

July 29, 2021

Dr. Reddy's Laboratories Ltd.: Rating reaffirmed

Summary of rating action

Instrument*	Previous Rated Amount (Rs. crore)	Current Rated Amount (Rs. crore)	Rating Action
Long-term, Fund-based / Non-fund Based Limits	500.0	500.0	[ICRA]AA+ (Stable) reaffirmed
Total	500.0	500.0	

*Instrument details are provided in Annexure-1

Rationale

The rating reaffirmation for Dr. Reddy's Laboratories Limited (DRL) factors in the healthy revenue growth in FY2021 which is expected to continue in the near to medium term led by new product introductions and the favourable growth prospects across key geographies coupled with the exclusive commercial sales of the Sputnik vaccine (Covid-19 vaccine) for 250 million doses over FY2022 and FY2023. DRL's operating income (OI) grew by 8.7% YoY in FY2021 (growth of 13.6% YoY in FY2021 adjusted for one-time sale of neurology products in FY2020) and 11.7% in Q1 FY2022 owing to healthy revenue growth across geographies. This growth was aided by increase in sales volume of existing products (formulations and APIs¹), new product launches, consolidation of acquired business (acquired in June 2020), penetration into new markets and benefits of foreign exchange, partially offset by price erosion in generic business across regulated and certain emerging markets.

ICRA notes that on July 06, 2021, DRL received a subpoena from the US SEC² for the production of documents pertaining to certain CIS³ geographies, and the company is in the process of responding to the same. DRL had earlier received an anonymous complaint alleging improper payments made to healthcare professionals in Ukraine and potentially other countries by or on behalf of the company, and DRL had disclosed the same to the SEC, the DoJ⁴ and SEBI⁵. This is a key rating monitorable and ICRA will continue to monitor the credit implication of the above development in this regard.

The rating continues to derive comfort from DRL's geographically diversified revenue mix, integrated presence across the value chain and healthy product pipeline. The rating factors in the company's increasing focus on limited competition niche products, injectables and biosimilars, which are expected to boost its revenues in the medium term, given its strong research and development (R&D) capabilities. Moreover, with the imminent commercial roll-out of the Sputnik vaccine, the revenues are expected to grow substantially in FY2022-FY2023. DRL has an exclusive license with Russian Direct Investment Fund (RDIF) to sell the first 250 million doses of Sputnik V in India.

DRL's operating profit margin (OPM) improved to 23.9% in FY2021 from 23.7% in FY2020 (adjusting for the one-time income from sale of neurology brands, OPM for FY2020 was 20.3%), aided by favourable product mix, including new product launches, cost optimisation initiatives and foreign exchange benefit, which was partly offset by price erosion in regulated and certain emerging markets. However, the company's OPM witnessed a decline to 18.6% in Q1 FY2022 (25.3% in Q1 FY2021) owing to price erosion in US and other emerging markets, increase in inventory related provisions in Q1 FY2022, increased investment in digitization and brand promotion and R&D expenses during the quarter. Going forward, ICRA expects the OPM to moderate slightly from FY2021 levels, but remain supported by DRL's product mix and roll-out of the Sputnik vaccine. DRL recognised Rs.

¹ Active pharmaceutical ingredients

² Securities and Exchange Commission

³ Commonwealth of Independent States

⁴ Department of Justice

⁵ Securities and Exchange Board of India

1,676.7 crore Rs. 676.8 crore and Rs. 183.8 crore towards impairment and/ or write-offs of certain acquired ANDAs⁶ in FY2020, FY2021 and Q1 FY2022, respectively. The company remains vulnerable to further deterioration in the market potential for various molecules, and this is a key monitorable. DRL continues to maintain a healthy financial profile characterised by robust credit metrics and strong liquidity. It remained cash surplus as of June 30, 2021, with cash and liquid investments of Rs. 3,435.6 crore, against total debt of Rs. 3,337.3 crore. The liquidity profile was further supported by undrawn working capital lines (standalone) of Rs. 1,886.1 crore as on March 31, 2021.

Despite facing delays in the launch of some key products (gNuvaring and gCopaxone), the company continues to focus on its annual launch momentum of 25-30 new products in the US markets. DRL's ability to maintain a healthy product portfolio in the US markets, secure timely approval for key launches and capability to continue to grow in other key geographies are critical for sustaining its profitability and strong credit metrics.

The operations of the company also remain exposed to regulatory risks, arising out of the scrutiny by regulatory agencies including the US SEC, US DOJ and USFDA⁷. ICRA notes the resolution of all past regulatory non-compliances by the company. DRL's API manufacturing plant at Middleburg, New York was issued a Form 483 with three observations on March 10, 2021. However, the sales from this plant were nil when it received the observations, thus mitigating any financial impact on DRL. The profitability of the company remains vulnerable to foreign exchange fluctuations on account of its foreign operations and foreign currency borrowings, though the company has a defined hedging policy in place. Further, the company's liability with respect to pending resolution of the ongoing industry-wide investigation by the anti-trust division of the US DoJ pertaining to price fixing and price collusion allegations remains a key sensitivity along with other ongoing product related litigations. Large inorganic investments by the company would remain an event risk, and the impact of such investments on the company's business and credit profile would be monitored on a case-by-case basis.

The Stable outlook reflects ICRA expectation that DRL will maintain its current healthy credit profile, aided by strong cash accruals and cash and bank balances coupled with healthy growth across major geographies.

Key rating drivers and their description

Credit strengths

Diversified geographic mix and integrated presence across the value chain – DRL has an established presence in both the emerging and the developed markets for branded formulations and generic businesses, respectively. The key markets for global generics and formulations are the US (35.3% of DRL's Q1 FY2022 revenues), Europe (8.1%), India (35.3%), Russia (7.1%), CIS (2.8%) and Rest of the World (RoW, 8.6%). DRL's global generics segment is backward integrated in APIs to the extent of around 50%. It derived 15.3% of its Q1 FY2022 revenues from the pharmaceutical services and active ingredients (PSAI) segment.

R&D capabilities supporting development of strong product pipeline across key markets – The company has been investing significantly in R&D (9.2% in Q1 FY2022), in line with its strategy to expand its focus on complex and differentiated formulations/injectables, first-to-file products and biosimilar compounds. DRL is one of the few Indian companies to have forayed into new drug discovery and development (NDDD) and new chemical entity (NCE) research, with a focus on therapies like oncology and biosimilars. The company launched 27 products in North America in FY2021, including some limited competition products and is focussed on continuing its momentum. As on June 30, 2021, DRL had 93 ANDAs and three new drug applications (NDAs) filed under the 505(b)(2) route pending approval from the USFDA. Of the 93 pending ANDAs, 47 are Paragraph IV applications, of which 24 are expected to have first-to-file status.

⁶ Abbreviated new drug applications

⁷ United States Food and Drug Administration

Healthy revenue growth across key geographies to sustain, going forward – Among the key global generic and formulations markets, DRL's US business grew by 9.0% YoY in FY2021 and 0.6% in Q1 FY2022, Europe by 31.6% YoY in FY2021 and 12.5% in Q1 FY2022, India by 15.5% YoY (2% YoY excluding the acquired business) in FY2021 and 69.3% in Q1 FY2022, CIS by 14.8% YoY in FY2021 and 3.7% in Q1 FY2022, RoW by 25.5% YoY in FY2021 and 25.2% in Q1 FY2022, while Russia business declined by 6.4% YoY (1% constant currency growth) in FY2021, but witnessed a YoY growth of 7.8% in Q1 FY2022. The robust growth witnessed in FY2021 and Q1 FY2022 is expected to sustain, supported by growth in generic formulations, branded generics and PSAI segment across key geographies.

Despite facing delays in launch of some key products (gNuvaring and gCopaxone), the company continues to focus on launching 25-30 new products annually in the US markets. The targeted launch momentum is backed by a healthy pipeline of molecules, including limited competition products. Additionally, with the commercial roll-out of the Sputnik vaccine, its revenues are expected to grow substantially in FY2022-FY2023. DRL has an exclusive license with RDIF to sell the first 250 million doses of Sputnik V in India. In FY2022, part of the doses will be imported from RDIF and the remaining will be procured from domestic manufacturers (contract manufacturers) who have a supply agreement with RDIF. In FY2023, all doses are expected to be procured from domestic manufacturers.

Healthy financial profile characterised by robust credit metrics and strong liquidity – The company's OPM improved to 23.9% in FY2021 from 20.3% in FY2020 (adjusted for sale of US and select territory rights for neurology franchise products for Rs. 748.6 crore). The improvement was led by a favourable product mix, including new product launches (including Covid-19 products), cost optimisation initiatives and foreign exchange benefit, which was partly offset by price erosion in the US, Europe and certain emerging markets. However, the company's OPM witnessed a decline to 18.6% in Q1 FY2022 (25.3% in Q1 FY2021) owing to price erosion in US and other emerging markets, increase in inventory related provisions in Q1 FY2022, increased investment in digitization and brand promotion and R&D expenses during the quarter. Going forward, ICRA expects the OPM to moderate from FY2021 levels, but remain supported by DRL's product mix and roll-out of the Sputnik vaccine.

The company's leverage and coverage indicators remain healthy as evinced by interest cover of 46.9 times (42.3 times as on March 31, 2020), TD/ OPBDITA of 0.7 times (0.5 times as on March 31, 2020) and total outside liabilities/total net worth of 0.4 times as on March 31, 2021 (0.4 times as on March 31, 2020). The company also remained cash surplus with cash and liquid investments of Rs. 3,434.7 crore, against total debt of Rs. 3,030.8 crore as on March 31, 2021 and cash and liquid investments of Rs. 3,435.6 crore, against total debt of Rs. 3,337.3 crore as on June 30, 2021.

Credit challenges

Ongoing industry-wide investigations, pending resolution of product litigations as well as exposure to regulatory risks – DRL is yet to resolve the ongoing industry-wide investigation by the anti-trust division of the US DOJ on price fixing and price collusion allegations as well as the ongoing product litigations. ICRA notes that on July 06, 2021, DRL received a subpoena from the US SEC for the production of documents pertaining to certain CIS geographies, and the company is in the process of responding to the same. DRL had earlier received an anonymous complaint alleging improper payments made to healthcare professionals in Ukraine and potentially other countries by or on behalf of the company, and DRL had disclosed the same to the SEC, the DoJ and SEBI. This is a key rating monitorable and ICRA will continue to monitor the developments in this regard. The operations of the company also remain exposed to regulatory risks, arising out of the greater scrutiny by regulatory agencies, including the USFDA. DRL's API manufacturing plant at Middleburg, New York, was issued a Form 483 with three observations on March 10, 2021. However, sales from this plant were nil when it received the observations, which mitigates any financial impact on DRL. There are no pending ANDAs or DMF⁸ filings from this facility. ICRA notes that DRL has successfully resolved all its past regulatory non-compliances from the USFDA.

Vulnerability of profitability to foreign exchange fluctuations – DRL's profitability remains vulnerable to foreign exchange fluctuations on account of its foreign operations as well as foreign currency borrowings, though it hedges the same through

⁸ Drug Master File

both derivative and non-derivative financial instruments, such as foreign exchange forward contracts, option contracts and currency swap contracts.

Liquidity position: Strong

The liquidity position of DRL is strong marked by consolidated unencumbered cash and bank balances, and liquid investments of Rs. 3,435.6 crore as on June 30, 2021 and undrawn working capital limits (standalone) of Rs. 1,886.1 crore as on March 31, 2021. The cash flow generation of the company is also expected to remain strong over the medium term, supported by Covid-19 vaccine roll-out and improvement in revenue growth across the major geographies. The annual capex of ~Rs. 1,200-1,500 crore is expected to be financed by internal accruals. DRL has no long-term debt repayments in FY2022.

Rating sensitivities

Positive factors – The rating may be upgraded if there is substantial growth in DRL’s revenues and profitability, leading to sustained improvement in return indicators and further strengthening of its financial risk profile.

Negative factors – The rating may be downgraded if there is a weakening in the company’s revenues and profitability and/or increase in debt levels, leading to an increase in net debt/ OPBDITA to above 1.0x on a sustained basis. Delays in resolution of existing regulatory non-compliances or any other regulatory non-compliance issued to DRL for its products and/or manufacturing facilities, thereby impacting its product launches and, thus, revenues and profitability, would also be a negative trigger. Large debt-funded inorganic investments by the company or any adverse outcome of ongoing litigations/lawsuits/investigations would remain an event risk, and the impact of such events on the company’s business and credit profile and liquidity position would be monitored on a case-by-case basis.

Analytical approach

Analytical Approach	Comments
Applicable Rating Methodologies	Corporate Credit Rating Methodology Rating Methodology for Entities in the Pharmaceutical Industry
Parent/Group Support	Not applicable
Consolidation/Standalone	For arriving at the ratings, ICRA has considered the consolidated financials of DRL. As on June 30, 2021, the company had 51 subsidiaries and step-down subsidiaries, three joint ventures and three other consolidating entities (where the company does not have any equity interests, but has significant influence or control over it) that are enlisted in Annexure-2.

About the company

DRL was incorporated by its promoter and founder chairman, the Late Dr. K. Anji Reddy, as a private limited company on February 24, 1984. The company was subsequently converted to a public limited one on December 6, 1985 and listed on the Bombay Stock Exchange (BSE) and the National Stock Exchange (NSE) in August 1986 as well as on the New York Stock Exchange (NYSE) on April 11, 2001. As on March 31, 2021, the promoters and the promoter Group held 26.74% stake in the company.

DRL offers a portfolio of products and services, including pharmaceutical generics, APIs, custom pharmaceutical services, biosimilars and differentiated formulations. It has three divisions—global generics (accounted for 83.6% of its revenues in Q1 FY2022), PSAI (15.3%) and proprietary products and others (PP and Aurigene Discovery Technologies Limited; 1.1%). The major therapeutic areas of focus for the company include central nervous system, gastro-intestinal, oncology, cardiovascular and pain management with the US, India, West Europe, Russia and the CIS countries being its major markets.

DRL has nine API-manufacturing facilities, of which six are in India, one in Mexico, one in the US and one in the UK, coupled with 11 formulations manufacturing facilities in India, and one each in the UK, the US and China. In addition, the company has a biologics facility in India and nine technology development and R&D centres in India and across the globe.

Key financial indicators (audited)

DRL Consolidated	FY2020	FY2021
Operating Income (Rs. crore)	17,517.0	19,047.5
PAT (Rs. crore)	1,969.9	1,903.6
OPBDIT/OI (%)	23.7%	23.9%
PAT/OI (%)	11.2%	10.0%
Total Outside Liabilities/Tangible Net Worth (times)	0.4	0.4
Total Debt/OPBDIT (times)	0.5	0.7
Interest Coverage (times)	42.3	46.9

PAT: Profit after Tax; OPBDIT: Operating Profit before Depreciation, Interest, Taxes and Amortisation

Status of non-cooperation with previous CRA: Not applicable

Any other information: None

Rating history for past three years

	Instrument	Current Rating (FY2022)				Chronology of Rating History for the past 3 years			
		Type	Amount Rated (Rs. crore)	Amount Outstanding (Rs. crore)	Date & Rating in	Date & Rating in	Date & Rating in	Date & Rating in	
					Jul 29, 2021	Jun 25, 2020	Nov 8, 2019	Dec 14, 2018	
1	Fund-based / Non-fund Based Limits	Long-term	500.0	-	[ICRA]AA+ (Stable)	[ICRA]AA+ (Stable)	[ICRA]AA+ (Stable)	[ICRA]AA+ (Stable)	
2	Fund-based / Non-fund Based Limits	Short-term	-	-	-	-	[ICRA]A1+; withdrawn	[ICRA]A1+	

*As on June 30, 2021

Complexity level of the rated instruments

Instrument	Complexity Indicator
Long-term, Fund-based / Non-fund Based Limits	Simple

The Complexity Indicator refers to the ease with which the returns associated with the rated instrument could be estimated. It does not indicate the risk related to the timely payments on the instrument, which is rather indicated by the instrument's credit rating. It also does not indicate the complexity associated with analyzing an entity's financial, business, industry risks or complexity related to the structural, transactional, or legal aspects. Details on the complexity levels of the instruments, is available on ICRA's website: [Click Here](#)

Annexure-1: Instrument details

ISIN No	Instrument Name	Date of Issuance / Sanction	Coupon Rate	Maturity Date	Amount Rated (Rs. crore)	Current Rating and Outlook
NA	Fund-based / Non-fund Based Limits	NA	NA	NA	500.0	[ICRA]AA+ (Stable)

Source: Company

Annexure-2: List of entities considered for consolidated analysis

Company Name	Ownership	Consolidation Approach
Subsidiaries	100.0%	Full Consolidation
Aurigene Discovery Technologies Limited	100.0%	Full Consolidation
Cheminor Investments Limited	100.0%	Full Consolidation
Dr. Reddy's Bio-Sciences Limited	100.0%	Full Consolidation
Dr. Reddy's Formulations Limited (incorporated effective 11 March 2021)	100.0%	Full Consolidation
Dr. Reddy's Farmaceutica Do Brasil Ltda.	100.0%	Full Consolidation
Dr. Reddy's Laboratories SA	100.0%	Full Consolidation
Idea2Enterprises (India) Private Limited	100.0%	Full Consolidation
Imperial Credit Private Limited	100.0%	Full Consolidation
Industrias Quimicas Falcon de Mexico, S.A.de C.V.	100.0%	Full Consolidation
Svaas Wellness Limited (Formerly known as Regkinetics Services Limited)	100.0%	Full Consolidation
	100.0%	
Step-down Subsidiaries	100.0%	
Aurigene Discovery Technologies (Malaysia) SDN BHD	100.0%	Full Consolidation
Aurigene Discovery Technologies Inc.	100.0%	Full Consolidation
Aurigene Pharmaceutical Services Limited, India (from 16 September 2019)	100.0%	Full Consolidation
Beta Institut gemeinnützige GmbH	100.0%	Full Consolidation
Betapharm Arzneimittel GmbH	100.0%	Full Consolidation
Chirotech Technology Limited	100.0%	Full Consolidation
DRL Impex Limited	100.0%	Full Consolidation
Dr. Reddy's Laboratories (Australia) Pty. Limited	100.0%	Full Consolidation
Dr. Reddy's (Beijing) Pharmaceutical Co. Limited (incorporated effective 19 August 2020)	100.0%	Full Consolidation
Dr. Reddy's Laboratories B.V. (Formerly Eurobridge Consulting B.V.)	100.0%	Full Consolidation
Dr. Reddy's Laboratories Canada, Inc.	100.0%	Full Consolidation
Dr. Reddy's Laboratories Chile SPA.	100.0%	Full Consolidation
Dr. Reddy's Laboratories (EU) Limited	100.0%	Full Consolidation
Dr. Reddy's Laboratories Inc.	100.0%	Full Consolidation
Dr. Reddy's Laboratories Japan KK	100.0%	Full Consolidation
Dr. Reddy's Laboratories Kazakhstan LLP	100.0%	Full Consolidation
Dr. Reddy's Laboratories LLC	100.0%	Full Consolidation
Dr. Reddy's Laboratories Louisiana LLC	100.0%	Full Consolidation
Dr. Reddy's Laboratories Malaysia Sdn. Bhd.	100.0%	Full Consolidation
Dr. Reddy's Laboratories New York, Inc. (transfer of ownership from DRL Swiss to DRL Inc. effective 29 October 2020 and conversion from Inc. to LLC effective 30 October 2020)	100.0%	Full Consolidation
Dr. Reddy's Laboratories Philippines Inc.	100.0%	Full Consolidation
Dr. Reddy's Laboratories (Proprietary) Limited	100.0%	Full Consolidation
Dr. Reddy's Laboratories Romania S.R.L.	100.0%	Full Consolidation
Dr. Reddy's Laboratories SAS	100.0%	Full Consolidation
Dr. Reddy's Laboratories Taiwan Limited	100.0%	Full Consolidation
Dr. Reddy's Laboratories (Thailand) Limited	100.0%	Full Consolidation
Dr. Reddy's Laboratories (UK) Limited	100.0%	Full Consolidation
Dr. Reddy's New Zealand Limited	100.0%	Full Consolidation
Dr. Reddy's Research and Development B.V.	100.0%	Full Consolidation
Dr. Reddy's Srl	100.0%	Full Consolidation
Dr. Reddy's (WUXI) Pharmaceutical Co. Limited	100.0%	Full Consolidation
Dr. Reddy's Venezuela, C.A.	100.0%	Full Consolidation
Lacock Holdings Limited	100.0%	Full Consolidation
OOO Dr. Reddy's Laboratories Limited	100.0%	Full Consolidation
OOO DRS LLC	100.0%	Full Consolidation

Company Name	Ownership	Consolidation Approach
Promius Pharma LLC	100.0%	Full Consolidation
Reddy Holding GmbH	100.0%	Full Consolidation
Reddy Netherlands B.V.	100.0%	Full Consolidation
Reddy Pharma Iberia SA	100.0%	Full Consolidation
Reddy Pharma Italia S.R.L	100.0%	Full Consolidation
Reddy Pharma SAS	100.0%	Full Consolidation
Joint Ventures		
DRES Energy Private Limited	26.0%	Equity Method
Kunshan Rotam Reddy Pharmaceutical Company Limited	51.3%	Equity Method
DRANU LLC	50.0%	Equity Method
Other Consolidating Entities*		
Cheminor Employees Welfare Trust	-	Full Consolidation
Dr. Reddy's Employees ESOS Trust	-	Full Consolidation
Dr. Reddy's Research Foundation	-	Full Consolidation

**The company does not have any equity interests in these entities, but has significant influence or control over it*

Source: DRL Q1 FY2022 result filing

ANALYST CONTACTS

Shamsher Dewan
+91 124 4545328
shamsherd@icraindia.com

Kinjal Shah
+91 022 61143400
kinjal.shah@icraindia.com

Gaurav Jain
+91 020 6606 9922
Gaurav.jain@icraindia.com

Vanshika Gupta
+91 020 6606 9919
Vanhika.gupta@icraindia.com

RELATIONSHIP CONTACT

L. Shivakumar
+91 22 6114 3406
shivakumar@icraindia.com

MEDIA AND PUBLIC RELATIONS CONTACT

Ms. Naznin Prodhani
Tel: +91 124 4545 860
communications@icraindia.com

Helpline for business queries

+91-9354738909 (open Monday to Friday, from 9:30 am to 6 pm)

info@icraindia.com

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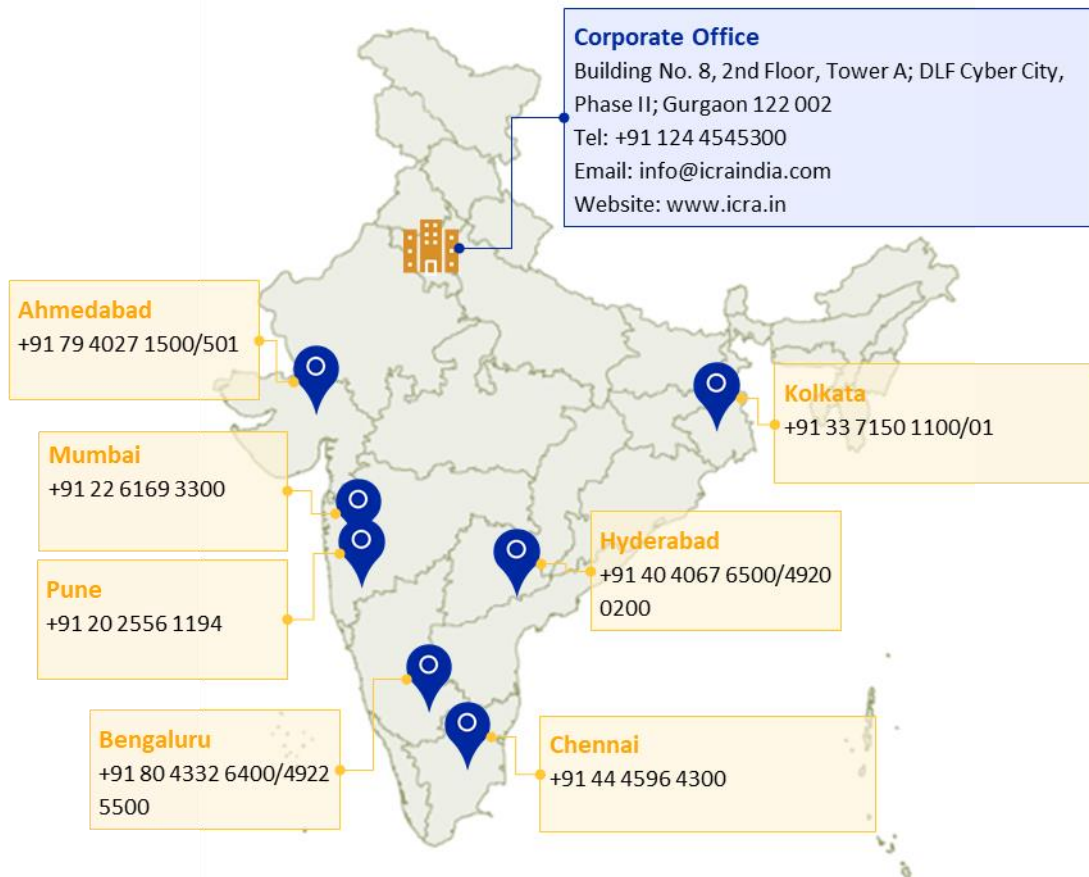
Registered Office

B-710, Statesman House, 148, Barakhamba Road, New Delhi-110001

Tel: +91 11 23357940-45



Branches



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