













# API

GENERICS 2024

# API PRODUCT LIST

Product	Polymorphic form	CAS No.									
			DMF	CEP	DMF	DMF	DMF	DMF	DMF	CADIFA	
1. Acenocumarol		152-72-7	✓								
2. Acetazolamide	Form II	59-66-5	✓	✓	✓			✓			✓
3. Alendronate sodium	Trihydrate	121268-17-5	✓	✓	✓		✓	✓	✓	P	✓
4. Aniracetam	Monoclinic form	72432-10-1	✓								
5. Antazoline HCL		2508-72-7	✓								
6. Antazoline mesylate		3131-32-6	✓								
7. Antazoline sulfate	Unique crystal form of dihydrated salt of di-Antazoline sulfate [di-1Himidazole-2-methanamine, 4,5-dihydro-N-phenyl-N-(phenyl methyl)-, sulfate (2:1), dihydrate].	24359-81-7	✓								
8. Aripiprazole	Type I	129722-12-9	✓	✓	✓						✓
9. Aripiprazole monohydrate (non-sterile)	Monohydrate	851220-85-4	✓		✓						
10. Baclofen	anhydrous polymorphic form	1134-47-0	✓	✓	✓		✓	✓	✓	P	✓
11. Carbamazepine	Form III	298-46-4	✓	✓	✓			✓			
12. Carvedilol	Form II	72956-09-3	✓	✓	✓		✓	✓			
13. Carvedilol phosphate hemihydrate	Form I	610309-89-2	✓		✓						
14. Clemastine fumarate	Substance does not show polymorphism	14976-57-9	✓								
15. Clopamide	Polymorphic form	636-54-4	✓								
16. Disulfiram	Substance does not show polymorphism	97-77-8	✓	P							
17. Etodolac	Crystalline racemate, none	41340-25-4	✓	✓	✓		✓	✓	✓	✓	
18. Hydrochlorothiazide	Form I	58-93-5	✓	✓	✓	✓	✓	✓	✓	P	✓
19. Ibandronate sodium	Monohydrate Form B	138926-19-9	✓	✓	✓	✓	✓	✓		P	CEP
20. ITCL Denotivir	Substance does not show polymorphism	51287-57-1	✓								
21. Lamotrigine	Anhydrous monoclinic	84057-84-1	✓	✓	✓	✓	✓	✓			
22. Molsidomine	Substance does not show polymorphism	25717-80-0	✓	✓							
23. Nefopam Hydrochloride	Substance does not show polymorphism	23327-57-3	✓								
24. Opipramol dihydrochloride	Crystalline form	909-39-7	✓								
25. Oxcarbazepine	Form A	28721-07-5	✓	P	✓						
26. Pentoxifylline	Form I	6493-05-6	✓	✓	✓	✓					✓
27. Phenyl salicylate	Crystalline orthorhombic form	118-55-8	✓								
28. Piracetam	Form II	7491-74-9	✓	✓						P	✓

# API PRODUCT LIST

Product	Polymorphic form	CAS No.									P	
			DMF	CEP	DMF	DMF	DMF	DMF	DMF	CADIFA		
29. Risedronate sodium	Form A	329003-65-8	✓	✓	✓		✓	✓	✓		P	✓
30. Salicylamide	Monoclinic form with space group 12/a	65-45-2	✓									
31. Sildenafil citrate	Anhydrous Form	171599-83-0	✓	✓	✓	✓	✓		✓			
32. Sitagliptin hydrochloride	Form III	862156-92-1	✓		✓							
33. Sodium salicylate	Monoclinic form (space group P21/m)	54-21-7	✓		✓		✓					
34. Tadalafil	Form A (form I)	171596-29-5	✓	✓	✓	✓	✓				P	
35. Tolterodine tartrate	Crystalline Form I	124937-52-6	✓	✓					✓			
36. Topiramate	Orthorhombic structure	97240-79-4	✓		✓			✓				
37. Undecylenic acid monoethanolamide		20545-92-0	✓									
38. Vardenafil hydrochloride	Trihydrate form	330808-88-3	✓	✓	✓	✓	✓	✓	✓			
39. Xylometazoline HCl	Substance does not show polymorphism	1218-35-5	✓	✓								
40. Zoledronic acid	Monohydrate	165800-06-6	✓	✓	✓		✓		✓		P	✓

P- pending

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# HP API PRODUCT LIST

Product	Polymorphic form	CAS No.	STATUS	OEB No.	SAMPLES
1. Palbociclib	crystal form A	571190-30-2	Under development	4	available
2. Carfilzomib	Amorphous	868540-17-4	Under development	4	Q4 2023
3. Trametinib	DMSO solvate	871700-17-3	Under development	5	Q4 2023
4. Cabozantinib			Initial stage	4	tbd
5. Ozanimod			Initial stage	4	tbd
6. Nalemedine			Initial stage	4	tbd
7. Vismodegib			Initial stage	5	tbd

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# DEVELOPED API

Product	Polymorphic form	CAS No.	 DMF	 CEP	 DMF	 DMF	 DMF	 DMF	 CADIFA
1. Apixaban	Crystalline form N-1	503612-47-3	✓		✓		✓		✓
2. Apremilast	Form B	608141-41-9	✓		✓			✓	
3. Baricitinib	Form I	1187594-09-7							
4. Brexpiprazole	anhydrous form (from I)	913611-97-9	✓		✓				
5. Dapagliflozin	Amorphous	461432-26-8	✓		✓		✓	✓	✓
6. Dapagliflozin Propanediol Monohydrate	Crystalline SC-3	960404-48-2	✓		✓				
7. Elagolix sodium	Amorphous	832720-36-2	P		P				
8. Empagliflozin	Crystalline anhydrous	864070-44-0	✓		✓	✓	✓		
9. Enzalutamide	Anhydrous form R1	915087-33-1							
10. Isavuconazonium sulfate	Amorphous	946075-13-4	✓		✓				
11. Linagliptin	Form: mix A&B	668270-12-0	✓		✓	✓	✓	✓	
12. Palbociclib	crystal form A	571190-30-2	P		P				
13. Pimavanserin tartrate	Crystalline anhydrous form C	706782-28-7	✓		✓				
14. Rivaroxaban	Modification I	366789-02-8	✓	✓	✓	✓	✓	✓	✓
15. Sacubitril/Valsartan complex	Crystalline	936623-90-4	✓		✓				
16. Safinamide methanesulfonate	Crystalline anhydrous form A1	202825-46-5	✓		✓				
17. Ticagrelor	Form II	274693-27-5	✓	✓	✓		✓	✓	✓

P- pending

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

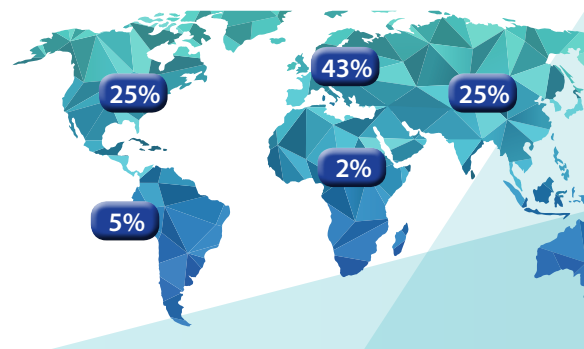
# WE ARE PROUD OF OUR 70 YEARS OF EXPERIENCE IN SUPPORTING PATIENTS' HEALTH WITH HIGH QUALITY APIs



## HYBRID BUSINESS MODEL

- ▲ >70 YEARS OF EXPERIENCE IN API BUSINESS
- ▲ GENERICS AND CDMO  
From development to commercial
- ▲ EUROPEAN LOCATION  
R&D and 2 manufacturing plants
- ▲ AGILE ORGANISATION  
Fast deciding making, top execution
- ▲ PROJECT MANAGEMENT EXCELLENCE

### ▲ GLOBAL MARKET PRESENCE



## KEY FACTS



>70

PRODUCTS

>70

COUNTRIES



~455 (R&D ~70, ~16 PHD)  
EMPLOYEES



### REGULATORY



### FULL VALUE CHAIN

R&D, PRODUCTION COMMERCIAL,  
SUPPLY CHAIN, PMO

## MAIN TECHNOLOGIES

### BROAD TYPE OF CHEMISTRIES

R&D, Kilo Lab, Pilot, Commercial

- Highly reactive compounds, organometallic, organophosphorus
- Powder handling (PSD adjustment) by milling and micronization & Solid-State Chemistry

### HIGH POTENT

- **PDL R&D:** OEB  $\leq 6$  (OEL > 10ng/m<sup>3</sup>)
- **GMP PP/KL:** OEB  $\leq 5$  (OEL > 200ng/m<sup>3</sup>)
- **GMP Commercial:** OEB  $\leq 6$  (OEL > 10ng/m<sup>3</sup>)

### CRYOGENIC

- **PP:** Reactor capacity range: 0.1 to 0.5 m<sup>3</sup>  
Operational temperature: down to -80°C
- **COMMERCIAL:** reactor capacity range: 2.5 to 6.3m<sup>3</sup>  
Total reactors vol: 23.5m<sup>3</sup>

### OLIGONUCLEOTIDES

- Development and GMP small scale production line by Q3 2024
- First product validated by Q2 2025

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strive for  
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SAVE THE API PRODUCT LIST