

Alembic Pharmaceuticals Limited

June 18, 2024

Facilities/Instruments	Amount (₹ crore)	Rating ¹	Rating Action
Commercial paper	750.00	CARE A1+	Reaffirmed

Details of instruments/facilities in Annexure-1.

Rationale and key rating drivers

The rating assigned to the commercial paper (CP) issue of Alembic Pharmaceuticals Limited (APL) continues to derive strength from its experienced and qualified management in the pharmaceutical industry, its long track record and established presence in the domestic formulation market with strong formulation portfolio, presence in major regulated markets, and its diversified revenue profile with vertically integrated operations. The rating further derives comfort from its healthy financial risk profile marked by large net worth base, low debt level, and strong liquidity.

Above rating strengths are, however, partially off-set by continued moderate operating profitability margin due to pricing pressure in the US generic market, and saleability risk and overhead cost associated with the recently commissioned new facilities, which shall restrict profitability and return ratio (return of capital employed; ROCE) in the near term. The rating is further constrained on account of its exposure to inherent regulatory risks associated with the pharmaceutical industry, intense competition and resultant pricing pressure in domestic and export markets.

Rating sensitivities: Factors likely to lead to rating actions Negative factors

- Significantly larger-than-envisaged capex or acquisition, adversely affecting its free cash flows and debt coverage indicators.
- Increasing overall gearing ratio to greater than 0.5x on a sustained basis.
- Declining profit before interest, lease rentals, depreciation, and taxation (PBILDT) margin below 15% and significant
 adverse impact on its ROCE on a sustained basis on account of lower-than-envisaged benefits from recently commissioned
 facilities.

Analytical approach: Consolidated.

CARE Ratings Limited (CARE Ratings) has considered consolidated financials of APL because of operational and financial linkages with its subsidiaries/joint ventures (JVs)/associates. The list of entities consolidated in APL as on March 31, 2024, are mentioned in **Annexure 6**.

Detailed description of key rating drivers:

Key strengths

Qualified and experienced management

Since its incorporation in 1907 (earlier known as Alembic Chemical Works) by B.D. Amin, the Amin family has driven APL's operations. Chirayu Amin (Chairman) is a third-generation entrepreneur and has more than three decades of experience in the Indian pharmaceutical industry (IPI). Pranav Amin (MD) and Shaunak Amin (MD), sons of Chirayu Amin, also possesses experience of more than a decade in the pharmaceutical industry. APL has well-qualified and experienced second-tier management with well-defined organisational structure and strong management information system.

Diversified and vertically integrated operations

APL's business is divided into three broad segments, (i) branded formulations (sale of formulations in the domestic market); (ii) international generic formulations (sale of formulations in export markets); and (iii) active pharmaceutical ingredients (API; catering to domestic and export markets). These segments contributed around 35%, 45% and 20% of its consolidated total operating income (TOI), respectively, in FY24 (FY refers to period April 01 to March 31) indicating a fairly diversified revenue stream. APL's revenue profile is also geographically well-diversified with presence in major regulated and semi-regulated markets; albeit there is greater focus on the US (generic formulation sales in the US contributed around 28% of its TOI in FY24).

The domestic branded formulation business grew by 7% on a relatively higher base of FY23, while the API business grew by 7% in FY24 on a y-o-y basis. APL's top 10 brands in the domestic market constituted around 40% of its branded formulation sales in FY24 (42% in FY23). Its top 10 generic formulations in the US market constituted around 45-50% of its US generic formulation sales in FY24, which indicates fair diversification. CARE Ratings expects APL to continue to benefit by its diversified

¹Complete definition of the ratings assigned are available at www.careedge.in and other CARE Ratings Ltd.'s publications.



product portfolio both in domestic and regulated market. Furthermore, with expectation of new product launches particularly in the US market, the revenue contribution from top 10 generic formulations is likely to reduce in future.

APL has vertically integrated operations, as it captively meets its API requirement for its key final products apart from selling API to customers. APL's ability to manufacture API for its key formulations partially protects it from supply uncertainties and volatility in the prices of API.

Long track record and established position in domestic formulation market

APL has an operational track record of over a century in the Indian pharmaceutical industry and is among the top 25 pharma players in the domestic formulation market. APL ranked 21st with market share of nearly 1.5% in the domestic pharmaceutical market (Source: APL). APL has a portfolio of 191 domestic formulation brands and has over 1,000 products (SKUs). APL has a field force of over 5,000 executives reaching around 2,33,000 medical practitioners across India. It earned nearly 73% of its domestic revenue from top five therapeutic segments including anti-infective (20% of its domestic revenue), veterinary (16%), cardiology (13%), gynaecology (13%) and gastrology (11%).

Large presence in regulated markets backed by consistent R&D focus

In the last 5-6 years, APL has gradually increased its presence in overseas markets, where majority contribution comes from regulated markets such as the US. Till FY21, APL demonstrated a strong operational performance in the US market led by increasing product approvals, new product launches, and several short-term supply opportunities due to regulatory issues faced by its competitors. However, APL's US generic business started facing pricing pressure from FY22, resulting in lower sales realisation and profitability. There has been consolidation of distributors in the US, where top three distributors account for more than 90% of the country's drug market. Hence, pricing power of suppliers have reduced considerably. Despite continued price erosion, APL grew its US generic business by 10% in FY24 over FY23 primarily on account of launches of new products and increase in the market share of existing products. Price erosion is expected to soften in FY25 to mid-single digit thereby supporting growth in the US generic business.

APL made sizable investments in its R&D capabilities (annual R&D spend of around 12%-16% of its consolidated sales in FY21-FY23) to grow its presence in regulated markets. However, the company has consciously decided to curtail its R&D budget (8% in FY24) considering competition in certain products in the US generics market. The company has decided to curtail its development projects of certain products, where patent expiry is towards FY29 and beyond. Reduced R&D expenditure is not expected to have material impact on the existing business and products under development for immediate period expiries. In FY24, the company filed 15 abbreviated new drug application (ANDAs), leading to cumulative ANDA filling of 260 as on March 31, 2024. The company received 15 ANDA approvals in FY24, leading to cumulative ANDA approvals of 194 as on March 31, 2024, which increased to 201 as on May 15, 2024. APL launched 27 products in FY24, and it envisages to launch nearly 15-20 products in the US market in FY25 and FY26. CARE Ratings expects its US business to grow by at least 10% per annum over FY25-FY27.

Comfortable capital structure and debt coverage indicators

APL's capital structure continued to remain comfortable marked by overall gearing ratio and total operating liabilities to total net worth (TOL/TNW) of 0.11x (PY: 0.17x) and 0.34x (0.41x) respectively as on March 31, 2024, supported by relatively low debt of ₹513 crore (including ₹83 crore of lease liability) and large net worth base of over ₹4,800 crore as on March 31, 2024. APL's overall gearing is expected to remain below 0.20x in the medium term in the absence of any major debt-funded capex plan. APL's debt coverage indicators also remain comfortable marked by total debt to PBILDT (TD/PBILDT) of 0.55x and TD to gross cash accruals (TD/GCA) of 0.61 years in FY24. Debt coverage indicators are expected to remain comfortable due to APL's healthy profitability. CARE Ratings expects cash accruals to remain adequate to meet its envisaged capex and working capital requirement and there would not be major reliance on external debt.

Stable growth prospects of Indian pharmaceuticals sector

The Indian pharmaceutical industry (IPI) comprises mainly formulations, API and contract research and manufacturing services (CRAMS) segments. The outlook for IPI is envisaged to remain stable in the medium to long term backed by growth opportunity in terms of capitalising on major blockbuster drugs coming off-patent, paving the way for entry of generics, especially in the US market, and geographical diversification in emerging markets. In the domestic market, growth in the formulations segment is expected to be led by rise in chronic diseases, increasing per capita income, government initiatives such as new national health protection scheme and Ayushman Bharat programme, improving access to healthcare facilities, and growing penetration of health insurance.

Liquidity: Strong

The company's liquidity is expected to remain strong in the absence of scheduled repayment obligation between FY25-FY27. APL's liquidity indicator continued to remain strong marked by current ratio of 2.14x as on March 31, 2024. APL's internal



accruals are expected to remain adequate to meet its capex and working capital requirement. Utilisation of its fund-based working capital limits (on a standalone basis) also remained at around 43% for the trailing 12 months ended April 2024. Its unutilised working capital limits provide additional liquidity cushion. Its healthy net-worth base and comfortable leverage provide significant financial flexibility to APL.

Key weaknesses

Continued moderate operating profitability margins and ROCE in FY24

APL's TOI grew by around 11% in FY24, primarily supported by healthy growth in revenue from international generic business followed by growth in API segment and domestic formulation market. Despite growth in revenue, APL's PBILDT margin continued to remain moderate at 15% in FY24 due to high overhead cost related to recently commissioned projects. With moderation in its profitability, the company's operating ROCE continued to remain moderate at 15% in FY24. However, cash accruals increased to ₹842 crore in FY24 as compared to ₹782 crore in FY23 backed by growth in TOI and stable profitability margins. Profitability and cash accruals during the year were supported by curtailed R&D spend, which was reduced to ₹480 crore in FY24 as against ₹720 crore in FY24.

Gradual ramp-up from of recently commissioned facilities shall restrict profitability and ROCE in the near term

APL embarked on the capex programme targeted towards increasing its presence in the US market by offering more complex and specialty products. APL set-up three new manufacturing facilities targeted to cater the US market. All three new manufacturing facilities are approved by the US Food and Drug Administration (USFDA). APL started commercial operations from one of its new manufacturing facilities in H2FY23, while it started commercial production of two other facilities in FY24. Management expects a gradual ramp-up in production and sales from these facilities.

Following the commercialisation of new facilities, overhead costs associated with these facilities are now being accounted for in the Profit and Loss (P&L) statement starting from FY24. This may have an impact on profitability and Return on Capital Employed (ROCE) in the near to medium term, until APL begins to generate sufficient returns from its new formulation assets. CARE Ratings expects PBILDT margin to remain at around 15-16% in FY25, which is likely to improve from FY26 onwards. ROCE to remain at 15-16% in FY25.

Inherent regulatory risk in domestic and international markets

APL derived around 35% of its consolidated revenue in FY24 from domestic formulation business. Around 15% of its formulations feature in the national list of essential medicine (NLEM). Inclusion of fresh formulations in NLEM and consequently in the drug prices control order (DPCO) may restrict pricing flexibility for APL. It is also exposed to regulatory changes in global markets (primarily the US) as international generic business contributed nearly 45% to its revenue in FY24. Continuous efforts by the US government to bring down drug prices, intense competition in the US generic market, and consolidation of the US pharmaceutical distributors, may pose vulnerability to its profitability. Pricing in generic formulations in the regulated market, especially the US, is mainly driven by the dynamics of demand and supply. The wholesale pharmacy market in the US is dominated by few distributors. Moreover, non-compliance with good manufacturing practice (GMP) and subsequent adverse action by USFDA may also pose threat to the revenue and profitability of the company. However, APL has establishment inspection report (EIR) in place for all its operational manufacturing facilities.

Environment, social, and governance (ESG) risks

Risk factors	Compliance and action by the company		
Environmental	The company has zero liquid discharge (ZLD) implemented facility. APL has taken several initiatives to reduce carbon emission and waste sent to landfill, by sending waste to the recycling and cement industries to an extent. In FY24, APL achieved a 16% reduction in total emission (Scope 1 and Scope 2). Company has also invested in renewable energy by installing windmills and solar panels. In FY24, APL commissioned a 12 MW Solar Park at Bhatpur, Gujarat.		
Social	APL faces a high social risk related to safety of consumers. APL is exposed to reputation risk related to quality of products/services. However, there have not been major instances of litigations and product recall in the past. APL continues to comply with the labour laws, adequate safety for workers, ensuring customer privacy and fair marketing practices to achieve long-term sustainability. APL has also implemented human rights policy and prevention of sexual harassment policy.		
Governance	APL has adequate governance structure, with majority of its board comprising independent directors, presence of investor grievance redressal mechanism, whistle-blower policy and extensive disclosures.		

Applicable criteria

<u>Definition of Default</u> <u>Liquidity Analysis of Non-financial sector entities</u> <u>Consolidation</u>



Manufacturing Companies
Pharmaceuticals
Financial Ratios – Non financial Sector
Short Term Instruments

About the company and industry Industry classification

Macro-economic indicator	Sector	Industry	Basic industry
Healthcare	Healthcare	Pharmaceuticals & biotechnology	Pharmaceuticals

APL is engaged in manufacturing and marketing branded formulations (in the domestic market), generic formulation (in overseas market) and API/ bulk drug in domestic and overseas markets. With effect from April 01, 2010, the core pharmaceutical business of Alembic Limited (which was originally incorporated in 1907 as Alembic Chemical Works) was demerged into APL. APL caters to several therapeutic segments, including anti-infective, gynaecology, cardiology, diabetes, dermatology and oncology, where the anti-infective segment contributes the most to its revenue in the domestic market. The US forms major share of APL's revenue in its export market. APL operates total nine manufacturing facilities at different locations in India (six formulation facilities and three API facilities).

Consolidated Brief Financials (₹ crore)	March 31, 2023 (A)	March 31, 2024 (Ab.)
Total operating income	5,631	6,236
PBILDT	847	941
PAT	342	616
Overall gearing (times)	0.17	0.11
Interest coverage (times)	16.88	16.74

A: Audited; Ab.: Abridged published results; Note: these are latest available financial results

Status of non-cooperation with previous CRA: Not applicable

Any other information: Not applicable

Rating history for last three years: Annexure-2

Covenants of rated instrument / facility: Annexure-3

Complexity level of instruments rated: Annexure-4

Lender details: Annexure-5

Annexure-1: Details of instruments/facilities

Name of the Instrument	ISIN	Date of Issuance (DD- MM-YYYY)	Coupon Rate (%)	Maturity Date (DD- MM-YYYY)	Size of the Issue (₹ crore)	Rating Assigned along with Rating Outlook
Commercial Papers	INE901L14AV7	21-Mar-2024	7.70%	18-June-2024	100.00	CARE A1+
Commercial Papers ^	NA	-	-	-	650.00	CARE A1+

The company has availed CP of ₹100.00 crore of the total rated CP issue of ₹750.00 crore as on June 06, 2024; ^ Proposed.

Annexure-2: Rating history for last three years

		Current Ratings			Rating History			
Sr. No.	Name of the Instrument/ Bank Facilities	Туре	Amount Outstanding (₹ crore)	Rating	Date(s) and Rating(s) assigned in 2024- 2025	Date(s) and Rating(s) assigned in 2023- 2024	Date(s) and Rating(s) assigned in 2022- 2023	Date(s) and Rating(s) assigned in 2021- 2022
1	Commercial Paper- Commercial Paper (Standalone)	ST	750.00	CARE A1+	-	1)CARE A1+ (19-Jun-23)	1)CARE A1+ (21-Jun-22)	1)CARE A1+ (22-Jun-21)

ST: Short term

Annexure-3: Detailed explanation of covenants of rated instruments/facilities: Not applicable



Annexure-4: Complexity level of instruments rated

Sr. No.	Name of the Instrument	Complexity Level
1	Commercial Paper-Commercial Paper (Standalone)	Simple

Annexure-5: Lender details

To view lender-wise details of bank facilities please click here

Annexure-6: List of entities consolidated

Sr No	Name of the entity	Extent of consolidation	Rationale for consolidation
1	Alembic Global Holding SA (AGH)	Full consolidation	
2	Alembic Pharmaceuticals (AP) Inc.	Full consolidation	Subsidiary; operational and financial linkages
3	Alembic Pharmaceuticals SPA	Full consolidation	Subsidiary, operational and ilitaricial linkages
4	Alembic Pharmaceuticals S.A. de C.V.	Full consolidation	
5	Alembic Pharmaceuticals Europe Limited	Full consolidation	
6	Alembic Pharmaceuticals Canada Limited	Full consolidation	
7	Alembic Pharmaceuticals Australia Pty Limited	Full consolidation	Cton down subsidiany approximational and financial
8	Alnova Pharmaceuticals SA	Full consolidation	Step down subsidiary; operational and financial linkages
9	Genius LLC	Full consolidation	illikages
10	Alembic Labs LLC	Full consolidation	
11	Okner Realty LLC	Full consolidation	
12	Incozen Therapeutics Pvt. Ltd.	Equity method	Associate of APL; operational and financial linkages
13	Rhizen Pharmaceuticals AG (RPAG)	Equity method	Associate of AGH; operational and financial linkages
14	Dahlia Therapeutics SA	Equity method	Subsidiary of RPAG; operational and financial
15	Rhizen Pharmaceuticals Inc.	Equity method	linkages

Note on complexity levels of rated instruments: CARE Ratings has classified instruments rated by it based on complexity. Investors/market intermediaries/regulators or others are welcome to write to care@careedge.in for clarifications.

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About us:

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