

# API Portfolio

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PRODUCT NAME	CAS No.	THERAPEUTIC CLASS	EU CTD	CEP	US DMF	GDUFA	CANADA DMF	JAPAN DMF	BRAZIL DMF	BRAZIL CADIFA	CHINA DMF
AMINOCAPROIC ACID*	60-32-2	Treatment of bleeding disorders	●		●	●					●
AMITRIPTYLINE HCl	549-18-8	Antidepressant	●	●	●				●		
BENSERAZIDE HCl	14919-77-8	Antiparkinson	●								
BIPERIDEN HCl	1235-82-1	Antiparkinson	●								
BUPROPION HBr	905818-69-1	Antidepressant									
BUPROPION HCl	31677-93-7	Antidepressant	●		●	●	●		●		
CANDESARTAN CILEXETIL	145040-37-5	Antihypertensive	●	○							
CHENODEOXYCHOLIC ACID*	474-25-9	Bile stone therapy, plain antitussives	●		●	●					
CHOLIC ACID	81-25-4	Bile acid synthesis disorders			○						
CRISABOROLE	906673-24-3	Treatment of atopic dermatitis and psoriasis	●								
CYCLOBENZAPRINE HCl	6202-23-9	Muscle relaxant	●		●	●	●		●	○	
DAPSONE	80-08-0	Antibacterial	●		●	●					
DEXLANSOPRAZOLE ANHYDROUS CRYSTALLINE	138530-94-6	Antiulcerative	●		●	●					
DICLOFENAC EPOLAMINE	119623-66-4	Anti-inflammatory	●		●						
DICLOFENAC POTASSIUM	15307-81-0	Anti-inflammatory	●		●						
DICLOFENAC SODIUM	15307-79-6	Anti-inflammatory	●		●	●	●				
DOTHIEPIN HCl (DOSULEPIN HCl)	897-15-4	Antidepressant	●								
DOXEPIN HCl	1229-29-4	Antidepressant	●		●	●	●				
EFINACONAZOLE	164650-44-6	Antifungal, treatment of onychomycosis	●		●	●	●				
ETRIPAMIL	1593673-23-4	Antiarrhythmic			○						
FESOTERODINE FUMARATE	286930-03-8	Antimuscarinic, treatment of urinary incontinence			●	●	●				
FEXOFENADINE HCl	153439-40-8	Antihistaminic	●		●	●		●			
GLIBENCLAMIDE (GLYBURIDE)	10238-21-8	Antidiabetic	●		●			●			
GLYCOCHOLIC ACID	475-31-0	Excipient									
IBUPROFEN LYSINE SALT	57469-76-8	Analgesic	●		●						

\* only for specific markets

● filed ○ under preparation

For certain products, submissions have also been filed with regulatory authorities beyond those listed. Dipharma is available to support customers according to their specific requirements, including the customisation of regulatory submissions.

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ISOSORBIDE DINITRATE	87-33-2	Vasodilator	●	●	●	●	●	●	●		●
ISOSORBIDE-5-MONONITRATE	16051-77-7	Vasodilator	●	●	●	●	●	●	●		●
LETERMOVIR	917389-32-3	Antiviral									
METARAMINOL*	33402-03-8	Antihypotensive	●								●
MINODRONIC ACID	155648-60-5	Treatment of osteoporosis	●					●			
MODAFINIL	68693-11-8	Psychostimulant	●		●	●					
NIFEDIPINE	21829-25-4	Antihypertensive	●	●	●	●					●
NITROGLYCERINE (GLYCERYL TRINITRATE)	55-63-0	Vasodilator	●		●	●	●				●
NORTRIPTYLINE HCl	894-71-3	Antidepressant	●		●	●	●	●	●		
PIRFENIDONE	53179-13-8	Immunosuppressant	●	○	●	●		●			
PIROXICAM	36322-90-4	Anti-inflammatory	●		●	●	●				
RUFINAMIDE	106308-44-5	Anticonvulsant	●		●	●	●				
SELEGILINE BASE*	14611-51-9	Antidepressant, antiparkinson	●		●	●					
SELEGILINE HCl	14611-52-0	Antiparkinson	●	●	●	●	●	●			
SODIUM PHENYLBUTYRATE	1716-12-7	Metabolic disorder	●		○						
TAUROURSOXYCHOLIC ACID	14605-22-2	Bile stone therapy	●								
TOLBUTAMIDE	64-77-7	Antidiabetic	●		●						
TRIAMTERENE	396-01-0	Diuretic	●	●	●	●	●				
URSOXYCHOLIC ACID	128-13-2	Cholelitholytic agent	●	●	●	●	●		●	●	●
VORTIOXETINE HBr	960203-27-4	Antidepressant			●	●					
ZONISAMIDE	68291-97-4	Anticonvulsant	●		●			●			

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## Contact us

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