



Our product **Portfolio**



API



FDF



Antiseptics

Medichem at a glance



Vertically
integrated

B2B
business



45 API



Operating since
1972 from Barcelona



20 FDF



650+
customers

60+
countries



Leader in
antiseptics



450+
international employees



CDMO
services

Recognized
globally



Making a positive impact on the world

We are a proud B Corp since 2025.

We strive to be transparent and accountable for our impact, and adapt our practices to reflect evolving social and environmental issues—aligning with consumer demands and values.

EcoVadis Sustainability Recognitions

In the last year, we have earned a **Silver Medal** for our API production facilities in Girona, Spain, and a **Bronze Medal** for our FDF manufacturing plant in Hal Far, Malta.

Reach out to the team:

bd@medichem.es
medichem.es

Certified



Corporation

This company meets verified standards for social and environmental business practices.
Learn more at [bcorp.com](https://www.bcorp.com)



Explore our product Portfolio

	API	4	
	Available Portfolio	4-5	
	FDF	6	
	Available Dossiers	6-7	
	Antiseptics	8	
	API	8	
	FDF Biocide Grade	8	
	FDF Pharmaceutical Grade	9	
	Cosmetic Grade	9	

API	Indication	IP advantage	EU-DMF/ CEP	US-DMF	CN- DMF	BR-DMF	JP- DMF
Adapalene	Acne vulgaris		✓	✓(AfR)	✱	✱	✱
✚ Apixaban	Stroke and systemic embolism, Deep Vein Thrombosis and Pulmonary embolism		✓	✓(AfR)	✱	✱	✱
Brimonidine Tartrate	Glaucoma and ocular hypertension, Rosacea erythema		✓(CEP)	✓(AfR)	✱	✱	✱
✚ Captopril	Hypertension, Heart failure			✓(AfR)			
Cinacalcet HCl	Hypercalcemia in hyperparathyroidism and parathyroid carcinoma		✓	✓(AfR)	✱	✱	✱
Clozapine	Schizophrenia		✓(CEP)	✓(AfR)	✱	✱	✓
Cyclobenzaprine HCl	Muscle relaxant			✓(AfR)			
Desvenlafaxine Base	Major depression		✱	✱	✱	✱	✱
Desvenlafaxine Succinate	Major depression		✱	✓(AfR)	✱	✱	✱
Edaravone	Amyotrophic lateral sclerosis (ALS)		✱	✓(AfR)	✱	✱	✱
Felodipine	High blood pressure (hypertension)		✓(CEP)	✓(AfR)	✱	✱	✱
Fluvoxamine	Obsessive compulsive disorder		✓	✓	✱	✱	✱
Guanfacine HCl	Attention deficit hyperactivity disorder (ADHD)		✱	✓(AfR)	✓	✱	✱
✚ Ivacaftor	Cystic fibrosis	✓	✓	✓(AfR)	✱	✱	✱
Lamotrigine	Epilepsy Bipolar disorder			✓			
✚ Lofexidine	Opioid withdrawal		✱	✓(AfR)	✱	✱	✱
Loxapine Base	Schizophrenia		✓	✓	✱	✱	✱
Loxapine Succinate	Schizophrenia		✓	✓(AfR)	✱	✱	✱
Mexiletine HCl	Ventricular arrhythmias		✱	✓(AfR)	✱	✱	✱
Micafungin Sodium	Candidemia, acute disseminated candidiasis and other invasive Candida infections		✓	✓(AfR)	✱	✓(CADIFA)	✱
✚ Mirtazapine	Major depression		✓(CEP)	✓(AfR)			

Available Portfolio

API



API	Indication	IP advantage	EU-DMF/ CEP	US-DMF	CN-DMF	BR- DMF	JP- DMF
Nepafenac Non Sterile	Ocular inflammation and pain associated with cataract surgery		✓	✓ (AfR)	✓	✓	✓
Nepafenac Sterile	Ocular inflammation and pain associated with cataract surgery		✓	✓ (AfR)	✓	✓	✓
Olopatadine HCl	Allergic rhinoconjunctivitis		✓	✓ (AfR)	✓	✓	✓
Opicapone	Parkinson's disease	✓	✓	✓	✓	✓	✓
Paroxetine HCl	Major depression, obsessive-compulsive, social anxiety, panic and posttraumatic stress disorders		✓ (CEP)	✓ (AfR)	✓	✓	✓
Pazopanib	Metastatic renal cell cancer		✓	✓ (AfR)	✓	✓	✓
Pimecrolimus	Atopic dermatitis		✓	✓ (AfR)	✓	✓	✓
✚ Prucalopride Succinate	Chronic constipation		✓	✓ (AfR)	✓	✓	✓
Quetiapine Fumarate	Bipolar disorder and schizophrenia		✓ (CEP)	✓ (AfR)	✓	✓	✓
Rasagiline Tartrate	Parkinson		✓	✓	✓	✓	✓
Relugolix	Advanced prostate cancer		✓	✓	✓	✓	✓
✚ Revefenacin	Chronic obstructive pulmonary disease (COPD)		✓	✓ (AfR)	✓	✓	✓
✚ Rivaroxaban	Stroke and systemic embolism, Deep Vein Thrombosis and Pulmonary embolism		✓ (CEP)	✓ (AfR)	✓	✓	✓
✚ Ruxolitinib Hemifumarate	Myelofibrosis, GvHD; atopic dermatitis, vitiligo	✓	✓	✓	✓	✓	✓
Sitagliptin phosphate	Type 2 diabetes mellitus		✓	✓	✓	✓	✓
✚ Sugammadex Sodium	Reversal of neuromuscular blockade in anesthesia		✓	✓ (AfR)	✓	✓	✓
✚ Sunitinib Malate	Renal carcinoma, pancreatic and stromal tumors		✓	✓ (AfR)	✓	✓	✓
✚ Varenicline L-Tartrate	Smoking cessation		✓	✓ (AfR)	✓	✓	✓
✚ Voclosporin	Lupus nephritis		✓	✓ (AfR)	✓	✓	✓

Molecule	Pharmaceutical form	Strength	Reference product	Indication	Dossier readiness
 Apixaban	Film-coated tablets	2.5 mg, 5 mg	Eliquis®, BMS / Pfizer	Prevention of stroke and systemic embolism Treatment of Deep Vein Thrombosis and Pulmonary embolism and prevention of recurrence	Approved: CIS, EU, SW, TH, UK, US, RUS, IL
 Captopril	Tablets	12.5 mg, 25 mg, 50 mg, 100 mg	Captopril, Mylan	Hypertension Heart failure	Approved: US
Daptomycin	Powder for solution for injection or infusion in glass vial	350 mg, 500 mg	Cubicin®, Merck	Skin and soft-tissue infections Endocarditis	Approved: AU, CA, EU, KR, UA, UK, ZA
 Ivacaftor	Film-coated tablets	75 mg, 150 mg	Kalydeco®, Vertex	Cystic fibrosis	Filed: EU
 Lofexidine	Film-coated tablets	0.18 mg	Lucemyra®, US WorldMeds	Opioid withdrawal	Ready to file: US
 Mirtazapine	Film-coated tablets	7.5 mg*, 15 mg, 30 mg, 45 mg	Remeron®, Organon	Major depression	Approved: EU, US
 Prucalopride Succinate	Film-coated tablets	1 mg, 2 mg	Motegrity®, Shire+O12 Resolor®, Takeda	Chronic constipation	Approved: EU, UK, US Filed: MENA
 Revefenacin	Solution for inhalation	175 mcg/3 mL	Yupelri®, Mylan	Chronic obstructive pulmonary disease (COPD)	Filed: US
 Rivaroxaban	Film-coated tablets	2.5 mg, 10 mg, 15 mg, 20 mg	Xarelto®, Bayer	Stroke and systemic embolism, Deep Vein Thrombosis and Pulmonary embolism	Approved: EU, FWA, IQ Filed: ESA



Molecule	Pharmaceutical form	Strength	Reference product	Indication	Dossier readiness
 Ruxolitinib Hemifumarate	Tablets	5 mg, 10 mg, 15 mg, 20 mg	Jakavi® (EU), Novartis Europharm / Incyte	Myelofibrosis Polycythemia vera Graft-versus-host disease (GvHD)	Approved: EU (NO, NL, MT, DK) Filed: EU (rest of EU in process), TR, CA, RS
 Sugammadex Sodium	Solution for injection	200 mg/2 ml, 500 mg/5 mL	Bridion®, MSD	Reversal of neuromuscular blockade in anesthesia	Approved: EU, HN, IL, MX, NZ, UK, SG, PH Filed: CA, KSA, UAE, VN
 Sunitinib Malate	Capsules	12.5 mg, 25 mg, 3.5 mg, 50 mg	Sutent®, Pfizer	Renal carcinoma Pancreatic and stromal tumors	Approved: EU, KSA, PE Filed: JO, MX
Thalidomide	Capsules	50 mg	Thalidomid Celgene®, Celgene	Multiple myeloma	Approved: EU, UK
Tobramycin	Nebulizer solution in plastic ampoule blow-fill-seal	300 mg/ 5 mL	Tobi®, Viatris	Chronic lung infections due to Pseudomonas aeruginosa in patients with cystic fibrosis	Approved: AU, BR, EU, GTC, KSA, NZ, UK, US
 Varenicline L-tartrate	Tablets	0.5 mg, 1 mg	Chantix®, Champix®, Pfizer	Smoking cessation	Approved: AU, EU, US Filed: US
 Voclosporin	Soft gel capsules	7.9 mg	Lupkynis®, Aurinia Pharmaceuticals / Otsuka Pharmaceutical	Lupus Nephritis	Filed: US

Antiseptics

API			
API - Antiseptics - Available Portfolio			
Chlorhexidine Base		Chlorhexidine Diacetate	CEP
Chlorhexidine Digluconate 20% Solution	CEP	Chlorhexidine Dihydrochloride	CEP
Octenidine Dihydrochloride	DMF		
FDF - Biocide grade			
Chlorhexidine Digluconate - Available Dossiers			
Product	Strength	Formats available	
Hydroalcoholic solution Transparent and coloured	2%	Plastic bottles	60 mL, 75 mL, 100 mL, 125 mL, 250 mL, 500 mL More formats on request
	0.50%		
Aqueous solution	2%	Blow-fill-seal ampoules and plastic bottles	Single dose (10 mL), 60 mL, 75 mL, 100 mL, 125 mL, 250 mL, 500 mL
	0.50%		10 mL, 60 mL, 75 mL
Wipes Aqueous	2%	Individual sachet Flow pack of 8 wipes	20 x 20 cm, 6 x 7 cm
Alcoholic		Individual sachet	
Hand scrub Transparent	4%	HDPE bottles with dosing pump	20 mL, 500 mL, 1000mL

Antiseptics



FDF - Pharmaceutical grade

Octenidine dihydrochloride - Under Development Dossiers

Product	Strength	Formats available		Dossier readiness
Hydroalcoholic solution Transparent	2%	Plastic bottles	30 mL 100 mL, 250 mL More formats on request	Approved: NL
Hydroalcoholic solution Transparent	0.50%	Plastic bottles	30 mL, 100 mL, 250 mL More formats on request	Approved: NL

Chlorhexidine digluconate - Under development dossier

Product	Strength	Formats available		Dossier readiness
Hydroalcoholic solution Coloured	2%	Plastic bottles	30 mL, 100 mL, 250 mL More formats on request	
Hydroalcoholic solution Coloured	0.50%	Plastic bottles	30 mL, 100 mL, 250 mL More formats on request	

Octenidine dihydrochloride - Available dossiers

Product	Formats available			Dossier readiness
Phenoxyethanol + octenidine	2% phenoxyethanol + 0.1% octenidine	Plastic bottles	1.000 mL	Approved: DE

FDF - Cosmetic grade

Octenidine dihydrochloride - Available dossiers

Product	Formats available			Indication	Dossier readiness
Octenidine cream	0,15%	Bottle with biodegradable pump	500 mL	Adjunct therapy for atopic dermatitis	Product file ready for notification



Reach out to the team today

bd@medichem.es



Visit Medichem

www.medichem.es



Connect with Medichem

Medichem

Certified



Corporation

This company meets verified standards for social and environmental business practices.

Learn more at bcorp.com



SCAN ME
to discover
the latest from
Medichem!

Products protected by valid patents or other intellectual property rights are not offered for sale, manufactured, or marketed in jurisdictions where such activities would constitute patent or intellectual property rights infringement. This brochure is informative only and it does not constitute any offer for sale or be construed as representing an offer for sale. The current list only reflects the products and/or technologies that are available, under development or under consideration at Medichem, S.A., Medichem Manufacturing (Malta) Ltd., or Combino Pharm (Malta) Ltd., as applicable. Some products may be developed or produced for internal and/or experimental uses/purposes with no commercial aim. For any query or commercial request, please, refer to your contacts at Medichem, S.A., Medichem Manufacturing (Malta) Ltd., or Combino Pharm (Malta) Ltd., as applicable.