KOSTER KEUNEN

WAX EXCIPIENTS FOR TABLETS

Controlled Release · Binding · Coating · Stability

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About Koster Keunen

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 applications, delivering solutions that meet the most stringent industry standards. All products are manufactured under GMP guidelines and produced in an SQF-certified facility.

The Role of Wax Excipients in Tablet Formulation

Wax excipients are essential ingredients in modern tablet manufacturing. They serve multiple critical functions across the formulation: acting as binders and release-rate modulators within the tablet matrix, providing protective coatings, improving mechanical strength, and ensuring consistent drug delivery over time.

Key functions of wax excipients in tablets include:

Controlled & Sustained Release: Wax matrices slow the diffusion of active ingredients, enabling extended therapeutic windows and improved patient compliance.

Encapsulation: Surrounds the active ingredient to protect it from the gastrointestinal environment until the desired release point.

Functional Form: Granulated wax forms are required for tablet applications, delivering consistent processing performance and reliable release results.

Higher Active Ingredient Efficiency: Wax excipients enable significantly higher active ingredient concentration with less filler, maximizing potency per tablet.

Melt Granulation: Improves flowability, compressibility, and stability of the formulation during processing.

Overcome Compression Challenges: Wax excipients support binding of difficult-to-compress actives, improving tablet integrity without negatively impacting dissolution.

Precision Dissolution Control: Wax excipients direct active ingredient release to the optimal point during ingestion, controlling where and when the active works.

Protective Coating & Polishing: Creates moisture-resistant barriers, improves swallowability, and delivers a professional tablet finish.

Reduce Tablet Size: Higher active loading enabled by wax excipients results in a significantly smaller tablet delivering the same therapeutic dose.

Tablet Binding: Wax enhances cohesion and mechanical strength, reducing chipping and friability throughout the tablet's shelf life.

Regulatory Compliance & Quality

All Koster Keunen wax excipients for tablet applications are manufactured to the highest pharmaceutical standards:

- Manufactured under current Good Manufacturing Practice (cGMP) guidelines
- SQF-Certified Facility
- Compliant with National Formulary (NF) monograph specifications
- Kosher Certified
- Halal Certified
- Regulatory documentation available upon request
- Independent third-party testing available on applicable products, including pesticides, heavy metals, microbiological, residual solvents, hydroxyl value, and fatty acid composition

RESEARCH STUDY

Research Study: Wax-Encapsulated Folic Acid Dissolution

In a dissolution study conducted by CellMark Ingredients in May 2026, Koster Keunen wax excipients demonstrated powerful controlled-release performance in folic acid tablet formulations. The study was performed using Gouming RC-1 apparatus in synthetic stomach fluid (0.1N HCl at 37°C), with UHPLC analysis to track active ingredient release over 6 hours.

Study Design**

Five tablet formulations were evaluated, each containing 75% Folic Acid, with the balance comprising MCC, Mannitol, and varying levels of wax excipient:

Sample	Formulation	Wax Level
Control	75% Folic Acid, 12.5% MCC, 11.5% Mannitol, 1% Mag Stearate	None
Sample 2	75% Folic Acid, 10.5% MCC, 10.5% Mannitol	4% Beeswax
Sample 3 ★	75% Folic Acid, 8.5% MCC, 8.5% Mannitol	8% Beeswax
Sample 4	75% Folic Acid, 6.5% MCC, 6.5% Mannitol	12% Beeswax
Sample 5	75% Folic Acid, 6.5% MCC, 6.5% Mannitol	12% Candelilla Wax

★ Recommended formulation

Dissolution Results — Average Folic Acid Released (%)

Sample	5 min	30 min	1 hr	2 hr	3 hr	4 hr	5 hr	6 hr
Control (no wax)	19.97%	50.36%	89.27%	86.09%	86.10%	84.17%	—	—
4% Beeswax	18.46%	79.33%	86.82%	86.73%	84.87%	83.86%	—	—
8% Beeswax ★	5.45%	17.61%	28.83%	50.08%	69.14%	82.61%	88.53%	89.76%
12% Beeswax	2.06%	6.71%	10.58%	16.42%	20.86%	24.86%	28.39%	30.45%
12% Candelilla Wax	2.11%	6.33%	8.75%	13.90%	17.24%	19.52%	20.92%	21.75%

***Recommendation:** The 8% Beeswax formulation (Sample 3) is the recommended tablet excipient ratio. It achieves near-complete dissolution at 6 hours, provides low early release, and demonstrates a smooth, predictable release curve.

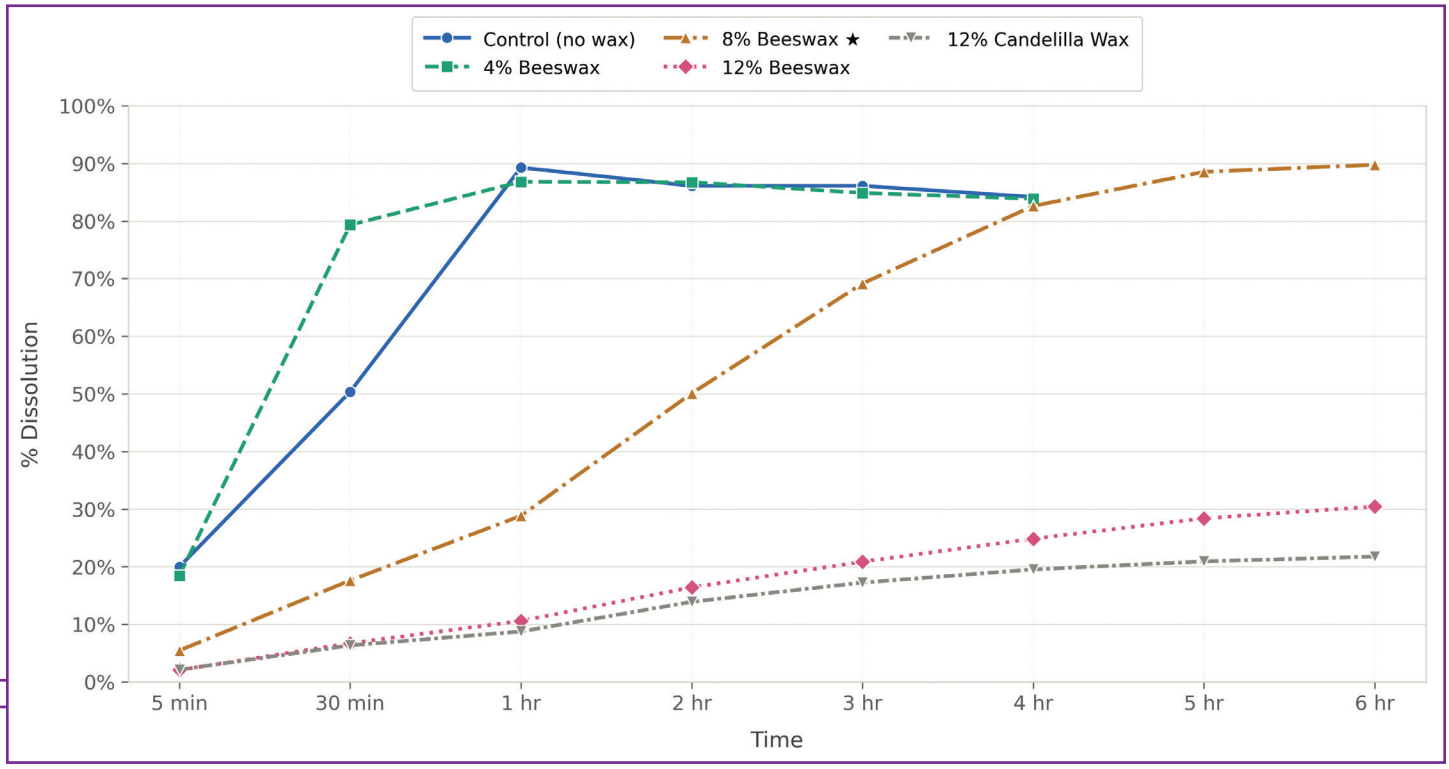
** Formulations and dissolution study done by CellMark Ingredients.

Higher Active Loading & Significantly Smaller Tablets

Wax excipients, specifically beeswax, enable active ingredient loading well above conventional levels — with this study demonstrating 75% loading and higher concentrations likely achievable. Substantially reduced excipient levels result in tablets that are 30–40% smaller

Key Findings

- Non-encapsulated folic acid dissolves rapidly, with the synthetic stomach fluid turning yellow almost immediately, indicating near-instant release.
- Wax-encapsulated tablets showed clearly delayed dissolution — the protective wax matrix held the active ingredient back and released it gradually.
- Higher wax concentration = slower release. At 8% Beeswax, approaches full dissolution at ~6 hours, demonstrating extended release potential.
- At 12% Beeswax or 12% Candelilla Wax, release remained below 31% even after 6 hours, demonstrating strong gastric protection potential.
- Beeswax demonstrated active ingredient loading at 75% in this study — with higher concentrations likely achievable — reducing tablet size by 30–40% while maintaining full dose. A significant advantage for patient compliance and manufacturing efficiency.
- Low-level beeswax inclusion increases early dissolution by 29% at 30 minutes, supporting hard-to-compress active ingredients by improving binding without compromising release speed.



Beeswax for Tablet Applications

Beeswax is a natural, biocompatible excipient recognized as GRAS by the FDA and compliant with USP/NF standards. Its unique composition of esters, fatty acids, and hydrocarbons makes it an outstanding binding, emulsifying, and film-forming agent for tablet formulations.

Tablet Functions

Stabilizer & Release Agent: Controls drug release rate in the tablet matrix for consistent therapeutic effect.

Dose Accuracy: Improves tablet ingestion and active ingredient uniformity.

Encapsulation: Used in base mixtures to support the matrix for sustained-release tablets.

Additional Information

Natural Origin: Biocompatible, GRAS certified, sustainably harvested through responsible beekeeping.

Versatility: Effective across immediate-release, sustained-release, and enteric tablet formats.

Test Options: USP 561 for Pesticides, Chloramphenicol, Nitrofuran Metabolites, Coumaphos.

Products

Product	Grade	Form	Wax #
Beeswax White NF	NF USP-561	Granulated	Wax #571G
Beeswax Yellow NF PAC	NF PAC	Granulated	Wax #525G
Beeswax Yellow NF	NF USP-561	Granulated	Wax #570G

Carnauba Wax for Tablet Applications

Carnauba wax is a plant-derived excipient with an exceptionally high melting point and strong moisture resistance. These properties make it ideal for tablet coatings, controlled-release formulations, and specialty tablet forms.

Tablet Functions

Tablet Coating & Binding: Provides a smooth, glossy finish, prevents chipping, and enhances tablet stability and shelf life.

Sustained-Release: 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.

Barrier Protection: Shields active ingredients from moisture and environmental degradation.

Commonly used in tablets for: Acetaminophen, Aspirin, Ibuprofen, Famotidine, Omeprazole, Diphenhydramine, Hydroxyzine, Montelukast, Cyclobenzaprine, Lovastatin, Atorvastatin, and more.

Products

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

Candelilla Wax for Tablet Applications

Candelilla wax is a plant-derived excipient valued for its hardness, superior binding properties, and ability to enhance stability in tablet formulations. The dissolution study confirms its effectiveness as a controlled-release agent at concentration levels of 8–12%.

Tablet Functions

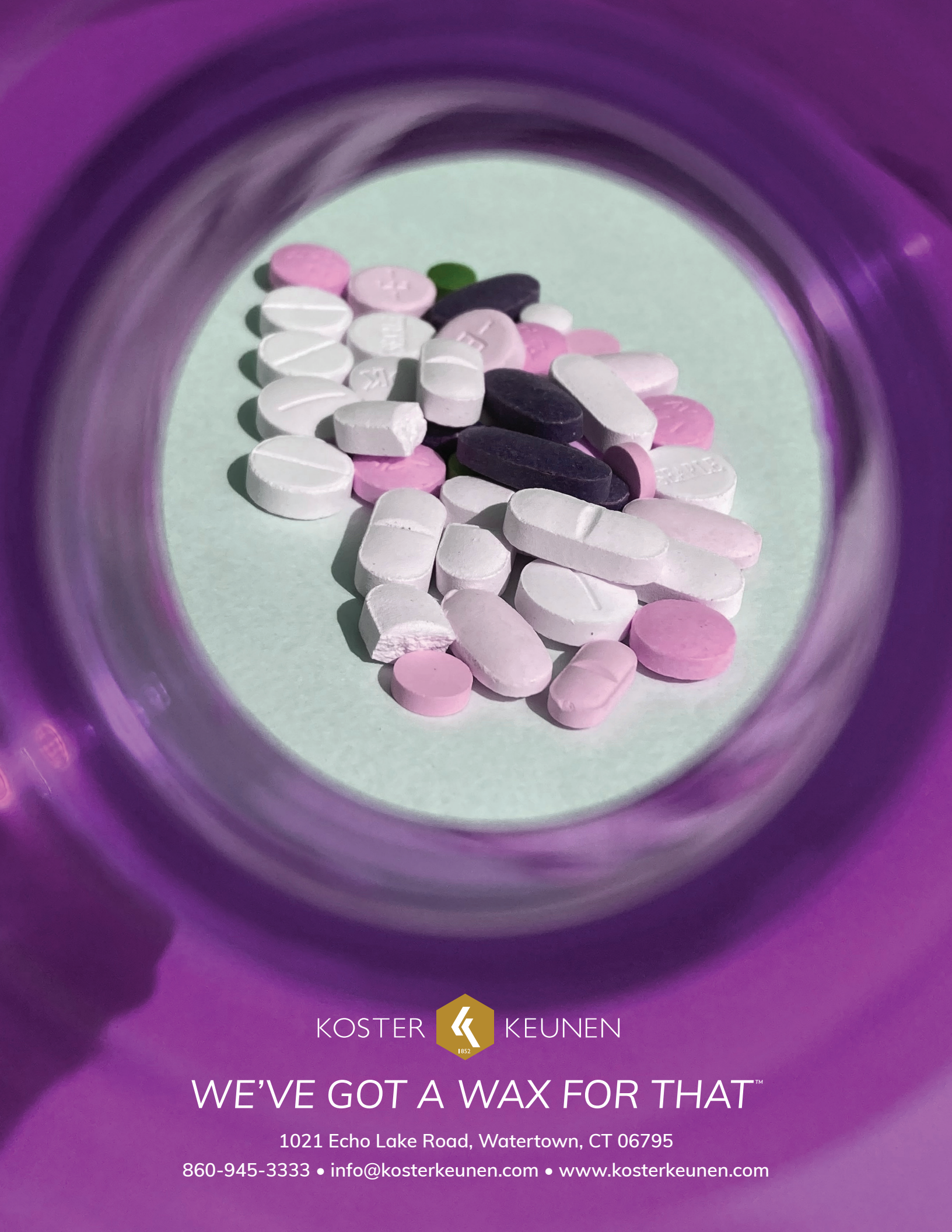
Tablet Binder: Improves tablet cohesion and mechanical strength, reducing breakage and chipping.

Glazing Agent: Enhances tablet surface finish, appearance, and moisture stability.

Controlled Release: Modifies drug dissolution rates when blended with other excipients — dissolution study shows sustained protection over 6+ hours at 12%.

Products

Product	Grade	Form	Wax #
Candelilla Wax NF	NF	Granulated	Wax #419G
Candelilla Wax NF	NF	Granulated	Wax#10091G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WE'VE GOT A WAX FOR THAT™
1021 Echo Lake Road, Watertown, CT 06795
860-945-3333 • info@kosterkeunen.com • www.kosterkeunen.com