



PRODUCT LIST

2025

GENERICs FDFs

Available Dossiers
Dossiers Under Development
Dossiers Under Consideration

GENERICs APIs

Available Portfolio
Under Development
Under Consideration

CHLORHEXIDINE AND OTHER ANTISEPTICS

APIs

FDFs

Biocide Grade
Pharmaceutical Grade
Cosmetic Grade





AVAILABLE DOSSIERS

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 Filed: RUS
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	Filed: 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 Resolor®, Takeda	Chronic constipation	Approved: EU, UK Filed: MENA, US
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 Pulmonary embolism	Approved: EU, FWA, IQ Filed: ESA
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 Filed: CA, KSA, PH, 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®, 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

MOLECULE	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	INDICATION	DOSSIER READINESS
Solid Dosage Form:					
Ivacaftor	Film coated tablets	75 mg, 150 mg	Kalydeco®, Vertex	Cystic fibrosis	Q1 2026
Liquid Dosage Form:					
Calcium Gluconate	Intravenous plastic vials	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	Q4 2026
Iron Ferric Carboxymaltose	Vial	50 mg/ml (2, 10, 15 & 20 ml vial)	Injectafer®, AM Regent (Daiichi) and Ferinject®, CSL (Vifor)	Iron-deficiency anemia	Q1 2028
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	142 mg/ml; 276 mg/ml	Sodium phosphates, 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	2028



DOSSIERS UNDER CONSIDERATION

MOLECULE	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	INDICATION
Solid Dosage Form:				
Deutivacaftor + Tezacaftor + Vanzacaftor	Film-coated tablets	50 mg, 20 mg, EQ 4 mg BASE; 25 mg, 50 mg, EQ 10 mg BASE	Alyftrek®, Vertex	Cystic fibrosis
Elacestrant	Film-coated tablets	86 mg, 345 mg	Orserdu®, Stemline Therapeutics	Breast cancer
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) and Kaftrio® (EU), Vertex	Cystic fibrosis
Relugolix	Film-coated tablets	120 mg	Orgovyx®, Myfembree® (US) / Ryeqo®, (EU), Myovant Sciences	Prostate cancer and uterine fibroid bleeding. Pain associated with endometriosis
Suvorexant	Film -coated tablets	5 mg, 10 mg, 15 mg, 20 mg	Belsomra®, Merck & Co	Treatment of insomnia
Liquid Dosage Form:				
Cangrelor	Intravenous powder (vial)	50 mg/ml	Kengreal® (US) and 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®, Abbvie	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® / Monoferric®, Pharmacosmos	Iron-deficiency anemia



DOSSIERS UNDER CONSIDERATION

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	Vial	309 mg/ml (1,5 ml), 300 mg	Sunlenca [®] , Gilead Sciences	VIH
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
Ropivacaine	Ready-to-use plastic bags	200 mg/100 ml, 400 mg/200 ml, 500 mg /100 ml, 1 g/200 ml	Naropin [®] , Fresenius Kabi	Production of local or regional anesthesia for surgery and for acute pain management
Trilaciclib	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
Vasopressin	Ready-to-use plastic bags	0.2 IU/ml (100 ml), 0.4 IU/ml (100 ml)	Vasopressin in Sodium Chloride 0.9%, Baxter	Indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines
Topical Dosage Form:				
Ruxolitinib Phosphate	Cream	1.5%	Opzelura [®] , Incyte	Atopic dermatitis and vitiligo
Innovation:				
High-dose oncological	Film-coated tablets	400 mg	NA	Leukemia



AVAILABLE PORTFOLIO

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 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)	⋯	✓ (CAFIDA)	⋯
⬡ Mirtazapine	Major depression		✓ (CEP)	✓ (AfR)			

⋯ Available for filing

✓ Filed

⬡ Vertically integrated [API / FDF]



AVAILABLE PORTFOLIO

API	INDICATION	IP ADVANTAGE	EU-DMF/CEP	US-DMF	CN-DMF	BR-DMF	JP-DMF
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)			
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		✓				
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

ACTIVE PHARMACEUTICAL INGREDIENT	REFERENCE PRODUCT	INDICATION	DMF READINESS	IP ADVANTAGE
 Elacestrant	Orserdu® Stemline Therapeutics	Metastatic breast cancer	Q3 2026	✓
Opicapone	Ongentys® Bial and Neurocrine Biosciences	“Off” episodes in Parkinson	Ready for submission	✓
 Relugolix	Orgovyx®, Myfembree® (US) / Ryeqo® (EU), Myovant Sciences	Prostate cancer and uterine fibroid bleeding Pain associated with endometriosis	Q2 2025	✓
 Ruxolitinib Phosphate	Jakavi®, tablets and oral solution (EU) / Jakafi®, tablets (US) and Opzelura® (EU/US)	Myelofibrosis, polycythemia vera Graft-versus-host-disease	DMF Ready Q2 2027	
Sitagliptin	Januvia® / Janument® / Janumet XR® Merck & Co	Type 2 diabetes mellitus	DMF Ready Q2 2026	
 Tezacaftor	Symdeko® (US), Symkevi® (EU) Vertex	Cystic fibrosis	DMF Ready Q3 2026	



UNDER CONSIDERATION

ACTIVE PHARMACEUTICAL INGREDIENTE	REFERENCE PRODUCT	INDICATION
Alectinib hydrochloride	Alecensa [®] , Genentech	Non-small cell lung cancer
Alogliptin benzoate	Nesina [®] , Takeda	Diabetes mellitus type 2
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
 Deutivacaftor	Alyftrek [®] , Vertex	Cystic fibrosis
Edoxaban tosylate	Savaysa [®] , Daiichi Sankyo	Atrial fibrillation, stroke and thromboembolic disorders
Encorafenib	Braftovi [®] , Pfizer	Melanoma, colorectal cancer and non-small cell lung cancer
 Elexacaftor	Trikafta [®] (US) and Kaftrio [®] (EU), Vertex	Cystic fibrosis
 Fezolinetant	Veozah [®] , Astellas Pharma	Vasomotor symptoms due to menopause
Glatiramer acetate	Copaxone [®] , Teva	Relapsing multiple sclerosis
Lonafarnib	Zokinvy [®] , Sentynl therapeutics	Progeria



UNDER CONSIDERATION

ACTIVE PHARMACEUTICAL INGREDIENTE	REFERENCE PRODUCT	INDICATION
Omadacycline	Nuzyra [®] , Paratek Pharmaceuticals	Pneumonia and skin infections
Osimertinib	Tagrisso [®] , AstraZeneca	Non-small cell lung cancer
Resmetirom	Rezdiffra [®] , Madrigal Pharmaceutical	NASH
Vamorolone	Agamree [®] , Santhera Pharmaceuticals	Duchenne muscular dystrophy
 Vanzacaftor	Alyftrek [®] , Vertex	Cystic fibrosis
Vibegron	Gemtesa [®] , Urovant	Overactive bladder symptoms
Vismodegib	Erivedge [®] , Genentech	Basal cell carcinoma



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 - BIOCIDES 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	20 x 20 cm, 6 x 7 cm
		Flow pack of 8 wipes	
Alcoholic		Individual sachet	
Hand scrub Transparent	4%	HDPE bottles with dosing pump	20 ml, 500 ml, 1000 ml



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 - AVAILABLE DOSSIERS

PRODUCT		FORMATS AVAILABLE		INDICATION	DOSSIER READINESS
Spray	2% phenoxyethanol + 0.1% octenidine	Plastic bottles	50 ml, 250 ml and 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	INDICATION	DOSSIER READINESS
Cream	Bottle with pump biodegradable 500 ml	Coadyudant for atopic dermatitis	Product file ready for notification



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