

Dr.Reddy's 

B2B
FORMULATIONS



**Good
Health
Can't
Wait.**

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: <ul style="list-style-type: none"> Analytical Method transfer Confirmatory Batch Exhibit batches Stability Studies Bio study Filing Approval 	Activities at partner end: <ul style="list-style-type: none"> Analytical Method transfer Confirmatory Batch Exhibit batches Stability Studies Bio study Filing Approval 	Activities at partner end: <ul style="list-style-type: none"> 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
<ul style="list-style-type: none"> Team of regulatory experts Support filing activities Across multiple countries of interest 	<ul style="list-style-type: none"> Complete knowledge transfer Support local manufacturing 	<ul style="list-style-type: none"> Clinical pharmacokinetic team available Design bio study protocol

3. Global Presence



Finished Dosage Forms - Product List:

Dr. Reddy's Laboratories is a leading API supplier, with a presence in over 80 countries and a portfolio of 200+ ANDA filings and approved dossiers. Our offering goes beyond APIs and our global customers have access to high-quality dossiers and finished dosage forms.

THERAPY AREA	PRODUCT NAME	ORAL	INJ	STRENGTH	LEAD MARKET DOSSIER STATUS
Oncology	Azacitidine		●	100 mg	Filed
Oncology	Bendamustine		●	25, 100 mg	Filed
Oncology	Bendamustine RTD		●	45 mg/ml (4 ml) and 25 mg/ml (4 ml)	Filed
Oncology	Bortezomib		●	3.5 mg	Filed
Oncology	Cabazitaxel		●	40 mg/ml (1.5 ml)	Filed
Oncology	Carfilzomib		●	60 mg	Filed
Oncology	Decitabine		●	50 mg	Filed
Oncology	Eribulin		●	0.5 mg/ml (2 ml)	Filed
Oncology	Fingolimod	●		0.5 mg	Filed
Oncology	Fulvestrant		●	50 mg/ml (5 ml)	Filed
Oncology	Liposomal Doxorubicin		●	2 mg/ml (10 ml and 25 ml)	Filed
Oncology	Palonosetron		●	0.075 mg/5 ml, 0.25 mg/ 5 ml	Filed
Oncology	Pemetrexed		●	100, 500, 1 gm	Filed
Oncology	Plerixafor		●	20 mg/ml (1.2 ml)	Filed
Oncology	Abiraterone*	●		250 mg, 500 mg	Filed
Oncology	Busulfan		●	6 mg/ml (10 ml)	Filed
Oncology	Capecitabine	●		150 mg, 500 mg	Filed
Oncology	Dasatinib	●		20, 50, 70, 80,100 and 140 mg	Filed
Oncology	Enzalutamide	●		40 mg, 80 mg	Under Development
Oncology	Everolimus	●		2.5, 5, 7.5, 10 mg	Filed
Oncology	Lenalidomide*	●		2.5, 5, 10, 15, 20, 25 mg	Filed
Oncology	Lenvatinib	●		4, 10 mg	Under Development
Oncology	Nilotinib	●		50, 150, 200 mg	Under Development

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

THERAPY AREA	PRODUCT NAME	ORAL	INJ	STRENGTH	LEAD MARKET DOSSIER STATUS
Oncology	Palbociclib	●		75, 100, 125 mg	Filed
Oncology	Pomalidomide	●		1,2,3,4 mg	Filed
Oncology	Imatinib Mesylate	●		100 mg, 400 mg	Filed
Oncology	Carmustine		●	100 mg	Filed
Oncology	Venetoclax	●		10 mg, 50 mg and 100 mg	Filed
Oncology	Sorafenib	●		200 mg	Filed
Oncology	Midostaurin	●		25 mg	Filed
Oncology	Sunitinib Malate	●		12.5, 25, 37.5 and 50 mg	Filed
Oncology	Nano Paclitaxel		●	100 mg	Under Development
Oncology	Cabozantinib	●		20 mg, 40 mg and 60 mg	Under Development
Oncology	Olaparib	●		100 mg and 150 mg	Under Development
Oncology	Pazopanib	●		200 and 400 mg	Under Development
Oncology	Dimethyl Fumarate	●		120 mg, 240 mg	Under Development
Oncology	Nintedanib	●		100 mg and 150 mg	Under Development
Oncology / Acromegaly	Octerotide		●	10 mg, 20 mg and 30 mg	Under Development
Oncology / Acromegaly	Lanreotide		●	60 mg/0.2 ml, 90 mg/0.3 ml and 120 mg/0.5 ml	Under Development
CNS	Glatiramer		●	20, 40 mg	Filed
CNS	Edaravone		●	60 mg/100 ml	Filed
CNS	Sugammadex		●	100 mg/ml (2 ml and 5 ml)	Filed
CNS	Topiramate ER	●		25, 50, 100 and 200 mg	Filed
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
CVD	Treprostinil		●	1 mg/ml, 2.5 mg/ml, 5 mg/ml and 10 mg/ml (20 ml)	Filed
CVD	Apixaban*	●		2.5, 5 mg	Filed
CVD	Dabigatran*	●		75, 110, 150 mg	Filed
CVD	Rivaroxaban	●		10, 15, 20 mg	Filed

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THERAPY AREA	PRODUCT NAME	ORAL	INJ	STRENGTH	LEAD MARKET DOSSIER STATUS
CVD	Sacubitril/ Valsartan*	●		24/26, 49/51, 97/103 mg	Filed
CVD	Ticagrelor	●		60, 90 mg	Filed
CVD	Tafamidis Meglumine	●		20 mg	Under Development
CVD	Edoxaban	●		15 mg, 30 mg, 60 mg	Under Development
CVD	Bempedoic acid	●		120 mg, 240 mg	Under Development
CVD	Bempedoic acid Ezetimibe	●		180 mg/10 mg	Under Development
Anti-Diabetic	Canagliflozin + Metformin	●		150 mg;1 g, 150 mg;500 mg, 50 mg;1 g, 50 mg;500 mg	Filed
Anti-Diabetic	Linagliptin	●		5 mg	Filed
Anti-Diabetic	Linagliptin + Metformin	●		2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1 g	Filed
Anti-Diabetic	Sitagliptin HCL	●		25, 50, 100 mg	Filed
Anti-Diabetic	Sitagliptin Phosphate	●		25, 50, 100 mg	Filed
Anti-Diabetic	Sitagliptin HCL + Metformin	●		50 + 500, 50 + 850,	Under Development
Anti-Diabetic	Sitagliptin Phosphate + Metformin	●		50 + 500, 50 + 1000 mg	Filed
Anti-Diabetic	Liraglutide		●	6 mg/ml (3 ml)	Under Development
Anti-Diabetic	Semaglutide		●	1.34 mg/ml (1.5 ml and 3 ml)	Filed
Anti-Obesity	Liraglutide		●	6 mg/ml (3 ml)	Under Development
GI	Esomeprazole	●		20, 40 mg	Filed
GI	Esomeprazole MG + Naproxen Na	●		20 mg/375 mg, 20 mg/500 mg	Filed
GI	Lansoprazole ODT	●		15 mg and 30 mg	Filed
Immuno suppressant	Sirolimus	●		1 mg and 2 mg	Filed

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THERAPY AREA	PRODUCT NAME	ORAL	INJ	STRENGTH	LEAD MARKET DOSSIER STATUS
Immuno suppressant	Tacrolimus	●		0.5 mg, 1 mg and 5 mg	Filed
Others	Daptomycin		●	350, 500 mg	Filed
Others	Iron Sucrose		●	100 mg/5 ml,200 mg/10 ml, 50 mg/2.5 ml	Filed
Others	Apremilast	●		10, 20, 30 mg	Filed
Others	Sevelamer Carbonate	●		800 mg	Filed
Others	Valganciclovir	●		450 mg	Filed
Others	Isotretinoin	●		10 mg, 20 mg, 30 mg and 40 mg	Filed
Others	Posaconazole	●		100 mg	Filed
Others	Naproxen Sodium *	●		275 mg, 550 mg	Filed
Others	Teriparatide		●	0.25 mg/ml (2.4 ml)	Filed
Others	Amphotericin B		●	50 mg	Under Development
Others	Mesalamine	●		250 and 500 mg	Under Development
Others	Tofacitinib XR	●		22 mg	Under development

*We also offer preformulations for the selected products.

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Products for Clinical trials

THERAPY AREA	PRODUCT NAME	DOSAGE FORM	US APPROVAL STATUS	EU APPROVAL STATUS
Oncology	Doxorubicin Hydrochloride Liposome Injection, 20 mg/10 ml (2 mg/ml) and 50 mg/25 ml (2 mg/ml) Single-dose Vials	Injection	Approved	Under Review
Oncology	Imatinib Mesylate Tablets 100/400 mg	Tablets	Approved	NA
Oncology	Imatinib Mesylate Capsules 50/100/400 mg	Capsules	NA	Approved
Oncology	Docetaxel Injection Concentrate and 80 mg/4 ml	Injection	Approved	Approved
Oncology	Bendamustine HCl Concentrate for Solution for Infusion 180 mg_4 ml	Infusion	NA	Approved
Oncology	Bendamustine Hydrochloride Injection 25 mg/Vial and 100 mg/Vial	Injection	Tentative Approved	NA
Oncology	Capecitabine Tablets 500 mg	Tablets	Approved	Approved
Oncology	Capecitabine Tablets 150 mg	Tablets	Approved	NA
Oncology	Fulvestrant Injection 250 mg/5 ml (50 mg/ml)	Injection	Approved	Approved
Oncology	Dasatinib 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, 140 mg Film tablet	Tablets	Tentative Approved	Under Review
Oncology	Bortezomib For Injection 3.5 mg/vial	Injection	Approved	Approved
Oncology	Decitabine for Injection 50 mg/Vial	Injection	Approved	NA
Oncology	Azacitidine for Inj 100 mg/vial	Injection	Approved	Approved
Oncology	Lenalidomide Capsules 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg and 25 mg	Capsules	Approved (2.5, 20 mg) Tentative approved (Other SKUs)	NA
Oncology	Pemetrexed, 100 mg, 500 mg, powder for concentrate for solution for infusion (Di Sodium Amorphous)	Infusion	Tentative Approved	Approved
Oncology	Pemetrexed for Injection 100 mg/Vial, 500 mg/Vial, 1g/vial	Injection	Tentative Approved	NA

THERAPY AREA	PRODUCT NAME	DOSAGE FORM	US APPROVAL STATUS	EU APPROVAL STATUS
Oncology	Pomalidomide Capsules 1 mg, 2 mg, 3 mg and 4 mg	Capsules	Tentative Approved	NA
Oncology	Carfilzomib for Injection 60 mg/vial	Injection	Approved	NA
Oncology	Palbociclib Capsules, 75 mg, 100 mg and 125 mg	Capsules	Tentative Approved	NA
Oncology	Abiraterone Acetate Tablets 250 mg	Tablets	Approved	NA
Oncology	Melphalan Hydrochloride for Injection, 50 mg Single-Dose Vial	Injection	Approved	NA
Oncology	Cabazitaxel Injection 60 mg/1.5 ml	Injection	Approved	Approved
Oncology	Sunitinib Malate	Capsules	Approved	NA
Immuno suppressant	Tacrolimus Capsules, 0.5 mg, 1 mg and 5 mg	Capsules	Approved	NA
Immuno suppressant	Sirolimus 1 mg and 2 mg	Tablets	Approved	NA





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