

Product List

2026



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FDFs

3

Available Dossiers	3
Dossiers Under Development	5
Dossiers Under Consideration	8

APIs

11








Available Portfolio	11
Under Development	13
Under Consideration	14

Antiseptics






16

APIs	16
FDFs	16
Biocide Grade	16
Pharmaceutical Grade	17
Cosmetic Grade	18




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

Available Dossiers

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 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	Unique selling proposition
Solid Dosage Form:						
 Abemaciclib	Film-coated tablets	50, 100, 150 & 200 mg (US) 50, 100 & 150 mg (EU)	Verzenio® (US) / Verzenios® (EU), Eli Lilly	Breast cancer	Q4 2028	Fully EU and US development
Belzutifan	Tablets	40 mg	Welireg®, MSD	Renal cell carcinoma and other malignancies	Q2 2032	EU supplier using ASD (Amorphous solid dispersion); Potential for VI (API+FDf); Alternative formulation targeting LoE2035
 Darolutamide	Tablets	300 mg	Nubeqa®, Bayer	Prostate cancer	Q4 2030	IP advantage
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 (EU) Q3 2026 (US)	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	Serious ventricular arrhythmias	Q4 2027	
Calcium Gluconate	Intravenous plastic vial	100 mg/mL	Calcium gluconate, Fresenius Kabi	Treatment of acute symptomatic hypocalcemia	Q4 2026	












Dossiers Under Development

Molecule	Pharmaceutical form	Strength	Reference product	Indication	Dossier readiness	Unique selling proposition
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
Inclisiran	Pre-filled syringe	189 mg/mL	Leqvio®, Novartis	Primary hyperlipidemia	Q3 2028	Complex
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	
Topical Dosage Form:						
Ruxolitinib Phosphate	Cream	1.5%	Opzelura®, Incyte	Atopic dermatitis and vitiligo	Q3 2028	Complex
Innovation:						
CNS long acting injectable	Subcutaneous or intramuscular injection	TBD	NA	Bipolar disorders	Q2 2028	IP advantage, complex




Dossiers Under Development

Molecule	Pharmaceutical form	Strength	Reference product	Indication	Dossier readiness	Unique selling proposition
Gynecological product	Bags	30IU/500ml	NA	Women's health	Q4 2028	IP advantage, complex



Dossiers Under Consideration

Molecule	Pharmaceutical form	Strength	Reference product	Indication
Solid Dosage Form:				
 Axitinib	Kidney cancer	1 mg, 5 mg	Inlyta®, PF Prism CV	Advanced renal cell carcinoma (RCC), primarily in second-line treatment.
 Camizestrant	TBD	TBD	No brand name registered yet, AstraZeneca	Breast cancer
 Capivasertib	Breast cancer	160 mg, 200 mg	Truqap®, AstraZeneca	Breast Cancer: Hormone receptor positive breast cancer
 Enlicitide	Tablets	20 mg	No brand name registered yet, MSD	Dyslipidemias
 Gepirone Hydrochloride	Extended Release Tablets	18,2 mg, 36,3 mg, 54,5 mg, 72,6 mg	Exxua®, Fabre Kramer	Major depressive disorder
 Giredestrant	Tablets	30 mg	No brand name registered yet, Roche	Breast cancer
 Ivacaftor + Tezacaftor + Elexacaftor	Film-coated tablets	75/50/100 mg, 37.5/25/50 mg	Trikafta® (US) / Kaftrio® (EU), Vertex	Cystic fibrosis
 Letermovir	Tablets	240 and 489 mg	Prevymis®, MSD	Viral infections
 Obefazimod	TBD	TBD	No brand name registered yet, Abivax	Inflammatory bowel disease
 Orforglipron	TBD	TBD	No brand name registered yet, Eli Lilly	Chronic weight management and Type II diabetes
 Palazestrant	Tablets	90 mg, 120 mg	No brand name registered yet, Olema Oncology	Breast cancer

Dossiers Under Consideration

Molecule	Pharmaceutical form	Strength	Reference product	Indication
 Sofosbuvir	Tablets	200 mg, 400 mg	Sovaldi®, Gilead	Hepatitis C
 Suvorexant	Tablets	5 mg, 10 mg, 15 mg, 20 mg	Belsomra®, MSD	Sleep Disorders: Insomnia
 Tedizolid Phosphate	Tablets	200 mg	Sivextro®, Cubist Pharms LLC	Acute bacterial skin and skin structure infections (ABSSSI)

Dossiers Under Consideration

Molecule	Pharmaceutical form	Strength	Reference product	Indication
Liquid Dosage Form:				
Angiotensin II Acetate	Vial	0,5 mL (0,5 mg/ mL), 1 mL (2,5 mg/ mL), 5 mL (2,5 mg/ mL)	Giapreza®, La Jolla Pharmaceutical	Distributive, hypovolemic, or septic shock
Cangrelor	Intravenous powder (vial)	50 mg/mL	Kengreal®, Chieasi	Fast-acting intravenous antiplatelet therapy with immediate onset and offset
Iron Ferric Derisomaltose	Vial	100 mg/mL (1, 5 & 10 mL vial)	Monoferric®, Pharmacosmos	Iron-deficiency anemia
Landiolol	Lyophilized vial	280 mg/vial	Rapiblyk®, AOP Health US	Supraventricular tachycardia
 Letermovir	Injection	241 and 489 mg	Prevymis® , MSD	Viral infections
Methylnaltrexone bromide	Subcutaneous PFS injection	12 mg/ 0.6 mL	Relistor® , Bausch	
 Added-value product	PFS	EQ 500 mg Base/5 mL (100 mg Base/mL) EQ 200 mg Base/2 mL (100 mg Base/mL)	NA	Medical Procedures (not otherwise classified): Reversal of neuromuscular blockade

APIs

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)	⚡	✓ (CADIFA)	⚡
⬡ Mirtazapine	Major depression		✓ (CEP)	✓ (AfR)			

Available Portfolio













APIs

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		Available for filing	✓ (AfR)	✓	Available for filing	Available for filing
Nepafenac Non Sterile	Ocular inflammation and pain associated with cataract surgery		Available for filing	✓ (AfR)	Available for filing	Available for filing	Available for filing
Olopatadine HCl	Allergic rhinoconjunctivitis		✓	✓ (AfR)	Available for filing	Available for filing	Available for filing
Opicapone	Ongentys®, Bial and Neurocrine Biosciences	✓	Available for filing	Available for filing	Available for filing	Available for filing	Available for filing
Paroxetine HCl	Major depression, obsessive-compulsive, social anxiety, panic and posttraumatic stress disorders		✓ (CEP)	✓ (AfR)	✓	Available for filing	Available for filing
Pazopanib	Metastatic renal cell cancer		Available for filing	✓ (AfR)	Available for filing	Available for filing	Available for filing
Pimecrolimus	Atopic dermatitis		Available for filing	✓ (AfR)	Available for filing	Available for filing	Available for filing
Prucalopride Succinate	Chronic constipation		✓	✓ (AfR)	Available for filing	Available for filing	Available for filing
Quetiapine Fumarate	Bipolar disorder and schizophrenia		✓ (CEP)	✓ (AfR)	✓	✓	Available for filing
Rasagiline Tartrate	Parkinson		✓	Available for filing	Available for filing	Available for filing	Available for filing
Relugolix	Advanced prostate cancer		Available for filing	Available for filing	Available for filing	Available for filing	Available for filing
Revefenacin	Chronic obstructive pulmonary disease (COPD)		Available for filing	✓ (AfR)	Available for filing	Available for filing	Available for filing
Rivaroxaban	Stroke and systemic embolism Deep vein thrombosis Pulmonary embolism		✓ (CEP)	✓ (AfR)	✓	Available for filing	Available for filing
Ruxolitinib Hemifumarate	Jakavi®, Novartis	✓	✓	Available for filing	Available for filing	Available for filing	Available for filing
Sugammadex Sodium	Reversal of neuromuscular blockade in anesthesia		✓	✓ (AfR)	✓	Available for filing	✓
Sunitinib Malate	Renal carcinoma Pancreatic and stromal tumors		✓	✓ (AfR)	✓	Available for filing	Available for filing
Varenicline L-Tartrate	Smoking cessation		✓	✓ (AfR)	✓	Available for filing	Available for filing
Voclosporin	Lupus nephritis		Available for filing	✓ (AfR)	Available for filing	Available for filing	Available for filing




Under Development

Active pharmaceutical ingredient	Reference product	Indication	DMF readiness	Unique selling proposition
 Abemaciclib	Verzenio® (US) / Verzenios® (EU), Eli Lilly	Breast cancer	Q2 2027	
 Darolutamide	Nubeqa®, Bayer	Prostate cancer	Q2 2028	IP advantage
 Elexacaftor	Trikafta® (US) / Kaftrio® (EU), Vertex	Cystic fibrosis	Q4 2027	
Ruxolitinib Phosphate	Jakavi®, tablets and oral solution (EU) / Jakafi®, tablets (US), Opzelura® (EU/US)	Myelofibrosis, polycythemia vera and Graft-versus-host-disease	Q4 2027	Enzymatic route
Sitagliptin phosphate	Januvia® / Janument® / Janumet XR® Merck & Co	Type 2 diabetes mellitus	Q3 2026	Enzymatic route
 Tezacaftor	Symdeko® (US) / Symkevi® (EU), Vertex	Cystic fibrosis	Q4 2026	Spray drying technology

Under Consideration

Active pharmaceutical ingredient	Reference product	Indication
 Axitinib	Inlyta®, Pfizer	Kidney cancer
 Belzutifan	Welireg®, Merck	Renal cell carcinoma and other malignancies
 Camizestrant	No Brand name yet, AstraZeneca	Breast cancer
 Capivasertib	Truqap®, Astra Zeneca	Breast cancer
 Enlicitide	No Brand name yet, Merck	Dyslipidemias
 Gedatolisib	No Brand name yet, Celcuity/Pfizer	Breast cancer
 Gepirone Hydrochloride	Exxua®, Fabre Kramer	Major depressive disorder
 Giredestrant	No Brand name yet, Genentech/Roche	Breast cancer
 Landiolol	Rapiblyk®, AOP Orphan	Supraventricular Tachycardia
 Letermovir	Prevymis®, MSD	Viral infections
 Obefazimod	No Brand name yet, Abivax	Inflammatory bowel diseases
 Orforglipron	No Brand name yet, Eli Lilly	Chronic weight management and Type II diabetes

Under Consideration

Active pharmaceutical ingredient	Reference product	Indication
 Palazestrant	No Brand name yet, Olema Oncology	Breast cancer
 Sofosbuvir	Sovaldi®, Gilead	Hepatitis C
 Suvorexant	Belsomra®, MSD	Sleep Disorders: Insomnia
 Tedizolid Phosphate	Sivextro®, Cubist Pharms LLC	Acute bacterial skin and skin structure infections (ABSSSI)

Antiseptics

APIs

API - Antiseptics - Available

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

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 Aqueous	2%	Individual sachet Flow pack of 8 wipes	20 x 20 cm, 6 x 7 cm
		Alcoholic	
Hand scrub Transparent	4%	HDPE bottles with dosing pump	20 mL, 500 mL, 1000mL

Antiseptics

FDFs - pharmaceutical grade

Octenidine dihydrochloride - Under Development 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	1.000 mL	Octenisept®	Submitted (Feb 2024)

Antiseptics

FDFs - cosmetic grade

Octenidine dihydrochloride - available dossiers

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



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