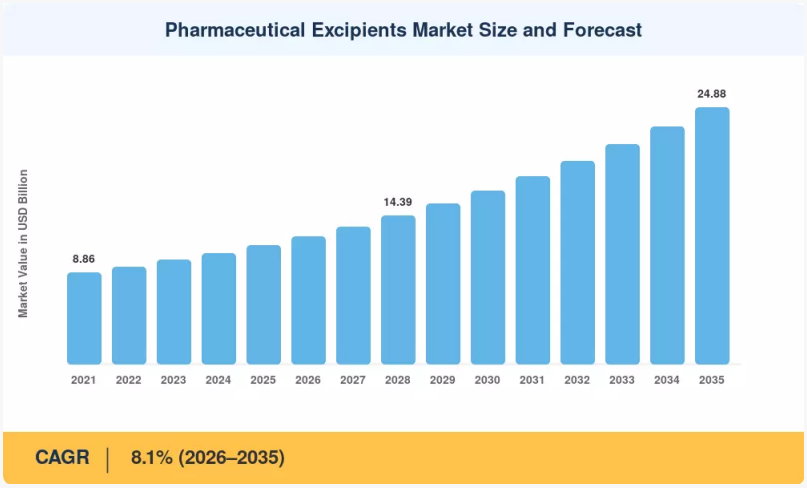
Pharmaceutical Excipients Market to reach USD 24.88 Billion by 2035 at 8.1% CAGR

Pharmaceutical Excipients Market to Surge from USD 11.47 Billion in 2025 to USD 24.88 Billion by 2035—Powered by Biosimilar and Biologics Pipeline Expansion



Pharmaceutical Excipients Market (2026 - 2035)

NY, CA, UNITED STATES, September 11, 2026 /EINPresswire.com/ -- As per Market Research Future, the global Pharmaceutical Excipients Market size is projected to reach USD 24.88 Billion by 2035 from USD 11.47 Billion in 2025, at a CAGR of 8.1% during the forecast period 2026–2035. The market base was estimated at USD 11.47 Billion in 2025, with the first year of the forecast period (2026) valued at USD 12.34 Billion.

The 8.1% CAGR is propelled by three converging forces: biosimilar and biologics pipeline expansion, with regulators now closely examining the formulation risk associated with polysorbate 80, poloxamer 188, sucrose, and arginine hydrochloride, and approximately USD 62 billion in original revenue losing exclusivity between 2026 and 2030; the shift to continuous manufacturing lines, with twin-screw wet granulation operating at 25 kg/hour amplifying any variation in flow index or particle size distribution into rejected product; and advanced drug-delivery platform adoption, with long-acting injectables, oral peptides, and inhaled biologics all converging on the same requirement for functional materials that control release with precision.

Global regulatory mandates and supply chain initiatives are amplifying this momentum. India's Production Linked Incentive scheme for bulk drugs, funded at roughly USD 2.0 billion, has pulled functional additive capacity onshore. The U.S. FDA's Quality Management Maturity program has pushed formulators toward suppliers who can document lot-to-lot consistency rather than simply meet compendial minimums. BASF, Roquette and DFE Pharma have collectively committed over USD 900 million since 2023 to co-processing and lipid-based capacity. Europe holds the largest slice at 34.6% of 2025 revenue, supported by EDQM certification depth and a

dense biologics manufacturing base, while Asia-Pacific compounds fastest at 9.9% through 2035.

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Key Market Trends & Growth Drivers

Biologics and Biosimilar Pipeline Expansion

Small compounds never needed protection, but protein therapies do. Regulators now closely examine the formulation risk associated with polysorbate 80, poloxamer 188, sucrose, and arginine hydrochloride. A number of sponsors were compelled to requalify stabilizer sources in the middle of the program due to the EMA's 2024 reflection report on polysorbate degradation. The need for low-peroxide, low-endotoxin grades is structurally locked in, with 118 biosimilar applications being reviewed by the FDA and EMA as of late 2025 and about USD 62 billion in original revenue losing exclusivity between 2026 and 2030.

Continuous Manufacturing and Process Redesign

Variable inputs were tolerated by batch granulation. Continuous lines don't. Any variation in the flow index or particle size distribution is amplified into rejected product by twin-screw wet granulation operating at 25 kg/hour. Since the method was developed, the FDA has authorized over 20 continuous manufacturing applications, each of which details the functional performance of the excipient in the submission. Compared to commodity equivalents, suppliers of immediately compressible co-processed blends with defined tabletability profiles now charge price premiums of 18–30%.

Emerging-Economy Generic Volume

India produced roughly 20% of global generic volume in 2025 yet imported close to 45% of its functional additive requirement. The USD 2.0 billion Production Linked Incentive scheme and 12 approved bulk-drug parks are designed to close that gap. China's NMPA volume-based procurement rounds have simultaneously compressed generic pricing, pushing formulators toward lower-cost regional supply. Both dynamics enlarge the addressable base while suppressing average selling prices.

Regulatory Pressure on Impurity and Elemental Profiles

ICH Q3D elemental impurity limits and the nitrosamine review cycle have made supplier qualification a technical exercise rather than a commercial one. EDQM issued 340 new Certificates of Suitability across 2023–2025, and buyers increasingly treat CEP coverage as a hard gate. Compliance cost has become a barrier that consolidates share among documented

suppliers.

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Market Segment Insights

BY PRODUCT TYPE

Organic Chemicals: Dominant segment with 69.7% share in 2025 , led by cellulosics and lactose derivatives. Organic chemistry dominates because oral solids dominate—microcrystalline cellulose alone underpins a majority of immediate-release tablet formulations.

Inorganic Chemicals: Growing at 7.95% CAGR (2026–2035) , as halites and calcium phosphates gain parenteral traction. Dibasic calcium phosphate substitution in moisture-sensitive formulations and sodium chloride demand from expanding parenteral volumes drive growth.

Carbohydrates: Significant segment with 24.3% share in 2025 , driven by lactose and starch in direct compression.

Petrochemicals: Significant segment with 21.4% share in 2025 , driven by povidone, polyethylene glycols, and acrylics.

BY FUNCTIONALITY

Fillers & Diluents: Largest segment with 29.9% share in 2025 , the single largest functional pool. Every solid dose needs bulk, making fillers the largest functional share.

Binders: Significant segment with 14.2% share in 2025 , driven by granulation strength in continuous lines.

Coatings: Significant segment with 12.6% share in 2025 , reflecting the shift to moisture-barrier and taste-masking films.

Sustained-Release Agents: Growing segment with 6.8% share in 2025 , carrying per-kilogram pricing several multiples above diluents and attracting intellectual property.

BY FORMULATION

Oral Solid Dosage Forms: Largest segment at USD 5.14 Billion in 2025, driven by generic tablet and capsule volume.

Parenteral: Fastest-expanding pool at USD 1.94 Billion in 2025, driven by biologics and biosimilar

expansion. Injectable formulations demand fewer distinct materials but at far higher purity.

Oral Liquid Dosage Forms: Significant segment at USD 1.66 Billion in 2025, driven by paediatric and geriatric dosing.

Topical: Significant segment at USD 1.53 Billion in 2025, driven by dermatology and transdermal systems.

BY SOURCE

Plant-Based: Fastest-growing source at 8.9% CAGR (2026–2035) , driven by clean-label and CSRD sustainability pressure. Pea starch, tapioca-derived maltodextrin, and non-GMO cellulose have moved from alternative to default in several European portfolios.

Synthetic / Chemical: Growing at 7.9% CAGR (2026–2035) , driven by precision-engineered polymer performance.

Mineral-Based: Growing at 7.2% CAGR (2026–2035) , driven by cost-efficient bulk diluents.

Animal-Based: Growing at 5.4% CAGR (2026–2035) , with legacy gelatin capsule demand retaining a defensible position in softgel capsules.

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Regional Outlook

Europe — Dominant Market (~34.6% Share, 2025)

Germany: Holds 24.6% of regional share , driven by dense biologics and CDMO base. Germany's cluster around Ludwigshafen and Darmstadt keeps technical service physically close to formulators.

United Kingdom: Holds 15.2% of regional share , driven by MHRA innovative licensing pathway.

France: Holds 13.4% of regional share , driven by France 2030 health sovereignty funding. France committed EUR 7.5 billion under France 2030 to health innovation, a portion routed into formulation input manufacturing.

Italy: Holds 10.8% of regional share , driven by contract manufacturing concentration.

Spain: Holds 8.1% of regional share , driven by generic export capacity.

Nordic Countries: Hold 6.3% of regional share , driven by protein therapeutic specialisation.

Russia: Holds 4.9% of regional share , driven by domestic substitution programmes.

Rest of Europe: Holds 16.7% of regional share , driven by Central European tolling capacity.

North America — Second Largest (USD 3.46 Billion, 2025)

United States: Holds 76.4% of regional share , driven by biosimilar filings and FDA continuous manufacturing pathway. The Administration for Strategic Preparedness and Response committed over USD 1.1 billion to domestic API and input manufacturing since 2023.

Canada: Holds 12.1% of regional share , driven by Biomanufacturing Strategy funding. Canada's USD 1.8 Billion Biomanufacturing and Life Sciences Strategy funds parallel capacity.

Mexico: Holds 11.5% of regional share , driven by nearshoring of generic fill-finish.

Asia-Pacific — Fastest-Growing Region (9.9% CAGR, 2026–2035)

China: Holds 32.4% of regional share , driven by scale chemical intermediates and NMPA reform.

India: Holds 22.1% of regional share , driven by PLI scheme and generic export volume. India's 12 bulk-drug parks and PLI disbursements have added fermentation and cellulose derivative lines that did not exist in 2020.

Japan: Holds 17.6% of regional share , driven by high-purity grades and geriatric formulations.

South Korea: Holds 8.9% of regional share , driven by biosimilar manufacturing base. South Korea's biosimilar producers consume disproportionate volumes of parenteral-grade stabilisers relative to national population.

ASEAN: Holds 11.3% of regional share , driven by halal-certified sourcing and local assembly.

South America — Growing Presence (4.9% Share, 2025)

Brazil: Anchors the region with 52.8% of revenue , driven by ANVISA-regulated domestic generic base.

Argentina: Holds 21.4% of regional share , driven by local biologics production.

Middle East & Africa — Emerging Opportunity (6.8% CAGR, 2026–2035)

Saudi Arabia: Holds 27.3% of regional share , driven by Vision 2030 localisation targets. The National Unified Procurement Company applies preference margins to locally manufactured medicines.

UAE: Holds 19.6% of regional share , driven by free-zone manufacturing and re-export.

South Africa: Holds 21.4% of regional share , driven by SAHPRA-regulated generic capacity. SAHPRA has cut backlog review times materially since 2022.

Egypt: Holds 12.9% of regional share , driven by largest regional dosage-form output.

Competitive Landscape and Recent Developments

Concentration sits in the medium band, with the top five suppliers holding an aggregate 34–41% of global revenue. Competition turns on regulatory documentation, technical service depth and supply-continuity guarantees rather than price alone.

KEY COMPANIES AND RECENT MILESTONES

BASF SE (September 2024): Launched an AI-supported formulation prediction service for solubility enhancement, bundling data services with material supply. Broadest portfolio with digital formulation tools. Estimated ~9–12% revenue share.

Roquette Frères (November 2023): Completed acquisition of a pharmaceutical solutions business and announced a EUR 25 million pea-protein capacity expansion, deepening plant-derived supply for clean-label formulations. Estimated ~7–10% revenue share.

Ashland Global Holdings (October 2025): Divested a non-core segment and redirected proceeds toward controlled-release polymer capacity, sharpening its specialty focus. Estimated ~6–9% revenue share.

DuPont / IFF Pharma Solutions: Hot-melt extrusion and bioavailability focus with Methocel and Affinisol hypromellose grades. Estimated ~5–8% revenue share.

Evonik Industries (March 2024): Opened expanded lipid manufacturing capacity at Lafayette, Indiana, backed in part by U.S. federal funding, targeting nucleic acid delivery demand. Estimated ~5–7% revenue share.

Croda International (May 2025): Announced a strategic supply agreement with a leading mRNA developer covering GMP ionisable lipid volumes through 2030. Estimated ~4–6% revenue share.

DFE Pharma (February 2025): Commissioned new inhalation-grade lactose capacity in Germany to serve dry powder inhaler programmes facing global supply tightness. Estimated ~3–5%

revenue share.

Other Key Players: JRS Pharma (~3–5%), Merck KGaA (~3–4%), Colorcon (~3–4%), Lubrizol Life Science (~2–4%), Kerry Group (~2–3%).

Recent Industry Developments:

FDA (July 2024): Expanded the Novel Excipient Review Pilot Program to a second cohort, giving developers a route to review material safety ahead of a drug application.
EDQM (August 2025): Published revised guidance on Certificate of Suitability applications, tightening nitrosamine and elemental impurity documentation expectations.
Future Outlook: 2026–2035

The Pharmaceutical Excipients Market is projected to reach USD 24.88 Billion by 2035, growing at a CAGR of 8.1%, driven by biosimilar and biologics pipeline expansion, continuous manufacturing adoption, and advanced drug-delivery platform adoption.

New opportunities lie in:

Oral Peptide and Permeation Enhancement: Sodium caprate, SNAC, and related enhancers have become marketable, with at least 14 peptide programs now focusing on oral methods. Suppliers who can provide GMP-grade enhancers with pre-assembled toxicological packages will gain disproportionate value.

Lipid Systems for Nucleic Acid Therapeutics: PEG-lipids, helper phospholipids, and ionizable lipids are still scarce, with global GMP lipid capacity increased by around three times between 2021 and 2025 but still falling short of anticipated mRNA and siRNA demand.

Emerging-Market Localisation: Africa imports over 70% of its finished pharmaceuticals, and the African Medicines Agency is financing local fill-finish and oral solid capacity.

Data and Digital Formulation Services: Subscription access to compaction simulation libraries, DoE templates and predictive stability models is emerging as a margin layer above the physical product.

Predictive Formulation and Digital Twins: Machine learning models trained on compaction and dissolution datasets are shortening formulation cycles from months to weeks, with model-informed grade selection becoming routine by 2030.

Paediatric and Geriatric Dosage Reformulation: Taste-masking polymers, orally disintegrating platforms and mini-tablet binders address a demand pool that regulation, not marketing, creates.

By 2035, the Pharmaceutical Excipients Market is expected to demonstrate robust growth, reflecting the transformation of excipients from commodity inputs to functional, documentation-rich platform materials.

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