

WAX EXCIPIENTS



Pharmaceuticals Ingestible & Topical Applications

Koster Keunen Wax Excipients

For over 170 years, Koster Keunen has been a global leader in wax manufacturing and innovation. Founded in 1852, Koster Keunen has pioneered advancements in wax technology, earning a reputation for unmatched quality, consistency, and technical expertise. With multiple manufacturing facilities worldwide and the unique capability to support internal Disaster Recovery Planning (DRP), Koster Keunen remains the trusted partner for pharmaceutical and topical applications, delivering solutions that meet the most stringent industry standards.



In pharmaceuticals, wax excipients play a vital role in ensuring stability, functionality, and aesthetic quality of formulations. Whether in controlled-release drug delivery systems, tablet coatings, or topical emulsions, waxes provide essential benefits that enhance product performance and consumer appeal. Koster Keunen offers a comprehensive portfolio of high-quality waxes, all designed to meet the diverse needs of pharmaceutical and healthcare formulations.

In ingestible applications, waxes are utilized for tablet coatings to enhance swallowability, provide controlled drug release, and protect against environmental degradation. They also act as stabilizers in capsules and supplements, polishing agents, and non-stick coatings for gummy vitamins. In topical products, wax excipients improve texture, stability, and skin protection in formulations such as creams, balms, and gels, while enabling protective and sustained-release delivery systems.

Koster Keunen's commitment to excellence in wax technology ensures that each excipient meets the rigorous demands of the pharmaceutical market. By offering unparalleled technical expertise, product consistency, and global supply capabilities, Koster Keunen supports formulators in developing innovative, effective, and reliable products. As a trusted partner in wax chemistries, Koster Keunen combines innovation and precision to empower the success of pharmaceutical solutions worldwide.

Wax Excipients for Ingestible Pharmaceuticals

- Beeswax
- Carnauba
- Candelilla
- Microcrystalline Wax
- Paraffin Wax

Wax Excipients for Topical Pharmaceuticals

- Beeswax
- Behenic Acid
- Candelilla Wax
- Ceresin Wax
- Cetyl Palmitate
- Cetylstearyl Alcohol
- Emulsifying Wax
- Ozokerite Wax
- Paraffin
- Rice Bran Wax

Wax Excipients For Pharmaceutical Applications

BEESWAX

Beeswax is a natural, biocompatible excipient widely used in pharmaceutical formulations for both ingestible and topical applications. Derived from honeybee secretions, it provides structural integrity, controlled release properties, and emollient benefits. Recognized as Generally Recognized as Safe (GRAS) by the FDA and compliant with the United States Pharmacopeia (USP) standards, beeswax is a preferred ingredient in formulations requiring stability, extended release, and moisture retention. Its unique composition of esters, fatty acids, and hydrocarbons makes it an effective binding, emulsifying, and film-forming agent. Additionally, sustainably sourced beeswax aligns with the increasing demand for natural and eco-conscious pharmaceutical ingredients.

PRODUCTS			
Beeswax	White	NF	Wax #421P
Beeswax	White	NF USP-561	Wax #571P
Beeswax	Yellow	NF	Wax #423P
Beeswax	Yellow	NF PAC	Wax #525P
Beeswax	Yellow	NF USP-561	Wax #570P



APPLICATIONS

INGESTIBLE

- ◆ Tablet stabilizer and release agent.
- ◆ Improves tablet ingestion and dose accuracy.
- ◆ Natural chewing gum additive for plasticity and structure.
- ◆ Sustained release additive in suppositories for enhance drug retention and control release rate.
- ◆ Used in soft gel capsule shell production as a stabilizer for oil-based contents.

TOPICAL & OTC PHARMACEUTICALS

- ◆ **Emulsifier:** Stabilizes O/W and W/O emulsions, improving texture and active ingredient stability. Can act as main emulsifier for in situ soap emulsions.
- ◆ **Skin Protectant:** Forms a breathable barrier to lock in moisture, shield wounds, and support healing.
- ◆ **Base for Balms & Ointments:** Provides structure, adhesion, and controlled melting for medicated applications.
- ◆ **Hydration & Skin Softening:** Helps soothe dry, irritated skin in treatments for eczema, psoriasis, and dermatitis.
- ◆ **Sustained Release:** Controls active ingredient absorption in transdermal patches and topical treatments.

ADDITIONAL INFORMATION:

- ◆ **Natural Origin:** Biocompatible and GRAS, certified for use in pharmaceuticals.
- ◆ **Versatility:** Effective in a wide range of pharmaceutical forms.
- ◆ **Sustainability:** Harvested through sustainable beekeeping practices.

TEST OPTIONS AVAILABLE:

- USP 561 for Pesticides
- Chloramphenicol
- Nitrofurans Metabolites
- Coumaphos

Microcrystalline Wax

Microcrystalline wax is a highly refined, versatile excipient widely used in pharmaceutical formulations for both oral and topical applications. Its fine crystalline structure, high molecular weight, and superior oil-binding capacity make it essential for controlled-release drug delivery, stabilization, and structural integrity. Recognized for its compatibility with a variety of polymers, resins, and oils, microcrystalline wax is particularly valuable in modified-release tablets, chewing gum-based drug delivery systems, and transdermal patches. Its barrier-forming properties also enhance product stability by protecting active ingredients from oxidation, moisture, and environmental degradation. With a long history of safe use, microcrystalline wax meets stringent pharmaceutical standards, ensuring efficacy and consistency in various dosage forms.

PRODUCTS		
Microcrystalline	170/180	Wax# 140S
Microcrystalline	170/180 NF	Wax# 860S
Microcrystalline	193/198 NF	Wax# 118P

APPLICATIONS

INGESTIBLE

- ◆ **Controlled-Release Excipients:** Forms a stable matrix in oral solid dosage forms to regulate drug release and improve bioavailability.
- ◆ **Encapsulation Agent:** For sustained drug release, enhance bioavailability and dose uniformity.
- ◆ Stabilizer in capsules for oil-based drug formulations.
- ◆ **Release Regulator:** Used in the formulation of NSAIDs and antibiotics for extended therapeutic effects.
- ◆ **Tablet Polishing:** Used to improve tablet appearance, reduce surface defects, and facilitate smoother swallowing.

Chewing Gum Drug Delivery:

- ◆ Imparts additional plasticity and stability alongside resins and softeners.
- ◆ Enhances compatibility between polymers, resins, and oils within the formulation.
- ◆ Acts as a release agent, reducing “dry tack” and improving chew texture.
- ◆ Prevents “cold flow” by reinforcing the crystalline structure of the matrix.
- ◆ Strong oil-binding capacity improves uniformity and stability of active ingredients in gum-based systems.

TOPICAL & OTC PHARMACEUTICALS

- ◆ **Barrier Protection:** Enhances the stability of active ingredients against oxidation and environmental degradation.
- ◆ Controlled-release matrix in transdermal drug delivery systems (e.g., pain management, hormone therapy, nicotine patches).
- ◆ Protective film-forming agent in wound care ointments to shield against environmental contaminants while aiding controlled ingredient absorption.
- ◆ Structural stabilizer in topical emulsions, creams, and gels for enhanced consistency and prolonged active ingredient efficacy.

ADDITIONAL INFORMATION

Pharmaceutical Compliance: Refined to meet USP-NF monograph standards and FDA regulatory requirements.



Paraffin Wax

Paraffin wax is a highly refined, hydrophobic excipient used in pharmaceutical formulations for its emollient, protective, and controlled-release properties. Its ability to create a moisture-resistant barrier makes it valuable in both topical and ingestible applications, improving drug stability, retention, and sustained release.

PRODUCTS		
Paraffin	130/135 NF	Wax# 10073P
Paraffin	140/145 NF	Wax# 500P

APPLICATIONS

INGESTIBLE

- ◆ **Sustained Release Matrix:** Used in spray congealing to develop drug-loaded microparticles, enhancing stability and controlled release.
- ◆ **Hydrophobic Barrier:** Reduces moisture absorption and drug degradation in the gastrointestinal tract.
- ◆ **Modulated Release:** Can be combined with hydrophilic lipids to fine-tune drug diffusion rates.

TOPICAL & OTC PHARMACEUTICALS

- ◆ **Emollient & Lubricant:** Commonly used in ophthalmic ointments for dry eye relief and ocular lubrication.
- ◆ **Protective Barrier:** Forms a hydrophobic layer in wound care and skin treatments to prevent moisture loss.
- ◆ **Stabilizer in Ointments & Creams:** Enhances texture, consistency, and prolonged release of active ingredients.



Carnauba Wax

Carnauba wax is a plant-derived excipient widely used in pharmaceutical coatings and controlled-release formulations. Its high melting point, moisture resistance, and non-toxic nature make it valuable for enhancing tablet stability, improving swallowability, and modulating drug release.

PRODUCTS		
Carnauba Wax	NF Flake	Wax# 420F
Carnauba Wax	NF Granulated	Wax# 325G
Carnauba Wax	NF Powdered	Wax# 149Q

APPLICATIONS

INGESTIBLE

- ◆ **Tablet Coating & Binding:** Provides a smooth, glossy finish, prevents chipping, and enhances tablet stability.
- ◆ **Sustained-Release Formulations:** Used in solid-dosage forms to regulate drug release and improve bioavailability.
- ◆ **Melt Granulation:** Enhances flowability and stability of granules, supporting extended-release formulations.
- ◆ **Mini-Tablets:** Ideal for pediatric and geriatric medications requiring precise dosing.
- ◆ **Gummy Vitamins & Mints:** Forms a nonstick, protective coating to prevent clumping and extend shelf life.
- ◆ **Barrier Protection:** Shields active ingredients from moisture and environmental degradation in chewables and lozenges.

TOPICAL & OTC PHARMACEUTICALS

- ◆ **Pain Relief & Anti-Inflammatory:**
Acetaminophen, Aspirin, Ibuprofen.
- ◆ **Gastrointestinal Treatments:** Famotidine, Omeprazole.
- ◆ **Allergy & Respiratory Relief:**
Diphenhydramine, Hydroxyzine, Montelukast.
- ◆ **Muscle Relaxants & CNS Agents:**
Cyclobenzaprine, Caffeine.

TOPICAL & OTC PHARMACEUTICALS

- ◆ **Thermal Stability:** Increases the melting point of formulations, improving stability in warmer climates.
- ◆ **Thickening Agent:** Enhances the viscosity and texture of ointments, balms, and sticks

Candelilla Wax

Candelilla wax is a plant-derived excipient valued for its hardness, binding properties, and ability to enhance stability in pharmaceutical formulations. It is commonly used in solid dosage forms for tablet binding, coating, and controlled-release applications.

PRODUCTS

Candelilla Wax NF

Wax# 419P

APPLICATIONS

INGESTIBLE

- ◆ **Tablet Binder:** Improves tablet cohesion and mechanical strength.
- ◆ **Glazing Agent:** Enhances tablet finish and stability.
- ◆ **Controlled Release:** Modifies drug dissolution rates when blended with other excipients.
- ◆ **Chewing Gum Additive:** Provides structure and reduces tackiness.

MEDICATIONS POTENTIALLY CONTAINING CANDELILLA WAX

- ◆ **Cholesterol Management:** Atoprev (Lovastatin), Atorvastatin, Lipitor.
- ◆ **Neurological Treatments:** Donepezil (Alzheimer's), Gabapentin (Nerve pain, seizures), Neurontin.

TOPICAL & OTC PHARMACEUTICALS

- ◆ **Texture Enhancer:** Increases viscosity and firmness in balms and ointments.
- ◆ **Film-Forming Agent:** Creates a protective barrier in topical formulations.
- ◆ **Water Resistance:** Improves longevity and moisture retention in therapeutic applications.



Topical & OTC Applications

The following waxes and fatty acids are widely used in topical and OTC pharmaceutical formulations due to their versatile properties, such as emulsion stabilization, thickening, and controlled release. These ingredients play a key role in enhancing the stability, texture, and performance of a wide range of creams, lotions, ointments, and other pharmaceutical products. Each compound is carefully selected for its ability to improve product efficacy and patient compliance, while also adhering to regulatory standards established by the FDA, USP, and NF.

Ozokerite Wax

Applications: Incorporated with oils to reduce greasiness and prevent sweating in formulations.

Ceresin Wax

Applications: Employed in protective, enteric, and sustained-release coatings for topical delivery systems.

Emulsifying Wax NF

Applications: A vegetable-based emulsifier used at approximately 5% to stabilize lotions, creams, and ointments.

Cetyl Palmitate

Applications: Found in moisturizers, gels, and ointments.

Cetylstearyl Alcohol

Applications: Functions as an emulsion stabilizer, opacifying agent, surfactant, and viscosity-increasing agent.

Rice Bran Wax

Applications: Acts as a binder, thickener, and emulsifier; improves texture and stability of formulations.

Behenic Acid

Applications: Used in medications and ointments to enhance shelf life and efficacy.

Regulatory Compliance

All listed ingredients in this section are recognized in the United States Pharmacopeia (USP) and the National Formulary (NF) for pharmaceutical use.

The Food and Drug Administration (FDA) approves these substances for inclusion in topical and over-the-counter (OTC) pharmaceutical products.

Note: Ensure formulations comply with current USP, NF, and FDA guidelines.

Product	Wax#	NF	Physical Appearance					Package Size				
			Pastille	Granules	Powder	Flake	Slabs	Cartons	Pail	Bag		
Beeswax, White NF	421P	X	X						X			25/Kg
Beeswax, White NF USP-561	571P	X	X						X			25/Kg
Beeswax, Yellow NF	423P	X	X						X			25/Kg
Beeswax, Yellow NF PAC	525P	X	X						X			25/Kg
Beeswax, Yellow NF USP-561	570P		X						X			25/Kg
Behenic Acid	220P		X						X			22.68/Kg
Candelilla Wax NF	419P	X	X						X			25/Kg
Carnauba Wax NF, Flake	420F	X						X		X		25/Kg
Carnauba Wax NF, Granulated	325G	X		X					DRUM			105/Kg
Carnauba Wax NF, Powdered	149Q	X			X				DRUM			50/Kg
Ceresin 130/135	107P		X						X			25/Kg
Ceresin 145	214P		X						X			25/Kg
Ceresin 192	159P		X						X			25/Kg
Ceresin 6510	515P		X						X			25/Kg
Ceresin Wax 140/150	108P		X						X			25/Kg
Ceresin Wax 155/165	390P		X						X			25/Kg
Ceresin Wax 1556	182P		X						X			25/Kg
Ceresin Wax 319	319P		X						X			25/Kg
Cetostearyl Alcohol NF	110F	X						X	X			25/Kg
Cetyl Alcohol	172P		X						X			25/Kg
Cetyl Esters Wax NF	177P	X	X						X			25/Kg
Cetyl Palmitate	120P		X						X			25/Kg
Cocoa Butter NF	286B	X								X		16/Kg
Emulsifying Wax NF RSPO	6109P	X	X						X			25/Kg
Microcrystalline 170/180	140S		X						X			28/Kg
Microcrystalline 170/180 NF	860S	X	X						X			25/Kg
Microcrystalline 193/198 NF	118P	X	X						X			25/Kg
Ozokerite 1090	318P		X						X			25/Kg
Ozokerite 164/170	116P		X						X			25/Kg
Ozokerite 170	117P		X						X			25/Kg
Ozokerite 175	451P		X						X			25/Kg
Ozokerite 180	156P		X						X			25/Kg
Ozokerite 203	334P		X						X			25/Kg
Ozokerite 2095	578P		X						X			25/Kg
Paraffin 130/135 NF	10073P	X	X						X			25/Kg
Paraffin 140/145 NF	500P	X	X						X			25/Kg
Rice Bran Wax	224P		X						X			25/Kg
Rice Bran Wax	849P		X						X			25/Kg
Synthetic Paraffin LM	178P		X						X			25/Kg

Products manufactured under GMP guidelines.

Produced and packaged in an SQF facility.



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