



API

Generics 2027

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	72432-10-1	✓								
5.	Antazoline HCL		2508-72-7	✓								
6.	Antazoline mesylate		3131-32-6	✓								
7.	Antazoline sulfate	Crystalline	24359-81-7	✓								
8.	Apremilast	Form B	608141-41-9	✓		✓			✓	✓		
9.	Aripiprazole	Type I	129722-12-9	✓	✓	✓						✓
10.	Baclofen	Anhydrous	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		14976-57-9	✓								
15.	Clopamide		636-54-4	✓								
16.	Disulfiram		97-77-8	✓	✓							
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	✓	✓	✓	✓	✓	✓		✓	✓
20.	Isavuconazonium sulfate	Amorphous	946075-13-4	✓		✓						
21.	ITCL Denotivir		51287-57-1	✓								
22.	Lamotrigine	Anhydrous monoclinic	84057-84-1	✓	✓	✓	✓	✓	✓			
23.	Molsidomine		25717-80-0	✓	✓				✓			
24.	Nefopam Hydrochloride		23327-57-3	✓								✓
25.	Opipramol dihydrochloride		909-39-7	✓								
26.	Pentoxifylline	Form I	1677687	✓	✓	✓	✓		✓			✓
27.	Phenyl salicylate	Crystalline orthorhombic	118-55-8	✓								
28.	Pimavanserin tartrate	Anhydrous form C	706782-28-7	✓		✓						
29.	Piracetam	Form II	7491-74-9	✓	✓						P	✓
30.	Risedronate sodium 2.5-hydrate	Form A	329003-65-8	✓	✓	✓		✓	✓	✓	P	

P - pending

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	Product	Polymorphic form	CAS No.	 DMF	 CEP	 DMF	 DMF	 DMF	 DMF	 DMF	 CADIFA	
31.	Rivaroxaban	Modification I	366789-02-8	✓	✓	✓	✓		✓	✓	✓	
32.	Salicylamide	Monoclinic form with space group I2/a	65-45-2	✓			P					
33.	Sildenafil citrate	Anhydrous	171599-83-0	✓	✓	✓	✓	✓				
34.	Sitagliptin hydrochloride	Form III	862156-92-1	✓		✓						
35.	Sodium salicylate	Monoclinic form (space group P2 ₁ /m)	54-21-7	✓		✓		✓				
36.	Tadalafil	Form I (form A)	171596-29-5	✓	✓	✓	✓	✓			P	
37.	Ticagrelor	Form II	274693-27-5	✓	✓	✓			✓	✓	P	
38.	Tolterodine tartrate	Crystalline form I	124937-52-6	✓	✓					✓		
39.	Topiramate	Orthorhombic structure	97240-79-4	✓		✓			✓			
40.	Vardenafil hydrochloride	Trihydrate form	330808-88-3	✓	✓	✓	✓	✓	✓	✓		
41.	Xylometazoline HCl		1218-35-5	✓	✓		P					
42.	Zoledronic acid monohydrate	Monohydrate	165800-06-6	✓	✓	✓		✓		✓	P	✓

Disclaimer

P - pending

These products are not offered for sale or made available in countries where such products are subject to patent (PTE) 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).

Developed & Pipeline*

	Product	Polymorphic form	CAS No.	 DMF	 CEP	 DMF	 DMF	 DMF	 DMF	 DMF	 CADIFA
1.	Apixaban	Form N-1	503612-47-3	✓		✓			✓		P
2.	Brexiprazole	Anhydrous form I	913611-97-9	✓		✓					P
3.	Dapagliflozin	Amorphous	461432-26-8	✓		✓		✓	✓	✓	P
4.	Dapagliflozin Propanediol Monohydrate	Crystalline SC-3	960404-48-2	✓	✓	✓					P
5.	Empagliflozin	Crystalline anhydrous	864070-44-0	✓		✓			✓	✓	P
6.	Enzalutamide	Form R1	915087-33-1	✓		✓		P			P
7.	Etrasimod**		1206123-97-8								
8.	Sacubitril/Valsartan complex	Crystalline	936623-90-4	✓		✓					
9.	Safinamide methanesulfonate	Crystalline anhydrous form A1	202825-46-5	✓		✓			P		

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P - pending

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, Brexiprazole, Empagliflozin, Enzalutamide, Palbociclib, Trametinib and Vismodegib, 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.

** Partnership with Egis

HP API Technology*



Enabling the Next Generation of Targeted Therapies

Our HPAPI platform combines advanced containment, process chemistry expertise, and regulatory excellence to support the development and manufacture of potent active pharmaceutical ingredients for global pharmaceutical markets.

What sets us apart

- ✓ Safe-by-design manufacturing approach
- ✓ Expertise in complex synthetic routes
- ✓ Strong analytical and impurity control strategies
- ✓ Seamless transfer from development to commercial scale
- ✓ Reliable European manufacturing base

GMP production

Kilo-Lab - OEL ≥ 10 ng/m ³	Kilo-Lab - OEL ≥ 200 ng/m ³
✓ Combined Isolators (Dispensing area, Wet and Dry area) ✓ Reactors: 35l, 15l, 5l	✓ RABS + Isolators (Dispensing area, Wet and Dry area) ✓ Reactors: 63l, 30l, 25l

	Product	OEB	Indication	Polymorphic form	CAS No.	Samples	DMF	DMF	DMF	CADIFA
1.	Abemaciclib**	4	Advanced or metastatic breast cancer; adjuvant treatment of high-risk early breast cancer	Form III	1231929-97-7	Available	✓	✓	P	P
2.	Baricitinib	4	Rheumatoid arthritis, alopecia areata, atopic dermatitis	Form I	1187594-09-7	Available	✓	✓		
3.	Inavolisib	5	PIK3CA-mutated HR+/HER2- locally advanced or metastatic breast cancer	Form A	2060571-02-8	Q2 2028				
4.	Palbociclib**	4	HR+/HER2- advanced or metastatic breast cancer	Crystalline form A	571190-30-2	Available	✓	✓	P	P
5.	Pirtobrutinib	4	Relapsed/refractory mantle cell lymphoma; chronic lymphocytic leukemia/small lymphocytic lymphoma	Form A	2101700-15-4	Q3 2028				
6.	Risdiplam	4	Spinal muscular atrophy (SMA)	Crystalline form A	1825352-65-5	H1 2027	2027	2027	2027	2027
7.	Selpercatinib	4	RET-driven lung, thyroid, and other solid cancers							
8.	Talazoparib	6	BRCA-mutated HER2-negative breast cancer; metastatic castration-resistant prostate cancer (with enzalutamide)	Crystalline	1207456-01-6	Available	2027	2027	2027	2027
9.	Trametinib Dimethyl Sulfoxide	5	Melanoma, lung cancer, thyroid cancer, and other solid tumors	Form M	1187431-43-1	Available	✓	✓	P	P
10.	Vismodegib	5	Advanced basal cell carcinoma (locally advanced or metastatic)	Form I	879085-55-9	Available	✓	✓	P	P

P - pending

Oligonucleotide Technology*

Where Chemistry Meets Precision Medicine

By combining expertise in complex chemistry, process development, and GMP manufacturing, we support the evolving needs of RNA and SMA based therapies

What sets us apart

- ✓ Specialized manufacturing know-how
- ✓ Integrated analytical capabilities
- ✓ Focus on process robustness and scalability
- ✓ Commitment to quality and regulatory
- ✓ European manufacturing excellence

GMP production

Purification Chromatography	Desalting Ultrafiltration	Final Processing Lyophilization
✓ Impurity removal step ensuring product purity ✓ Primary impurities: shortmers (N-1, N-2) ✓ Secondary impurities: remaining process- and sequence-related species ✓ High-resolution separation required due to structural similarity ✓ Key impact on final quality and compliance	✓ Removes salts and low-molecular impurities ✓ Membrane-based separation ✓ Retains oligonucleotide product ✓ Enables buffer exchange ✓ Supports final product purity and stability	✓ Performed under isolator conditions ✓ Protects from moisture exposure ✓ Sensitive to oxygen ✓ Controlled microbiological environment ✓ Ensures product stability and sterility

	Product	Therapeutic Category	Polymorphic form	CAS No.	Samples	DMF	DMF	DMF	CADIFA
1.	Nusinersen	Antisense Oligonucleotide, SMA therapy	Amorphous	1258984-36-9	Available	2026	2026	2026	2026
2.	Vutrisiran	siRNA, RNA interference therapy		1867157-35-4					

Precision. Partnership. Progress

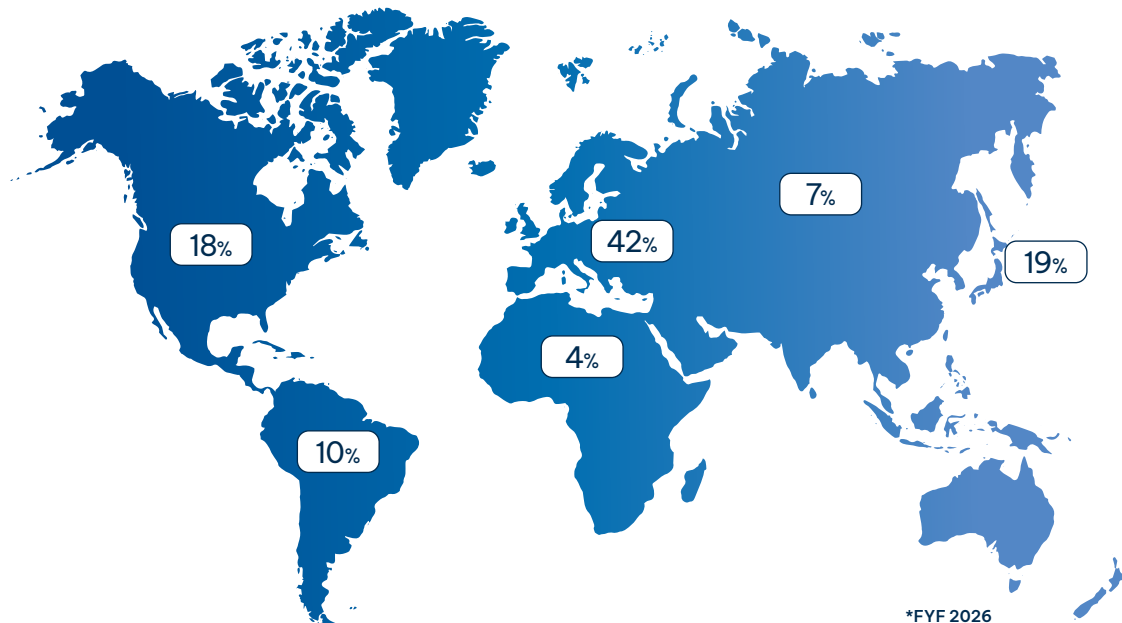
We are proud of our **75 years of experience** in supporting patients' health with **high quality APIs**



Hybrid Business Model

- ✓ **Generics & CDMO**
From development to commercial manufacturing, tailored to your business needs.
- ✓ **Trusted Quality, Proven Compliance**
EU GMP-certified operations covering all manufacturing sites and API products.
- ✓ **End-to-End Technology Excellence**
Broad technology platforms delivering seamless solutions across the entire product lifecycle.
- ✓ **Full Transparency, Audit-Ready at Every Step**
Complete documentation, raw data access, and full process visibility.
- ✓ **Digital Quality Ecosystem**
Integrated systems, ensuring data integrity and operational excellence.
- ✓ **Agile European Manufacturing Partner**
2 manufacturing plants in Central Europe combining flexibility, responsiveness, and reliable supply.

Global market presence*



*FYF 2026

Regulatory Expertise

Global Compliance and Market Access

- ✓ RA ensures adherence to regulations across 70 countries
- ✓ Long-term experience on major markets of the USA, Europe, Japan, Brazil, China, S. Korea and others
- ✓ Enables smooth market entry and supports customer reputation

Strategic Support for Product Launches

- ✓ Supports the launch of new generic products
- ✓ Assists CDMO customers with proprietary molecules
- ✓ Accelerates time-to-market and competitiveness

High Regulatory Standards

- ✓ Ensuring APIs meet stringent international standards
- ✓ Enables customers to thrive in complex regulatory environments
- ✓ Provide end-to-end support across the entire product lifecycle

75 Years of Precision, Built for What's Next

We develop and manufacture complex molecules using scalable synthetic routes designed from early-phase till commercial supply



75

Products

65

Patents

70

Markets

500

Employees

35

Audits per year

Connect & Collaborate

Talk to us

Get access to our experts

Visit our site

Virtually or in person

Get the proposal

Tailored, comprehensive and transparent

Feel the difference

Move forward with trust, clarity, and peace of mind

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Visit our HP
API plant –
Virtual tour



API
Generics
2027



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