Dr.Reddy's

B2B FORMULATIONS

Good Health Can't Wait.

2024

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

3. Global Presence

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

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

THERAPY AREA	PRODUCT NAME	ORAL	INJ	STRENGTH	LEAD MARKET DOSSIER STATUS#
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

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

THERAPY AREA	PRODUCT NAME	ORAL	INJ	STRENGTH	LEAD MARKET DOSSIER STATUS#
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

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

THERAPY AREA	PRODUCT NAME	ORAL	INJ	STRENGTH	LEAD MARKET DOSSIER STATUS#
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.**

****Disclaimer:**
No information in this catalog - including any reference to any product or service - constitutes an offer for sale, or be construed as representing an offer for sale. Products protected under valid patents are not offered or supplied for commercial use. However, the research quantities of such products may be offered for the purpose of regulatory submissions, wherever such regulatory exemptions exist. The buyers should make their independent evaluation of the patent scenario for their respective markets and will be responsible for all patent related liabilities. Products protected under valid patents in India are not available for commercial use but would be available for Section 107A purposes.

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

Products for Clinical trials**

THERAPY AREA	PRODUCT NAME	DOSAGE FORM	US APPROVAL STATUS	EU APPROVAL STATUS
CVD	Ambrisentan 5 mg & 10 mg	Tablets	NA	Approved
Immunosup-pressant	Fingolimod 0.5 mg	Capsules	Approved	Approved
	Sirolimus 1 mg and 2 mg	Tablets	Approved	NA
	Tacrolimus Capsules, 0.5 mg, 1 mg and 5 mg	Capsules	Approved	NA
Oncology	Abiraterone Acetate Tablets 250 mg	Tablets	Approved	NA
	Azacitidine for Inj 100 mg/vial	Injection	Approved	Approved
	Bendamustine HCl Concentrate for Solution for Infusion 180 mg/ml	Infusion	NA	Approved
	Bendamustine Hydrochloride Injection 25 mg/vial and 100 mg/vial	Injection	Tentative Approved	NA
	Bortezomib For Injection 3.5 mg/vial	Injection	Approved	Approved
	Cabazitaxel Injection 60 mg/1.5 ml	Injection	Approved	Approved
	Capecitabine Tablets 150 mg	Tablets	Approved	NA
	Capecitabine Tablets 500 mg	Tablets	Approved	Approved
	Carfilzomib for Injection 60 mg/vial	Injection	Approved	NA
	Dasatinib 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, 140 mg Film tablet	Tablets	Tentative Approved	Under Review
	Decitabine for Injection 50 mg/vial	Injection	Approved	NA
	Docetaxel Injection Concentrate and 80 mg/4 ml	Injection	Approved	Approved
	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
	Everolimus 2.5 mg, 5 mg & 10 mg	Tablets	NA	Approved
	Fulvestrant Injection 250 mg/5 ml (50 mg/ml)	Injection	Approved	Approved
	Imatinib Mesylate Capsules 50/100/400 mg	Capsules	NA	Approved

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

THERAPY AREA	PRODUCT NAME	DOSAGE FORM	US APPROVAL STATUS	EU APPROVAL STATUS
Oncology	Imatinib Mesylate Tablets 100/400 mg	Tablets	Approved	NA
	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
	Melphalan Hydrochloride for Injection, 50 mg Single-Dose vial	Injection	Approved	NA
	Palbociclib Capsules, 75 mg, 100 mg and 125 mg	Capsules	Tentative Approved	NA
	Pemetrexed for Injection 100 mg/vial, 500 mg/vial, 1g/vial	Injection	Tentative Approved	NA
	Pemetrexed, 100 mg, 500 mg, powder for concentrate for solution for infusion (Disodium Amorphous)	Infusion	Tentative Approved	Approved
	Pomalidomide Capsules 1 mg, 2 mg, 3 mg and 4 mg	Capsules	Tentative Approved	NA
	Sunitinib Malate	Capsules	Approved	NA

****Disclaimer:**
No information in this catalog - including any reference to any product or service - constitutes an offer for sale, or be construed as representing an offer for sale. Products protected under valid patents are not offered or supplied for commercial use. However, the research quantities of such products may be offered for the purpose of regulatory submissions, wherever such regulatory exemptions exist. The buyers should make their independent evaluation of the patent scenario for their respective markets and will be responsible for all patent related liabilities. Products protected under valid patents in India are not available for commercial use but would be available for Section 107A purposes.

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

Dr.Reddy's

api.drreddys.com | api@drreddys.com