Global Pharma Intermediates Technology Review: Routes, Compliance Cost and Maturity

From beta-lactam nuclei to continuous flow: who can synthesise reliably at the lowest compliance cost

Base year	History	Forecast
2025	**2019–2025**	**2026–2031**
Regions	Segments	Formats
4	**5**	**PDF / Excel / PPT**

Abstract

This report treats pharma intermediates as a technology and compliance question, not a market-sizing question. Three layers of competition overlap: synthetic routes are largely public knowledge, gaps in tonne-scale process capability are narrowing, and the layer still diverging is compliance engineering — whether a process is accepted by the site, passes customer audits and survives regulatory change control. The same molecule can be quoted 30% apart by two plants with near-identical certificates of analysis; the difference sits in that third layer.

It places six institutional estimates side by side (USD 14.0–187.73 bn for 2024/2025, more than an order of magnitude apart) and uses only the merchant-intermediate cluster of USD 36.60–45.45 bn: a primary anchor of USD 45.45 bn (2025) and a secondary anchor of USD 39.23 bn (2024). No averaging, no ultra-broad or narrow scopes. The 71 registered sources are graded A/B/C, 34 of 71 opened on the spot, and verification rates are reported against three separate denominators — nowhere does this report claim 100%.

Key findings (excerpt)

- Reports sharing the name 'pharma intermediates market' cannot be compared directly: six institutions give USD 14.0–187.73 bn, over an order of magnitude apart; four merchant-scope estimates fall in USD 36.60–45.45 bn (a 24% spread explainable within one definition). Anchors are USD 45.45 bn (2025, Mordor) and USD 39.23 bn (2024, SkyQuest). The arithmetic mean of USD 41.23 bn is explicitly discarded — averaging disguises a definition gap as estimation error.
- Technical competition in commodity beta-lactam nuclei is over: 6-APA comes from penicillin G potassium salt in one immobilised acylase hydrolysis step, with 85%–90% isolated yield over 10 consecutive 10 L pilot batches (S25); the two-enzyme route to 7-ACA reached 85% molar

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yield in 1995 versus about 72% for chemical cleavage (S24). New capacity competes on enzyme lifetime, batch consistency, wastewater load and phenylacetic acid recovery — not on whether to use enzymes.

- Cost steps come from removing steps, not from lifting single-step yield: a new ATS-8 atorvastatin side-chain route uses two fewer steps for 79.5% overall yield versus 67.7% (supplier-relayed patent, grade C, to be verified); remdesivir from GS-441524 takes 3 steps at 76% versus 43% for the original route; enzymatic molnupiravir cuts more than five steps to two at 41% versus 17%. One or two fewer steps also remove solvent types, unit operations and impurity profiles.
- Continuous flow must be judged on two levels: nitration residence times down to minutes, a kilogram-scale electrochemical coupling running 120 hours and AbbVie photoredox at 500 kg show that hazardous single steps are commercial (maturity grade 7). FDA-approved continuous manufacturing, however, sits in drug-product manufacture, with no verifiable end-to-end API case; whole lines remain at pilot scale (no grade, 5–10 years). 'Mature' and 'not yet deployed' both omit the object being assessed.
- Compliance is the gate on capacity and belongs in the quote: China's elimination catalogue lists 12 outdated hazardous process technologies and equipment items (4 processes, 8 equipment types); EU REACH requires registration above 1 tonne/year, with strictly controlled intermediate dossiers costing EUR 4,000–6,000 / 10,000–30,000 by volume band, and 86% of the 400-plus intermediate dossiers sampled by ECHA in 2011 failed the reduced-data conditions. Together with regulatory starting material (RSM) change control, compliance decides whether capacity can legally exist.
- Regions are layered, not substitutes, and precise shares are refused: China exported USD 42.98 bn of APIs in 2024 (an API scope that includes but is not equal to intermediates); India imported USD 4.348 bn of APIs/intermediates in FY2024-25, 73.71% from China; Europe produced 64% of APIs locally (value versus tonnage undisclosed, flagged to be verified). Of 62 data rows, 34 are primary, 24 secondary and 4 unverified. Advanced intermediate capacity has no public verifiable data, so this report constructs no CR4 or HHI.

Global pharma intermediates sizing: six institutional definitions compared

Source and scope	Base-year size	CAGR	Scope cluster	Treatment
Mordor Intelligence (merchant, broad)	45.45 bn USD (2025)	7.05% (2026–2031)	Merchant cluster	Adopted as primary anchor
SkyQuest (merchant, broad)	39.23 bn USD (2024)	6.37%	Merchant cluster	Adopted as secondary anchor

Source and scope	Base-year size	CAGR	Scope cluster	Treatment
Future Market Insights (merchant, broad)	36.60 bn USD (2025)	4.5% (2026–2036)	Merchant cluster	Listed, not averaged
TSCI via GII (merchant, broad)	43.64 bn USD (2025)	5.61%	Merchant cluster	Listed, not averaged
Dimension Market Research (narrow)	14.00 bn USD (2033)	13.4% (different denominator)	Outside the cluster	Rejected, listed separately
Intel Market Research (ultra-broad)	187.73 bn USD (2024)	—	Outside the cluster, likely includes APIs and contract manufacturing	Rejected, listed separately

Four merchant-scope estimates fall in USD 36.60–45.45 bn, a 24% spread explainable within one definition; the narrow 14.0 and the ultra-broad 187.73 differ by an order of magnitude and are listed separately. No averaging, no residual convergence.

Source: 各机构公开发布摘要，2024–2026；口径裁决见报告附录 B

6 in total, all listed in the full edition

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Method and definitions

This brief is built from public sources: Chinese and English industry and consultancy reports, annual reports and prospectuses, customs and statistical series, and public capacity or expansion announcements by main participants. Where two sources disagree on the same metric, both figures are shown with the reason for the gap instead of being averaged. Amounts are in USD at nominal value unless stated; capacity is in 10k t/yr. Forecast window 2026–2031, base year 2025.

Data updated：{'zh': '半年度更新', 'en': 'Semi-annual'}

Coverage

- China (commodity cost curve and enzyme engineering)
- India (regulated formulations and upstream import dependence)
- Europe (high-potency and complex chiral APIs)
- North America (demand side and innovator outsourcing)

Excerpts below let you judge structure and methodology; the paid edition lists everything.

Main participants (excerpt)

- Lonza
- CARBOGEN AMCIS
- Neuland Laboratories
- Evonik
- BASF
- Merck KGaA

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Sources (excerpt)

1. A 应急管理部《淘汰落后危险化学品安全生产工艺技术设备目录（第一批）》解读：列 12 项，其中工艺 4 项、设备 8 项。
   https://www.mem.gov.cn/gk/zcjd/202011/t20201127_372281.shtml（2026-11 访问）
2. A 印度新闻局 PIB：2024–25 财年 API / 原料药 / 中间体进口 43.48 亿美元，中国占 73.71%。
   https://www.pib.gov.in/PressReleasePage.aspx?PRID=2222528（2026-11 访问）
3. B Mordor Intelligence《Pharmaceutical Intermediates Market》：2025 年 45.45 bn USD、2026–2031 CAGR 7.05%，本报告主锚。
   https://www.mordorintelligence.com/industry-reports/pharmaceutical-intermediates-market（2026-11 访问）

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The full edition includes

- PDF full report with all data tables and sources
- Excel data workbook (tables and original rows)
- PPT management summary (selected reports)

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