

Product List

2025



Certified



Corporation



medichem

Partner of choice

GENERICS FDFs

3

Available Dossiers	3
Dossiers Under Development	5
Dossiers Under Consideration	7

GENERICS APIs

9

Available Portfolio	9
Under Development	11
Under Consideration	12

Chlorhexidine and other antiseptics

13

APIs	13
FDFs	13
Biocide Grade	13
Pharmaceutical Grade	14
Cosmetic Grade	15



Available Dossiers

Generics FDFs

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
 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+012 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, 20mg	Xarelto®, Bayer	Stroke and systemic embolism Deep vein thrombosis Pulmonary embolism	Approved: EU, FWA, IQ Filed: ESA



Available Dossiers

Generics FDFs

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)	Filed: EU, TR
 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	Chronic lung infections due to Pseudomonas aeruginosa in patients with cystic fibrosis	300 mg/5 mL	Tobi®, Novartis	Cystic fibrosis	Approved: AU, BR, EU, GT, KSA, NZ, UK, US
 Varenicline L-tartrate	Tablets	0.5 mg, 1 mg	Chantix®, Champix®, Pfizer	Smoking cessation	Approved: AU, EU Filed: US
 Voclosporin	Soft gel capsules	7.9 mg	Lupkynis®, Aurinia Pharmaceuticals / Otsuka Pharmaceutical	Lupus Nephritis	Filed: US



Dossiers Under Development

Generics FDFs

Molecule	Pharmaceutical form	Strength	Reference product	Indication	Dossier readiness	Unique selling proposition
Solid Dosage Form:						
Elacestrant	Film-coated tablets	86 mg, 345 mg	Orserdu®, Stemline Therapeutics	Breast cancer	2027	IP advantage, complex
 Ivacaftor	Film-coated tablets	75 mg, 150 mg	Kalydeco®, Vertex	Cystic fibrosis	Q2 2026	IP advantage, complex, spray drying technology
Osimertinib mesylate	Tablets	40 mg and 80 mg	Tagrisso®, AstraZeneca	Non-small cell lung cancer (NSCLC)	Q3 2028	IP advantage
Liquid Dosage Form:						
Amiodarone	Bags	150 mg/100 mL 360 mg/200 mL	Nexterone®, Baxter	Nausea or Vomiting	Q4 2027	
Calcium Gluconate	Intravenous plastic vial	100 mg/mL	Calcium gluconate, Fresenius Kabi	Treatment of acute symptomatic hypocalcemia	Q4 2026	
Esmolol	Ready-to-use plastic bags	10 mg/mL 20 mg/mL	Brevibloc® in plastic container, Baxter	Supraventricular tachycardia or non-compensatory sinus tachycardia, intraoperative and postoperative tachycardia and hypertension	Q1 2027	IP advantage
Iron Ferric Carboxymaltose	Vial	50 mg/mL (2, 10, 15 & 20 mL vial)	Injectafer®, AM Regent, Dalichi and Ferinject®, CSL, Vifor	Iron-deficiency anemia	Q1 2028	Complex



Dossiers Under Development

Generics FDFs

Molecule	Pharmaceutical form	Strength	Reference product	Indication	Dossier readiness	Unique selling proposition
Nicardipine	Ready-to-use plastic bags	20 mg/200 mL (0.86% NaCl), 40 mg/200 mL (0.83% NaCl), 20 mg/200 mL (0.9% NaCl), 40 mg/200 mL (0.9% NaCl)	Cardene IV®, Chiesi Nicardipine HCl, Hikma	Short term treatment of hypertension when oral therapy is not feasible	Q2 2027	
Potassium Phosphate, Dibasic; Potassium Phosphate, Monobasic	Intravenous plastic vial	236 mg/mL; 224 mg/mL	Potassium phosphates, Fresenius Kabi	Phosphorus replacement indicated as a source of phosphorus in intravenous fluids to correct hypophosphatemia and for parenteral nutrition	Q4 2026	
Sodium Phosphate, Dibasic, Heptahydrate; Sodium Phosphate, Monobasic, Anhydrous	Intravenous plastic vial	4.02 gm/15 mL; 4.14 gm/15 mL (268 mg/mL; 276 mg/mL)	Sodium Phosphates in plastic container, Hospira	Source of phosphorus, for addition to large volume intravenous fluids, to prevent or correct hypophosphatemia. Also used as an additive for parenteral fluid	Q4 2026	
Innovation:						
CNS long acting injectable	Subcutaneous or intramuscular injection	TBD	NA	Bipolar disorders	Q2 2028	IP advantage, complex



Dossiers Under Consideration

Generics FDFs

Molecule	Pharmaceutical form	Strength	Reference product	Indication
solid Dosage Form:				
 Deutivacaftor + Tezacaftor + Vanzacaftor	Film-coated tablets	50 mg, 20 mg, EQ 4 mg Base; 125 mg, 50 mg, EQ 10 mg Base	Alyftrek®, Vertex	Cystic fibrosis
 Fezolinetant	Film-coated tablets	45 mg	Veozah®, Astellas Pharma	Moderate to severe vasomotor symptoms associated with menopause
 Ivacaftor + Tezacaftor + Elexacaftor	Film-coated tablets	75/50/100 mg, 37.5/25/50 mg	Trikafta® (US) / Kaftrio® (EU), Vertex	Cystic fibrosis
Liquid Dosage Form:				
Cangrelor	Intravenous powder (vial)	50 mg/mL	Kengreal® (US) / Kengrexal® (EU), Chiesi	Adjunct to percutaneous coronary intervention
Casimersen	Vial	50 mg/mL	Amondys 45®, Sarepta	Duchenne muscular dystrophy
Cupric Sulfate + Manganese Sulfate + Selenious Acid + Zinc Sulfate	Vial	0.3 mg/mL (cupric sulfate) + 55 mcg/mL (manganese sulfate) + 60 mcg/mL (selenious acid) + 3 mg/mL (zinc sulfate)	Tralement®, AM Reagent	Source of zinc, copper, manganese, and selenium
Dalbavancin	Intravenous powder (vial)	500 mg	Dalvance® (US) / Xydalba® (EU), Abbie	Skin infections
Etelcalcetide	Vial	5 mg/mL	Parsabiv®, Amgen	Secondary hyperparathyroidism
Inclisiran	Pre-filled syringe	189 mg/mL	Leqvio®, Novartis	Primary hyperlipidemia
Iron Ferric Derisomaltose	Vial	100 mg/mL (1.5 & 10 mL vial)	Monover®, Monoferri® Pharmacosmos	Iron-deficiency anemia



Dossiers Under Consideration

Generics FDFs

Molecule	Pharmaceutical form	Strength	Reference product	Indication
Liquid Dosage Form:				
Iron Ferric Sucrose	Vial	20 mg/mL (2.5, 5 & 10 mL vial)	Venofer®, AM Regent, Daiichi Ferrologic®, Fresenius	Iron-deficiency anemia
Lanreotide Acetate	Pre-filled syringe	60 mg/0.2 mL, 90 mg/0.3 mL, 120 mg/0.5 mL	Somatuline depot®, Ipsen	Acromegaly & gastrointestinal tumors
Lenacapavir Sodium	Subcutaneous solution (vial)	EQ 463.5 mg Base/1.5 mL (EQ 309 mg Base/mL)	Sunlenca®, Gilead Sciences	VIH
Norepinephrine bitartrate	Bags	4 mg / 250 mL 8 mg / 250 mL 16 mg / 250 mL	Norepinephrine bitartrate 5% in dextrose®, Baxter	Restoration of blood pressure in adult patients with acute hypotensive states
Trilaciclib dihydrochloride	Intravenous powder (vial)	300 mg/mL	Cosela®, G1 Therapeutics / Boehringer Ingelheim	Chemotherapy-induced bone marrow suppression
Triptorelin Pamoate	Intravenous powder (vial) & pre-filled syringe	3.75 mg, 11.25 mg, 22.5 mg	Trelstar®, Verity	Prostate cancer
Topical Dosage Form:				
Ruxolitinib Phosphate	Cream	1.5%	Opzelura®, Incyte	Atopic dermatitis and vitiligo



Available Portfolio

Generics APIs

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 and thrombosis Pulmonary embolism		✓	✓ (AfR)	✓	⚡	⚡
Brimonidine Tartrate	Glaucoma and ocular hypertension Rosacea erythema		✓ (CEP)	✓ (AfR)	⚡	⚡	⚡
⬡ Captopril	Hypertension Heart failure			✓ (AfR)			
Cinacalcet H	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)	⚡	⚡	⚡

⚡ Available for filing

✓ Filed

⬡ Vertically integrated [API / FDF]



Available Portfolio

Generics APIs

API	Indication	IP advantage	EU-DMF/CEP	US-DMF	CN-DMF	BR-DMF	JP-DMF
Mirtazapine	Major depression		✓ (CEP)	✓ (AfR)			
Nepafenac Sterile	Ocular inflammation and pain associated with cataract surgery			✓ (AfR)	✓		
Nepafenac Non Sterile	Ocular inflammation and pain associated with cataract surgery			✓ (AfR)			
Olopatadine HCl	Allergic rhinoconjunctivitis		✓	✓ (AfR)			
Opicapone	Ongentys®, Bial and Neurocrine Biosciences						
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		✓	✓			
Quetiapine Fumarate	Bipolar disorder and schizophrenia		✓ (CEP)	✓ (AfR)	✓	✓	
Rasagiline Tartrate	Parkinson		✓				
Revefenacin	Chronic obstructive pulmonary disease (COPD)			✓ (AfR)			
Rivaroxaban	Stroke and systemic embolism Deep vein thrombosis Pulmonary embolism		✓ (CEP)	✓ (AfR)	✓		
Ruxolitinib Hemifumarate	Jakavi®, Novartis	✓	✓				
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)			

Available for filing Filed Vertically integrated [API / FDF]



Under Development

Generics APIs

Active pharmaceutical ingredient	Reference product	Indication	DMF readiness	Unique selling proposition
 Deutivacaftor	Alyftrek®, Vertex	Cystic fibrosis	Q2 2028	Spray drying technology
 Elexacaftor	Trikafta® (US) / Kaftrio® (EU), Vertex	Cystic fibrosis	Q4 2027	
Encorafenib	Braftovi®, Pzifer	Metastatic melanoma and for adult patients with metastatic colorectal cancer or metastatic non-small cell lung cancer	Q4 2027	Hot Melt extrusión technology
Relugolix	Orgovyx®, Myfembree® (US) / Ryeqo® (EU), Myovant Sciences	Prostate cancer and uterine fibroid bleeding ain associated with endometriosis	Q2 2025	IP Advantage
Ruxolitinib Phosphate	Jakavi®, tablets and oral solution (EU) / Jakafi®, tablets (US), Opzelura® (EU/US)	Myelofibrosis, polycythemia vera Graft-versus-host-disease	Q2 2027	Enzymatic route
Sitagliptin phosphate	Januvia®, Janument®, Janumet XR® Merck & Co	Type 2 diabetes mellitus	Q2 2026	Enzymatic route
 Tezacaftor	Symdeko® (US) / Symkevi® (EU), Vertex	Cystic fibrosis	Q4 2026	Spray drying technology
 Vanzacaftor	Alyftrek®, Vertex	Cystic fibrosis	Q2 2028	IP advantage



Under consideration

Generics APIs

Active pharmaceutical ingredient	Reference product	Indication
Abemaciclib	Verzenio®, Eli Lilly	Breast Cancer
Acoramidis	Attruby®, Bridgebio Pharma	Transthyretin-mediated amyloidosis (ATTR-CM)
Alectinib hydrochloride	Alecensa®, Genentech	Non-small cell lung cancer
Cabotegravir	Apretude®, ViiV Healthcare	HIV-1 prophylaxis
Dabrafenib mesylate	Tafinlar®, Novartis	Melanoma, non-small cell lung cancer and a naplastic thyroid cancer
Darolutamide	Nubeqa®, Bayer	Prostate cancer
Elinzanetant	Lynkuet®, Bayer	Moderate to severe vasomotor symptoms associated with menopause
Fezolinetant	Veozah®, Astellas Pharma	Vasomotor symptoms due to menopause
Oclacitinib maleate	Apoquel®, Zoetis	Pruritus associated with allergic dermatitis and atopic dermatitis in dogs
Paltusotine	No brand name yet, Crinetics	Intended for the treatment of acromegaly and carcinoid syndrome associated with neuroendocrine tumors (NETs)
Vibegron	Gemtesa®, Urovant	Overactive bladder symptoms
Ziftomenib	No brand name yet, Kura Oncology	Acute Myeloid Leukemia (AML)



Chlorhexidine and other antiseptics

APIs

API - Antiseptics - Available

Chlorhexidine Base		Chlorhexidine Diacetate	CEP
Chlorhexidine Digluconate 20% Solution	CEP	Chlorhexidine Dihydrochloride	CEP
Octenidine Dihydrochloride	DMF		

FDFS - 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		Individual sachet	
Aqueous	2%	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



Chlorhexidine and other antiseptics

FDFs - pharmaceutical grade

Chlorhexidine Digluconate - Available Dossiers

Product	Strength	Formats available		Reference product	Dossier readiness
Hydroalcoholic solution Transparent	2%	Plastic bottles	30 mL 100 mL, 250 mL More formats on request		Submitted Q3 2023
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			
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 - A vailable dossiers

Product		Formats available		Indication	Dossier readiness
Hydroalcoholic solution Coloured	2% phenoxyethanol + 0.1% octenidine	Plastic bottles	50 mL, 250 mL, 1.000 mL	Octenisept®	Submitted (Feb 2024)



Chlorhexidine and other antiseptics

FDFs - pharmaceutical grade

Octenidine dihydrochloride - under development dossiers

Product	Strength	Formats available	Reference product	Dossier readiness
Combination of two active ingredients	TBD	Gel	NA	2028

FDFs - cosmetic grade

Octenidine dihydrochloride - available dossiers

Product	Formats available	Reference product	Dossier readiness
Cream	Bottle with pump biodegradable 500 mL	Coadyudant for atopic dermatitis	Product file ready for notification



Visit Medichem

 <https://www.medichem.es/>

Connect with Medichem

 Medichem S.A.

 Medichem

Reach out the team today

 bd@medichem.es

Certified



Corporation



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.