

API

PRODUCT LIST



API PRODUCT LIST

	Product	Therapeutic Category	Polymorphic form	CAS No.	EU DMF/CEP	US DMF	CHINESE DMF	JAPANESE DMF	KOREAN DMF	CANADIAN DMF	CADIFA	injectable form
1.	Acenocumarol*	Cardiovascular system		152-72-7	✓							
2.	Acetazolamide	Cardiovascular system	Form II	59-66-5	CEP	✓			✓			✓
3.	Alendronate sodium	Musculo-skeletal system	Trihydrate	121268-17-5	CEP	✓		✓	✓	✓		✓
4.	Aniracetam	Nervous system	Monoclinic form	72432-10-1	✓							
5.	Aripiprazole	Nervous system	Type I	129722-12-9	CEP	✓						✓
6.	Aripiprazole monohydrate (non-sterile)	Nervous system	Monohydrate	851220-85-4	✓	✓						
7.	Baclofen	Musculo-skeletal system	Form B	1134-47-0	CEP	✓		✓	✓	✓	P	✓
8.	Carbamazepine	Nervous system	Form III	298-46-4	CEP	✓			✓			
9.	Carvedilol	Cardiovascular system	Form II	72956-09-3	CEP	✓		✓	✓			
10.	Carvedilol phosphate hemihydrate	Cardiovascular system	Form I	610309-89-2	✓	✓						
11.	Clemastine fumarate*	Antineoplastic & immuno-modulating agents		14976-57-9	✓							
12.	Cloпамide*	Cardiovascular system		636-54-4	✓							
13.	Disulfiram*	Alimentary tract & metabolism		97-77-8	✓/P							
14.	Etodolac	Musculo-skeletal system	Crystalline racemate, none	41340-25-4	CEP	✓		✓	✓	✓	P	
15.	Hydrochlorothiazide	Cardiovascular system	Form I	58-93-5	CEP	✓	✓	✓	✓	✓	P	✓
16.	Ibandronate sodium	Musculo-skeletal system	Monohydrate Form B	138926-19-9	CEP	✓	✓	✓	✓		P	CEP
17.	Lamotrigine	Nervous system	Anhydrous monoclinic	84057-84-1	CEP	✓	✓	✓	✓			
18.	Molsidomine*	Cardiovascular system		25717-80-0	CEP							
19.	Nefopam Hydrochloride*	Nervous system		23327-57-3	✓							
20.	Opiпramol dihydrochloride	Nervous system	Amorphous	909-39-7	✓							
21.	Oxcarbazepine	Nervous system	Form A	28721-07-5	✓	✓						

P-pending

DISCLAIMER

Products protected by patents (SPC) in Poland are developed solely for the purpose of Regulatory Submissions or R&D purposes intended to support Regulatory Submissions. These products are not offered for sale or made available in countries where such products are subject to patent (SPC) protection and where the offer for sale or any related activity constitutes patent infringement. It is within the buyer's responsibility and liability to check the patent situation of the product in the import market(s).

API PRODUCT LIST

	Product	Therapeutic Category	Polymorphic form	CAS No.	EU DMF/CEP	US DMF	CHINESE DMF	JAPANESE DMF	KOREAN DMF	CANADIAN DMF	CADIFA	injectable form
22.	Pentoxifylline	Cardiovascular system	Form I	6493-05-6	CEP	✓	✓					✓
23.	Phenyl salicylate	Antipyretic, analgesic and anti-inflammatory	Crystalline orthorhombic form	118-55-8	✓							
24.	Piracetam	Nervous system	Form II	7491-74-9	CEP						P	✓
25.	Risedronate sodium	Musculo-skeletal system	Form A	329003-65-8	CEP	✓		✓	✓	✓	P	✓
26.	Salicylamide	Antipyretic, analgesic and anti-inflammatory	Monoclinic form with space group 12/a	65-45-2	✓							
27.	Sildenafil citrate	Genito-urinary system & sex hormones	Anhydrous Form	171599-83-0	CEP	✓	✓	✓		✓		
28.	Sitagliptin hydrochloride	Alimentary tract & metabolism	Form III	862156-92-1	✓	✓						
29.	Sodium salicylate	Antipyretic, analgesic and anti-inflammatory	Monoclinic form (space group P21/m)	54-21-7	✓	✓		✓				
30.	Solifenacin succinate	Genito-urinary system & sex hormones	Form I	242478-38-2	CEP	✓						
31.	Tadalafil	Genito-urinary system & sex hormones	Form A (form I)	171596-29-5	CEP	✓	✓	✓			P	
32.	Tolterodine tartrate	Genito-urinary system & sex hormones	Crystalline Form I	124937-52-6	CEP					✓		
33.	Topiramate	Nervous system	Orthorhombic structure	97240-79-4	✓	✓			✓			
34.	Vardenafil hydrochloride	Genito-urinary system & sex hormones	Trihydrate form	330808-88-3	CEP	✓	✓	✓	✓	✓		
35.	Xylometazoline HCl*	Respiratory system		1218-35-5	CEP							
36.	Zoledronic acid	Musculo-skeletal system	Monohydrate	165800-06-6	CEP	✓		✓		✓	P	✓

* Ipochem API branch manufacturing site in Warsaw

P- pending

DISCLAIMER

Products protected by patents (SPC) in Poland are developed solely for the purpose of Regulatory Submissions or R&D purposes intended to support Regulatory Submissions. These products are not offered for sale or made available in countries where such products are subject to patent (SPC) protection and where the offer for sale or any related activity constitutes patent infringement. It is within the buyer's responsibility and liability to check the patent situation of the product in the import market(s).

INTERMEDIATES

1.	2-(2-CHLOROETHYL)-1-METHYLPYRROLIDINE HYDROCHLORIDE
2.	4-HYDROXYBENZYL ALCOHOL
3.	8-HYDROXYQUINALDINE
4.	1-METHYL-2-PYRROLIDINEETHANOL
5.	POTASSIUM ETHYL CARBONATE
6.	N-(p-TOLUENESULFONYL)-L-GLUTAMIC ACID

DEVELOPED API

	API Product	Therapeutic Category	Polymorphic form	CAS No.	EU DMF/CEP	US DMF	CHINESE DMF	KOREAN DMF	CANADIAN DMF	CADIFA
1.	Apixaban	Blood & blood forming organ	Crystalline form N-1	503612-47-3	✓	✓		✓		P
2.	Apremilast	Musculo-skeletal system	Form B	608141-41-9	✓	✓				
3.	Baricitinib	Antineoplastic & immunomodulating agents	Form I	1187594-09-7						
4.	Brexpiprazole	Nervous system	Crystalline anhydrous	913611-97-9	✓	✓				P
5.	Dapagliflozin	Alimentary tract & metabolism	Amorphous	461432-26-8	✓	✓		✓	✓	P
6.	Dapagliflozin Propanediol Monohydrate	Alimentary tract & metabolism	Crystalline SC-3	960404-48-2	✓	✓				
7.	Elagolix sodium	Genito-urinary system & sex hormones	Amorphous	832720-36-2						
8.	Empagliflozin	Alimentary tract & metabolism	Crystalline anhydrous	864070-44-0	✓	✓	✓	✓		P
9.	Enzalutamide	Oncology	Anhydrous form R1	915087-33-1						
10.	Isavuconazonium sulfate	Antifungal agent	Amorphous	946075-13-4	P					
11.	Linagliptin	Alimentary tract & metabolism	Form: mix A&B	668270-12-0	✓	✓	✓	✓	✓	
12.	Pimavanserin tartrate	Nervous system	Crystalline anhydrous form C	706782-28-7	✓	✓				
13.	Rivaroxaban	Blood & blood forming organs	Modification I	366789-02-8	CEP	✓	✓	✓		P
14.	Sacubitril/Valsartan complex	Cardiovascular system	Crystalline	936623-90-4	✓	✓				
15.	Safinamide methanesulfonate	Nervous system	Crystalline anhydrous form A1	202825-46-5	✓	✓				
16.	Ticagrelor	Blood & blood forming organs	Form II	274693-27-5	✓	✓			✓	P

P-pending

DISCLAIMER

Products protected by patents (SPC) in Poland are developed solely for the purpose of Regulatory Submissions or R&D purposes intended to support Regulatory Submissions. These products are not offered for sale or made available in countries where such products are subject to patent (SPC) protection and where the offer for sale or any related activity constitutes patent infringement. It is within the buyer's responsibility and liability to check the patent situation of the product in the import market(s).

Based on exemption under art. 5(2) of the Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products Apixaban, Rivaroxaban and Ticagrelor, which are protected by SPCs in Poland, can be manufactured and offered only for the purpose of export to non-EU countries, provided all requirements of the Regulation are met.

July 2023

WE PROVIDE

professional support in areas related to technology, analytical and special services



WE COLLABORATE

closely with you in order to search for and suggest solutions on a day-to-day basis working in parallel with your technicians and analysts to offer the best solutions along the way

WE SUPPORT

by a tailored solutions, according to your needs in order to help you overcome challenges during your formulation development



EUROPEAN CDMO PARTNER AND API MANUFACTURER SINCE 1951

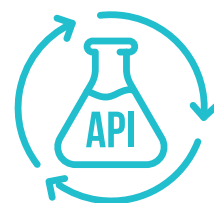
OVER 70 YEARS OF EXPERIENCE IN PROCESS
DEVELOPMENT AND COMMERCIAL
PRODUCTION OF ACTIVE INGREDIENTS

STRATEGIC INVESTMENT IN HP API AND
CRYOGENIC TECHNOLOGIES

PRODUCTION CAPACITY AND
COMPETENCES, FDA-APPROVED SITE
INTEGRATING R&D, PILOT AND LARGE
SCALE COMMERCIAL PLANTS

DEVELOPMENT AND MANUFACTURING
SERVICES FROM EARLY CLINICAL PHASES
TO FULL LIFE CYCLE MANAGEMENT

> 50



> 70



MORE THAN 50 APIS ACTIVELY SOLD
GLOBALLY IN MORE THAN
70 OF THE BIGGEST MARKETS
ON 6 CONTINENTS

CONTACT US

API SALES

@ api@polpharma.com

🌐 api.polpharma.com

CDMO

@ cdmo@polpharma.com

🌐 cdmo.api.polpharma.com

Technical Customer Support

@ techCS.API@polpharma.com



MEET US

LinkedIn

🌐 <https://www.linkedin.com/showcase/polpharma-api/>

POLPHARMA

Pelplinska 19
83-200 Starogard Gdanski
Poland

📞 +48 58 563 16 00

strive for
better 



SAVE THE API PRODUCT LIST