



API

PRODUCT LIST

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	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	✓		✓	✓	✓	S	✓
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*	Antipyretic, analgesic and anti-inflammatory		14976-57-9	✓							
12.	Clopamide*	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	✓		✓	✓	✓	S	
15.	Hydrochlorothiazide	Cardiovascular system	Form I	58-93-5	CEP	✓	✓	✓	✓	✓	S	✓
16.	Ibandronate sodium	Musculo-skeletal system	Monohydrate Form B	138926-19-9	CEP	✓	✓	✓	✓		S	CEP
17.	Lamotrigine	Nervous system	Anhydrous monoclinic	84057-84-1	CEP	✓	✓	✓	✓			
18.	Molsidomine*	Cardiovascular system		25717-80-0	CEP							
19.	Nefopam Hydrochloride*	Respiratory system		23327-57-3	✓							
20.	Opi Pramol dihydrochloride	Nervous system	Amorphous	909-39-7	✓							
21.	Oxcarbazepine	Nervous system	Form A	28721-07-5	✓	✓						

P- pending S- submitted

DISCLAIMER

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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						S	✓
25.	Risedronate sodium	Musculo-skeletal system	Form A	329003-65-8	CEP	✓		✓	✓	✓	S	✓
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.	Tadalafil	Genito-urinary system & sex hormones	Form A (form I)	171596-29-5	CEP	✓	✓	✓			S	
31.	Tolterodine tartrate	Genito-urinary system & sex hormones	Crystalline Form I	124937-52-6	CEP					✓		
32.	Topiramate	Nervous system	Orthorhombic structure	97240-79-4	✓	✓			✓			
33.	Vardenafil hydrochloride	Genito-urinary system & sex hormones	Trihydrate form	330808-88-3	CEP	✓	✓	✓	✓	✓		
34.	Xylometazoline HCl*	Respiratory system		1218-35-5	CEP							
35.	Zoledronic acid	Musculo-skeletal system	Monohydrate	165800-06-6	CEP	✓		✓		✓	S	✓

* Ipochem API branch manufacturing site in Warsaw

S- submitted

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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	✓	✓		✓		S
2.	Apremilast	Musculo-skeletal system	Form B	608141-41-9	✓	✓				
3.	Baricitinib	Antineoplastic & immunomodulating agents	Form I	1187594-09-7						
4.	Brexiprazole	Nervous system	Crystalline anhydrous	913611-97-9	✓	✓				S
5.	Dapagliflozin	Alimentary tract & metabolism	Amorphous	461432-26-8	✓	✓		✓	✓	S
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	✓	✓	✓	✓		S
9.	Enzalutamide	Oncology	Anhydrous form R1	915087-33-1						
10.	Isavuconazonium sulfate	Antifungal agent	Amorphous	946075-13-4	✓	✓				
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.	Palbociclib*	Oncology	polymorphic form: crystal form A	571190-30-2		P				
14.	Rivaroxaban	Blood & blood forming organs	Modification I	366789-02-8	CEP	✓	✓	✓		S
15.	Sacubitril/Valsartan complex	Cardiovascular system	Crystalline	936623-90-4	✓	✓				
16.	Safinamide methanesulfonate	Nervous system	Crystalline anhydrous form A1	202825-46-5	✓	✓				
17.	Ticagrelor	Blood & blood forming organs	Form II	274693-27-5	CEP	✓			✓	S

* Product developed under strategic cooperation Polpharma & Egis

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Based on the exemption under art. 5(2) of the Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products Apixaban, Rivaroxaban, Ticagrelor, Dapagliflozin, and Linagliptin, 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.

October 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

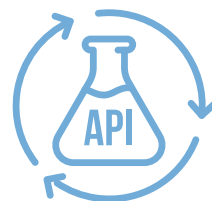
DEVELOPMENT AND MANUFACTURING
SERVICES FROM EARLY CLINICAL PHASES
TO FULL LIFE CYCLE MANAGEMENT

STRATEGIC INVESTMENT IN HP API
AND CRYOGENIC TECHNOLOGIES

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

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

> 50



> 70



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

HP API PIPELINE

POLPHARMA'S STRATEGIC INVESTMENT IN HPAPI FACILITY, THE FIRST OF THIS KIND IN POLAND

With the strategic investment in a HPAPI facility, Polpharma, and Poland are becoming a strong pillar of the European pharmaceutical industry in the coming decades.

We are investing € 35 million into a specialized facility for the R&D and Production of highly active substances with an **OEL value down to 10 ng/m³ (OEB 6)**.

Construction of the new manufacturing building includes a separate **process development laboratory (PDL)**, **analytical development laboratory (ADL)** with **QC analysis capabilities** and a **GMP kilo-lab scale** production line of max batch size up to 1.5 kg, with further expansion potential to double its capacity. HPAPI kilo-lab will have three reactors ranging from 5L to 35 L. The plant's design assumes best-in-class isolator technology to be used for personnel and product safety.

The unit will become operative in Q3 2024. We are proudly joining the forefront of global API manufacturers with the ability to **deliver highly potent substances** which are critical for saving lives and treating patients around the world.

UNDER DEVELOPMENT

Product

Samples Availability

▲ Enzalutamide	available
▲ Palbociclib*	available
▲ Carfilzomib	Q4 2023
▲ Trametinib	Q4 2023

INITIAL STAGE

Product

▲ Azacitidine	▲ Ibrutinib*
▲ Baricitinib*	▲ Ozanimod
▲ Cabozantinib	▲ Vismodegib
▲ Fulvestrant	

* Products developed under strategic cooperation Polpharma & Egis

- ▲ OVER 70 YEARS OF EXPERIENCE IN DEVELOPMENT, SCALE-UP AND MANUFACTURING
- ▲ FDA-APPROVED PLANT LOCATED IN CENTRAL EUROPE
- ▲ R&D EXPERIENCED IN DEVELOPMENT OF CHEMICAL PROCESSES AND COMPLEX PROJECTS
- ▲ WORLD-CLASS REGULATORY SUPPORT

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better 



SAVE THE API PRODUCT LIST