



B2B FORMULATIONS



**Good
Health
Can't
Wait.**

The image features a solid purple background. In the center is a bright yellow circle. Surrounding this central circle are several concentric, lighter purple circles of varying thicknesses, creating a ripple effect. The text is centered within the yellow circle.

OUR VISION
TO REACH 1.5 BILLION
PEOPLE ACROSS THE
GLOBE

Dr. Reddy's API:

Dr. Reddy's supplies high-quality APIs to leading formulation manufacturers across the world, enabling them to develop affordable medicines for patients worldwide. We are the preferred API partner to pharma companies across the US, Europe, Latin America, Japan, China, Korea and emerging markets.

B2B Formulations:

To enable access to medicines in countries where we are not directly present, we supply the finished products to our partners for them to distribute and commercialize.

We offer market specific products and dossiers which meets the local requirements in securing the marketing authorization followed by commercialization.

The products and dossiers can be customized as per country requirements.



Our Business Model:

Technology Transfer	Pre-formulation Supply	Formulation Supply
Activities at partner end: ● Analytical Method transfer ● Confirmatory Batch ● Exhibit batches ● Stability Studies ● Bio study ● Filing ● Approval	Activities at partner end: ● Analytical Method transfer ● Confirmatory Batch ● Exhibit batches ● Stability Studies ● Bio study ● Filing ● Approval	Activities at partner end: ● Filing ● Approval

In addition to formulation, pre-formulation supplies and technology transfer, we also focus on increasing our presence across:

- A. Clinical Trial Supplies
 - i. Concise product list of oncology assets
 - ii. Regulatory approvals across the globe
 - iii. Single batch sourcing for global studies
 - iv. Optimised delivery timelines
- B. Drug Shortages/Emergency supplies
 - i. Catering to patients affected with drug shortage
 - ii. Forecasting drug shortages
 - iii. Country specific regulatory licenses
 - iv. Shorter delivery lead time

Product Capabilities

1. R&D and Manufacturing Capabilities

Research and Development	Manufacturing Facilities	Niche Product Opportunities	Vertical Integration
4 State-of-the-art R&D centres in India, U.K., U.S., and Netherlands 1200+ research scientists working on various projects	11 formulations manufacturing facilities	Peptides, Prostaglandins, HPAPIs, Innovative drug delivery, Novel dosage forms, Complex Injectables	More than 60% of our formulations are backward integrated with our In-house API

Our 11 formulations manufacturing facilities that are operated in accordance with cGMP (ICH Q7a) and regularly inspected/audited by international regulatory authorities and customers (USFDA, MHRA, EMA, PMDA, TGA, SAHPRA, ANVISA, Russian MoH, CFDA, COFEPRIS and Health Canada).

2. Product Capabilities

Dr. Reddy's has an expertise of developing and manufacturing various dosage forms:

Oral Solids	Injectables	Novel Dosage Forms
Tablets, Chewable tablets, Oro-dispersible tablets, Capsules, soft gel capsules Pellets and Granules (pre-formulation)	Lyophilized product and Liquid solution	Emulsions, Suspensions, Microspheres Liposomes and Nanoparticles

3. Service Capabilities

Highly experienced and integrated technical team to support from filing-to-launch.

Highly experienced technical and global regulatory teams with experience of 350+ Filings and 150+ approvals across B2B markets.

Regulatory services	Tech Transfer support	Bio Study design support
• Team of regulatory experts • Support filing activities • Across multiple countries of interest	• Complete knowledge transfer • Support local manufacturing	• Clinical pharmacokinetic team available • Design bio study protocol



Finished Dosage Forms - Product List**:

THERAPY AREA	PRODUCT NAME	ORAL	INJ	STRENGTH	LEAD MARKET DOSSIER STATUS#
Anti-Diabetic	Linagliptin	●		5 mg	Filed
	Linagliptin + Metformin	●		2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1 g	Filed
	Liraglutide		●	6 mg/ml (3 ml)	Filed
	Sitagliptin HCl	●		25, 50, 100 mg	Filed
	Sitagliptin HCl + Metformin	●		50 + 500, 50 + 850	Filed
	Sitagliptin Phosphate	●		25, 50 and 100 mg	Filed
	Sitagliptin Phosphate + Metformin	●		50 + 500, 50 + 1000 mg	Filed
Anti-Obesity	Liraglutide		●	6 mg/ml (3 ml)	Filed
CNS	Carboprost		●	USP Inj 250 mcg/ml PFS	Filed
	Colchicine	●		0.6 mg	Filed
	Edaravone		●	60 mg/100 ml	Filed
	Glatiramer		●	20 mg and 40 mg	Filed
	Sugammadex		●	100 mg/ml (2 ml and 5 ml)	Filed
	Topiramate ER	●		25, 50, 100 and 200 mg	Filed
	Vigabatrin	●		USP 500 mg	Filed
CVD	Apixaban*	●		2.5 mg and 5 mg	Filed
	Bempedoic acid	●		120 mg and 240 mg	Filed
	Bempedoic acid Ezetimibe	●		180 mg/10 mg	Filed
	Dabigatran*	●		75 mg, 110 mg and 150 mg	Filed
	Edoxaban	●		15 mg, 30 mg and 60 mg	Filed
	Eltrombopag	●		12.5, 25, 50 and 75 mg	Filed

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Lead Market Dossier means Dossier submitted to SRA (Stringent Regulatory Authorities) markets

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CVD	Fondaparinux		●	2.5 mg/0.5 ml, 5 mg/0.4 ml, 7.5 mg/0.6 ml and 10 mg/0.8 ml	Filed
	Rivaroxaban	●		10, 15 and 20 mg	Filed
	Sacubitril/ Valsartan*	●		24/26, 49/51, 97/103 mg	Filed
	Tafamidis Meglumine	●		20 mg	Under Development
	Ticagrelor	●		60 mg and 90 mg	Filed
	Treprostinil		●	1 mg/ml, 2.5 mg/ml, 5 mg/ml and 10 mg/ml (20 ml)	Filed

GI	Esomeprazole	●		20 mg and 40 mg	Filed
	Esomeprazole Mg + Naproxen Na	●		20 mg/375 mg, 20 mg/500 mg	Filed
	Lansoprazole ODT	●		15 mg and 30 mg	Filed

Immunosup- pressant	Sirolimus	●		1 mg and 2 mg	Filed
	Tacrolimus	●		0.5 mg, 1 mg and 5 mg	Filed

Oncology	Abiraterone*	●		250 mg and 500 mg	Filed
	Azacitidine		●	100 mg	Filed
	Bendamustine		●	25 and 100 mg	Filed
	Bendamustine RTD		●	45 mg/ml (4 ml) and 25 mg/ml (4 ml)	Filed
	Bortezomib		●	3.5 mg	Filed
	Busulfan		●	6 mg/ml (10 ml)	Filed
	Cabazitaxel		●	40 mg/ml (1.5 ml)	Filed
	Cabozantinib	●		20 mg, 40 mg and 60 mg	Under Development
	Capecitabine	●		150 mg, 500 mg	Filed
	Carfilzomib		●	60 mg	Filed
	Carmustine		●	100 mg	Filed
	Dasatinib	●		20, 50, 70, 80, 100 and 140 mg	Filed

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Oncology	Decitabine		●	50 mg	Filed
	Dimethyl Fumarate	●		120 mg and 240 mg	Filed
	Enzalutamide	●		40 mg and 80 mg	Under Development
	Eribulin		●	0.5 mg/ml (2 ml)	Filed
	Everolimus	●		2.5, 5, 7.5, 10 mg	Filed
	Fingolimod	●		0.5 mg	Filed
	Fulvestrant		●	50 mg/ml (5 ml)	Filed
	Imatinib Mesylate	●		100 mg, 400 mg	Filed
	Lenalidomide*	●		2.5, 5, 10, 15, 20, 25 mg	Filed
	Lenvatinib	●		4 mg and 10 mg	Filed
	Liposomal Doxorubicin		●	2 mg/ml (10 ml and 25 ml)	Filed
	Midostaurin	●		25 mg	Filed
	Nano Paclitaxel		●	100 mg	Under Development
	Nilotinib	●		50, 150 and 200 mg	Filed
	Nintedanib	●		100 mg and 150 mg	Filed
	Olaparib	●		100 mg and 150 mg	Under Development
	Palbociclib	●		75, 100 and 125 mg	Filed
	Palonosetron		●	0.075 mg/5 ml, 0.25 mg/ 5 ml	Filed
	Pazopanib	●		200 and 400 mg	Filed
	Pemetrexed		●	100, 500 and 1 gm	Filed
	Plerixafor		●	20 mg/ml (1.2 ml)	Filed
	Pomalidomide	●		1 mg, 2 mg, 3 mg and 4 mg	Filed
	Sorafenib	●		200 mg	Filed
	Sunitinib Malate	●		12.5, 25, 37.5 and 50 mg	Filed
	Venetoclax	●		10 mg, 50 mg and 100 mg	Filed

Oncology / Acromegaly	Lanreotide		●	60 mg/0.2 ml, 90 mg/0.3 ml and 120 mg/0.5 ml	Under Development
	Octerotide		●	10 mg, 20 mg and 30 mg	Under Development

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Others	Amphotericin B		●	50 mg	Under Development
	Apremilast	●		10, 20 and 30 mg	Filed
	Daptomycin		●	350 and 500 mg	Filed
	Ferric CarboxyMaltose		●	50 mg/ml	Filed
	Iron Sucrose		●	100 mg/5 ml, 200 mg/10 ml and 50 mg/2.5 ml	Filed
	Isotretinoin	●		10 mg, 20 mg, 30 mg and 40 mg	Filed
	Mesalamine	●		250 and 500 mg	Under Development
	Naproxen Sodium*	●		275 mg and 550 mg	Filed
	Posaconazole	●		100 mg	Filed
	Sevelamer Carbonate	●		800 mg	Filed
	Teriparatide		●	0.25 mg/ml (2.4 ml)	Filed
	Thiamine		●	200 mg/2 ml 25's	Filed
	Tofacitinib XR	●		22 mg	Under development
	Valganciclovir	●		450 mg	Filed

***We also offer preformulations for the selected products.**

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