



METROCHEM

Product List

FY' 26-27

APIs & Pellets



20+ Years of Excellence

\$150M+ Revenue for FY24-25

3500+ Our Current Workforce

350+ Team of R&D Scientists

300+ Products in high growth
therapeutic categories

3000 KL+ Overall Reactor
Capacities

350+ Reactors ranging from
5L to 15KL

60+ Countries Served



About

Metrochem is a customer-driven company with a focus on chemistry and innovation. At Metrochem, we understand our responsibility to deliver high quality pharmaceutical products which keeps us pushing ourselves to continuously improve and achieve our vision of providing reliable end to end pharmaceutical support in high growth and high impact therapeutic areas. We began our humble journey in the year 2004, with a single unit Active Pharmaceutical Ingredient (API) manufacturing facility with 2 products in our pipeline.

Quickly, we backward integrated to intermediates by starting our Intermediate manufacturing facility in 2005. Over the course of years, we started 2 more intermediate manufacturing facilities to fulfill our upstream needs. Since our inception, we focused on generating value through vertical integration and continuous improvement of our infrastructure and manpower. This foresight about the importance of being vertically integrated allowed us to be always one step ahead of the competition.

It helped us to better control the quality of ingredients that go into the final product, and have better command on the pricing along with an extreme efficiency in terms of deliveries. We have also focused on hiring the right, qualified teams to ensure the critical safety, and oversee the Production, QA, QC and Regulatory activities. Over the years, our ground-level efforts, coupled with our expertise in product development helped Metrochem clear several regulatory audits such as USFDA, PMDA, WHO-GMP and enabled us to become a strong, reliable and trustworthy partner to our clients globally.

At Metrochem, we never rest, we are always up for bigger and better challenges. To extend our impeccable service to the global markets and to meet the increasing demand across our portfolio, we have initiated the construction of a green-field 10 acre Vizag facility in 2012. It was built as a gateway to Metrochem's foray into the regulatory markets. Our plants have an overall reactor volume of 3000KL with a range of 0.005KL to 15KL. The units are manned by over 3500 well-qualified and experienced Pharma professionals. In the financial year 2022-23 alone we have filed 19 USDMFs and are ranked #1 in the world. Our total USDMF filings stand at 81 till date.



Research & Development Focus

At Metrochem, we have a strong zeal for innovation and readiness for investments in Research and Development. This attitude has trickled down from the top, with our founder Dr. N.V. Rao being an expert in organic chemistry. We have extensively worked on and delivered new products across a wide variety of therapeutic segments and as a company we have built strong expertise in new product development.

With R&D efficiency as a core competency, Metrochem expanded its product portfolio from 2 to 350+ within a very short span and this number has been continuously increasing. To date, Metrochem has filed more than 217 patents and 28 patents have been successfully granted.

We have 3 stand-alone R&D centers located in Hyderabad with State-of-the-art analytical facilities and over 350 scientists. Our R&D focused culture allows us and our teams to work with passion and commitment, and therefore research out novel and economical routes efficiently.

We have invested \$5 million in 2019 alone to further upgrade our Analytical R&D. Annually, we invest >5% of our revenue in Research & Development activities. We also have a dedicated Formulation R&D center and a Process R&D lab that focuses on the application of flow chemistry and chemical engineering principles to improve our manufacturing capabilities, and achieve an overall operational excellence.

PRODUCT PORTFOLIO

PRODUCT NAME	THERAPY AREA	REGULATORY FILINGS	
		USDMF	CEP
*Alogliptin benzoate	Antidiabetic	☒	
Antazoline (Hcl, Phosphate)	Antihistamine	☒	☒
*Apixaban	Anticoagulant/Antithrombotic	☒	
*Azilsartan medoxomil potassium	Antihypertensive		
*Bempedoic acid	Antihyperlipidemic	☒	
Bepotastine besilate	Antihistamine		
Bilastine	Antihistamine	☒	
*Cenobamate	Antiepileptic	☒	
Cinitapride	Antiemetic		
Crisaborole	Atopic Dermatitis		
Clopidogrel (hydrogen sulphate, bisulphate)	Antiplatelet	☒	☒
Dabigatran etexilate mesylate	Anticoagulant/Antithrombotic	☒	☒
Dapagliflozin (Propanediol, Amorphous & Citrate)	Antidiabetic	☒	☒
Dexketoprofen trometamol	Analgesic	☒	
Dexlansoprazole (Sesquihydrate, Amorphous & Anhydrous)	Antiulcerative	☒	
Dextrabeprazole sodium	Antiulcerative		
Dimetindene maleate	Antihistamine		☒
*Edoxaban tosylate monohydrate	Anticoagulant/Antithrombotic	☒	
Elagolix	Uterine Fibroids		
Elobixibat	Irritable Bowel Syndrome - Constipation	☒	
*Eltrombopag	Antianemic		
*Empagliflozin	Antidiabetic	☒	
Ertugliflozin	Antidiabetic		
*Esaxerenone	Antihypertensive		

*Products with existing unexpired Patents or Market Exclusivities

☒ Available

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PRODUCT PORTFOLIO

PRODUCT NAME	THERAPY AREA	REGULATORY FILINGS	
		USDMF	CEP
Esomeprazole (Sodium, Mg dihydrate, Mg trihydrate)	Antiulcerative	✓	✓
Etoricoxib	Analgesic	✓	
Febuxostat	Antirheumatic	✓	
Flecainide Acetate	Antiarrhythmic		
Fosravuconazole	Antifungal	✓	
*Gepirone	Antidepressant		
Ilaprazole	Antiulcerative		
Imeglimin hydrochloride	Antidiabetic	✓	
*Isavuconazonium sulfate	Antifungal	✓	
Itraconazole	Antifungal		
Lacosamide	Antiepileptic	✓	✓
Lansoprazole	Antiulcerative	✓	✓
*Lasmiditan	Antimigraine		
Levocetirizine dihydrochloride	Antihistamine	✓	✓
Lotilaner	Demodex Blepharitis		
Loxoprofen sodium	Analgesic	✓	
Lurasidone hydrochloride	Antipsychotic	✓	
Manidipine Hydrochloride	Antihypertensive		
*Mavacamten	Cardiomyopathy	✓	
Migalastat Hydrochloride	Fabry disease	✓	
Mirabegron	Over Active Bladder	✓	
*Mirogabalin	Neuropathic Pains		
Montelukast sodium	Antiasthmatic		
Netupitant	Antiemetic		

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✓ Available

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PRODUCT PORTFOLIO

	PRODUCT NAME	THERAPY AREA	REGULATORY FILINGS	
			USDMF	CEP
	Nicardipine hydrochloride	Antihypertensive		
	Omecamtiv Mecarbil	Chronic Heart Failure		
	Omeprazole (Magnesium, Sodium)	Antiulcerative		
	Oxiconazole nitrate	Antifungal		
	Ozenoxacin	Antibiotic		
	Pantoprazole (Magnesium, Sodium)	Antiulcerative		
	Prucalopride Succinate	Chronic Idiopathic Constipation		
	Rabeprazole sodium	Antiulcerative		
	Ranolazine	Antianginal		
	*Resmetirom	Gastroenterology		
	*Rimegepant Sulfate	Antimigraine		
	Saxagliptin hydrochloride dihydrate	Antidiabetic		
	Silodosin (α,β,γ Forms)	Benign Prostatic Hyperplasia		
	Stiripentol	Antiepileptic		
	*Tapinarof	Antipsoriatic		
	*Tedizolid phosphate	Antibiotic		
	Teneligliptin hydrobromide hydrate	Antidiabetic		
	Tofacitinib citrate	Antirheumatic		
	Topiroxostat	Antirheumatic		
	*Trelagliptin succinate	Antidiabetic		
	*Upadacitinib hemihydrate	Antirheumatic		
	Vigabatrin	Antiepileptic		
	Vildagliptin	Antidiabetic		
	*Vonoprazan fumarate	Antiulcerative		
	Vortioxetine (Hbr, Hcl)	Antidepressant		

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Available

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PIPELINE PRODUCTS

	PRODUCT NAME	THERAPY AREA	US FILING (NCE-1)	EU FILING (DE-2)	
	Abrocitinib	Atopic Dermatitis	Expired	10 Dec, 2029	
	Acoramidis	Transthyretin-mediated amyloidosis	22 Nov, 2028	Not approved	
	Acotiamide Hydrochloride	Dyspepsia	Nil	Nil	
	Apremilast	Antipsoriatic	Expired	Nil	
	Aprocitentan	Antihypertensive	22 Mar, 2028	26 Apr, 2032	
	Atogepant	Antimigraine	Expired	14 Aug, 2031	
	Avatrombopag	Antianemic	Expired	24 Jan, 2027	
	Baloxavir	Antiviral	Expired	8 Jan, 2029	
	Bexagliflozin	Antidiabetic	20 Jan, 2027	Nil	
	Brexpiprazole	Antipsychotic	Expired	30 Jul, 2026	
	Brivaracetam	Antiepileptic	Expired	Expired	
	Canagliflozin	Antidiabetic	Expired	Expired	
	Chiglitazar/ Carfloglitazar	Antidiabetic	Nil	Nil	
	Crinecerfont	Congenital Adrenal Hyperplasia	13 Dec, 2028	Not approved	
	Daprodustat	Anemia in Chronic Kidney Disease	01 Feb, 2027	Nil	
	Delafloxacin	Antibiotic	Expired	19 Dec, 2027	
	Efinaconazole	Antifungal	Nil	Expired	
	Elafibranor	Primary Biliary Cholangitis	10 Jun, 2028	19 Sep, 2032	

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PIPELINE PRODUCTS

	PRODUCT NAME	THERAPY AREA	US FILING (NCE-1)	EU FILING (DE-2)	
	Eluxadoline	Irritable Bowel Syndrome - Diarrhea	Nil	Expired	
	Ensifentrine	Chronic Obstructive Pulmonary Disease (COPD)	26 Jun, 2028	Not approved	
	Etrasimod	Ulcerative Colitis	12 Oct, 2027	19 Feb, 2032	
	Fezolinetant	Vasomotor Symptoms	12 May, 2027	12 Dec, 2031	
	Finerenone	Diabetic Nephropathy	Expired	17 Feb, 2030	
	Flurbiprofen	Analgesic	Expired	Expired	
	Gemigliptin	Antidiabetic	Nil	Nil	
	Ipragliflozin	Antidiabetic	Nil	Nil	
	Iptacopan	Paroxysmal Nocturnal Haemoglobinuria, IgA Nephropathy	5 Dec, 2027	21Mar, 2032	
	Ivacaftor	Cystic Fibrosis	Expired	Expired	
	Lotilaner	Demodex Blepharitis	24 Jul, 2027	Expired	
	Mavacamten	Cardiomyopathy	Expired	27 Jun, 2031	
	Nintedanib	Idiopathic Pulmonary Fibrosis	Expired	Expired	
	Obicetrapib	Hypercholesterolemia	Under NDA	Not approved	
	Pemafibrate	Antihyperlipidemic	Nil	Nil	
	Perfluorohexyloctane	Dry Eyes disease	18 May, 2027	Nil	
	Ponesimod	Multiple Sclerosis	Expired	21 May, 2029	
	Relugolix	Uterine Fibroids	Expired	04 May, 2030	
	Resmetirom	Non Alcoholic Steatohepatitis (NASH)	14 Mar, 2028	Not approved	

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PIPELINE PRODUCTS

	PRODUCT NAME	THERAPY AREA	US FILING (NCE-1)	EU FILING (DE-2)	
	Riociguat	Pulmonary Arterial Hypertension	Expired	Expired	
	Ritlecitinb	Alopecia Areata	23 Jun, 2027	18 Sep, 2031	
	Sarpogrelate	Antiplatelet	Nil	Nil	
	Seladelpar	Primary Biliary Cholangitis	14 Aug, 2028	Not approved	
	Siponimod	Multiple Sclerosis	Expired	15 Jan, 2028	
	Sotagliflozin	Heart Failure	26 May, 2027	30 Apr, 2027	
	Sparsentan	IgA Nephropathy	17 Feb, 2027	23 Apr, 2032	
	Suvorexant	Neuropsychiatry	Expired	Nil	
	Suzetrigine	Analgesic	30 Jan, 2029	12 Apr, 2040	
	Tecarfarin	Anticoagulant/ Antithrombotic	Under NDA	Not approved	
	Tenapanor	Irritable Bowel Syndrome - Constipation	Expired	Nil	
	Ticagrelor	Antiplatelet	Expired	Expired	
	Tosufloxacin	Antibiotic	Nil	Nil	
	Vadadustat	Anemia in Chronic Kidney Disease	27 Mar, 2028	25 Apr, 2031	
	Vericiguat	Heart Failure	Expired	20 Jul, 2029	
	Vibegron	Over Active Bladder	Expired	27 Jun, 2032	
	Xanomeline	Schizophrenia	26 Sep, 2028	Not approved	
	Zastaprazan	Antiulcerative	Under NDA	Not approved	
	Zavegepant	Antimigraine	09 Mar, 2027	Nil	

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BRAZIL - CADIFA's

	PRODUCT NAME	APPROVAL STATUS	PRODUCT NAME	APPROVAL STATUS	
	Clopidogrel Bisulfate	Under Review	Bilastine	Submitted	
	Esomeprazole Sodium	Under Review	Alogliptin Benzoate	Submitted	
	Vonoprazan Fumarate	Approved	Pantoprazole Magnesium	Submitted	
	Dexlansoprazole (DXJ)	Submitted	Etoricoxib	Submitted	
	Omeprazole Sodium	Submitted	Edoxaban Tosylate Monohydrate	Submitted	
	Dapagliflozin Propanediol Monohydrate	Submitted	Vortioxetine Hydrobromide	Submitted	
	Levocetirizine Dihydrochloride	Submitted	Cenobamate	Submitted	
	Esomeprazole Magnesium Trihydrate	Submitted	Posaconazole (Form-I)	Submitted	
	Pantoprazole Sodium Sesquihydrate	Submitted	Silodosin Alpha	Submitted	
	Lurasidone Hydrochloride	Submitted	Prucalopride Succinate	Submitted	
	Empagliflozin (FOR)	Under Review	Ranolazine	Under Review	
	Omeprazole USP	Submitted	Rabeprazole Sodium Form-Y	Submitted	
	Imeglimin Hydrochloride	Submitted	Febuxostat Form-A	Submitted	
	Dexketoprofen Trometamol	Submitted	Empagliflozin (EFG)	Under Review	
	Bempedoic acid	Submitted	Lacosamide Ph.Eur.	Submitted	
	Tofacitinib Citrate (PAR)	Submitted	Lacosamide USP	Submitted	
	Apixaban	Submitted	Rimegepant Sulfate	Submitted	

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KOREA - DMF

PRODUCT NAME	APPROVAL STATUS
Lansoprazole	Approved
Esomeprazole Magnesium Trihydrate	Approved
Esomeprazole Magnesium Dihydrate	Approved
Esomeprazole Sodium	Approved
Rabeprazole Sodium	Approved
Montelukast Sodium	Approved
Dapagliflozin Citric acid	Under Review
Vonoprazan Fumarate	Submitted
Dexketoprofen Trometamol	Submitted
Febuxostat (Form-A)	Submitted
Levocetirizine Dihydrochloride	Submitted
Teneligliptin Hydrobromide Hydrate (MAD)	Submitted
Clopidogrel Bisulfate	Under Review
Empagliflozin (EFG)	Submitted
Dapagliflozin Propanediol Monohydrate	Submitted
Edoxaban Tosylate Monohydrate	Submitted
Silodosin Gamma form	Submitted
Alogliptin Benzoate	Submitted
Empagliflozin (Amorphous)	Submitted
Teneligliptin Hydrochloride Hydrate (TGH)	Under Review

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CHINA - NMPA

PRODUCT NAME	APPROVAL STATUS
Rabeprazole Sodium	Approved
Rabeprazole Sodium	Approved
Lansoprazole	Approved
Omeprazole (EA Route)	Commercialized
Omeprazole Sodium	Commercialized
Esomeprazole Magnesium Trihydrate	Commercialized
Lurasidone Hydrochloride	Commercialized
Silodosin	Under Review
Pantoprazole Sodium Sesquihydrate	Commercialized
Teneligliptin Hydrobromide Hydrate	Commercialized
Prucalopride Succinate	Commercialized
Bilastine	Commercialized
Lansoprazole (LAN) site change	Under Review
Bempedoic Acid (HAN)	Under Review
Febuxostat (Form-A) (FBA)	Under Review
Loxoprofen Sodium Hydrate (LSD)	Under Review
Oxiconazole Nitrate	Under Review
Lacosamide	Under Review
Vigabatrin	Under Review

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JAPAN DMF

PRODUCT NAME	APPROVAL STATUS
Rabeprazole Sodium	Approved
Lansoprazole	Approved
Levocetirizine Dihydrochloride	Commercialized
Clopidogrel BiSulfate	Commercialized
Teneligliptin Hydrobromide Hydrate (MAJ)	Under Review

CANADA FILINGS

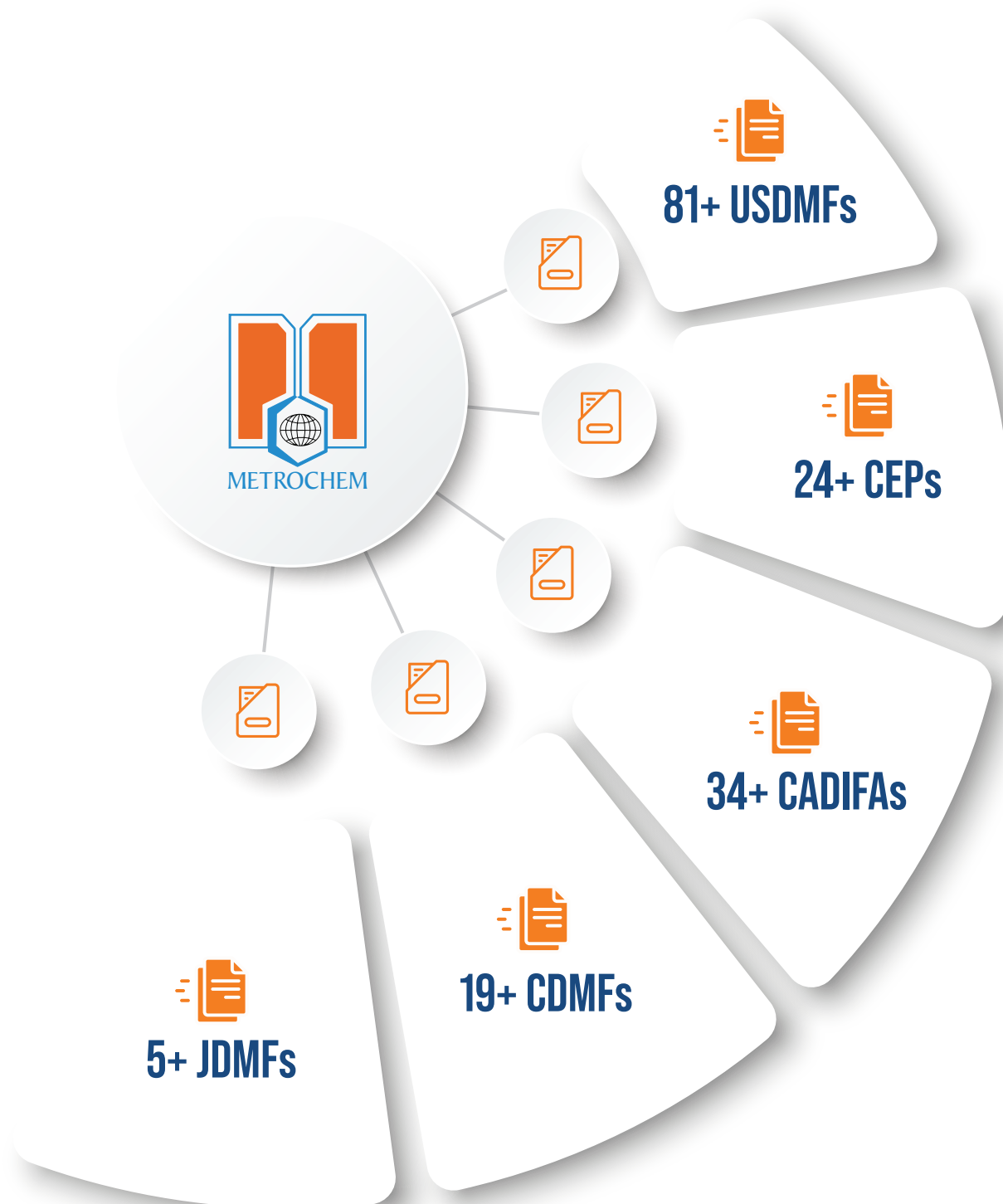
Edoxaban Tosylate Monohydrate	Under Review
Tofacitinib Citrate (PAI)	Under Review
Empagliflozin	Under Review

EUDMF/ASMF FILINGS

Silodosin Beta	Approved
Posaconazole (Form-I)	Approved
Dapagliflozin Propanediol Monohydrate	Commercialized
Empagliflozin	Commercialized
Edoxaban Tosylate Monohydrate	Under Review
Febuxostat (Form-A)	Commercialized
Tofacitinib Citrate	Under Review

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METROCHEM FILINGS



320+ API & Pellet registrations across various countries

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Accreditations



Metrochem API Private Limited

Corporate Office:

Metrochem API Private Limited
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