

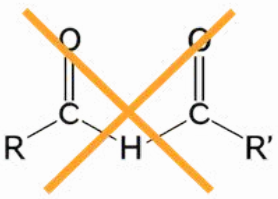
High humidity

Light

Storage Conditions

4 HOW TO RESOLVE CROSS-LINKING ISSUES

A AVOID CARBONYL COMPOUNDS

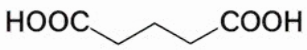


Use excipients free of aldehydes, ketones, and other carbonyl-containing compounds.

B MINIMIZE METAL IONS

Minimize the use of metal ions in softgel formulations

C USE SUCCINATED GELATIN

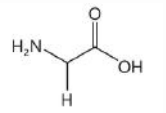


Gelatin is succinylated with succinic acid to reduce aldehyde-induced cross-linking.

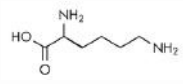
Note:

- Incompatible with ethanol and propylene glycol.
- Ineffective in the presence of metal ions.

D USE AMINO ACID



Glycine



Lysine

- Competitive reactants with amino groups in gelatin. Used at 0,2 – 5% (w/w) of capsule shell solids
- Carboxylic acid esters (C4–C20) with 2–3 carbonyl groups are added to capsule shells or fill formulations to improve effectiveness.

E OTHER CAPSULE SHELL ADDITIVES

- Carboxylic acids (Citric acid, Succinic acid)
- semicarbazide
- Hydroxylamine
- Hydrochloride
- Piperazides
- Pyridine
- Pentamethylene imine
- Glycerine
- p-Aminobenzoic acid

F MAINTAIN STORAGE CONDITIONS

Temperature ≤ 25 °C

Humidity < 60% RH

Protect from light

Store softgels in appropriate, stable conditions.

H UTILIZE SUITABLE PACKAGING

Use packaging with high moisture, oxygen, and light barrier properties (e.g., Alu–Alu, HDPE).

G USE AMMONIUM SALTS

Reduce cross-linking induced by polyol excipients (e.g., sorbitol, mannitol).

TYLOXAPOL

MODERN PHARMACEUTICAL FORMULATION

MULTIPURPOSE NONIONIC SURFACTANTS IN PHARMACEUTICAL PRODUCTION

ENHANCE WETTING CAPACITY
Decreases surface tension, enhances wettability, and improves drug dispersion

ENHANCED SOLUTION
The formation of micelles enhances the solubility of poorly water-soluble APIs

DISPERSION STABILIZATION
Stabilizes dispersions, prevents aggregation, and maintains particle size

ASSISTANCE IN MUCUS REMOVAL
Reduces mucus viscosity, facilitates mucus drainage, and promotes airway clearance

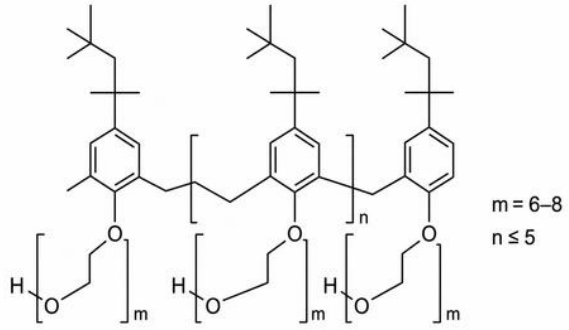
1 INTRODUCTION TO

TYLOXAPOL

Tyloxapol is a non-ionic surfactant classified within the alkylaryl polyether alcohol polymer group, synthesized through the polymerization of alkylphenol with formaldehyde and ethylene oxide.

By reducing surface tension, enhancing wetting properties, and stabilizing dispersed systems, Tyloxapol is widely used in modern pharmaceutical formulations, particularly in ophthalmic preparations, aerosols, suspensions, emulsions, and nanocarrier drug delivery systems.

A CHEMICAL COMPOSITION



Alkylaryl polyether alcohol polymer

The amphiphilic structure consists of a hydrophobic moiety (alkylphenyl group) and a hydrophilic moiety (polyoxyethylene chain). This structure enables molecules to adsorb at the interface between the two phases, thereby reducing surface tension and forming micelles.

B PHYSICAL PROPERTIES

ATTRIBUTES	CHARACTERISTIC	NOTES
Apperance	Viscous fluid	Viscosity enhancement & dispersion stability
Color	Colorless to pale yellow	Maintains product clarity
Odor	Almost odorless	Minimizes impact on flavor
Solubility	Freely soluble in water	Easy to incorporate into O/W emulsions
Compatible solvents	Methanol, Isopropanol, Propylene Glycol, Glycerol	Formula flexibility
Specific gravity	1.03–1.06 g/mL (25 °C)	Comparable to specific gravity of water
Solubility in oil	Insoluble or practically insoluble	Suitable for O/W emulsions
Hygroscopi-city	Slightly hygroscopic	Tightly sealed storage
HLB value	13–14	O/W emulsifying agent

Water

Propylene Glycol

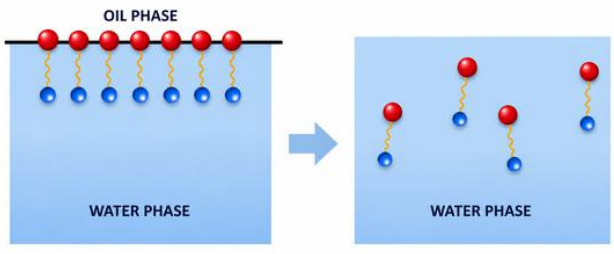
Ethanol

Oil

2 SURFACE ACTION MECHANISM

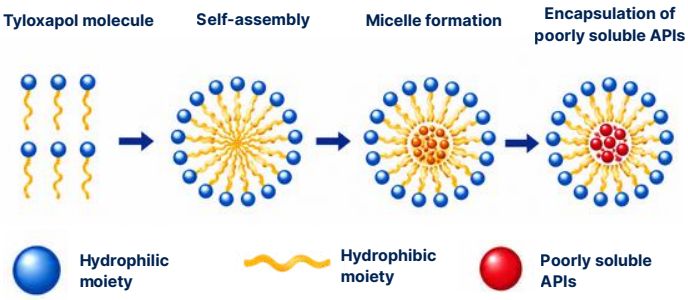
A DECREASE SURFACE TENSION

Similar to other surfactants, Tyloxapol features a structure comprising a hydrophilic head and a hydrophobic tail, thereby diminishing the oil-water interfacial tension. This facilitates the rapid wetting of solid particles, such as lipophilic active ingredients, enhancing uniform dispersion and minimizing the risk of agglomeration.



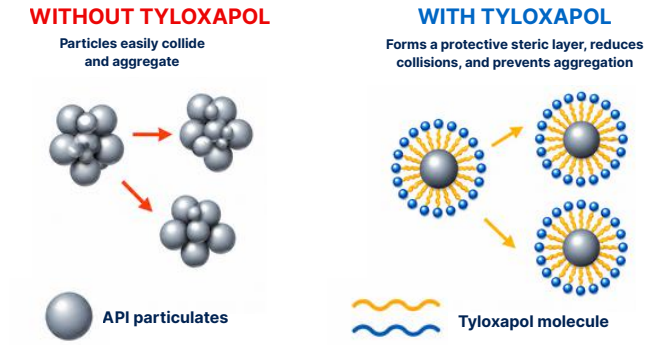
B MICELLE FORMATION

The formation of micelles, comprising a hydrophobic core that encapsulates hydrophobic active pharmaceutical ingredients (APIs) or poorly soluble APIs, and a hydrophilic outer shell, enhances the solubility and dispersibility of solid particles in the solvent



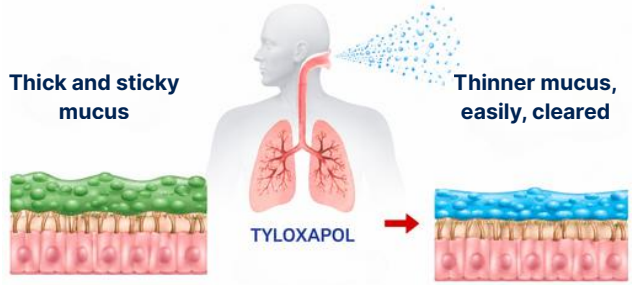
C STABILIZATION OF DISPERSION SYSTEM

Tyloxapol adsorbs onto the surfaces of API particles, forming a hydration barrier and steric hindrance. This reduces interparticle collisions, minimizes aggregation, and maintains a stable particle size throughout the shelf life.



D REDUCED RESPIRATORY SECRETION VISCOSITY

Tyloxapol reduces the surface tension between mucus and air, making secretions less viscous, reducing mucus adherence to the respiratory mucosa, and facilitating mucus drainage and clearance. This is one of the key characteristics that allows Tyloxapol to be utilized as an API in respiratory drug formulations.



3 ADVANTAGES OF TYLOXAPOL

01 NON-IONIC

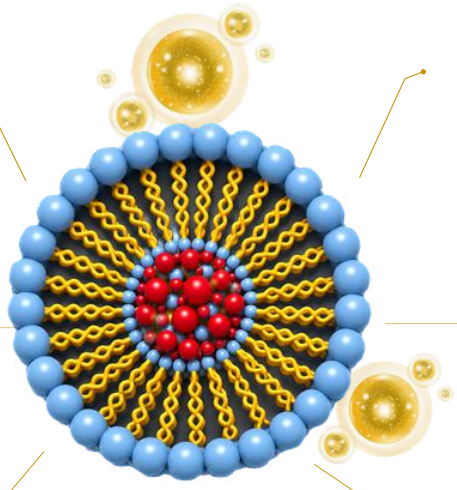
Non-ionic, thus it has minimal interaction with charged APIs or excipients, low complexation tendency, and is minimally affected by environmental pH

02 STABILITY OVER A WIDE pH RANGE

Remains stable across a broad pH range of 3 to 10.

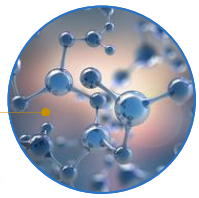
03 LOW TOXICITY, HIGH COMPATIBILITY

Suitable for ophthalmic drops and inhalation formulations.



04 EXCELLENT DISPERSING & SOLUBILITY

Enhances the solubility and dispersibility of poorly soluble APIs, retards aggregation, and stabilizes the finished product.



05 NANOSYSTEM STABILIZATION

Reduces particle size, prevents aggregation, and maintains a stable particle size distribution during storage.

06 LOW-FOAMING, ODORLESS

Low foaming tendency and lacks characteristic odor, facilitating convenient formulation manufacturing and administration.

4 APPLICATIONS AND PRODUCTS CONTAINING TYLOXAPOL

Due to its ability to reduce surface tension, enhance dispersion, and stabilize dispersion systems, Tyloxapol is widely applied in various modern dosage forms.

A. APPLICATIONS IN PHARMACEUTICAL DOSAGE FORMS

01 INJECTABLE PHARMACEUTICALS

Improves the solubility and stability of API dispersion systems in injectable pharmaceutical.

02 OPHTHALMIC DROPS

Enhances the dispersibility of poorly soluble APIs and improves the physical stability of ophthalmic suspensions.

03 INHALATION & NEBULIZER FORMULATIONS

Reduces the surface tension of respiratory secretions and facilitates mucus drainage and clearance.

04 ORAL SUSPENSION

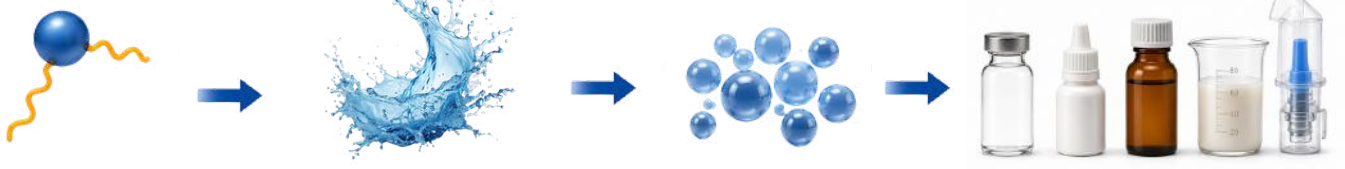
Maintains uniform dispersibility of solid particles throughout the shelf life.

05 EMULSION

Stabilizes oil-in-water (O/W) emulsion systems and prevents phase separation or flocculation during storage.

06 NANO-DRUG DELIVERY SYSTEMS

Reduces particle size, limits aggregation, and maintains stable particle size in nanocarrier systems.



B. COMMERCIAL PRODUCTS CONTAINING TYLOXAPOL

TOBREX®

Tobramycin 0.3% ophthalmic solution

FLAREX®

Fluorometholone 0.1% ophthalmic solution

NEVANAC®

Nepafenac 0.1% ophthalmic solution

MOXEZA®

Moxifloxacin hydrochloride 0.5% ophthalmic solution

Tyloxapol is a multifaceted non-ionic surfactant that enhances formulation efficiency, stability, and drug delivery across various contemporary dosage forms.

MILK THISTLE

DRY EXTRACT

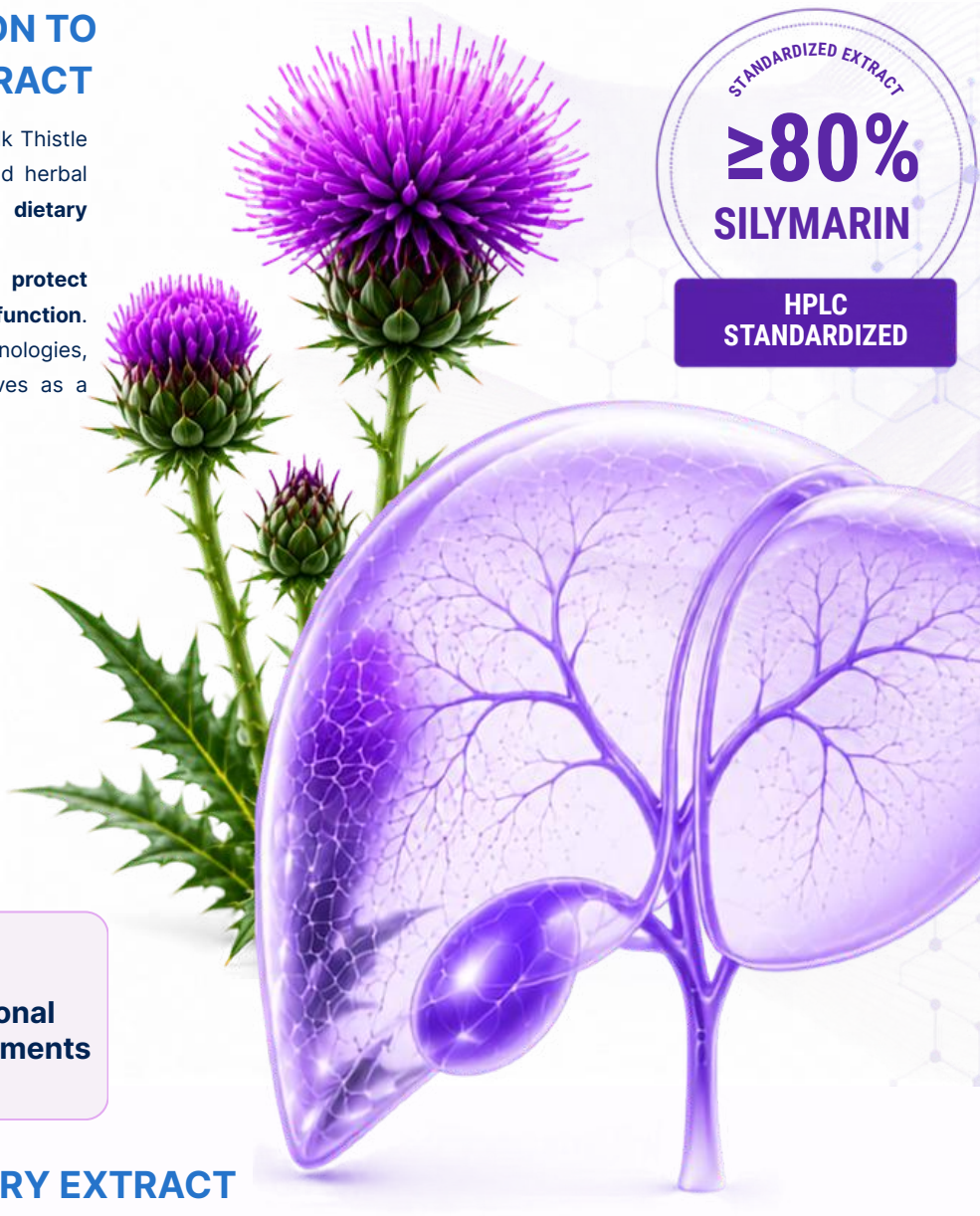
MILK THISTLE EXTRACT RICH IN SILYMARIN
SUPPORTS LIVER PROTECTION AND DETOXIFICATION

1 GENERAL INTRODUCTION TO MILK THISTLE DRY EXTRACT

Milk Thistle Dry Extract (dry extract derived from Milk Thistle - *Silybum marianum*) is one of the most widely used herbal ingredients in **pharmaceutical products** and **dietary supplements for liver support.**

Milk Thistle is highly regarded for its ability to **protect hepatocytes** (liver cells), **detoxify**, and **restore liver function**. With advancements in modern extraction technologies, Silymarin-standardized Milk Thistle Dry Extract serves as a strategic raw material in formulations for:

- Liver function support
- Liver detoxification
- Antioxidant products
- Liver protection for alcohol consumers



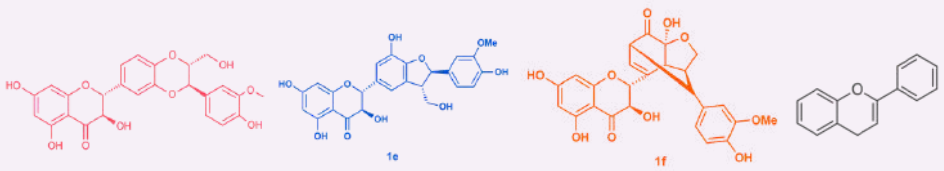
APPLICATIONS IN

- Pharmac -euticals
- Nutritional supplements

2 ACTIVE INGREDIENT: DRY EXTRACT OF MILK THISTLE

The efficacy of Milk Thistle Dry Extract is attributed to the flavonolignan complex Silymarin, recognized as the primary active component responsible for its hepatoprotective properties.

The primary components consist of:



Silybin (Silybinin)	Silychristin	Silydianin	Natural flavonoids
The most effective active ingredient for hepatocyte protection.	Antioxidant and stabilization of cell membranes.	Supports liver function	Enhances free radical scavenging capacity.

KEY HIGHLIGHT

Standardized Milk Thistle Extract

≥ 80% Silymarin

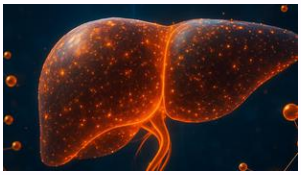
Ensuring purity, stability, and bioavailability in formulations for liver support.

3 ADVANTAGE

HIGH PURITY
Standardized dry extract guarantees a consistent Silymarin content of ≥ 80%, ensuring reliable biological efficacy for pharmaceutical and dietary supplement formulations.

SCIENTIFICALLY PROVEN EFFICACY
Multiple clinical studies have demonstrated the potent hepatoprotective and antioxidant effects of Silymarin.

LONG HISTORY OF TRADITIONAL USE
Globally, Milk Thistle extract has a centuries-old history of use in supporting liver health.



THE MECHANISM OF ACTION IS WELL-DEFINED
Helps build trust among manufacturers and consumers

MARKET TREND
Proactive liver healthcare and prevention of liver diseases are growing rapidly, especially among alcohol consumers.

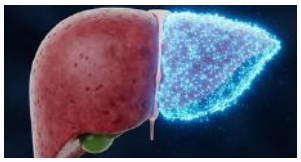
BOTANICAL ORIGIN
Aligns with current health supplement trends, fostering consumer trust.

SIMPLE TO STANDARDIZE AND QUALITY CONTROL
Silymarin is a thoroughly researched group of active compounds that can be quantified via HPLC, making content standardization straightforward.

MULTI-INGREDIENT COMBINATION TREND
Easily combined with other hepatoprotective and antioxidant active ingredients such as Curcumin, Coenzyme Q10, Vitamin E, Resveratrol, Choline, Inositol, Omega-3, Alpha-lipoic acid.

4 APPLICATION

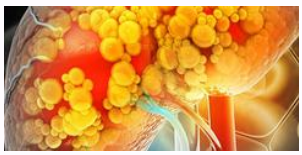
Protects hepatocytes against toxins and free radicals



Supports regeneration of damaged hepatocytes

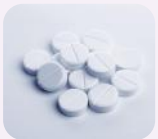
Enhances liver detoxification function

Reduces hepatic oxidative stress



Supports management of chronic liver diseases

Milk Thistle Dry Extract is provided in powdered form, appropriate for a range of processing techniques:


Tablets


Hard capsules


Oral suspension


Suspension powder/granules

KEY HIGHLIGHTS

≥80%
Standardized Silymarin

HPLC Standardization
Precise measurement, quality control

Botanical Source
Botanical origin (*Silybum marianum*)

Pharmaceutical Quality
Complies with SMP and international standards.

BORIC ACID

APPLICATIONS IN PHARMACEUTICAL DOSAGE FORMS.

Boric acid, also known as orthoboric acid, is an inorganic compound with the chemical formula H_3BO_3. It is a weak acid of boron that has long been used in the pharmaceutical field due to its **mild antiseptic, pH-adjusting**, and **buffering properties**.

In pharmaceutical formulation and manufacturing, boric acid is used not only as an active pharmaceutical ingredient (API) in certain topical preparations but also serves as a functional excipient in **ophthalmic drops, topical formulations,** and specialized buffer systems. Owing to its relatively high safety profile in local application and good compatibility with various ingredients, boric acid is a common raw material in numerous pharmaceutical dosage forms.

BORIC ACID

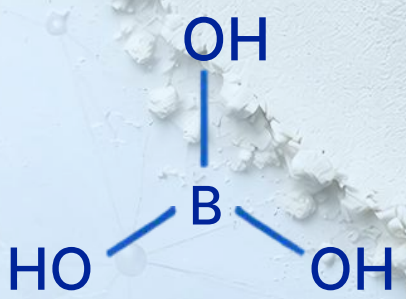
CHEMICAL FORMULA

H_3BO_3

Other name: Boric acid

COMMONLY UTILIZED IN:

- Ophthalmic drugs
- Topical drugs
- Buffer systems
- Preservatives

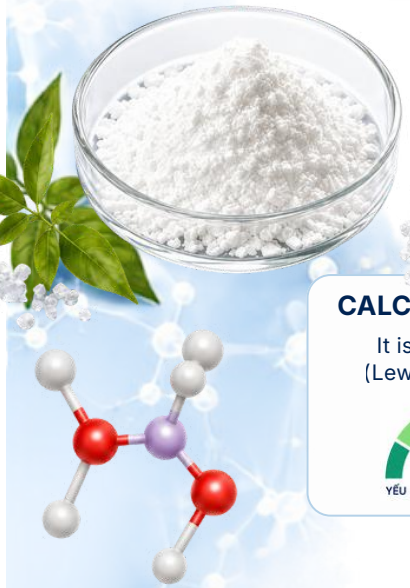


BORIC ACID STRUCTURE

1 PROPERTIES OF BORIC ACID

MOLECULAR FORMULA
H_3BO_3

MOLECULAR MASS
61,83 g/mol



PHYSICAL CHARACTERISTICS

- White crystalline powder or colorless crystalline flakes
- Odorless
- Slightly sour taste

SOLUBILITY

Dissolves more effectively in hot water than in cold water

Souble in:

- Glycerin
- Polyethylene glycol (PEG)

CALCULATE ACID.

It is a weak acid (Lewis weak acid).

COMPLEXATION WITH DIOL COMPOUNDS

It forms complexes with compounds that contain diol groups, such as:

MELTING POINT

About **170°C**

STABILITY

Stable under standard storage conditions

NOTE

Has potential to interact with:

- **Strong alkalis**
- **Compounds capable of complexing with borate.**

May lead to borate complex formation or pH alteration, affecting formulation stability.

2 ADVANTAGES OF BORIC ACID

EFFICIENT pH ADJUSTMENT

When combined with sodium borate, it forms a borate buffer system that maintains a stable pH, enhances the stability of the APIs, and minimizes pH fluctuations during storage. This is particularly crucial for ophthalmic drugs.

MILD ANTISEPTIC & ANTIFUNGAL ACTIVITY

It inhibits bacterial growth, limits yeast and mold proliferation, supports preservative efficacy, and enhances the performance of topical drugs.

BROAD BUFFERING CAPACITY

Widely applied as a buffer system across various liquid dosage forms.

HIGH STABILITY & COMPATIBILITY

It exhibits excellent stability, is compatible with various APIs and excipients without causing incompatibilities upon formulation.

RELATIVELY HIGH SAFETY PROFILE

At appropriate concentrations, it causes minimal skin and mucosal irritation with good ocular tolerance. Long history of clinical application in ophthalmic drug products.

ENHANCES API SOLUBILITY

It forms complexes with polyols or compounds that possess adjacent hydroxyl groups, aiding in solubility enhancement and solution stability.

COST-EFFECTIVE & EASY TO USE

Readily available raw material, low cost, simple formulation process, and straightforward quality control.

3 APPLICATIONS OF BORIC ACID

OPHTHALMIC DRUGS

- pH adjustment: maintains the optimal pH level for eye drops.
- Components of the borate buffer system: stabilize the active ingredient.
- Tonicity adjusting agent: enhances ocular upon administration.

TOPICAL DRUGS

- Topical antiseptic solution: due to its gentle antiseptic properties.
- Creams, ointments, topical powders: support treatment of cutaneous fungal infections soothes irritated skin areas.

GYNECOLOGICAL DRUGS

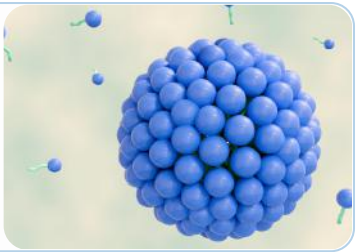
- Modifying vaginal pH.
- Supports treatment of recurrent vulvovaginal candidiasis.
- Inhibits growth of pathogenic microorganisms.

BUFFER SYSTEMS IN LIQUID DOSAGE FORMS

- Ophthalmic drugs.
- Eye wash solutions.
- Select topical liquid formulations.

TONICITY AGENT

- Tonicity agent
- Minimizes ocular irritation
- Easily compatible with borate buffer systems.



PRECAUTIONS FOR USING BORIC ACID IN FORMULATION

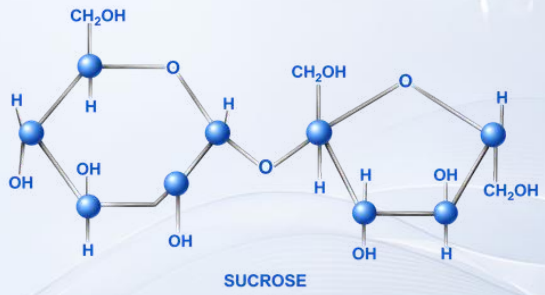
- Avoid high concentrations in preparations with high potential for systemic absorption.
- Avoid prolonged application on extensive areas of damaged skin.
- Use with caution in neonates and young children.
- In multidose ophthalmic drugs, boric acid cannot completely replace dedicated antimicrobial preservatives.
- Evaluate formulation compatibility when combined with APIs sensitive to pH or borate ions.

SUCROSE

MULTIFUNCTIONAL EXCIPIENTS IN PHARMACEUTICAL FORMULATION DEVELOPMENT

- Sweetening agent
- Multifunctional excipient
- Safe & Reliable
- Botanical origin

MOLECULAR FORMULA: $C_{12}H_{22}O_{11}$



STRUCTURE OF SUCROSE

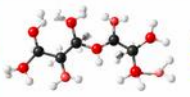
GENERAL INTRODUCTION

Sucrose (saccharose or cane sugar) is a natural disaccharide composed of **one glucose molecule and one fructose molecule** linked together via a glycosidic bond. With the molecular formula $C_{12}H_{22}O_{11}$, sucrose is one of the most widely used excipients in the pharmaceutical industry due to its **pleasant sweet taste**, **high safety profile**, and **multifunctional properties**

In pharmaceutical dosage forms, sucrose serves not only as a sweetening agent but also plays various functional roles such as a **diluent**, **binder**, **bodying agent, structural agent**, **and stabilizer across various dosage forms**. Owing to its versatility and high compatibility with numerous active pharmaceutical ingredients (APIs), sucrose is present in many solid dosage forms such as tablets, sugar-coated tablets, powders, and sachets, as well as liquid dosage forms including syrups and oral suspensions.

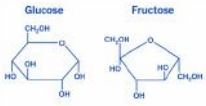
1 PROPERTIES OF SUCROSE IN PHARMACEUTICAL DOSAGE FORMS

CHEMICAL CHARACTERISTICS

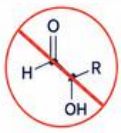


$C_{12}H_{22}O_{11}$

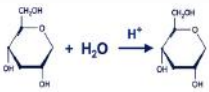
Molecular weight:
342.30 g/mol



Disaccharide consisting of glucose and fructose.



Non-reducing sugar: Lacks free aldehyde or ketone groups



Undergoes acid-catalyzed hydrolysis to yield glucose and fructose.

Stable in neutral media and under standard storage conditions

PHYSICAL PROPERTIES

White crystalline substance or white crystalline powder.

Odorless, with a pleasant sweet taste

Assigned a reference value of 100, commonly used as a benchmark for other sweetening agents.

Undergoes acid-catalyzed hydrolysis to yield glucose and fructose.

Stable in neutral media and under standard storage conditions.

FORMULATION PROPERTIES

Exhibits brittle fracture mechanism, providing relatively good compressibility in direct compression

Imparts an attractive glossy finish to sugar-coated tablets

In liquid dosage forms, sucrose creates high-viscosity solutions, imparting body and texture to preparations

Demonstrates mild antibacterial and antifungal properties

Easily compatible with various other excipients in formulation.

2 ADVANTAGES OF SUCROSE

EFFECTIVE SWEETENING & FLAVOR-MASKING CAPACITY

Provides natural sweetness and effectively masks bitter or astringent tastes of APIs, thereby improving patient compliance.

HIGH SAFETY PROFILE

Low toxicity, minimal irritation, and widely approved for use in food, pharmaceuticals, and health products by global regulatory agencies.

MULTIFUNCTIONALITY

Serves multiple functional roles within formulation: sweetening agent, diluent, binder, viscosity-increasing agent, cryoprotectant, and supportive preservative.

PROTEIN & BIOLOGICAL STABILIZATION

Protects native protein structure, prevents denaturation and aggregation, thereby enhancing the stability of vaccines, recombinant proteins, and lyophilized products.

CONSOLIDATED WITH

CELLULOSE

CROSCARMELLOSE

PVP K30

MAGNESIUM STEARATE

POLYETHYLENE GLYCOL (PEG)

3 APPLICATIONS OF SUCROSE IN PHARMACEUTICAL DOSAGE FORMS

SWEETENING & FLAVOR-MASKING AGENT

Provides a pleasant sweet taste and masks bitter, astringent, or unpalatable tastes in oral liquid preparations, powders/ sachets, chewable tablets, lozenges, and orally disintegrating tablets (ODTs).

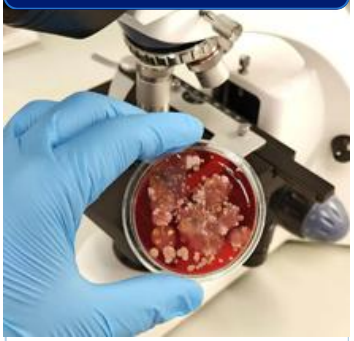
STABILIZING AGENT

Exhibits mild reducing activity and high viscosity, thereby inhibiting oxidation of certain APIs and stabilizing liquid dosage forms

VISCOSITY MODIFIER

Imparts viscosity and stabilizes liquid drug products, particularly oral suspensions by reducing the sedimentation rate of suspended particles during storage and use.

PRESERVATIVE



At high sucrose concentrations, the resulting high osmotic pressure draws water out of microbial cells, thereby inhibiting microbial growth.

4 USE OF SUCROSE IN PHARMACEUTICAL DOSAGE FORMS

Sucrose is frequently utilized in various pharmaceutical dosage forms.

SOLID DOSAGE FORM

TABLETS

Exhibits brittle fracture behavior, making it suitable as a diluent. Co-processed forms enhance flowability and compressibility.

SUGAR-COATED TABLETS

Provides a smooth, glossy coating layer for sugar-coated tablets.

CHEWABLE TABLETS LOZENGES/ ODTs

Imparts a pleasant sweet taste, partially masking bitter or astringent tastes of the dosage form.

POWDER

SACHET

Provides a pleasant, sweet taste and masks bitter/astringent notes, improving palatability for powder and sachets.

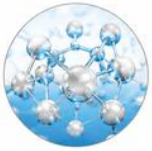
LIQUID DOSAGE FORM

SYRUP

- Flavoring agent, sweetener, and taste-masking agent
- Enhance viscosity and stabilize the dosage form
- Natural preservative effect.

SUSPENSIONS

- Enhance viscosity and stabilize the dosage form
- Reduces particle sedimentation rate during storage and administration



LIQUID SOLUTIONS

- Flavoring, sweetening, and taste-masking agent
- Enhance viscosity and stabilize the dosage form
- Natural preservative effect

ETHANOL

AN ESSENTIAL SOLVENT IN THE PHARMACEUTICAL INDUSTRY.

Pure solvent solutions ensure optimal efficiency in pharmaceutical formulation and manufacturing.

High purity
96 – 100%

Pharmacopoeia standards
USP, Ph. Eur., BP, JP

Varied applications
In each phase of product manufacturing

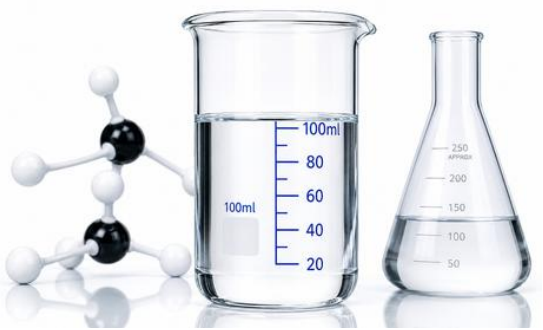
GENERAL INTRODUCTION

Ethanol (ethyl alcohol, C_2H_5OH) is one of the most widely used organic solvents in the pharmaceutical industry owing to its excellent solvency for various APIs, suitable volatility, high compatibility with various APIs and excipients, and a well-established safety profile. In pharmaceutical manufacturing, ethanol functions not only as a processing solvent but also plays crucial roles in essential processing steps such as herbal extraction, granulation liquid in wet granulation, solvent for film-coating solutions, equipment disinfection, and formulation of advanced drug delivery systems.

Depending on the intended application, ethanol is available in various grades and concentrations. Among these, pure ethanol 96 - 100% is preferred in pharmaceutical production due to its low moisture content, high chemical purity, and ability to comply with stringent International Pharmacopeial standards.

1 APPLICATIONS OF ETHANOL IN PHARMACEUTICAL DOSAGE FORMS

Ethanol is widely used in the pharmaceutical industry as a solvent, excipient, and functional agent across numerous manufacturing processes, from API solubilization and herbal extraction to pharmaceutical manufacturing and quality control.



SOLVENTS, THE ACTIVE INGREDIENT, AND EXCIPIENTS

APIs

- Vitamins A, D, E, K
- Steroids
- Essential oils
- Alkaloids
- Flavonoids
- Lipophilic APIs

EXCIPIENTS

- Film-forming polymers
- Plasticizers
- Flavoring agents
- Preservatives

DOSAGE FORMS

SOLVENT FOR HERBAL EXTRACTION

- Polyphenols
- Flavonoids
- Curcuminoids
- Alkaloids
- Glycosides
- Coumarins
- Terpenoids

50% → 70% → 80% → 96%

OPTIMIZING EXTRACTION YIELD

GRANULATING SOLVENT IN THE WET GRANULATION PROCESS

- PVP
- HPMC
- Ethyl cellulose
- Copovidone

Wet granulation in a high-shear mixer

Wet granule drying in a fluid bed dryer

Milling in a vertical cone mill

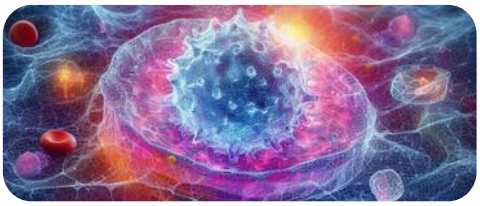
- Reduces hydrolysis risk
- Shortens drying time
- Produces uniform granules
- Improves granule flowability

SOLVENT FOR FILM-COATING SOLUTIONS

POLYMER USED

- Shellac
- Ethylcellulose
- Acrylic Polymer
- Taste-Masking Polymers

MANUFACTURING OF ADVANCED DRUG DELIVERY SYSTEMS



- Nanoparticles
- Liposomes
- Nanoemulsions
- Solid dispersions
- Polymeric Micelles
- SEDDS / SMEDDS

Ethanol plays a key role in solubilizing lipids, polymers, or APIs before nano-dispersion systems.

DISINFECTION AND SANITATION IN MANUFACTURING

- Equipment cleaning
- Surface disinfection
- Pipeline cleaning
- Cleanroom sanitation
- Tool disinfection

USAGE CONCENTRATION

70%	Disinfection
96–100%	Preparation of antiseptic solutions

2 WHY USE PURE ETHANOL (96–100%) IN PHARMACEUTICAL MANUFACTURING?

Although ethanol is a common raw material, not all ethanol grades are suitable for pharmaceutical production. Ethanol used in pharmaceuticals must meet stringent quality standards to ensure safety, efficacy, and product stability.

A MINIMIZES HARMFUL IMPURITIES

- Methanol
- Acetaldehyde
- Fusel oil
- Benzene
- Heavy metals
- Other volatile organic compounds

Pure ethanol reduces the risk of toxic impurity contamination in pharmaceutical products, especially in oral, injectable, and pediatric dosage forms.

B DECREASE WATER CONTENT

- Minimizes hydrolysis reactions
- Enhances chemical stability
- Reduces microbial growth risk
- Enhance solubility lipophilic compounds
- Enhance extraction yield

Crucial for moisture-sensitive APIs and excipients.

C ENSURES PROCESS REPEATABILITY

- Consistent solvency capacity
- Uniform evaporation rate
- Stable viscosity and specific gravity
- Granulation efficiency during wet granulation
- Uniform film-coating quality

Consistent ethanol purity maintains process reproducibility and batch-to-batch uniformity.

D MEETS INTERNATIONAL PHARMACOPOEIA

- Assay
- Specific gravity
- Acidity/Alkalinity
- Nonvolatile residue
- Clarity and color of solution
- Absorbance
- Other physicochemical parameters

Selecting pharmacopeial-grade ethanol enables manufacturers to comply with GMP requirements and international quality standards.

ADVANTAGES OF PURE ETHANOL 96–100%

A SECURE AND RELIABLE CHOICE FOR PHARMACEUTICAL MANUFACTURING.

- High Purity (Low Toxic Impurities)
- Low water content
- Elevated stability for the APIs
- Ensure the reproducibility of the pharmaceutical manufacturing.
- Adheres to the international Pharmacopoeias (USP, Ph. Eur., BP, JP)

CONCLUSION

High-purity ethanol is essential in pharmaceutical manufacturing, as it ensures quality and efficacy, mitigates toxicity risks, and improves the stability of pharmaceutical products.

Selecting compliant ethanol sources not only satisfies strict regulatory requirements but also elevates brand reputation and manufacturing efficiency.

Biorich supplies pharmaceutical-grade ethanol with comprehensive quality certifications, fully supporting businesses to achieve maximum efficiency and sustainable growth at the highest standards.

BIORICH SUPPLIES PHARMACEUTICAL-GRADE PURE ETHANOL

With complete regulatory documentation and quality certificates, complying with the strict requirements of the International Pharmacopeias

WHO GMP · ISO 9001:2015 · USP · Ph. Eur. · JP · BP · ACS

APPLICATIONS OF BETA CYCLODEXTRIN

IN ENHANCING SOLUBILITY AND TASTE-MASKING FOR HERBAL ACTIVE INGREDIENTS

Solubility Enhancement • Taste-Masking • Stabilization of Herbal Ingredients

Herbal active ingredients often face two major limitations: **poor aqueous solubility** and **a bitter** or **unpalatable taste**, which negatively impact bioavailability and patient compliance.

In recent years, **Cyclodextrins**, particularly **β-cyclodextrin**, have been extensively utilized to enhance solubility, increase stability, and mask the bitterness of herbal active ingredients, opening up significant potential for advanced drug delivery systems.

POOR SOLUBILITY

Poorly water-soluble herbal active ingredient

HOST-GUEST COMPLEX

β-Cyclodextrin encapsulates the active ingredient via a host-guest complex formation mechanism.

ENHANCE SOLUBILITY

The inclusion complex significantly enhances the aqueous solubility of the active ingredient

1 WHAT ARE CYCLODEXTRIN AND BETA-CYCLODEXTRIN?

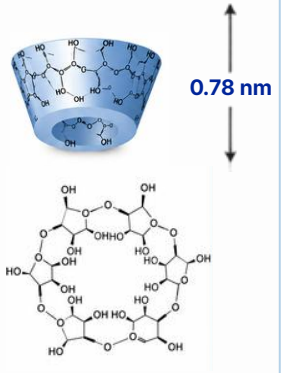
Cyclodextrin (CD) is a cyclic oligosaccharide consisting of glucose units linked by α-1,4-glycosidic bonds. The production of cyclodextrin is facilitated by the enzyme cyclodextrin glycosyltransferase (CGTase), which acts on starch.

CYCLODEXTRIN PRODUCTION PROCESS

TYPES OF CYCLODEXTRIN

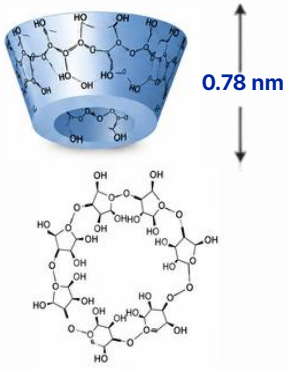
- **Natural cyclodextrin**: Comprising 6, 7, or 8 dextrose units, referred to as α-, β-, and γ-CD, respectively.

α-Cyclodextrin (α-CD)



6 glucose

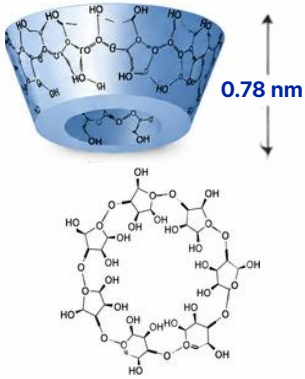
β-Cyclodextrin (β-CD)



7 glucose

MOST WIDELY USED

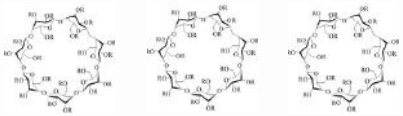
γ-Cyclodextrin (γ-CD)



8 glucose

CYCLODEXTRIN DERIVATIVES

Attachment of substituents: sulfobutyl, hydroxypropyl, random methylation



SBECD Sulfobutyether-β-CD

HP-BCD Hydroxypropyl-β-CD

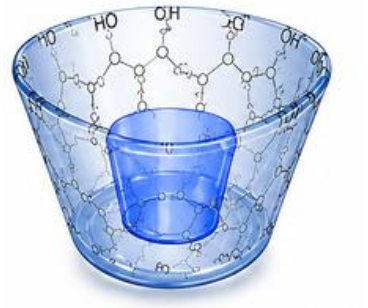
RM-BCD Methyl β-CD

WHY IS BETA-CYCLODEXTRIN PREFERRED?

- Hydrophobic cavity suitable for a wide range of herbal active ingredients.
- Cost-effective
- Large-scale manufacturability
- High safety profile

2 MECHANISM OF SOLUBILITY ENHANCEMENT AND BITTERNESS MASKING VIA BETA-CYCLODEXTRIN

STRUCTURE OF BETA-CYCLODEXTRIN



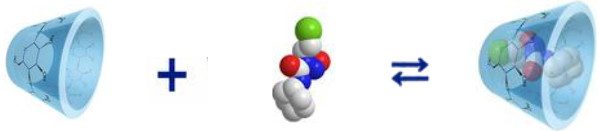
HYDROPHILIC OUTER SURFACE

Hydrophilic outer surface (–OH groups)

HYDROPHOBIC INNER CAVITY

The hydrophobic cavity can encapsulate hydrophobic molecules

HOST-GUEST COMPLEX MECHANISM



HOST
β-Cyclodextrin

GUEST MOLECULE
herbal active ingredient

INCLUSION COMPLEX
Host-Guest Complex

COMPLEXATION FORMATION VIA NON-COVALENT INTERACTIONS

- Van der Waals forces, hydrophobic interactions, hydrogen bonds, and dipole interactions.
- The process is reversible and does not modify the chemical structure of the active ingredient.

RESULTS OF BETA-CYCLODEXTRIN INCLUSION COMPLEXATION

ENHANCE SOLUBILITY

The poorly soluble active ingredient is encapsulated within a β-CD cavity, → increased surface area in contact with water, lowers solvation energy, and improves dispersibility.

ENHANCED BIOAVAILABILITY

β-CD complex form nanoparticles and disperse uniformly → enhancing the surface area in contact with digestive fluids, enhances dissolution rate and improving oral bioavailability.

TASTE MASKING

Hydrophobic functional group responsible for bitterness is entrapped inside the β-CD cavity → reduces free active molecules minimizes contact with taste receptors, making it easier for patients to swallow.

REDUCTION OF IRRITATION

Reduces/ prevents local gastrointestinal irritation caused by active ingredients, thereby minimizing adverse effects

INTERACTION REDUCTION

Reduces interactions between the active ingredient and other ingredients or excipients

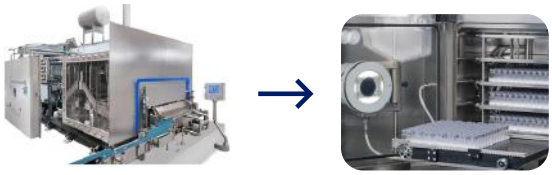
PROTECTION AGAINST LIGHT

Inhibits oxidation, mitigate the effects of temperature and light exposure, and reduce volatilization of volatile active ingredients.

INHIBITION OF CRYSTALLIZATION

Minimizes crystallization and maintains the active ingredient in an amorphous state, enabling longer stability in the dissolution media

3 METHODS FOR PREPARING BETA-CYCLODEXTRIN–ACTIVE INGREDIENT INCLUSION COMPLEXES

METHOD	ILLUSTRATION	DESCRIBE
1 KNEADING METHOD		Moisten β-cyclodextrin with water or a mixture of ethanol and water to create a paste, followed by the addition of the active ingredient. The mixture is continuously kneaded for 30–60 minutes, then dried, milled, and sieved to yield a complex powder.
2 GRINDING/ BALL MILLING		Utilize a ball mill or high-energy mills for several hours to produce the complex in powder form.
3 SPRAY DRYING		A solution of β-cyclodextrin and a solution of the active ingredient are mixed thoroughly to allow complexation. The mixture is subsequently dried using a spray dryer or a fluid bed granulator to obtain a powder.
4 FREEZE-DRYING/ LYOPHILIZATION		The solution, following complex formation, is frozen, and the water is sublimated to yield a porous, readily soluble powder.
5 ULTRASONICA -TION METHOD		Utilizing ultrasonic energy to improve the interactions between β-cyclodextrin and the active ingredient, thereby accelerating the complexation process.

GENERAL CONSIDERATIONS

1:1
1:2
2:1

The standard mixing ratio of β-cyclodextrin to the active ingredient is 1:1 by molar ratio; however, certain active ingredients may necessitate a ratio of 1:2 or 2:1 to enhance the efficiency of complex formation.

4 ADVANTAGES OF UTILIZING BETA-CYCLODEXTRIN

Typically, herbal active ingredients lack ionizable charged functional groups; therefore, common taste-masking approaches, such as ion-exchange resin complexation, are inapplicable. β-Cyclodextrin does not rely on specific chemical structure; instead, it depends on molecular dimensions, spatial geometry, hydrophobicity, and cavity inclusion capability of the active ingredients. Consequently, β-cyclodextrin can form inclusion complexes with a broad spectrum of herbal active ingredients, delivering superior solubility enhancement and taste-masking efficiency.

Requires only a short incubation time within a few hours.

Eliminates the need for organic solvents, reducing residual solvent risks and explosion hazards.

Does not alter the chemical structure or biological activity of the active ingredient.

Highly compatible with various active ingredients and excipients

Suitable for diverse solid and liquid dosage forms, as well as diverse classes of herbal compounds

Flexible formulation and manufacturing processes, easily scalable for industrial production.

Well-established safety

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For samples and technical documentation

+84 834 560 500

director@biorichgroup.com