BIORICH GROUP

AUGUST
08
2026

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INSIGHTS

PHARMACEUTICAL INGREDIENTS,
HEALTH SOLUTIONS & INNOVATION

PATIENT CENTRIC FORMULATION

DESIGNING BETTER MEDICINES FOR BETTER PATIENT OUTCOMES

Pharmaceutical ingredient solutions designed to elevate the patient medication experience

ENHANCING PATIENT EXPERIENCE

Taste masking, sweetening, and palatability enhancement to enhance the medication experience.

TREATMENT ADHERENCE

Enhancing patient acceptability and compliance

OPTIMIZED & STABLE FORMULATION

Selecting excipients to improve therapeutic efficacy, product stability, and overall quality

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KNOWLEDGE FOR BETTER HEALTH

Providing in-depth expertise on pharmaceutical ingredients and solutions for the pharmaceutical industry.

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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

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TASTE-MASKING COATING

COMMON TASTE-MASKING TECHNIQUES FOR APIs IN PHARMACEUTICAL FORMULATION

Improving patient acceptability, treatment compliance, and therapeutic efficacy

EFFECTIVE TASTE-MASKING

Blocks API interaction with taste receptors to eliminate bitterness

STABILITY & APPEARANCE

Protects core tablets from environmental factors while enhancing product appearance

IMPROVED COMPLIANCE

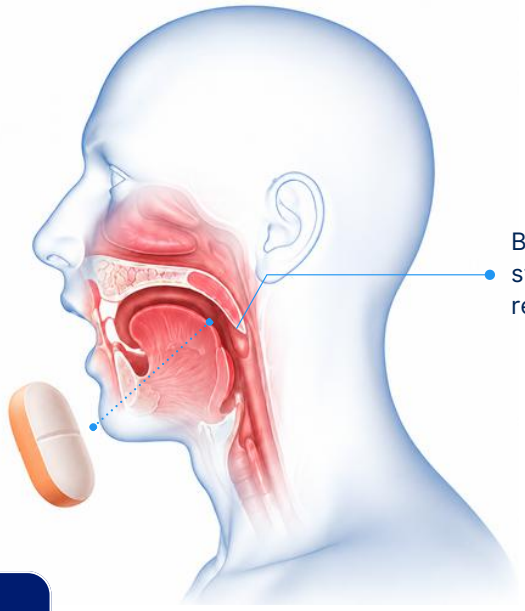
Enhances patient acceptability, especially in pediatric and geriatric populations

> *SCIENCE OF STRUCTURAL VALUE CREATION IN SUPERIOR TREATMENT*

1 WHY IS TASTE-MASKING NECESSARY FOR APIs?

In pharmaceutical formulation, **optimizing the patient medication experience** has become an increasing priority. Alongside bioavailability, parameters such as taste, appearance, and convenience play a critical role in driving patient treatment adherence.

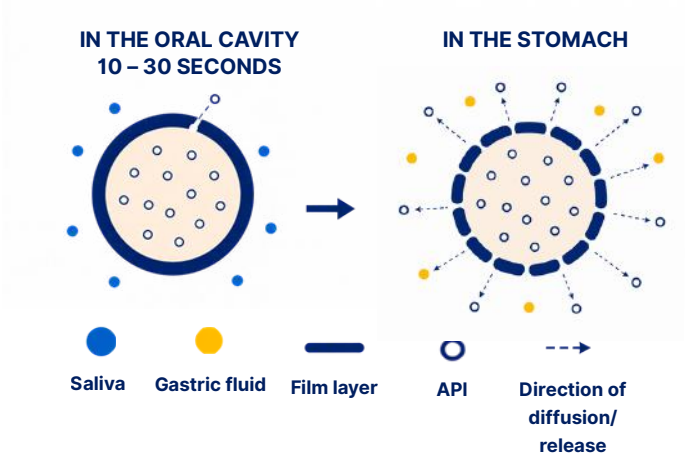
A common challenge is that many APIs, particularly natural extracts or structurally complex chemical compounds, often have unpleasant tastes and odors. These organoleptic properties can make oral administration difficult and may induce nausea and vomiting, especially in pediatric and elderly patients, thereby negatively affecting treatment adherence.



TASTE-MASKING IS BASED TWO MAIN MECHANISMS

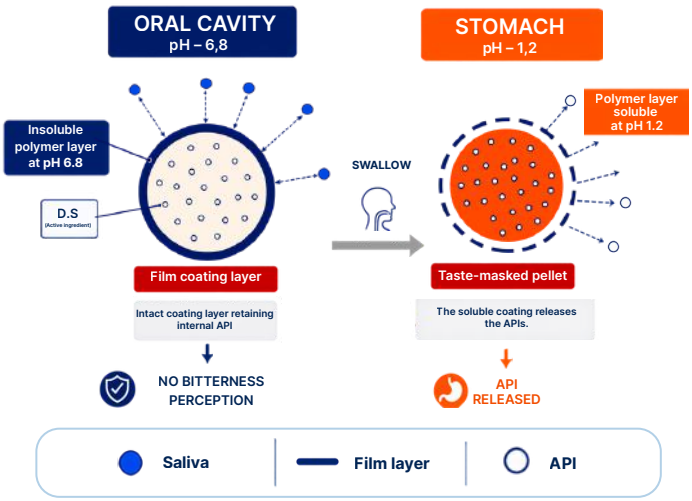
01 DIFFUSION RATE CONTROL

The thickness of the film coating layer is precisely controlled to allow slow dissolution in the oral cavity while dissolving rapidly in gastric fluid. Consequently, the API concentration remains below the threshold required to trigger taste perception in the mouth.



02 pH-DEPENDENT SOLUBILITY BARRIER

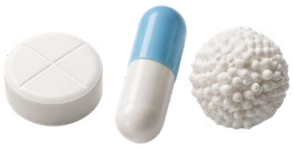
The film coating layer remains insoluble or dissolves extremely slowly in saliva (pH ~ 6.8), preventing the API from diffusing out while in the oral cavity. Subsequently, API release is initiated upon reaching the stomach (pH ~ 1.2).



ADVANTAGES OF MASKING FILM

- Masking bitter tastes and unpleasant odors
- Enhancing product organoleptic appeal
- Suitable for diverse patient populations
- Improving patient acceptability and treatment compliance
- Protecting tablet core and maintaining API stability

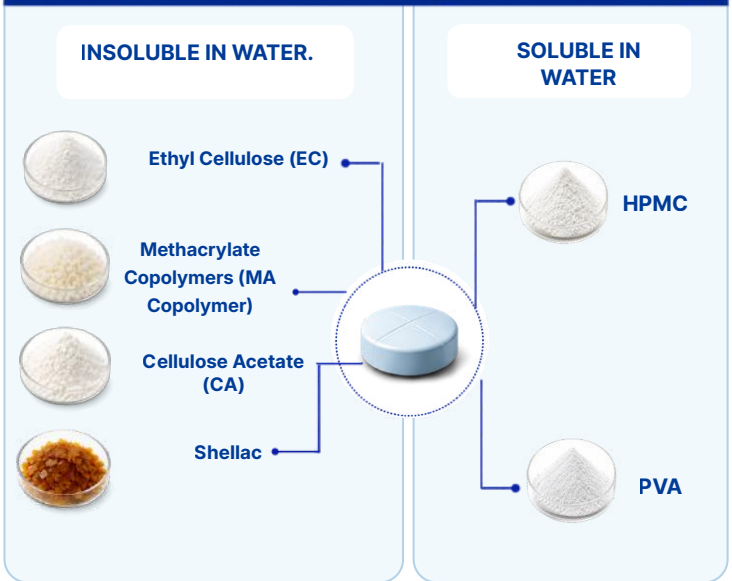
2 TASTE-MASKING FILM COATING: ADVANTAGES & DISADVANTAGES

Category	Characteristic	Advantage	Disadvantages
EQUIPMENT AND PROCESS 	Compatible with existing film-coating equipment at pharmaceutical manufacturing facilities	• Requires no investment in new equipment or technology • Well-established and robust industrial process • Easily scalable	• Coating efficiency heavily relies on operators' experience and skills
API COMPATIBILITY 	The film coating forms a physical barrier without altering the chemical nature of the active ingredient.	• Minimal impact on chemical stability • Minimal risk of incompatibility.	• Extends manufacturing process time and increases production costs
PROTECTION & FILM PROPERTIES 	A protective film layer shields the core tablet from environmental factors (humidity, oxygen, light).	• Protects the tablet from environmental factors • Improves product appearance and swallowability • Negligible increase in tablet size: the film coating typically accounts for only ~3 – 5% of the tablet weight	• May delay drug dissolution
APPLICATION 	Effective taste-masking across a wide range of bitter APIs.	• Highly effective for various bitter APIs. E.g.: **clarithromycin, cetirizine, dextromethorphan, diphenhydramine**	• Unsuitable for: – Chewable tablets – ODTs – Powder/granule for oral suspension

3 COMMON POLYMERS USED IN TASTE-MASKING COATING

Polymers used in flavor-masking films include insoluble or sparingly soluble varieties, such as ethyl cellulose, methacrylate copolymer, cellulose acetate, and shellac. Additionally, water-soluble polymers such as HPMC and PVA may also be utilized.

POLYMER CATEGORIZATION



METHACRYLATE COPOLYMERS
One of the most frequently utilized polymers

1 *Soluble in ethanol, IPA, acetone; insoluble in water.*

2 *Soluble at pH < 5.0; insoluble in oral cavity effectively masks taste, and ensures gastric drug release.*

3 *Rapidly dissolves in the stomach, preventing delayed dissolution.*

4 *Forms a durable, glossy film with good adhesion and swallowability.*

5 *High taste-masking efficiency, requiring only low weight gains*

6 *Low viscosity facilitates coating and minimizes spray gun clogging.*

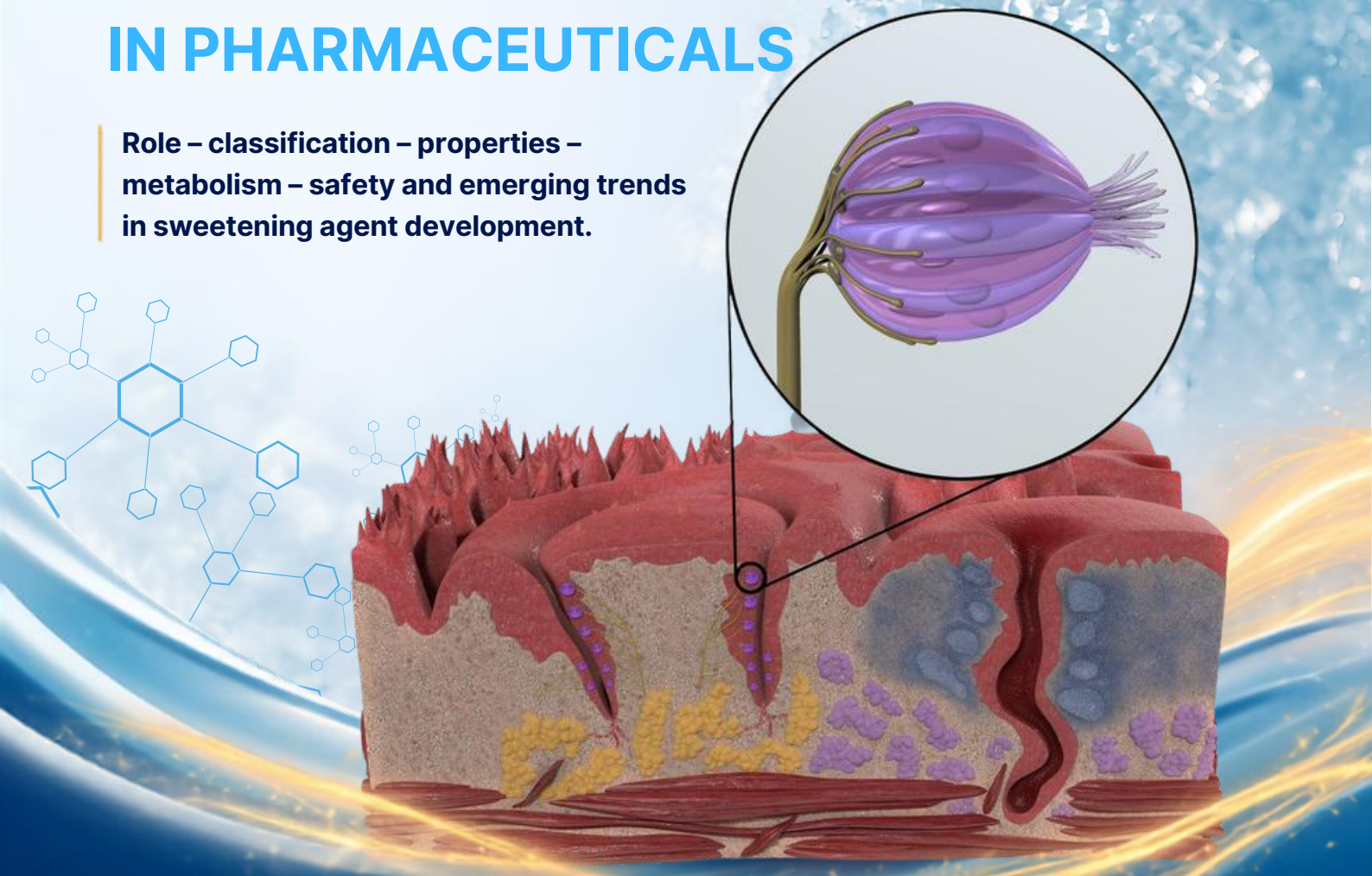
7 *Compatible with a wide range of APIs and excipients.*

8 *Monographed in pharmacopeias (Ph. Eur., USP/NF).*

OVERVIEW OF SWEETENING AGENTS

IN PHARMACEUTICALS

Role – classification – properties – metabolism – safety and emerging trends in sweetening agent development.



1 THE IMPORTANCE OF SWEETENING AGENTS

Sweetness has long been associated with **happiness and euphoria** in humans. Studies suggest that the preference for sweetness is an innate trait. Physiologically, stimulation of sweet taste receptors by sweeteners, regardless of their caloric value, activates the brain's reward system and **promotes the release of neurotransmitters such as dopamine**, creating a pleasant sensation and enhancing the acceptability of food and pharmaceutical products.

In pharmaceutical formulation, leveraging this "happiness signal" plays an important role in **improving treatment compliance**, particularly in pediatric populations. Beyond their organoleptic role, sweetening excipients also provide important technical functions, including structure, viscosity control, and product stability.

MECHANISM OF SWEETNESS ACTIVATION & PLEASANT SENSATION CREATION

SWEET RECEPTOR STIMULATION

Sweeteners stimulate sweet taste receptors on the tongue

REWARD SYSTEM ACTIVATION

Signals are transmitted to the brain, triggering the release of dopamine

PLEASANT SENSATION

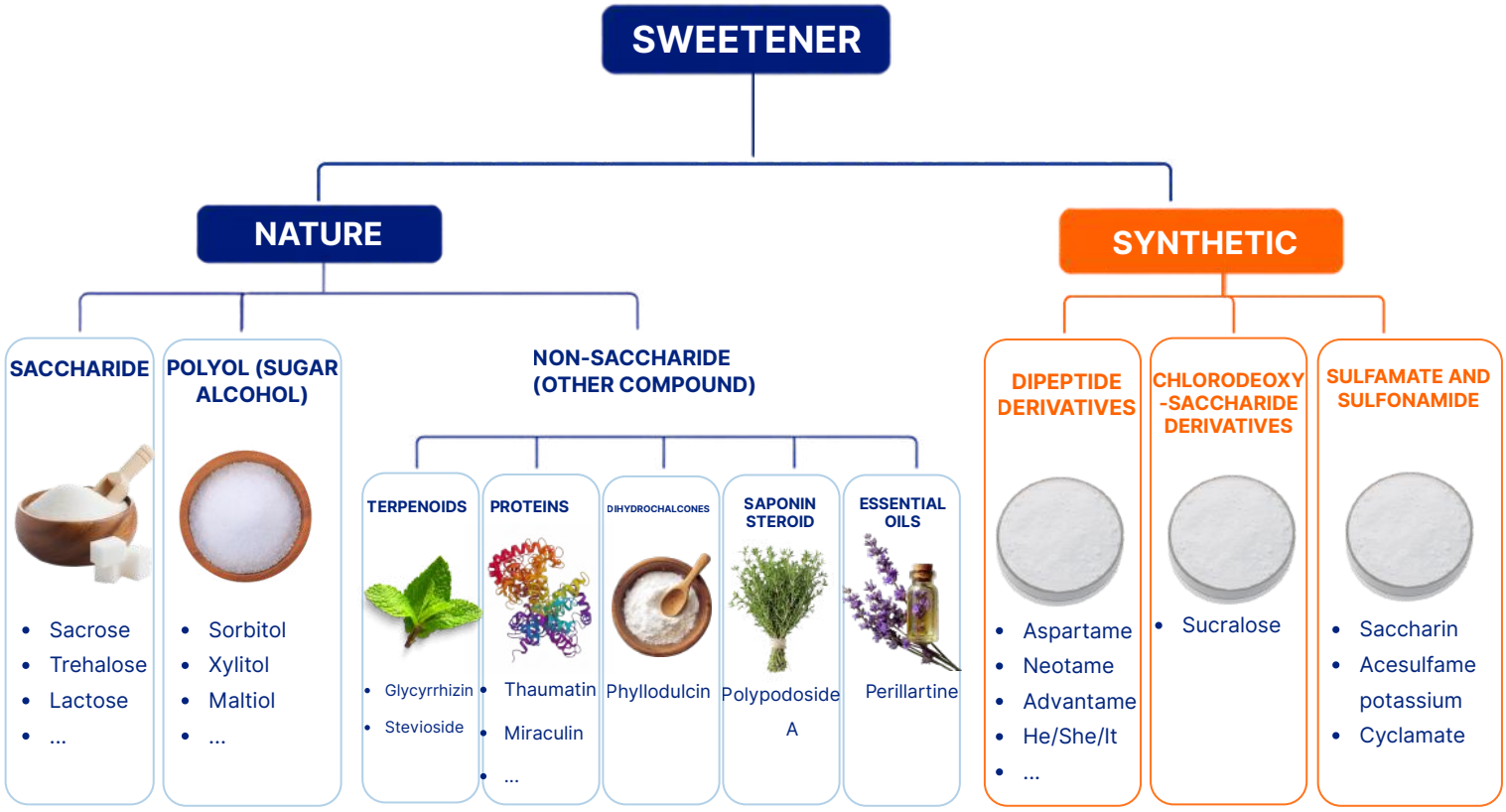
Creates a pleasant, happy, and euphoric sensation

ENHANCES ACCEPTANCE & ADHERENCE

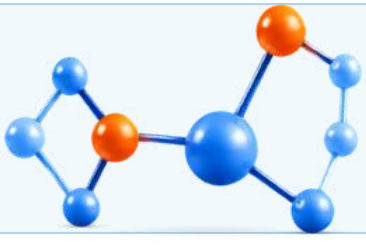
Enhances acceptability and treatment compliance, especially in pediatrics

Sweetness signals not only enhance organoleptic properties but also contribute to improving user experience and long-term therapeutic outcomes

2 CLASSIFICATION OF SWEETENERS

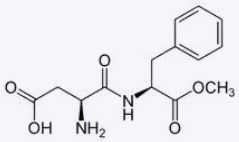
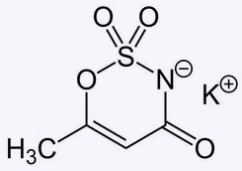
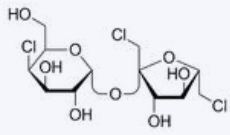
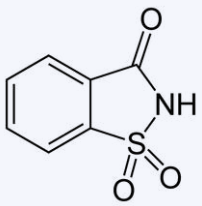


SWEETNESS IS NOT MERELY AN ORGANOLEPTIC FACTOR
IT IS AN INTEGRAL PART OF A
PATIENT-CENTRIC FORMULATION DEVELOPMENT STRATEGY



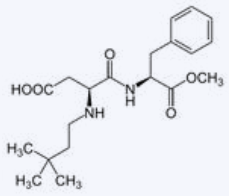
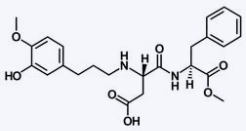
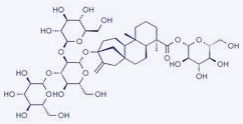
3 COMMONLY UTILIZED SUPERSWEETENING AGENTS

PROPERTIES, METABOLISM, AND SAFETY OF SUPERSWEETENING AGENTS

EXCIPIENTS	NATURE	METABOLISM	SAFE	ADI (mg/kg/day)
 **Aspartame**	**SWEETNESS*** (compared to sucrose) 180 – 200 time **SOLUBILITY** Sparingly soluble in water and slightly soluble in 95% ethanol **STABILITY** Stable at pH 4–5; hydrolyzes outside this range. Unstable under prolonged heat **INCOMPATIBILITY** Dicalcium phosphate, magnesium stearate, and polyol sugars	**METABOLIC PRODUCTS** Acid aspartic, phenylalanine, and methanol. **WARNING** **Phenylketonuria (PKU)** poses significant risks for patients due to the presence of phenylalanine metabolites. Warning labeling is required.	**SAFETY EVALUATION** Despite clinical studies addressing short-term toxicity and cancer risk, the FDA, EFSA, and more than 90 countries continue to acknowledge its safety when utilized within acceptable daily intake limits.	50 mg/kg/day
 **Acesulfame Potassium**	**SWEETNESS*** (compared to sucrose) 200 time **SOLUBILITY** Freely soluble in water, slightly soluble in 95% ethanol. **STABILITY** Stable at high temperatures and strongly acidic pH; more stable than aspartame. **INCOMPATIBILITY** Metal cations	**METABOLIC PRODUCTS** It is not metabolized by the body; consequently, it yields no calories and does not influence blood sugar or insulin levels. **WARNING** Resistant to conventional wastewater treatment (potential for environmental accumulation).	**SAFETY EVALUATION** Acetoacetamide degradation impurity may be toxic at high doses, but exposure from normal consumption is considered negligible.	15 mg/kg/day
 **Sucralose**	**SWEETNESS*** (compared to sucrose) 300 – 1.000 time **SOLUBILITY** Freely soluble in water and ethanol (95%). **STABILITY** Stable at high temperatures and at pH >3 (optimal stability at pH 5–6). **INCOMPATIBILITY** Prolonged storage at high temperatures may release HCl, causing product discoloration	**METABOLIC PRODUCTS** Approximately 11-27% is absorbed into the bloodstream; however, it is not metabolized and is excreted in the urine. **WARNING** Studies (Sylvetsky, 2017); (Park, 2017) reported higher blood sucralose levels in children, warranting further evaluation of its safety in this population.	**SAFETY EVALUATION** Approved by the FDA since 1998 (based on over 110 toxicity studies) it has been confirmed to have no association with cancer risk.	5 mg/kg/day
 **Saccharin**	**SWEETNESS*** (compared to sucrose) 300 – 600 time **SOLUBILITY** Slightly soluble in water and sparingly soluble in ethanol (95%). **STABILITY** Stable at high temperatures across a broad pH range of 2 to 7. **INCOMPATIBILITY** Forms complexes with large molecules, causing precipitation or solution turbidity.	**METABOLIC PRODUCTS** Well absorbed through the digestive tract, not metabolized, and excreted unchanged in the urine → Yields no calories. **WARNING** Caution is recommended for pregnant or breastfeeding women (as it crosses the placenta). There is a risk of cross-allergy in children who are allergic to sulfonamides.	**SAFETY EVALUATION** The bladder cancer mechanism reported in 1977 occurred **only in rats** and has been confirmed **safe for humans** at typical intake levels.	15 mg/kg/day

3 COMMONLY UTILIZED SUPERSWEETENING EXCIPIENTS (CONTINUED)

PROPERTIES, METABOLISM, AND SAFETY OF SUPERSWEETENING EXCIPIENTS

EXCIPIENTS	NATURE	METABOLISM	SAFE	ADI (mg/kg/day)
 **Neotame**	**SWEETNESS*** (compared to sucrose) **7.000 – 13.000** time **SOLUBILITY** Slightly soluble in water and sparingly soluble in ethanol (95%). **STABILITY** More stable than aspartame under storage conditions and non-hygroscopic **INCOMPATIBILITY** Virtually no incompatibilities.	**METABOLIC PRODUCTS** Rapidly metabolized and fully excreted, with no blood accumulation. **WARNING** **Safety** for patients with PKU	**SAFETY EVALUATION** Approved by the FDA as a versatile sweetener since 2002.	**0.3** mg/kg/day
 **Advantame**	**SWEETNESS*** (compared to sucrose) **20.000 – 37.000** time **SOLUBILITY** Practically insoluble in water. **STABILITY** Stable at high temperatures and low pH. **INCOMPATIBILITY** Virtually no incompatibilities.	**METABOLIC PRODUCTS** In contrast to Neotame, Advantame is metabolized into phenylalanine. **WARNING** **Phenylketonuria (PKU)** poses significant risks for patients due to the presence of phenylalanine metabolites. Warning labeling is required.	**SAFETY EVALUATION** Approved by the FDA as a versatile sweetener since 2014, it has been established as non-toxic and non-carcinogenic.	**32.8** mg/kg/day
 **Rebaudioside A (Steviol glycoside)**	**SWEETNESS*** (compared to sucrose) **300** time **SOLUBILITY** Slightly soluble in water. **STABILITY** Stable at a temperature and pH range of 2 to 10. **INCOMPATIBILITY** Virtually no incompatibilities.	**METABOLIC PRODUCTS** Contains no calories and does not influence blood sugar levels. Safe for individuals with diabetes and obesity. **WARNING** No significant warnings	**SAFETY EVALUATION** Approved as safe by the FDA and EFSA, it aids in reducing blood pressure, combating tooth decay, and exhibits potential anti-inflammatory and anti-cancer properties.	**12** mg/kg/day

- **SWEETNESS:** Sweetness intensity relative to a 10% (w/v) sucrose solution in purified water, standardized to 1.0. Data sourced from the FDA's "Safe Levels of Sweeteners."

- **ADI (Acceptable Daily Intake):** The estimated amount of a substance (excipient, additive, or chemical) that can be consumed daily over a lifetime without appreciable health risk

4 EMERGING TRENDS IN THE APPLICATION OF SWEETENING AGENTS

Sweetness has long been perceived as a taste sensation associated with feelings of happiness and euphoria in humans.

However, recent studies indicate that, in addition to positive perceptions, consumers are increasingly linking sweetness with notions of "unhealthiness." This trend is propelling the development and utilization of alternative sweeteners to diminish sugar content in pharmaceutical and food formulations. **The following are the primary trends observed:**

01 PREFERENCE FOR REDUCED-SUGAR / SUGAR-FREE PRODUCTS

Targeting special populations such as diabetic patients, obese individuals, and the elderly.

DIABETIC PATIENTS

OBESE INDIVIDUALS

ELDERLY POPULATION

02 SHIFT TOWARD NATURAL SWEETENING AGENTS

Preference is given to substances such as Stevia, Glycyrrhizin, Neohesperidin, Thaumatin, or Monk Fruit Extract (Mogrosides) due to their high safety profiles and strong consumer preference for natural products.

STEVIA

GLYCYRHIZIN

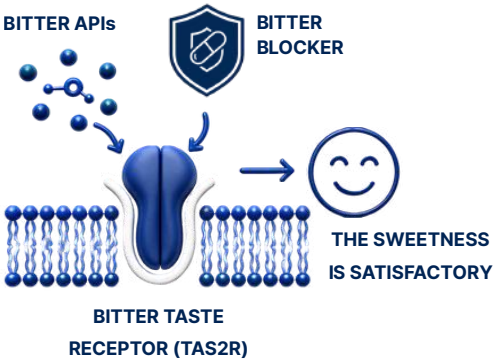
NEOHESPERIDIN

THAUMATIN

MOGROSIDES

03 COMBINING BITTER BLOCKERS TO REDUCE SWEETENING AGENT LOADS

Blocks bitter taste receptors (TAS2R), helping to mask unpleasant bitter or metallic off-tastes of the Active Pharmaceutical Ingredient (API). This solution minimizes the required load of sweetening excipients while enhancing patient compliance.



OPTIMAL TASTE-MASKING STRATEGY

SELECT THE SUITABLE SWEETENING AGENT + COMBINING BITTERNESS BLOCKER MECHANISMS → DECREASE SUGAR CONTENT + IMPROVING ORGANOLEPTIC PROPERTIES

SAFE, PALATABLE PRODUCTS WITH ENHANCED PATIENT COMPLIANCE

Hydroxypropyl-β-Cyclodextrin (HP-β-CD)

EXCIPIENTS ENHANCE THE SOLUBILITY AND STABILITY OF INJECTABLE DRUGS.

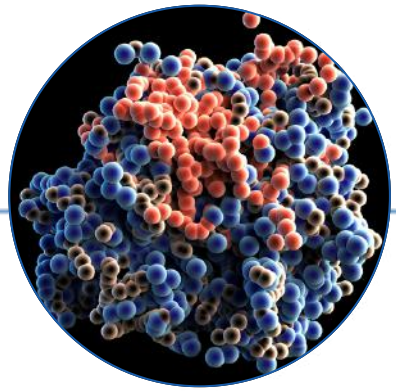
Solubility • Stability • Injectable Safety

Hydroxypropyl-β-cyclodextrin (HP-β-CD) is a derivative of β-cyclodextrin that improves the solubility, stability, and bioavailability of poorly water-soluble active ingredients.

With its inclusion complexation capacity, HP-β-CD serves as an optimal solution for modern injectable formulations - offering safety, efficacy, and reduced nephrotoxicity compared to β-CD.

ENHANCE SOLUBILITY

Improves apparent solubility for poorly soluble APIs



INCLUSION COMPLEXATION

Encapsulates and protects the active ingredient, enhancing chemical stability.

OPTIMIZED FOR INJECTABLES

Reduces irritation, eliminates the need for organic solvents or surfactants, and enhances biocompatibility

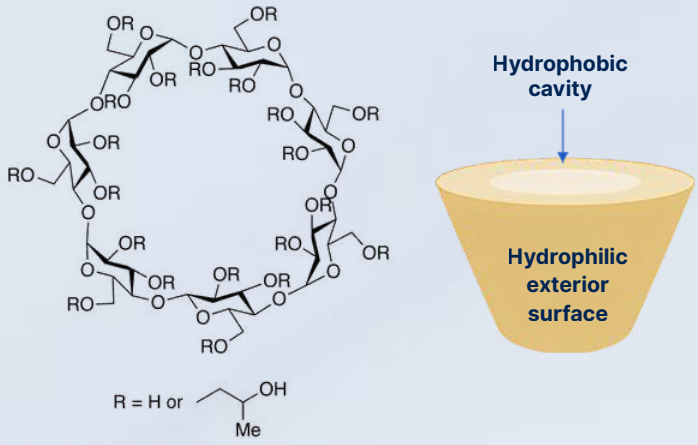
1 GENERAL INTRODUCTION TO HYDROXYPROPYL-β-CYCLODEXTRIN (HP-β-CD)

Hydroxypropyl-β-cyclodextrin (HP-β-CD) is a semi-synthetic derivative of β-cyclodextrin, created by the attachment of **hydroxypropyl groups** to the hydroxyl groups of the β-cyclodextrin molecule. This structural modification markedly enhances water solubility, diminishes nephrotoxicity, and restricts crystallization in comparison to the original β-cyclodextrin.

Due to its ability to form inclusion **complexes with numerous poorly water-soluble active ingredients**, HP-β-CD is presently one of the most extensively utilized excipients in injectable drug formulations.

This excipient enhances **solubility** and improves the **chemical stability** of hydrophobic active ingredients without requiring substantial quantities of organic solvents or surfactants.

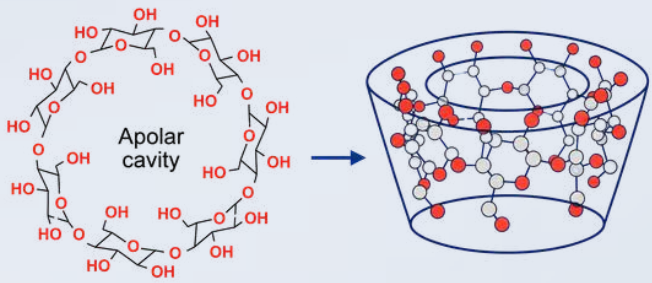
At present, HP-β-CD has received approval for use in numerous injectable formulations from regulatory bodies such as the FDA and EMA, with a variety of commercial products already accessible globally.



2 STRUCTURE AND CHARACTERISTICS

HP-β-CD maintains the distinctive truncated cone configuration of cyclodextrin, which encompasses:

- **Internal hydrophobic cavity**
- **Hydrophilic exterior surface**
- **The mean particle size is approximately 1,300 – 1,500 Da (depending on the degree of hydroxypropyl substitution).**



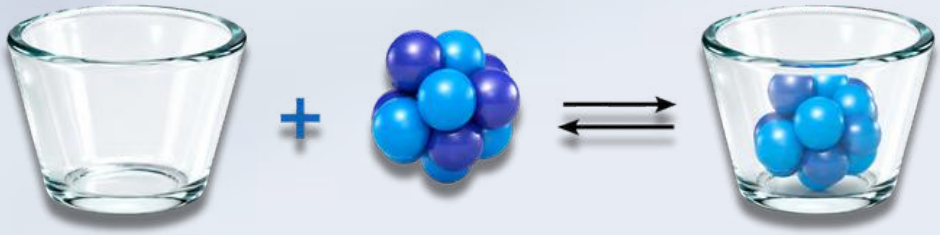
THE INCORPORATION OF HYDROXYPROPYL GROUPS PRESENTS NUMEROUS BENEFITS.

- **The aqueous solubility of β-CD increased from approximately 18 mg/mL to more than 500–600 mg/mL.**
- **Reduces crystallization tendency.**
- **Minimizes interaction with cell membrane cholesterol.**
- **Minimizes the risk of nephrotoxicity.**
- **Suitable for infusion and intravenous injections.**

3 OPERATING MECHANISM

The hydrophobic cavity of HP-β-CD can encapsulate either a portion or the entirety of the hydrophobic active molecule via non-covalent interactions.

HP-β-CD + API ⇄ API–HP-β-CD complex



This process maintains the active ingredient in its free state while ensuring that the encapsulated complex remains in a state of dynamic equilibrium.

Upon injection into the body, the complex will swiftly dissociate as the active substance is absorbed or distributed.

Administering the active ingredient to produce its therapeutic effect.

4 ADVANTAGES OF COMPLEX FORMATION WITH HP-β-CD

01 *ENHANCING APPARENT SOLUBILITY*

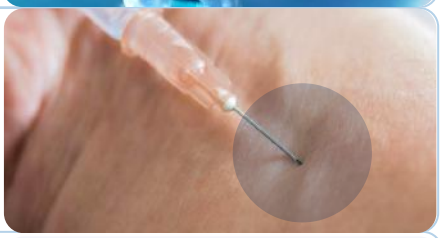
HP-β-CD markedly enhances the solubility of the active ingredient in the solvent, preserves precipitation, maintains solution clarity, and improves bioavailability for parenteral formulations. The degree of solubility enhancement can range from several-fold to hundreds-fold, depending on the chemical structure of the active ingredient and the complexing constant.

02 *API PROTECTION AND STABILITY ENHANCEMENT*

When encapsulated in cyclodextrin, the active ingredient is shielded from environmental factors such as oxygen, light, moisture, and metal ions, thereby enhancing the stability of the sensitive compound. This contributes to extending the shelf life of the drug product.

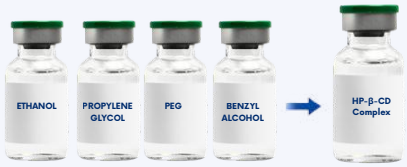
03 *MINIMIZING LOCAL INJECTION SITE IRRITATION*

A fraction of the active ingredient is encapsulated within the HP-β-CD compartment, substantially diminishing the quantity of free active ingredient directly exposed to tissue. This minimizes tissue irritation, reduces injection pain, and lowers the risk of drug precipitation at the injection site.



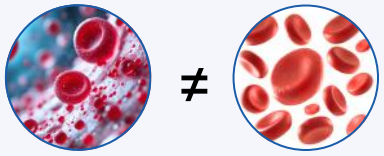
04 *MINIMIZING THE NEED FOR ORGANIC SOLVENTS.*

The use of HP-β-CD markedly reduces or eliminates the need for co-solvents such as ethanol, propylene glycol, polyethylene glycol, and benzyl alcohol, thereby minimizing injection site irritation and reducing the risk of adverse effects associated with organic solvents.



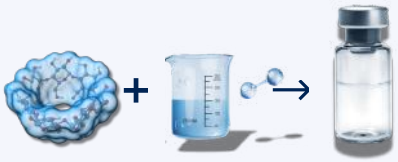
05 *ENHANCING BIOCOMPATIBILITY*

In comparison to β-CD, HP-β-CD presents a reduced risk of hemolysis and nephrotoxicity. Due to its favorable safety profile and excellent tolerability, HP-β-CD has emerged as a commonly utilized complexing agent in numerous commercial injectable drug formulations.



06 *HIGH COMPATIBILITY WITH OTHER EXCIPIENTS*

Owing to its high water solubility and non-ionic nature, HP-β-CD easily combines with various common excipients in parenteral formulations with minimal risk of incompatibility.



5 APPLICATIONS OF HP-β-CD IN INJECTABLE PHARMACEUTICALS

HP-β-CD is utilized in injectable pharmaceuticals for:

- *Enhance solubility*
- *Protecting and stabilizing the API*
- *Reduced irritation and pain*
- *Prolonging the product's shelf life*

In addition to intravenous injection, HP-β-CD is utilized in:

Some appropriate active ingredients for use with HP-β-CD:

API	The function of HP-β-CD
Voriconazole	Enhance solubility, replacing organic solvents
Ziprasidone mesylate	Enhanced solubility and stability
Aripipazole	Supporting solubility in injectable solutions
Itraconazole	Enhance solubility and bioavailability.
Diclofenac	Minimizes irritation, enhances solubility
Dexamethasone	Stabilize the solution and enhance solubility

PEG

MULTIPURPOSE POLYMER

FOR USE IN PHARMACEUTICAL FORMULATION APPLICATIONS

VARIED APPLICATIONS

INJECTABLE PHARMACEUTICALS
Solvents, co-solvents

TABLETS
Binder, lubricant, matrix structure

SOFT CAPSULES
Solvent

TOPICAL
ointment base, humectant

SUPPOSITORIES
suppository base, enhances mechanical strength.

NANO TRANSPORT SYSTEM
Stabilizes the system and extends circulation time.

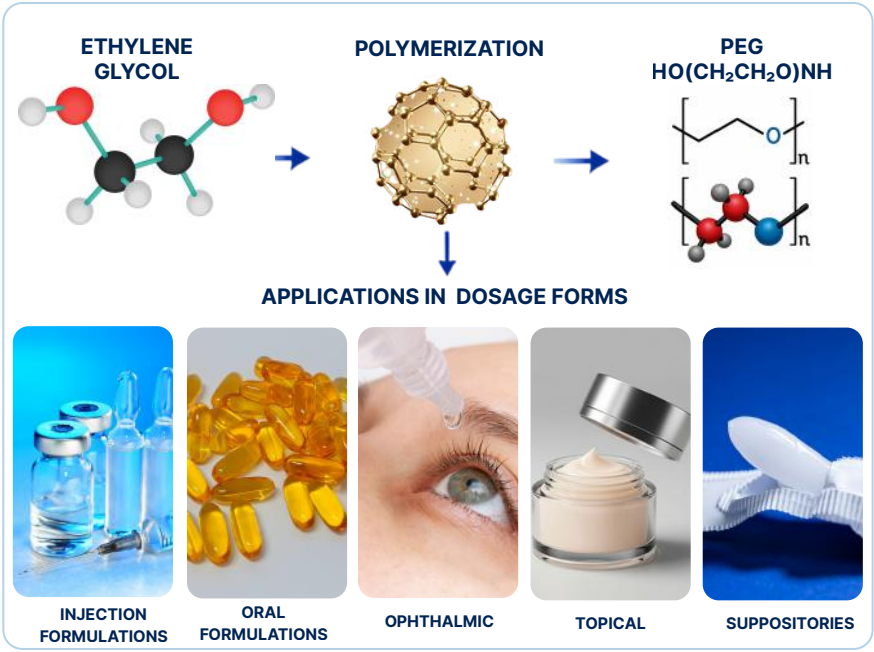
"HIGH PURITY, BIOCOMPATIBILITY, AND EXCEPTIONAL APPLICABILITY.

1 GENERAL INTRODUCTION TO POLYETHYLENE GLYCOL EXCIPIENTS

Polyethylene glycol (PEG), also known as **Macrogol**, is a linear polymer composed of ethylene glycol monomers -(CH_2CH_2O)-, generally exhibiting molecular weights between 200 and 20,000 Da.

Owing to its **high hydrophilicity, versatility, biocompatibility**, and **non-toxicity**, PEG is extensively utilized in various dosage forms, including injectable drugs, topical, ophthalmic, oral formulations, suppositories, and advanced drug delivery systems.

Hydrophilic | Biocompatible | Versatile | Non-toxic



FREQUENTLY UTILIZED PEG TYPES

2 PHYSICAL CHARACTERISTICS

LOW MOLECULAR WEIGHT (PEG 200 – 600)

- State: liquid
- Hygroscopicity: high
- Viscosity: low
- Melting point: Freezing point 4–15 °C
- Solubility: soluble in water and ethanol; insoluble in oils and fats.

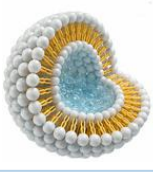
MEDIUM MOLECULAR WEIGHT (PEG 900 – 1500)

- State: solid (soft)
- Hygroscopicity: moderate
- Viscosity: moderate
- Melting point: low (35 - 48°C)
- Solubility: soluble in water and ethanol; insoluble in oils and fats.

HIGH MOLECULAR WEIGHT (PEG 4000 – 20000)

- State: solid
- Hygroscopicity: Low or non-hygroscopic
- Viscosity: high
- Melting point: high (35 – 63°C)
- Solubility: soluble in water and ethanol; insoluble in oils and fats.

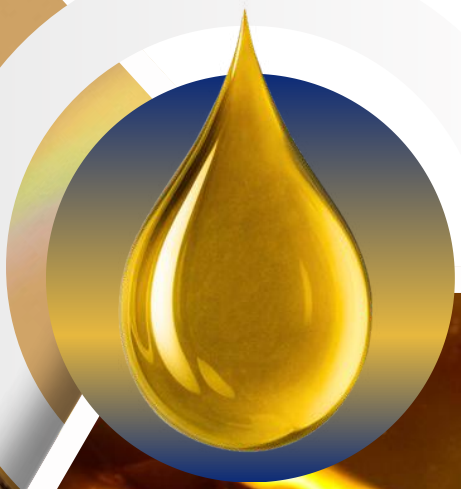
3 APPLICATIONS OF POLYETHYLENE GLYCOL

APPLICATION	DOSAGE FORM	COMMONLY USED PEG GRADES	ADVANTAGES OF PEG
1 SOLVENT	 Soft capsules (Hydrophilic fill)	PEG 300 PEG 400 PEG 600	• Co-solvents enhance the solubility of the active ingredient • Elevated biocompatibility • Stable over a wide pH range
	 Topical	PEG 300 PEG 400 PEG 600	
	 Injectable, ophthalmic, nasal, and otic products	PEG 300 PEG 400	
2 EMULSION STABILIZERS	 Topical emulsion	PEG 400	• Enhance the viscosity of the dispersion medium (continuous phase)
	 Oral emulsion	PEG 400	
3 SUSPENDING, THICKENING, AND STABILIZING AGENTS	 Oral suspension	PEG 400	• Dissolve efficiently, rapidly, and is easy to incorporate in manufacturing
4 PLASTICIZERS	 Film-coated tablets	PEG 3350 PEG 4000 PEG 6000	• Enhance the mechanical characteristics of the coating film. • Compatible with various polymers
	 Microencapsulated formulations	PEG 300 PEG 400	
5 MATRIX FORMING AGENTS	 Extended-release tablets	PEG 4000 PEG 6000	• Compatible with various polymers • Combine PEGs to control drug release rate
6 TOPICAL BASES	 Ointments, creams, and gels	PEG 1450 PEG 3350 PEG 4000	• Non-irritating • Humectant • API-compatible • Customizable consistency
7 SUPPOSITORY BASES	 suppositories	PEG 3350 PEG 4000 PEG 6000	• Chemically stable & mold-resistant • Enhances drug mechanical properties • Compatible with various active ingredients
8 BINDER	 Tablets	PEG 6000	• Enhance interparticle binding • Enhance the mechanical strength of granules and tablets.
9 MELTING PROCEDURE	 Melt granulation, Hot-melt extrusion, Solid dispersions	PEG 4000 PEG 6000	• Appropriate viscosity • Uniform distribution of the API • Low melting temperature • Combine PEGs to modify the desired properties.
10 LUBRICANT	 Effervescent tablets	PEG 6000	• Enhances tablet surface gloss & smoothness • Promotes rapid disintegration without affecting dissolution • Fully water-soluble, residue-free
	 Dispersible tablets (ODT/DT)	PEG 6000	
11 NANO-BASED DRUG DELIVERY SYSTEMS	 Liposomes, lipid nanoparticles (LNP), solid lipid nanoparticles (SLN), nanoemulsions	PEG 2000 PEG 4000	• Stabilizes nanosystems • Inhibits phagocytosis & prolongs circulation • Enhances drug delivery efficacy

MEDIUM-CHAIN TRIGLYCERIDES

- MCT OIL -

Oil-based carriers for poorly water-soluble API - Prevents cross-linking in soft capsules.



Oil-based carrier excipient
Enhances solubility
Improves formulation efficacy

- Chemically inert
- Versatile applications
- Solubilizing lipophilic APIs
- High quality standards

1 INTRODUCING MCT OIL

Medium-chain triglycerides (MCT oil) are a mixture of triglycerides produced by the esterification reaction between glycerol and the fatty acids **caprylic acid** and **capric acid** derived from coconut or palm oil, exhibiting the properties shown in the table.

PHYSICAL AND CHEMICAL CHARACTERISTICS

Status	The oil appears clear, colorless, or pale yellow.
Odor	Odorless
Taste	Tasteless
HLB Index	1
Freezing point	0°C

Solubility

Water	✗
Methanol	✓
Dichloromethane	✓
Soybean oil	✓
Alternative petroleum ethers	✓

2 APPLICATIONS OF MCT OIL IN PHARMACEUTICAL MANUFACTURING

APPLICATIONS AS ACTIVE INGREDIENTS

01

INJECTABLE INFUSION

Utilized to supply energy in injectable and Infusion formulations.

02

NUTRITIONAL SUPPLEMENTS

Suitable for dietary supplements providing energy and nutrients.

APPLICATIONS OF EXCIPIENTS

A. TABLETS

Lubricant for punches and dies.

B. HARD CAPSULES, SUGAR-COATED TABLETS

An agent that enhances the absorption of the active ingredient in the intestine.

C. GELATIN CAPSULES

Oil-base carriers for fill solution; provide energy; enhance the solubility of poorly soluble APIs.

D. LIQUID DOSAGE FORMS

Used in emulsions, microemulsions, self-emulsifying systems, solutions, and suspensions for unstable or poorly water-soluble APIs (e.g., Calciferol).

E. INJECTABLE FORMULATION

Solubilizer for poorly water-soluble drugs in oily injections, emulsions, and suspensions, enhancing solubility and absorption.

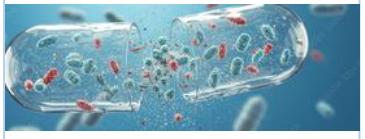
F. TOPICAL FORMULATION

Oil-based formulations for topical medications enhance the solubility and bioavailability of lipophilic active ingredients.

G. SUPPOSITORIES

Suppository base

H. ADDITIONAL



Utilized as an alternative antimicrobial agent in pharmaceutical formulations.

3 ADVANTAGES OF MCT OIL

MCT oil is an ideal solvent and excipient in pharmaceuticals due to its outstanding **purity**, **stability** and **compatibility.**

01
Dissolving lipophilic APIs, enhances solubility and bioavailability.

02
Stable against oxidizing agents such as atmospheric oxygen and peroxides

03
Chemically inert; compatible with APIs and excipients

04
Free from antioxidants, residual solvents, catalysts.

05
High capacity for active ingredient loading

06
Short-chain structure enables rapid metabolism and absorption in the gastrointestinal tract.

07
Suitable for softgels, minimizing the risk of gelatin cross-linking.

08
For topical formulations: supports skin permeation and acts as a humectant.

09
High purity, stringent production processes, and quality assurance.

4 REDUCED CROSS-LINKING IN SOFTGEL CAPSULE

PEG AND VEGETABLE OILS	NATURE	MCT OIL (C8 AND C10)
Unsaturated fatty acids → Oxidation → Hydroperoxide → Degradation → Aldehyde Ketone Hydrogen peroxide decomposes to produce **Aldehydes**, which are the primary contributors to cross-linking with the gelatin capsule shell.	A EXTREMELY LOW ALDEHYDE AND PEROXIDE VALUES	Saturated fatty acids (C8, C10) → Stable Oxidation-resistant MCT oil consists entirely of saturated fatty acids, with no double bonds, making it highly resistant to oxidation → virtually eliminating the formation of aldehydes.
PEG 400, highly hydrophilic Softgel fill, Softgel shell, PEG 400, Humidity (Environment) → Enhanced hydrolysis reaction and crosslinking → Elevated risk of cross-linking Water is drawn from the environment into the softgel shell and subsequently into the softgel fill	B HUMIDITY AND POLARITY	**MCT has low polarity, low hygroscopicity** Softgel fill, Softgel shell, MCT, Humidity (Environment) → Restrict cross-linking Forms a hydrophobic barrier, stabilizes the capsule shell, and limits water uptake.
PEG 400 PEG 400 → Draw glycerin from the capsule shell into the fill The capsule shell loses its plasticizer, resulting in brittleness and cracking	C COMPATIBILITY	**MCT Oil** MCT → Glycerin is not soluble in MCT Retains glycerin in the capsule shell, maintaining flexibility and elasticity

ISOPROPYL ALCOHOL

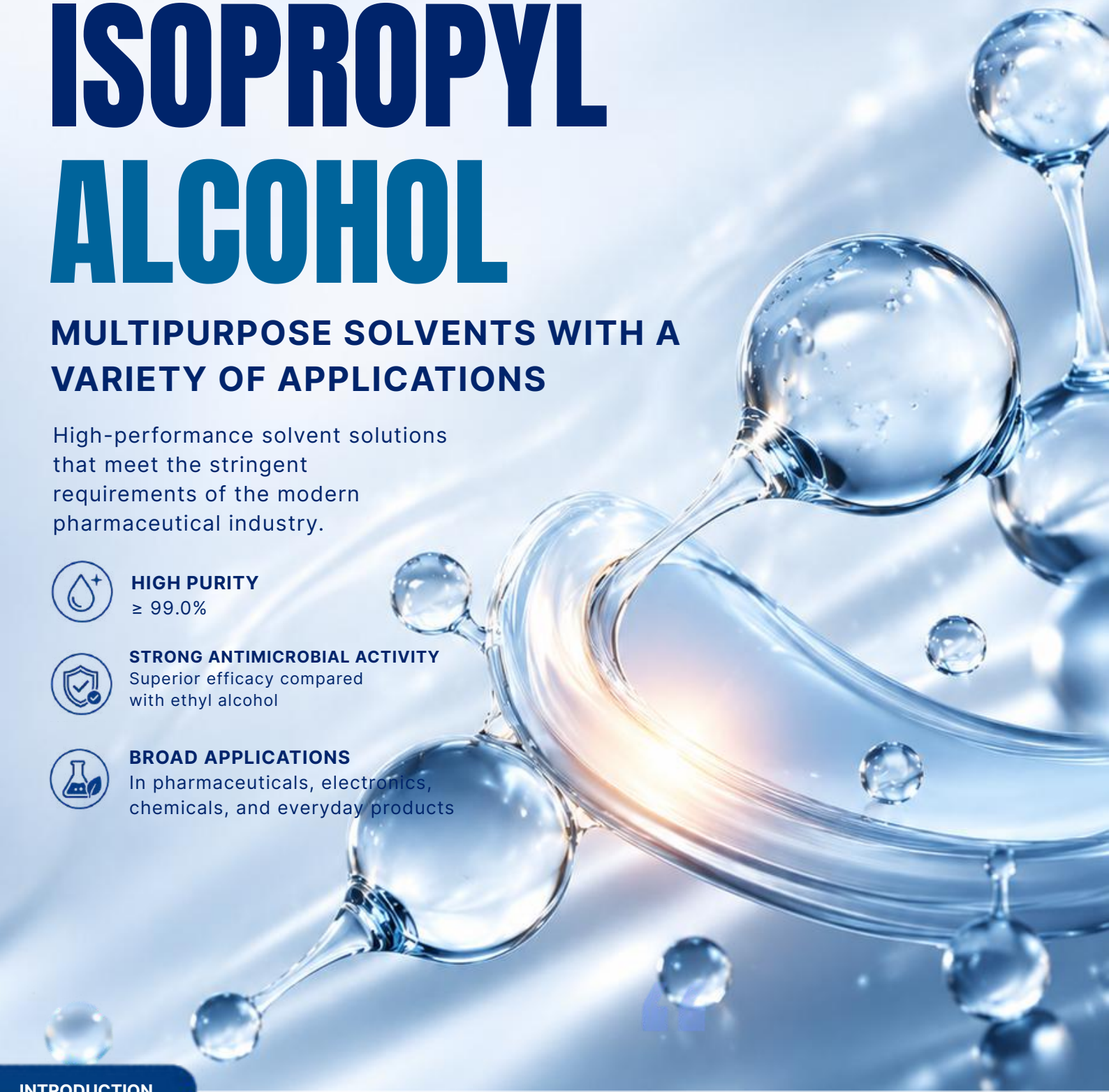
MULTIPURPOSE SOLVENTS WITH A VARIETY OF APPLICATIONS

High-performance solvent solutions that meet the stringent requirements of the modern pharmaceutical industry.

HIGH PURITY
≥ 99.0%

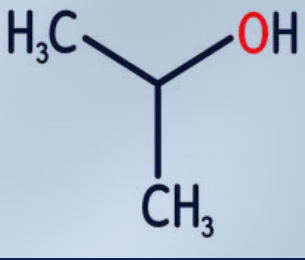
STRONG ANTIMICROBIAL ACTIVITY
Superior efficacy compared with ethyl alcohol

BROAD APPLICATIONS
In pharmaceuticals, electronics, chemicals, and everyday products



INTRODUCTION

Isopropyl alcohol (IPA), also referred to as isopropanol, 2-propanol, or dimethylcarbinol, is an organic compound classified within the category of secondary alcohols. IPA is a colorless, volatile, and flammable liquid with a characteristic odor similar to a mixture of ethanol and acetone. Among the lower alcohols (C1–C5), IPA ranks as the third in global production, after ethanol and methanol.



1 COMPARISON OF THE PROPERTIES OF ETHYL ALCOHOL AND ISOPROPYL ALCOHOL

PROPERTIES	ETHYL ALCOHOL	ISOPROPANOL
Structural formula	$H_3C - CH_2 - OH$	$H_3C - CH(OH) - CH_3$
Molecular formula	C_2H_6O	C_3H_8O
Molecular mass	46.07 g/mol	60.10 g/mol
Boiling point	78,4 °C	82,5 °C
Flashpoint	13 °C	11,7 °C
Autoignition temperature	362 °C	425 °C
LD_{50} (oral, rat)	7,06 g/kg	5,05 g/kg
ICH Q3C	Group 3	Group 3
Antimicrobial activity	Medium	More potent than Ethyl Alcohol
Source	Fermentation or total synthesis	Petroleum
Legal control	Strictly regulated	Less regulated
Application	In developed countries such as Europe, the U.S., and Japan, ethyl alcohol is subject to a specific excise tax. Derived mainly from natural sources, it is widely used in beverages, fuel, solvents, and other applications.	Owing to its potent antibacterial properties, isopropyl alcohol is extensively utilized in detergents, disinfectants, and antiseptics.

2 WIDESPREAD USES OF ISOPROPYL ALCOHOL

HEALTHCARE, PHARMACY

- Disinfectants and antiseptics
- Solvent for extraction and purification (recrystallization)
- Granulating solvent in the process of wet granulation

ELECTRONICS & SEMICONDUCTOR TECHNOLOGY

- Clean printed circuit board and semiconductor chips
- Cleaning optical components
- Dewatering agent

CHEMICAL, PAINTS & COATINGS INDUSTRY

- Solvent
- Chemical precursors

DAILY LIFE & TRANSPORTATION

- Household detergents
- Antifreeze in fuel

GINKGO BILOBA EXTRACT

GINKGO BILOBA EXTRACT IS RICH IN FLAVONOIDS AND TERPENOIDS.

Helps enhance cerebral circulation, antioxidant protection, and support memory function.

- ENHANCE CEREBRAL CIRCULATION
- POTENT ANTIOXIDANT
- SUPPORT MEMORY FUNCTION
- PROMOTE RADIANT SKIN

1 INTRODUCING GINKGO BILOBA EXTRACT

Ginkgo Biloba Extract is derived from the **leaves of the Ginkgo biloba tree**, one of the **oldest plant species** in the world, and is **widely used** in both **modern medicine** and **traditional medicine**.

In pharmaceutical and dietary supplements, Ginkgo Biloba Extract is regarded as a strategic component in products that promote **cerebral circulation**, **enhance memory**, and **provide neuroprotective antioxidant effects**.

Thanks to contemporary extraction technology, **Ginkgo Biloba Extract is generally standardized to a ratio of 24% flavone glycosides and 6% terpene lactones**, thereby ensuring consistent biological efficacy and adherence to international pharmaceutical standards.

For manufacturers of pharmaceuticals and dietary supplements, Ginkgo Biloba Extract serves as both a traditional herbal component and a highly valuable active ingredient in formulations aimed at supporting brain and nervous system health.

2 ACTIVE COMPONENTS

The biological efficacy of Ginkgo Biloba Extract primarily attributed to its potent bioactive compounds.
The primary components consist of:

FLAVONOID GLYCOSIDE (≥ 24%)

This collection of compounds exhibits potent antioxidant properties, aiding in the protection of nerve cells from damage induced by free radicals

TERPENE LACTONE (≥ 6%)

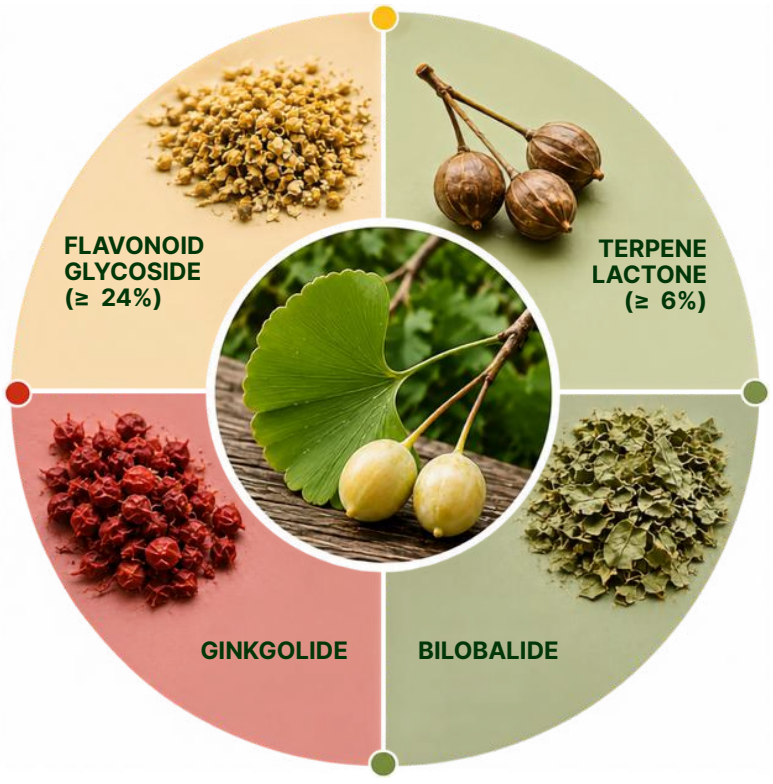
Comprising Ginkgolide and Bilobalide, it contributes to the enhancement of cerebral blood circulation and the improvement of neurological function.

GINKGOLIDE

It inhibits platelet-activating factor (PAF), thereby enhancing blood circulation.

BILOBALIDE

Promotes the safeguarding of nerve cells and improves cognitive function.



With its natural origin, stringent standardization, and strong scientific foundation, ***Ginkgo Biloba Extract*** *is an optimal choice for formulations supporting brain and neurological health.*

3 ADVANTAGES OF GINKGO BILOBA EXTRACT

Ginkgo Biloba Extract is regarded as a premium ingredient for brain and nervous system health products, offering several outstanding benefits:

01 STANDARDIZED ACTIVE INGREDIENT CONTENT

Standardized concentrations of flavonoids and terpene lactones contribute to the maintenance of consistent biological efficacy.

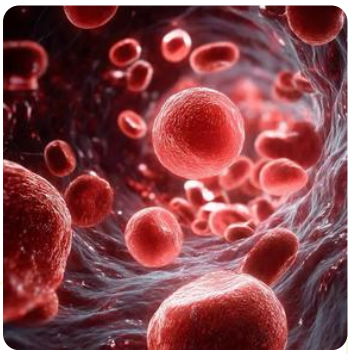
02 EXTENSIVE CLINICAL STUDIES

Numerous clinical studies have established the efficacy of Ginkgo Biloba in enhancing memory and cerebral circulation.

03 STRONG MARKET TREND

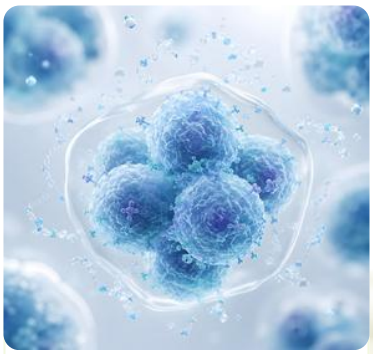
Products designed to enhance memory, support cognitive function, and mitigate neurogaming are witnessing significant growth in the global market.

4 APPLICATIONS OF GINKGO BILOBA EXTRACT



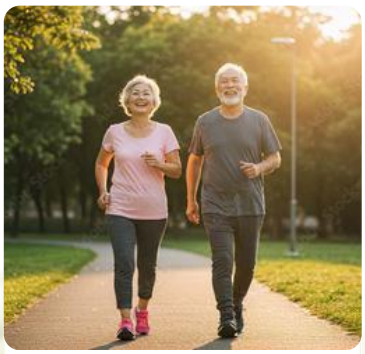
Enhance blood circulation

Enhances blood circulation to the brain and peripheral organs by regulating platelet function and vascular dynamics.



Antioxidant properties

Provides antioxidant protection for the brain, retina, and cardiovascular system.



Slowing Down Manifestations of Aging

Helps relieve age-related memory loss, cognitive decline, dizziness, and headaches.

Enhance Memory and Cognitive Function

Supports memory enhancement, concentration, and overall cognitive functions.

SUITABLE FOR VARIOUS DOSAGE FORMS

Tablets

Hard capsules

Oral solution

Powder/granules for oral suspension

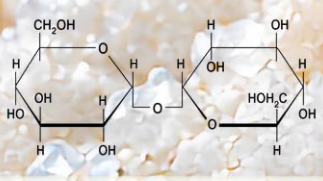
TREHALOSE

Sweetening agent & stabilizers for lyophilized powder formulations.

Trehalose (α,α-trehalose, mycose) is a non-reducing disaccharide composed of two glucose molecules connected by an α,α-1,1-glycosidic bond.

Natural compounds exhibit distinctive physical and chemical properties that are essential for safeguarding organisms against adverse environmental conditions.

Widely used in pharmaceuticals as a sweetening agent, stabilizing, and protective excipient for proteins, vaccines, and biologics during lyophilization and storage.



HISTORY OF TREHALOSE

1832 — **H.A.L. Wiggers**

Isolation of a **non-reducing sugar** from the fungus (*Claviceps purpurea*), which parasitizes rye.

1857 — **Mitscherlich**

Determine the chemical properties of this compound and designated as **mycose**.

1858 — **M. Berthelot**

A compound was extracted from **trehalis manna**, the sweet secretion encasing the cocoons of the beetles *Larinus nidificans*, and designated as **trehalose**.

1876 — **M. A. Müntz**

Demonstrate that **mycose** and **trehalose** are **the same compound**, thereby allowing for the consistent use of the name trehalose.

1 PHYSICOCHEMICAL CHARACTERISTICS OF TREHALOSE

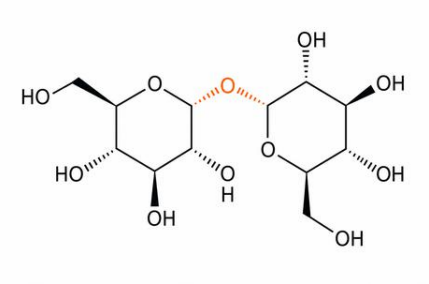
FUNDAMENTAL SPECIFICATIONS

Recipe chemistry	$C_{12}H_{22}OH$ (anhydrous form) **$C_{12}H_{22}OH.2H_2O$ (dihydrate form)**
Molecular mass	**342.30 g/mol** (anhydrous form) **378.33 g/mol** (dihydrate form)
Link	α,α-1,1-glycosidic
Sweetness	Trehalose has a mild sweetness, approximately **45%** that of sucrose.
Solubility	Soluble in water; slightly soluble in ethanol.
pH (30% solution)	**4,5 – 6,5**

EXCEPTIONAL PHYSICAL AND CHEMICAL PROPERTIES

CHARACTERISTIC STRUCTURE

It is a **disaccharide** composed of **two glucose molecules** linked by an α,α-1,1-glycosidic bond.



α,α-1,1-glycosidic

HIGH STABILITY

Because the two glucose molecules are linked through their **reducing ends**, trehalose is highly stable.

- Does not participate in the Maillard reaction
- Stable across a broad pH range of 3.5 to 10
- High thermal stability
- Non-hygroscopic

POLYMORPHISMS

TREHALOSE

- **DIHYDRATE FORM**
- **ANHYDROUS FORM**
- **AMORPHOUS FORM**

T_h

It is the **most stable** and **most common** form of Trehalose at room temperature.

This form has **low hygroscopicity** and retains its water content at approximately 9.5%, even when exposed to relative humidity of up to 92%. However, at high humidity (>90%), it may undergo liquefaction.

The melting point, essentially the dehydration process, occurs at approximately 97°C.

~97°C dehydration process

T_α

Metastable forms occur when T_h is dehydrated in a vacuum at 85°C for a duration of 4 hours.

The most significant characteristic of this form is its ability to reversibly convert back to the original form upon exposure to moisture, without altering the primary crystal lattice structure

Metastable

T_β

It is the **most stable anhydrous form**, produced through the dehydration of T_h at temperatures ranging from 125 to 150°C.

This form has a very **high melting point** of approximately 210 to 215°C.

210 – 215°C most resilient

T_γ

It is a **metastable** form formed by dehydrating T_h at temperatures below 100°C, which also produces the T_α form and the amorphous form.

At temperatures below 80°C, the T_γ form can be transformed into T_α and the amorphous form, or into the T_h form under humid conditions.

Metastable

AMORPHOUS FORM

Trehalose can readily transition to the amorphous state through **lyophilization**, **spray drying**, or **rapid cooling from the molten state**.

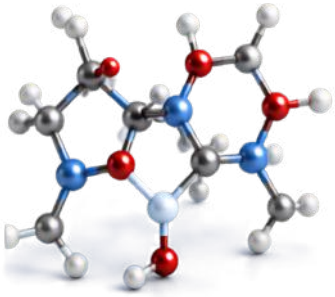
The glass transition temperature (T_g) is very high, approximately 110 to 120°C in the completely anhydrous form. This is the highest among disaccharides, enabling the formation of a highly viscous matrix that immobilizes biomolecules.

Tg 110 – 120°C

2 ADVANTAGES OF TREHALOSE

Due to its unique structure and outstanding physicochemical properties, trehalose offers numerous benefits for the protection and stabilization of biomolecules, as well as applications in food technology and health.

01 EXCEPTIONAL CHEMICAL & THERMAL STABILITY



< 1 kcal/mol
Very low energy requirement

100°C / 24 hours
Stable under prolonged heating without degradation

pH 3,5 – 10
Stable over a broad pH range

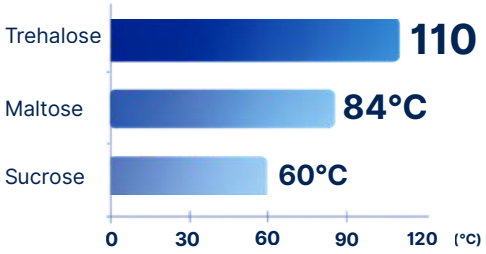
Compared with sucrose, trehalose has a **higher glycosidic bond energy >27 kcal/mol**, making it more resistant to hydrolysis under acidic conditions.

02 DOES NOT PARTICIPATE IN MAILLARD REACTIONS

Non-reducing disaccharide
No reducing end is available for glycosidic linkage, leaving no free aldehyde group.

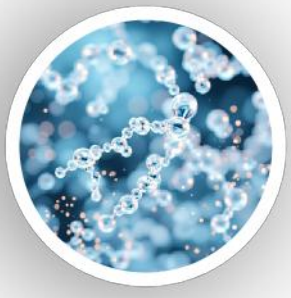
Preserves color & quality
Minimizes Maillard reactions with amino acids and proteins, helping prevent browning during high-temperature processing.

03 HIGH GLASS TRANSITION TEMPERATURE

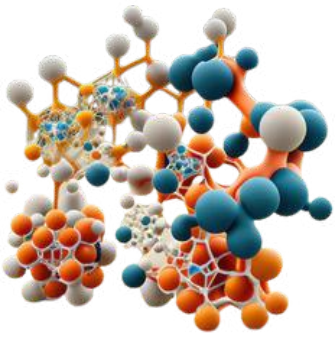


Forms a **stable "glass-like" matrix** at room temperature.

helping **encapsulate and immobilize biomolecules** (proteins, enzymes, vaccines), thereby reducing molecular mobility and degradation.



04 SUPERIOR BIOPROTECTIVE PROPERTIES



Water replacement
Forms hydrogen bonds with the polar groups of proteins and cell membranes, preserving structural integrity during drying.

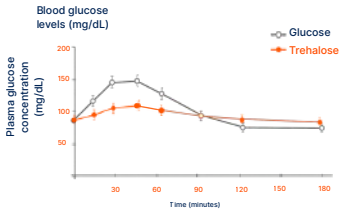
Antioxidants
Its substrate-stabilizing and antioxidant effects provide superior efficacy versus mannitol, galactose, and sucrose.

05 ADVANTAGES OF FOOD TECHNOLOGY

Anti-staling (starch antistaling)
It more effectively prevents the "stalling" process (hardening due to starch antistaling) in baked goods and starchy foods than any other type of sugar.

Odor Control
Inhibits fatty acid oxidation and the decomposition of sulfur compounds, helping to reduce foul odors in food (such as fish and meat) as well as body odor.

06 PHYSIOLOGICAL ADVANTAGES FOR THE BODY



Source: Yoshizane C. et al. 2017, Glycemic, Insulinemic, and Incretin Responses Following Oral Trehalose Ingestion in Healthy Subjects, Nutrition Journal

Compared to glucose, trehalose leads to a **lower rise in blood glucose and insulin levels**, providing a sustained source of energy for the body.

3 APPLICATIONS OF TREHALOSE

Trehalose is widely utilized in the food and pharmaceutical industries due to its exceptional biostabilizing properties.

FOOD INDUSTRY

01 Sweeteners and flavor enhancement

- Sweetness ~ 45% compared to sucrose.
- Clean sweet taste without unpleasant aftertaste; effectively masks off flavors.

02 Starch anti-staling

- Prevents the hardening of starch.
- Extends freshness for bread, cooked rice, mochi, and other starch-rich products.

03 Preservation of dried and frozen foods

- Through vitrification and water replacement, it preserves the structure, color, and natural aroma of fruits, vegetables, and meat after processing.

04 Lipid and protein stabilization

- Inhibits fatty acid oxidation, preventing malodors.
- Protects proteins against denaturation during long-term storage.

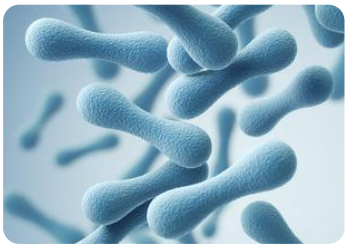
PHARMACEUTICALS AND BIOTECHNOLOGY

01 Stabilization of vaccines and monoclonal antibodies

- Forms complexes and preserves protein structure in lyophilized powders, minimizing denaturation, aggregation, and oxidation through water replacement.

02 Vitamin stabilization

- Interacts with transition metal ions (Fe, Cu) which act as potent oxidation catalysts.
- Prevents vitamin degradation and maintains biological activity



03 Stabilization of probiotic formulations in lyophilization

- Protects probiotic cells against damage caused by freeze-drying and dehydration.
- Enhances stability and viability rates of probiotics.

04 Diluent for solid dosage forms

- High chemical stability as a non-reducing sugar, with excellent compressibility, porosity and rapid disintegration.
- A potential alternative to mannitol, sucrose, or lactose in tablets, ODTs, and capsules.

COMMERCIAL FORMULATIONS CONTAINING TREHALOSE

Herceptin
(Trastuzumab)

Dosage form
Injectable lyophilized powder

Trehalose utilization **30** mg/ml

Avastin
(Bevacizumab)

Dosage form
Solution for *Injection*

Trehalose utilization **60** mg/ml

Lucentis
(Ranibizumab)

Dosage form
Solution for Injection

Trehalose utilization **100** mg/ml

Advate®
(Recombinant)

Dosage form
Lyophilized injectable powder

Trehalose utilization **10** mg/ml

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AUGUST
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