



- CORTICOIDS & HORMONES
- SMALL & COMPLEX MOLECULES SYNTHESIS
- OPIATES AND CONTROLLED SUBSTANCES
- PROSTAGLANDINS
- VITAMIN B12 AND ANTI-INFECTIVES

Product list 2024-2025

Product name	Platform	Therapeutic ATC class 4th level	Page
Alimemazine Tartrate ⁽²⁾	Small Molecules Synthesis	R06A0 : SYSTEMIC ANTIHISTAMINES	P.8
Alprostadil (Prostaglandin E1)	Prostaglandins	C01X0 : ALL OTHER CARDIAC PREPARATIONS - C04A1 : CEREBRAL AND PERIPHERAL VASOTHERAPEUTICS EXCLUDING CALCIUM ANTAGONISTS WITH CEREBRAL ACTIVITY - D03A9 : ALL OTHER WOUND HEALING AGENTS	P.13
Alprostadil Alfadex (PGE1alfa-CD)	Prostaglandins	C01X0 : ALL OTHER CARDIAC PREPARATIONS - C04A1 : CEREBRAL AND PERIPHERAL VASOTHERAPEUTICS EXCLUDING CALCIUM ANTAGONISTS WITH CEREBRAL ACTIVITY - D03A9 : ALL OTHER WOUND HEALING AGENTS	P.13
Altrenogest	Corticoids & Hormones	ATCvet: QG03DX90	P.6
Amiodarone Hydrochloride ⁽¹⁾	Small Molecules Synthesis	C01B0 : ANTI-ARRHYTHMICS	P.8
Amisulpride ⁽¹⁾	Small Molecules Synthesis	N05A1 : ATYPICAL ANTIPSYCHOTICS	P.8
Apomorphine Hydrochloride (micronized)	Opiates & Controlled Substances	N04A0 : ANTI-PARKINSON DRUGS	P.12
Apomorphine Hydrochloride (sieved)	Opiates & Controlled Substances	N04A0 : ANTI-PARKINSON DRUGS	P.12
Beraprost Sodium	Prostaglandins	B01C4 : PLATELET CAMP ENHANCING PLATELET AGGREGATION INHIBITORS - C06B3 : PROSTACYCLIN AGONIST PAH PRODUCTS	P.13
Bimatoprost	Prostaglandins	S1E2: MIOTICS+ANTIGLAUCOMA TOP	P.13
Canrenoate Potassium	Corticoids & Hormones	C03A1 : POTASSIUM-SPARING AGENTS PLAIN	P.6
Canrenone (micronized)	Corticoids & Hormones	C03A1 : POTASSIUM-SPARING AGENTS PLAIN	P.6
Carboprost Tromethamine	Prostaglandins	G02A0 : LABOUR INDUCERS	P.13
Clobazam	Small Molecules Synthesis	N03A0 : ANTI-EPILEPTICS	P.8
Clobazam (micronized)	Small Molecules Synthesis	N03A0 : ANTI-EPILEPTICS	P.8
Clopidogrel Hydrogen Sulfate ⁽¹⁾	Small Molecules Synthesis	B01AC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	P.8
Cloprostenol Sodium	Prostaglandins	G2A0: UTEROTONIC PRODUCTS	P.13
Codeine Camphosulfonate (sieved)	Opiates & Controlled Substances	R05D2 : ANTITUSSIVES IN COMBINATIONS	P.12
Codeine Monohydrate (milled)	Opiates & Controlled Substances	N02B: NON-NARCOTIC ANALGESICS / R5D ANTITUSSIVES	P.12
Codeine Phosphate Hemihydrate (milled and sieved)	Opiates & Controlled Substances	N2B: NON-NARCOTIC ANALGESICS / N2A NARCOTIC ANALGESICS	P.12
Cortisone Acetate (micronized)	Corticoids & Hormones	H02A2 : ORAL CORTICOSTEROIDS, PLAIN	P.6
Cyamemazine	Small Molecules Synthesis	N5A: ANTIPSYCHOTICS	P.8
Cyamemazine Tartrate	Small Molecules Synthesis	N5A: ANTIPSYCHOTICS	P.8
Cyanocobalamin - Vitamin B12 (fine granulometry)	Vitamin B12	A11F0: VITAMIN B12 PLAIN	P.14
Cyanocobalamin - Vitamin B12 (high quality grade)	Vitamin B12	A11F0: VITAMIN B12 PLAIN	P.14
Cyanocobalamin - Vitamin B12 (standard quality)	Vitamin B12	A11F0: VITAMIN B12 PLAIN	P.14
Desoximetasone (micronized)	Corticoids & Hormones	D07A0 : PLAIN TOPICAL CORTICOSTEROIDS	P.6
Dexamethasone (micronized)	Corticoids & Hormones	H02A2 : ORAL CORTICOSTEROIDS, PLAIN	P.6

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Product name	Platform	Therapeutic ATC class 4th level	Page
Dexamethasone Acetate (micronized)	Corticoids & Hormones	H02A1 : INJECTABLE CORTICOSTEROIDS, PLAIN	P.6
Dexamethasone Sodium Metasulfobenzoate	Corticoids & Hormones	S02C0 : OTIC CORTICOSTEROID/ANTI-INFECTIVE COMBINATIONS	P.6
Dexamethasone Sodium Phosphate	Corticoids & Hormones	H02A1 : INJECTABLE CORTICOSTEROIDS, PLAIN	P.6
Dinoprost (Prostaglandin F2 alpha)	Prostaglandins	G02A0 : LABOUR INDUCERS	P.13
Dinoprost Tromethamine	Prostaglandins	G2A0: UTEROTONIC PRODUCTS	P.13
Dinoprostone (Prostaglandin E2)	Prostaglandins	G02A0 : LABOUR INDUCERS	P.13
Drotaverine Hydrochloride	Small Molecules Synthesis	A03AD02: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS – PAPAVERINE DERIVATIVES	P.8
Eflornithine Hydrochloride ⁽²⁾	Small Molecules Synthesis	D11A: OTHER DERMATOLOGICAL PRD	P.8
Epoprostenol Sodium	Prostaglandins	C06B3 : PROSTACYCLIN AGONIST PAH PRODUCTS	P.13
Ethylmorphine Hydrochloride (sieved)	Opiates & Controlled Substances	R05D2 : ANTITUSSIVES IN COMBINATIONS	P.12
Fexofenadine Hydrochloride	Small Molecules Synthesis	R06A0 : SYSTEMIC ANTIHISTAMINES	P.8
Fluorometholone (micronized and non micronized)	Corticoids & Hormones	S01B0 : OPHTHALMOLOGICAL CORTICOSTEROIDS	P.6
Fluticasone propionate (micronized and non micronized)	Corticoids & Hormones	R3F: B2-AGONIST AND CORTICOID COMBINATIONS	P.6
Furosemide ⁽⁵⁾	Small Molecules Synthesis	C03A2 : LOOP DIURETICS PLAIN	P.9
Glimepiride	Small Molecules Synthesis	A10H0 : SULPHONYLUREA ANTIDIABETICS	P.9
Human Recombinant Insulin ⁽³⁾	Small Molecules Synthesis	A10C1 : HUMAN INSULINS AND ANALOGUES, FAST-ACTING	P.9
Hydrocortisone (micronized)	Corticoids & Hormones	D07A0 : PLAIN TOPICAL CORTICOSTEROIDS	P.6
Hydrocortisone Acetate (micronized)	Corticoids & Hormones	C05A1 : TOPICAL ANTI-HAEMORRHOIDALS WITH CORTICOSTEROIDS	P.6
Hydrocortisone Hydrogen Succinate	Corticoids & Hormones	H02A1 : INJECTABLE CORTICOSTEROIDS, PLAIN	P.7
Hydrocortisone Sodium Phosphate	Corticoids & Hormones	H02A1 : INJECTABLE CORTICOSTEROIDS, PLAIN	P.7
Hydroxocobalamin Acetate	Vitamin B12	A11E1 : PLAIN VITAMIN B COMPLEX	P.14
Hydroxocobalamin Base	Vitamin B12	A11F0 : PLAIN VITAMIN B12	P.14
Hydroxocobalamin Chloride	Vitamin B12	N06E0 : NEUROTONICS AND OTHER MISCELLANEOUS PRODUCTS	P.14
Hydroxychloroquine Sulfate	Small Molecules Synthesis	M01C0 : SPECIFIC ANTI-RHEUMATIC AGENTS	P.9
Iloprost (CH)	Prostaglandins	B01C4 : PLATELET CAMP ENHANCING PLATELET AGGREGATION INHIBITORS - C06B3 : PROSTACYCLIN AGONIST PAH PRODUCTS, Iloprost is used in PAH treatment (prostacyclin family C0683)	P.13
Irbesartan	Small Molecules Synthesis	C9: RENIN ANGIOTENSIN SYS	P.9
Ketoprofen ⁽⁶⁾	Small Molecules Synthesis	M01A1 : ANTI-RHEUMATICS, NON-STEROIDAL PLAIN	P.9
Latanoprost	Prostaglandins	S1E2: MIOTICS+ANTIGLAUCOMA TOP	P.13
Levomepromazine Hydrochloride	Small Molecules Synthesis	N05A9 : CONVENTIONAL ANTIPSYCHOTICS	P.9
Levomepromazine Maleate	Small Molecules Synthesis	N05A9 : CONVENTIONAL ANTIPSYCHOTICS	P.9

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⁽⁵⁾ Production site transfer planned for 2025

Product name	Platform	Therapeutic ATC class 4th level	Page
Levomethadone Hydrochloride	Opiates & controlled substances	N07F: DRUGS USED IN OPIOID DEPENDENCE / N2A NARCOTIC ANALGESICS	P.12
Limaprost Alfadex	Prostaglandins	B01C4 : PLATELET CAMP ENHANCING PLATELET AGGREGATION INHIBITORS	P.13
Loprazolam Mesylate (Loprazolam Methanesulfonate)	Small Molecules Synthesis	N05B1 : NON-BARBITURATES, PLAIN	P.9
Meglumine Antimoniate ⁽¹⁾	Small Molecules Synthesis	P1G: OTHER ANTI-PARASITICS	P.9
Metamizole Magnesium (granules) ⁽⁵⁾	Small Molecules Synthesis	N02B0 : NON-NARCOTICS AND ANTI-PYRETICS	P.9
Metamizole Magnesium (powder) ⁽⁵⁾	Small Molecules Synthesis	N02B0 : NON-NARCOTICS AND ANTI-PYRETICS	P.10
Metamizole Sodium (superfine) ⁽⁵⁾	Small Molecules Synthesis	N02B0 : NON-NARCOTICS AND ANTI-PYRETICS	P.10
Metamizole Sodium (technical) ⁽⁵⁾	Small Molecules Synthesis	N02B0 : NON-NARCOTICS AND ANTI-PYRETICS	P.10
Methylprednisolone (micronized)	Corticoids & Hormones	H02A1 : INJECTABLE CORTICOSTEROIDS, PLAIN	P.7
Methylprednisolone Acetate micronized)	Corticoids & Hormones	H02A1 : INJECTABLE CORTICOSTEROIDS, PLAIN	P.7
Methylprednisolone Hydrogen Succinate	Corticoids & Hormones	H02A1 : INJECTABLE CORTICOSTEROIDS, PLAIN	P.7
Morphine Hydrochloride (sieved)	Opiates & Controlled Substances	N02A0 : NARCOTICS	P.12
Morphine Sulfate (micronized)	Opiates & Controlled Substances	N02A0 : NARCOTICS	P.12
Nadolol	Small Molecules Synthesis	C7A: B-BLOCKING AGENTS, PLAIN	P.10
Nalbuphine Hydrochloride (sieved)	Opiates & Controlled Substances	N02A0 : NARCOTICS	P.12
Naloxone Hydrochloride (micronized)	Opiates & Controlled Substances	N02B: NON-NARCOTIC ANALGESICS / N02A: NARCOTIC ANALGESICS V03A: ANTIDOTES	P.12
Naloxone Hydrochloride (milled)	Opiates & Controlled Substances	N02B: NON-NARCOTIC ANALGESICS / N02A: NARCOTIC ANALGESICS V03A: ANTIDOTES	P.12
Naloxone Hydrochloride (sieved)	Opiates & Controlled Substances	N02B: NON-NARCOTIC ANALGESICS / N02A: NARCOTIC ANALGESICS - V03A: ANTIDOTES	P.12
Naltrexone Hydrochloride (sieved)	Opiates & Controlled Substances	N07F0 : DRUGS USED IN OPIOID DEPENDENCE	P.12
Norepinephrine (noradrenaline) Bitartrate	Small Molecules Synthesis	C01C1 : CARDIAC STIMULANTS EXCLUDING DOPAMINERGIC AGENTS	P.10
Norepinephrine (noradrenaline) Hydrochloride	Small Molecules Synthesis	C01C1 : CARDIAC STIMULANTS EXCLUDING DOPAMINERGIC AGENTS	P.10
Noscapine (milled)	Opiates & Controlled Substances	R05D2 : ANTITUSSIVES IN COMBINATIONS	P.12
Oxycodone Hydrochloride (milled)	Opiates & Controlled Substances	N02A0 : NARCOTICS	P.12
Oxycodone Hydrochloride (sieved)	Opiates & Controlled Substances	N02A0 : NARCOTICS	P.12
Piretanide	Small Molecules Synthesis	C03A2 : LOOP DIURETICS PLAIN	P.10
Prednicarbate	Small Molecules Synthesis	D07A0 : PLAIN TOPICAL CORTICOSTEROIDS	P.10
Prednisolone (micronized)	Corticoids & Hormones	H02A2 : ORAL CORTICOSTEROIDS, PLAIN	P.7
Prednisolone Acetate (micronized)	Corticoids & Hormones	S01B0 : OPHTHALMOLOGICAL CORTICOSTEROIDS	P.7
Prednisolone Hydrogen Succinate	Corticoids & Hormones	H02A1 : INJECTABLE CORTICOSTEROIDS, PLAIN	P.7

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Product name	Platform	Therapeutic ATC class 4th level	Page
Prednisolone Sodium Metasulfobenzoate	Corticoids & Hormones	H02A2 : ORAL CORTICOSTEROIDS, PLAIN	P.7
Prednisone (micronized)	Corticoids & Hormones	H02A2 : ORAL CORTICOSTEROIDS, PLAIN	P.7
Prenoxdiazine Hydrochloride	Small Molecules Synthesis	R5D: ANTITUSSIVES	P.10
Ramipril	Small Molecules Synthesis	C09A0 : ACE INHIBITORS, PLAIN	P.10
Rifampicin (Rifampin) (injectable grade available upon request)	Anti-infectives	J04A1 : ANTITUBERCULARS, SINGLE INGREDIENT	P.14
Rifampicin (Rifampin) (standard grade)	Anti-infectives	J04A1 : ANTITUBERCULARS, SINGLE INGREDIENT	P.14
Rifamycin SV Sodium (standard grade)	Anti-infectives	J01M0 : RIFAMPICIN/RIFAMYCIN	P.14
Rifamycin SV Sodium (suitable for injection use)	Anti-infectives	J01M0 : RIFAMPICIN/RIFAMYCIN	P.14
Rifapentine	Anti-infectives	J4A: ANTITUBERCULAR PRODUCTS	P.14
Rifaximin ⁽⁴⁾	Anti-infectives		P.14
Riluzole	Small Molecules Synthesis	N07X0 : ALL OTHER CNS DRUGS	P.10
Roxithromycin	Anti-infectives	J01F0 : MACROLIDES AND SIMILAR TYPES	P.14
Selegiline Hydrochloride	Small Molecules Synthesis	N04A0 : ANTI-PARKINSON DRUGS	P.11
Sevelamer Carbonate	Small Molecules Synthesis	V03AE: MEDICINES FOR HYPERKALIEMIA AND HYPERPHOSPHOREMIA	P.11
Sevelamer Hydrochloride	Small Molecules Synthesis	V03AE: MEDICINES FOR HYPERKALIEMIA AND HYPERPHOSPHOREMIA	P.11
Sodium Cromoglicate (milled) ⁽¹⁾	Small Molecules Synthesis	A07E9 : INFLAMMATORY BOWEL DISORDER PRODUCTS, OTHER	P.11
Sodium Valproate ⁽¹⁾	Small Molecules Synthesis	N03A0 : ANTI-EPILEPTICS	P.11
Spirolactone (micronized)	Corticoids & Hormones	C03A1 : POTASSIUM-SPARING AGENTS PLAIN	P.7
Tafluprost	Prostaglandins	S1E: MIOTICS+ANTIGLAUC.PREPS.	P.13
Teicoplanin	Anti-infectives	J01X1 : GLYCOPEPTIDE ANTIBACTERIALS	P.14
Tiaprofenic acid (micronized)	Small Molecules Synthesis	M01A1 : ANTI-RHEUMATICS, NON-STEROIDAL PLAIN	P.11
Travoprost	Prostaglandins	S1E2 : MIOTICS+ANTIGLAUCOMA TOP	P.13
Trenbolone Acetate	Corticoids & Hormones	ATCvet: QA14	P.7
Treprostinil Sodium	Prostaglandins	C06B3 : PROSTACYCLIN AGONIST PAH PRODUCTS	P.13
Triamcinolone Acetonide (micronized)	Corticoids & Hormones	H02A1 : INJECTABLE CORTICOSTEROIDS, PLAIN	P.7
Valproic acid ⁽¹⁾	Small Molecules Synthesis	N03A0 : ANTI-EPILEPTICS	P.11
Zolpidem Tartrate ⁽¹⁾	Small Molecules Synthesis	N05B1 : NON-BARBITURATES, PLAIN	P.11
Zopiclone ⁽¹⁾	Small Molecules Synthesis	N05B1 : NON-BARBITURATES, PLAIN	P.11

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Corticoids & Hormones

PRODUCT NAME	SUPPORTIVE REGULATORY DOCUMENTATION						
	US DMF	JAPAN DMF	CEP	ASMF	China	India	CADIFA (Brazil)
Altrenogest	•			•			
Canrenoate Potassium				•			
Canrenone (micronized)				•			
Cortisone Acetate (micronized)		•		•			
Desoximetasone (micronized)	•						
Dexamethasone (micronized)	•	•	•				
Dexamethasone Acetate (micronized)	•		•			•	
Dexamethasone Sodium Metasulfobenzoate				•		•	
Dexamethasone Sodium Phosphate	•	•	•				
Fluorometholone (micronized and non micronized)	•	•		•		•	
Fluticasone propionate (micronized and non micronized)		•	•				
Hydrocortisone (micronized)	•	•	•				
Hydrocortisone Acetate (micronized)		•	•			•	

PRODUCT NAME	SUPPORTIVE REGULATORY DOCUMENTATION						
	US DMF	JAPAN DMF	CEP	ASMF	China	India	CADIFA (Brazil)
Hydrocortisone Hydrogen Succinate			●	●			
Hydrocortisone Sodium Phosphate		●					
Methylprednisolone (micronized)	●		●				
Methylprednisolone Acetate (micronized)	●						
Methylprednisolone Hydrogen Succinate	●	●	●				
Prednisolone (micronized)	●	●	●				
Prednisolone Acetate (micronized)	●	●	●				
Prednisolone Hydrogen Succinate		●		●			
Prednisolone Sodium Metasulfobenzoate				●			
Prednisone (micronized)	●		●				
Spirolactone (micronized)	●	●	●			●	
Trenbolone Acetate	●						
Triamcinolone Acetonide (micronized)	●			●			

Small & Complex Molecules Synthesis

PRODUCT NAME	SUPPORTIVE REGULATORY DOCUMENTATION						
	US DMF	JAPAN DMF	CEP	ASMF	China	India	CADIFA (Brazil)
Alimemazine Tartrate ⁽²⁾			Pending	Pending			
Amiodarone Hydrochloride ⁽¹⁾			•		•		
Amisulpride ⁽¹⁾			•				
Clobazam	•	•	•				
Clobazam (micronized)			•			•	
Clopidogrel Hydrogen Sulfate ⁽¹⁾				•			
Cyamemazine				•			
Cyamemazine Tartrate				•			
Drotaverine Hydrochloride					•		
Eflornithine Hydrochloride ⁽²⁾	•			•			
Fexofenadine Hydrochloride		•	•			•	

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PLATFORM Small & Complex Molecules Synthesis

PRODUCT NAME	SUPPORTIVE REGULATORY DOCUMENTATION						
	US DMF	JAPAN DMF	CEP	ASMF	China	India	CADIFA (Brazil)
Furosemide ⁽⁵⁾	●	●	●			●	
Glimepiride	●		●		●	●	
Human Recombinant Insulin ⁽³⁾							
Hydroxychloroquine Sulfate	●			●			
Irbesartan	●		●		●		
Ketoprofen ⁽⁵⁾	●	●	●				
Levomepromazine Hydrochloride		●		●			
Levomepromazine Maleate			●				
Loprazolam Mesylate (Loprazolam Methanesulfonate)							
Meglumine Antimoniate ⁽¹⁾							
Metamizole Magnesium (granules) ⁽⁵⁾				●			

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⁽⁵⁾ Production site transfer planned for 2025

Small & Complex Molecules Synthesis

PRODUCT NAME	SUPPORTIVE REGULATORY DOCUMENTATION						
	US DMF	JAPAN DMF	CEP	ASMF	China	India	CADIFA (Brazil)
Metamizole Magnesium (powder) ⁽⁵⁾				•			
Metamizole Sodium (superfine) ⁽⁵⁾			•			•	
Metamizole Sodium (technical) ⁽⁵⁾			•				
Nadolol			•				
Norepinephrine (noradrenaline) Bitartrate			•				
Norepinephrine (noradrenaline) Hydrochloride			•				
Piretanide			•				
Prednicarbate			•				
Prenoxdiazine Hydrochloride							
Ramipril			•			•	
Riluzole							

⁽⁵⁾ Production site transfer planned for 2025

PRODUCT NAME	SUPPORTIVE REGULATORY DOCUMENTATION						
	US DMF	JAPAN DMF	CEP	ASMF	China	India	CADIFA (Brazil)
Selegiline Hydrochloride	●	●	●		●		
Sevelamer Carbonate							
Sevelamer Hydrochloride	●	●					
Sodium Cromoglicate (milled) ⁽¹⁾	●		●				
Sodium Valproate ⁽¹⁾			●				
Tiaprofenic acid (micronized)			●				
Valproic acid ⁽¹⁾			●				
Zolpidem Tartrate ⁽¹⁾			●				
Zopiclone ⁽¹⁾			●				

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Opiates and Controlled Substances

PRODUCT NAME	SUPPORTIVE REGULATORY DOCUMENTATION						
	US DMF	JAPAN DMF	CEP	ASMF	China	India	CADIFA (Brazil)
Apomorphine Hydrochloride (micronized)	•			•			
Apomorphine Hydrochloride (sieved)	•		•				
Codeine Camphosulfonate (sieved)							
Codeine Monohydrate (milled)			•				
Codeine Phosphate Hemihydrate (milled and sieved)			•			•	
Ethylmorphine Hydrochloride (sieved)			•				
Levomethadone Hydrochloride			•				
Morphine Hydrochloride (sieved)			•				
Morphine Sulfate (micronized)			•				
Nalbuphine Hydrochloride (sieved)	•			•	•		
Naloxone Hydrochloride (micronized)	•						
Naloxone Hydrochloride (milled)	•		•				
Naloxone Hydrochloride (sieved)	•	•	•		•		
Naltrexone Hydrochloride (sieved)	•		•		•		
Noscapine (milled)							
Oxycodone Hydrochloride (milled)			•		•		
Oxycodone Hydrochloride (sieved)			•		•		

Prostaglandins

PRODUCT NAME	SUPPORTIVE REGULATORY DOCUMENTATION						
	US DMF	JAPAN DMF	CEP	ASMF	China	India	CADIFA (Brazil)
Alprostadiil (Prostaglandin E1)	●	●	●		●		
Alprostadiil Alfadex (PGE1alfa-CD)		●		●			
Beraprost Sodium		●			● (exclusivity)		
Bimatoprost	● (standard grade and CH grade)	●		●	●		
Carboprost Tromethamine	●				● (exclusivity)	●	
Cloprostenol Sodium							
Dinoprost (Prostaglandin F2 alpha)		●		●			
Dinoprost Tromethamine	● (standard grade and CH grade)		● CH grade only	● Standard grade only	● Standard grade only		
Dinoprostone (Prostaglandin E2)	●	●		●		●	
Epoprostenol Sodium	●			●			
Iloprost (CH)	●			●	● (excipient)		
Latanoprost	● (CH1 grade only)	● (TST grade only)	● CH grade only	● (exclusivity)		●	● (TST grade and CH grade)
Limaprost Alfadex		● (standard grade and CH grade)			● (exclusivity)		
Tafuprost							
Travoprost	●	●		●			
Treprostinil Sodium	●						

Anti-Infectives and Vitamin B12

PRODUCT NAME	SUPPORTIVE REGULATORY DOCUMENTATION						
	US DMF	JAPAN DMF	CEP	ASMF	China	India	CADIFA (Brazil)
Rifampicin (Rifampin) (injectable grade available upon request)	•			•			
Rifampicin (Rifampin) (standard grade)	•	•		•			
Rifamycin SV Sodium (standard grade)			•				
Rifamycin SV Sodium (suitable for injection use)			•				
Rifapentine							
Rifaximin ⁽⁴⁾	•	•		•			
Roxithromycin				•			
Teicoplanin		•		•			
Cyanocobalamin - Vitamin B12 (fine granulometry)			•				
Cyanocobalamin - Vitamin B12 (high quality grade)		•					
Cyanocobalamin - Vitamin B12 (standard quality)	•	•	•			•	
Hydroxocobalamin Acetate	•	•	•				
Hydroxocobalamin Base	•	•		•			
Hydroxocobalamin Chloride			•				

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Products under development

Platform	Product Name	ATC 4 CLASS	Development stage
Anti-infectives	Daptomycin	J1X9: ALL OTHER ANTIBACTERIALS	Early development
Anti-infectives	Fidaxomicin	A7A: INTESTINAL ANTI-INFECTIVES	Early development
Anti-infectives	Tulathromycin	VETERINARY USE ONLY - QJ01FA MACROLIDES	Early development
Corticoids & Hormones	Fluticasone Furoate	R3F1: B2-AGONIST AND CORTICOID COMBINATIONS, INHALANT R1A: TOPICAL NASAL PREPARATIONS	Early development
Corticoids & Hormones	Estradiol	QG03CA03: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM NATURAL AND SEMI SYNTHETIC ESTROGENS, PLAIN	Samples available
Oligonucleotides & Peptides	Inclisiran	C10A9: ALL OTHER CHOLESTEROL/TRIGLYCERIDE REGULATORS	Early development
Opiates & Controlled Substances	Buprenorphine Base	N7F: DRUGS USED IN OPIOID DEPENDENCE N2A: NARCOTIC ANALGESICS	Development
Opiates & Controlled Substances	Buprenorphine hydrochloride	N7F: DRUGS USED IN OPIOID DEPENDENCE N2A: NARCOTIC ANALGESICS	Samples available
Prostaglandins	Lubiprostone	A6A9: OTHER DRUGS FOR CONSTIPATION A3G: GASTRO-INTESTINAL SENSORIMOTOR MODULATORS	Early development
Prostaglandins	Misoprostol	G3X : OTHER SEX HORMONES AND SIMILAR PRODUCTS A2B3: PROSTAGLANDIN ANTIULCERANTS	Early development
Prostaglandins	Misoprostol HPMC dispersion	G3X : OTHER SEX HORMONES AND SIMILAR PRODUCTS A2B3: PROSTAGLANDIN ANTIULCERANTS	Early development
Small Molecules Synthesis	Adrenaline (Epinephrine) base	C1C1 : CARDIAC STIMULANTS EXCLUDING DOPAMINERGIC AGENTS - R3X1 : ALL OTHER ANTI-ASTHMA AND COPD PRODUCTS, INHALANT - N1B1: ANAESTHETICS LOCAL, MEDICAL INJECTABLES - D3A9: ALL OTHER WOUND HEALING AGENTS	Early development
Small Molecules Synthesis	Adrenaline (Epinephrine) bitartrate	C1C1 : CARDIAC STIMULANTS EXCLUDING DOPAMINERGIC AGENTS - N1B1: ANAESTHETICS LOCAL, MEDICAL INJECTABLES	Early development
Small Molecules Synthesis	Adrenaline (Epinephrine) hydrochloride	C1C1 : CARDIAC STIMULANTS EXCLUDING DOPAMINERGIC AGENTS - R3X1 : ALL OTHER ANTI-ASTHMA AND COPD PRODUCTS, INHALANT - N1B1: ANAESTHETICS LOCAL, MEDICAL INJECTABLES - D3A9: ALL OTHER WOUND HEALING AGENTS	Early development
Small Molecules Synthesis	Selegiline Base		Samples available

ATC classes mentioned in this document can be broader for certain APIs. This is a selection of the main ones, and they are only given as an indication. For more information, please visit the World Health Organization: www.who.int

see you soon

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