



METROCHEM

Product List

FY' 22-23



20+

Years of Excellence

\$150M

Revenue for FY 2022

3500+

Our current workforce

300+

Team of R&D Scientists

300+

Products in high growth
therapeutic categories

3000
KL+

With volumes ranging
from 0.5KL to 15KL

350+

Reactors ranging from
5L to 15KL

60+

Countries served
across the globe



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 0.5KL to 15KL. The units are manned by over 3000 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, with this our total USDMF filings stand at 53.



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 300+ within a very short span and this number has been continuously increasing. To date, Metrochem has filed more than 102 patents and 17 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 300 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.

GENERIC API PORTFOLIO

PRODUCT NAME	FILINGS			THERAPEUTIC CATEGORY / INDICATION
	DMF	USDMF	CEP	
Antazoline (Hydrochloride & Phosphate)	✓	✓	✓	Antihistamine
Bepotastine Besilate	✓	I	R	Antihistamine
Bilastine	✓	✓	R	Antihistamine
Cinitapride Hydrogen Tartrate	✓	I	S	Antiemetic
Clopidogrel Bisulphate (Form I & II)	✓	✓	✓	Antiplatelet
Dabigatran Etexilate Mesylate	✓	✓	R	Anticoagulant / Antithrombotic
Dexketoprofen Trometamol	✓	✓	R	Analgesic
Dexlansoprazole (Sesquihydrate & Amorphous)	✓	✓	R	Antiulcerative
Dexrabeprazole Sodium	✓	S	R	Antiulcerative
Dimetindene Maleate	✓	R	✓	Antihistamine
Elobixibat Hydrate	✓	✓	R	Irritable Bowel Syndrome - Constipation
Esomeprazole (Sodium, Magnesium Dihydrate and Trihydrate)	✓	✓	✓	Antiulcerative
Etoricoxib	✓	✓	R	Analgesic
Febuxostat (All Forms)	✓	✓	R	Antirheumatic
Flecainide Acetate	S	S	S	Antiarrhythmic
Fosravuconazole	✓	R	R	Antifungal
Gabapentin	✓	R	R	Antiepileptic
Ilaprazole	✓	I	I	Antiulcerative
Imeglimin Hydrochloride	✓	✓	R	Antidiabetic

✓ Available
I Initiated
S Scheduled
R Ready to file

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GENERIC API PORTFOLIO

PRODUCT NAME	FILINGS			THERAPEUTIC CATEGORY / INDICATION
	DMF	USDMF	CEP	
Itraconazole	✓	I	I	Antifungal
Lacosamide	✓	R	R	Antiepileptic
Lansoprazole	✓	✓	✓	Antiulcerative
Levocarnitine	S	S	S	Carnitine Deficiency in patients with Kidney Disease
Levocetirizine Dihydrochloride	✓	✓	R	Antihistamine
Loxoprofen Sodium	✓	✓	I	Analgesic
Montelukast Sodium	✓	I	I	Antiasthmatic
Nicardipine	✓	R	R	Antihypertensive
Omeprazole (Magnesium & Sodium)	✓	✓	✓	Antiulcerative
Oxiconazole Nitrate	✓	✓	R	Antifungal
Pantoprazole (Magnesium, Sodium, Sesquihydrate)	✓	✓	✓	Antiulcerative
Posaconazole	✓	✓	R	Antifungal
Rabeprazole (Sodium)	✓	✓	✓	Antiulcerative
Ranolazine	✓	✓	R	Antianginal
Silodosin (α & β forms)	✓	✓	S	Benign Prostatic Hyperplasia
Teneligliptin Hydrobromide Hydrate	✓	✓	R	Antidiabetic
Vigabatrin	R	R	S	Antiepileptic
Vildagliptin	✓	R	R	Antidiabetic

✓ Available
I Initiated
S Scheduled
R Ready to file

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ADVANCED API PORTFOLIO

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PRODUCT NAME	FILINGS			THERAPEUTIC CATEGORY / INDICATION
	DMF	USDMF	CEP	
Alogliptin Benzoate	✓	✓	Ⓜ	Antidiabetic
Apixaban	✓	✓	Ⓜ	Anticoagulant / Antithrombotic
Azilsartan Medoxomil Potassium	✓	Ⓜ	Ⓜ	Antihypertensive
Bempedoic acid	✓	✓	Ⓜ	Antihyperlipidemic
Cenobamate	Ⓜ	Ⓜ	Ⓜ	Antiepileptic
Dapagliflozin (Propanediol Monohydrate, Amorphous, Citrate)	✓	✓	Ⓜ	Antidiabetic
Edoxaban Tosylate Monohydrate	✓	✓	Ⓜ	Anticoagulant / Antithrombotic
Empagliflozin	✓	✓	Ⓜ	Antidiabetic
Isavuconazonium Sulfate	✓	✓	Ⓢ	Antifungal
Lasmiditan	Ⓜ	Ⓜ	Ⓜ	Antimigraine
Lurasidone Hydrochloride	✓	✓	Ⓜ	Antipsychotic
Migalastat Hydrochloride	✓	✓	Ⓜ	Fabry Disease
Mirabegron	✓	✓	Ⓢ	Over Active Bladder
Ozenoxacin	✓	✓	Ⓜ	Antibiotic
Prucalopride Succinate	✓	✓	Ⓜ	Chronic Idiopathic Constipation
Saxagliptin Hydrochloride	✓	ⓘ	ⓘ	Antidiabetic
Tedizolid Phosphate	✓	✓	Ⓜ	Antibiotic
Tofacitinib Citrate	✓	✓	Ⓜ	Antirheumatic
Vonoprazan Fumarate	✓	✓	Ⓜ	Antiulcerative

✓ Available ⓘ Initiated Ⓢ Scheduled Ⓜ Ready to file

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DEVELOPMENT API PORTFOLIO

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PRODUCT NAME	STATUS			THERAPEUTIC CATEGORY / INDICATION
	LAB VALIDATION	SCALE UP	PROCESS VALIDATION	
Acotiamide Hydrochloride			✓	Gastroprokinetic
Elagolix Sodium			✓	Pain associated with Endometriosis
Eltrombopag			✓	Thrombocytopenia
Fenticonazole Nitrate			✓	Antifungal
Lercanidipine Hydrochloride			✓	Antihypertensive
L-Glutamine			✓	Antianaemic
Lifitegrast			✓	Dry Eye Disease
Siponimod			✓	Multiple Sclerosis
Stiripentol			✓	Antiepileptic
Tegoprazan			✓	Antiulcerative
Topiroxostat			✓	Antigout
Upadacitinib Tartrate			✓	Antirheumatic
Vortioxetine Hydrobromide			✓	Antidepressant
Brexpiprazole		✓		Antipsychotic
Brivaracetam		✓		Antiepileptic
Crisaborole		✓		Atopic Dermatitis
Efinaconazole		✓		Antifungal
Epalrestat		✓		Diabetic Neuropathy
Ertugliflozin L-PGA		✓		Antidiabetic
Ferric Maltol		✓		Antianaemic
Fingolimod Hydrochloride		✓		Multiple Sclerosis
Ipragliflozin		✓		Antidiabetic
Ivabradine Hydrochloride		✓		Heart Failure
Mavacamten		✓		Hypertrophic Cardiomyopathy

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PRODUCT NAME	STATUS			THERAPEUTIC CATEGORY / INDICATION
	LAB VALIDATION	SCALE UP	PROCESS VALIDATION	
Ponesimod		✓		Multiple Sclerosis
Relugolix		✓		Uterine Fibroids
Rimegepant		✓		Antimigraine
Selexipag		✓		Pulmonary Arterial Hypertension
Tapinarof (or) Benvitimod		✓		Plaque Psoriasis
Trelagliptin Succinate		✓		Antidiabetic
Apremilast	✓			Antipsoriatic
Baloxavir Marboxil	✓			Antiviral
Canagliflozin Hemihydrate	✓			Antidiabetic
Chiglitazar/Carfloglitazar	✓			Antidiabetic
Daprodustat	✓			Anaemia in Chronic Kidney Disease
Edaravone	✓			Amyotrophic Lateral Sclerosis (ALS)
Ezetimibe	✓			Antihyperlipidemic
Faropenem	✓			Antibiotic
Fexuprazan	✓			Antiulcerative
Finerenone	✓			Diabetic Nephropathy
Fosfomycin Trometamol	✓			Antibiotic
Garenoxacin Mesylate	✓			Antibiotic
Ivacaftor	✓			Cystic Fibrosis
Levomilnacipran Hydrochloride	✓			Antidepressant
Linagliptin	✓			Antidiabetic

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PRODUCT NAME	STATUS			THERAPEUTIC CATEGORY / INDICATION
	LAB VALIDATION	SCALE UP	PROCESS VALIDATION	
Molnupiravir (Cytidine)	✓			Antiviral
Niclosamide	✓			Anthelmintic
Nintedanib	✓			Idiopathic Pulmonary Fibrosis
Pemafibrate	✓			Antihyperlipidemic
Perampanel	✓			Antiepileptic
Pirfenidone	✓			Idiopathic Pulmonary Fibrosis
Rifaximin	✓			Irritable Bowel Syndrome
Riociguat	✓			Pulmonary Arterial Hypertension
Rivaroxaban	✓			Anticoagulant / Antithrombotic
Roxadustat	✓			Anaemia in Chronic Kidney Disease
Safinamide	✓			Parkinson's Disease
Suvorexant	✓			Insomnia
Tafenoquine Succinate	✓			Antimalarial
Tecarfarin	✓			Anticoagulant / Antithrombotic
Tenatoprazole Sodium	✓			Antiulcerative
Tolvaptan	✓			Autosomal Dominant Polycystic Kidney Disease
Vadadustat	✓			Anaemia in Chronic Kidney Disease
Vericiguat	✓			Heart Failure
Vibegron	✓			Over Active Bladder
Zavegepant	✓			Antimigraine

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PROSPECTIVE WISHLIST

PRODUCT NAME	THERAPEUTIC CATEGORY / INDICATION
Abrocitinib	Atopic Dermatitis
Atogepant	Antimigraine
Bexagliflozin	Antidiabetic
Flurbiprofen	Antibiotic
Galantamine	Alzheimer's Disease
Linezolid	Antibiotic
Linzagolix	Uterine Fibroids
Mirogabalin	Neuropathic Pains
Netupitant	Antiemetic
Ozanimod	Multiple Sclerosis
Prulifloxacin	Antibiotic
Risdiplam	Spinal Muscular Atrophy
Rosuvastatin	Antihyperlipidemic
Ruxolitinib	Atopic Dermatitis, Myelofibrosis
Sitagliptin	Antidiabetic
Sulconazole Nitrate	Antifungal
Ubrogepant	Antimigraine
Viloxazine	Attention Deficit Hyperactivity Disorder

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NICHE JAPANESE MOLECULES & KEY APIs

PRODUCTS OFFERED	提供される製品
Elobixibat Hydrate	エロビキシバット水和物
Garenoxacin Mesylate Monohydrate	メシル酸ガレノキサシン一水和物
Fosravuconazole	ホスラブコナゾール
Ozenoxacin	オゼノキサシン
Edoxaban Tosylate	エドキサバントシラート
Vonoprazan Fumarate	ボノプラザン フマル酸塩
Clopidogrel Hydrogen Sulfate [Form II]	クロピドグレル硫酸水素塩 [Form II]
Relugolix	レルゴリクス
Vibegron	ビベグロン
Apremilast [Form A & Form B]	アプレミラスト【フォームA&フォームB】
Topiroxostat	トピロキシスタット
Bilastine	ビラスチン
Silodosin	シロドシン
Teneligliptin Hydrobromide Hydrate	テネリグリプチン臭化水素酸塩水和物
Alogliptin Benzoate	ハログリプチン安息香酸塩
Eltrombopag Olamine	エルトロンボパグ オラミン
Ipragliflozin L-Proline	イブラグリフロジン L-プロリン
Dapagliflozin	ダパグリフロジン
Empagliflozin	エンパグリフロジン
Imeglimin Hydrochloride	イメグリミン塩酸塩
Febuxostat [All forms]	フェブクソスタット【全形態】
Tofacitinib Citrate	トファシチニブクエン酸塩
Posaconazole	ポサコナゾール
Lacosamide	ラコサミド
Migalastat	ミガラスタット
Upadacitinib Tartrate	ウパダシチニブ酒石酸塩
Isavuconazonium Sulfate	硫酸イサブコナゾニウム
Bempedoic acid	ベンペド酸
Itraconazole	イトラコナゾール

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USDMF FILINGS

PRODUCT NAME	USDMF NUMBER
Oxiconazole Nitrate	34173
Antazoline Phosphate USP	34330
Clopidogrel Bisulfate USP	34334
Etoricoxib	34537
Silodosin	34538
Dexketoprofen Trometamol	34732
Levocetirizine Dihydrochloride USP	34731
Omeprazole USP	34759
Lurasidone Hydrochloride	34756
Prucalopride Succinate	34790
Vonoprazan Fumarate	35150
Dexlansoprazole	34971
Empagliflozin	35345
Omeprazole Magnesium USP	35390
Rabeprazole Sodium USP	35344
Esomeprazole Magnesium Trihydrate USP	35400
Lansoprazole USP	35485
Ozenoxacin	35487
Esomeprazole Magnesium Dihydrate USP	35519
Apixaban	35518
Posaconazole	35517
Febuxostat USP	35578
Tedizolid Phosphate	35515
Pantoprazole Magnesium	35516
Febuxostat (Form-A) USP	35797
Teneligliptin Hydrobromide Hydrate	35576
Pantoprazole Sodium USP	35577

PRODUCT NAME	USDMF NUMBER
Tofacitinib Citrate	35976
Dapagliflozin Propanediol Monohydrate	36048
Bempedoic Acid	36085
Imeglimin Hydrochloride	36107
Silodosin (βForm)	36132
Loxoprofen Sodium Hydrate	36114
Dapagliflozin (Amorphous)	36608
Zinc Chloride USP	36964
Zinc Sulfate Heptahydrate USP	36963
Mirabegron	36973
Bilastine	36965
Isavuconazonium Sulfate	36974
Cupric Chloride Dihydrate USP	36961
Selenious Acid USP	36958
Manganese Sulfate Monohydrate USP	36960
Cupric Sulfate Pentahydrate USP	36962
Chromic Chloride Hexahydrate USP	36959
Posaconazole (Form - I)	36969
Ranolazine	37339
Elobixibat	37340
Dabigatran Etxilate Mesylate	37633
Rabeprazole Sodium (Form - Y)	37630
Fosravuconazole L-Lysine Ethanolate	37342
Edoxaban Tosylate Monohydrate	37896
Alogliptin Benzoate	37908
Migalastat Hydrochloride	37632

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CEP FILINGS

PRODUCT NAME	CEP NUMBER
Antazoline Hydrochloride EP	CEP 2020-060
Clopidogrel Hydrogen Sulfate EP	CEP 2020-093
Copper Sulfate Pentahydrate	CEP 2022-438
Dimetindene Maleate	CEP 2021-080
Esomeprazole Magnesium Dihydrate EP	CEP 2021-022
Esomeprazole Magnesium Trihydrate EP	CEP 2020-386
Esomeprazole Sodium EP	CEP 2020-214
Lansoprazole	CEP 2021-009
Manganese Sulfate Monohydrate Ph. Eur.	CEP 2022-464
Omeprazole EP	CEP 2020-182
Omeprazole Magnesium EP	CEP 2020-380
Omeprazole Sodium EP	CEP 2020-372
Pantoprazole Sodium Sesquihydrate	CEP2021-168
Rabeprazole Sodium Hydrate (RBL process)	CEP 2022-429
Rabeprazole Sodium Hydrate (Y Form)	CEP 2022-468
Rabeprazole Sodium Hydrate EP	CEP 2020-387
Zinc Chloride	CEP 2022-426
Zinc Sulfate Heptahydrate	CEP 2022-422

NMPA FILINGS

PRODUCT NAME	MONOGRAPH
Rabeprazole Sodium	IHS
Lansoprazole	Ph. Eur
Omeprazole (EA Route)	Ph. Eur
Omeprazole Sodium	Ph. Eur
Esomeprazole Magnesium Trihydrate	Ph. Eur
Lurasidone Hydrochloride	JP
Silodosin	IHS
Pantoprazole Sodium Sesquihydrate	USP

JDMF FILINGS

PRODUCT NAME	JDMF NUMBER
Rabeprazole Sodium	221MF10282
Lansoprazole	223MF10044
Levocetirizine Dihydrochloride	302MF10110
Clopidogrel Hydrogen Sulfate	304MF10071

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MFDS FILINGS

PRODUCT NAME	FACILITY	STATUS
Esomeprazole Magnesium Dihydrate	I	<input checked="" type="checkbox"/>
Esomeprazole Magnesium Trihydrate	I & IV	<input checked="" type="checkbox"/>
Esomeprazole Sodium	I	<input checked="" type="checkbox"/>
Rabeprazole Sodium	I	<input checked="" type="checkbox"/>
Montelukast Sodium	I	<input type="checkbox"/>
Clopidogrel Bisulfate (Form - I)	IV	<input type="checkbox"/>
Febuxostat (Form - B)	IV	<input type="checkbox"/>
Dexlansoprazole	IV	<input type="checkbox"/>
Vonoprazan Fumarate	IV	<input type="checkbox"/>
Levocetirizine Dihydrochloride	IV	<input type="checkbox"/>
S-Pantoprazole Sodium	I	<input type="checkbox"/>
Rabeprazole Chloro Compound	C	<input type="checkbox"/>

Approved Submitted

CADIFA FILINGS

PRODUCT NAME	REFERENCE NUMBER
Clopidogrel Bisulfate (CPB)	25351498617202218
Esomeprazole Sodium (ESS)	25351172172202249
Empagliflozin (PRL)	25351003836202310

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Accreditations



Member of BDMA
(Bulk Drugs Manufacturers Association)



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