polpharma API

# API

Generics 2026

# 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 | Crystalline form | 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 | | 14976-57-9 | ✓ | P | | | | | | | |
| 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 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | P | ✓ |
| 20. | ITCL Denotivir | | 51287-57-1 | ✓ | | | | | | | | |
| 21. | Lamotrigine | Anhydrous monoclinic | 84057-84-1 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | | |
| 22. | Molsidomine | | 25717-80-0 | ✓ | ✓ | | | | ✓ | | | |
| 23. | Nefopam Hydrochloride | | 23327-57-3 | ✓ | | | | | | | | ✓ |
| 24. | Opipramol dihydrochloride | Crystalline form | 909-39-7 | ✓ | | | | | | | | |
| 25. | Pentoxifylline | Form I | 6493-05-6 | ✓ | ✓ | ✓ | ✓ | | ✓ | | | ✓ |
| 26. | Phenyl salicylate | Crystalline orthorhombic form | 118-55-8 | ✓ | | | | | | | | |
| 27. | Piracetam | Form II | 7491-74-9 | ✓ | ✓ | | | | | | P | ✓ |
| 28. | Risedronate sodium 2.5-hydrate | Form A | 329003-65-8 | ✓ | ✓ | ✓ | | ✓ | ✓ | ✓ | P | |

P - pending

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 29. | Rivaroxaban | Modification I | 366789-02-8 | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ | ✓ | |
| 30. | Salicylamide | Monoclinic form with space group I2/a | 65-45-2 | ✓ | | | P | | | | | |
| 31. | Sildenafil citrate | Anhydrous Form | 171599-83-0 | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| 32. | Sitagliptin hydrochloride | Form III | 862156-92-1 | ✓ | | ✓ | | | | | | |
| 33. | Sodium salicylate | Monoclinic form (space group $P2_1/m$) | 54-21-7 | ✓ | | ✓ | | ✓ | | | | |
| 34. | Tadalafil | Form A (form I) | 171596-29-5 | ✓ | ✓ | ✓ | ✓ | ✓ | | | P | |
| 35. | Tolterodine tartrate | Crystalline Form I | 124937-52-6 | ✓ | ✓ | | P | | | ✓ | | |
| 36. | Topiramate | Orthorhombic structure | 97240-79-4 | ✓ | | ✓ | | | ✓ | | | |
| 37. | Vardenafil hydrochloride | Trihydrate form | 330808-88-3 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | |
| 38. | Xylometazoline HCl | | 1218-35-5 | ✓ | ✓ | | P | | | | | |
| 39. | Zoledronic acid monohydrate | Form I | 165800-06-6 | ✓ | ✓ | ✓ | | ✓ | | ✓ | 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).

# Oncology / HPAPI Developed & Pipeline

| | Product | Polymorphic form | CAS No. | OEB | Samples | DMF | DMF | DMF | CADIFA |
|---|---|---|---|---|---|---|---|---|---|
| 1. | Abemaciclib* | Form III | 1231929-97-7 | 4 | Available | ✓ | ✓ | P | P |
| 2. | Enzalutamide | Anhydrous form R1 | 915087-33-1 | 3 | Available | P | ✓ | P | P |
| 3. | Inavolisib | | 2060571-02-8 | 5 | Q2 2028 | | | | |
| 4. | Palbociclib* | Crystal form A | 571190-30-2 | 4 | Available | ✓ | ✓ | P | P |
| 5. | Talazoparib | Amorphous | 1207456-01-6 | 6 | Q4 2027 | | | | |
| 6. | Trametinib dimethyl sulfoxide | Crystalline form | 1187431-43-1 | 5 | Available | ✓ | ✓ | P | P |
| 7. | Vismodegib | Crystalline form I | 879085-55-9 | 5 | Available | ✓ | ✓ | P | P |

* partnership with Egis

# Developed API & Pipeline

| | Product | Polymorphic form | CAS No. | DMF | CEP | DMF | DMF | DMF | DMF | DMF | CADIFA |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1. | Apixaban | Form N-1 | 503612-47-3 | ✓ | | ✓ | | | ✓ | | P |
| 2. | Apremilast | Form B | 608141-41-9 | ✓ | | ✓ | | | ✓ | ✓ | |
| 3. | Baricitinib | Form I | 1187594-09-7 | ✓ | | ✓ | | | ✓ | | |
| 4. | Brexpiprazole | Anhydrous form (form I) | 913611-97-9 | ✓ | | ✓ | | | | | P |
| 5. | Dapagliflozin | Amorphous | 461432-26-8 | ✓ | | ✓ | | ✓ | ✓ | ✓ | P |
| 6. | Dapagliflozin Propanediol Monohydrate | Crystalline SC-3 | 960404-48-2 | ✓ | P | ✓ | | | | | P |
| 7. | Empagliflozin | Crystalline anhydrous | 864070-44-0 | ✓ | | ✓ | | | ✓ | ✓ | P |
| 8. | Etrasimod | | 1206123-97-8 | | | | | | | | |
| 9. | Isavuconazonium sulfate | Amorphous | 946075-13-4 | ✓ | | ✓ | | | | | |
| 10. | Nusinersen sodium | Amorphous | 1258984-36-9 | 2026 | | 2026 | | 2026 | | | 2026 |
| 11. | Pimavanserin tartrate | Crystalline anhydrous form C | 706782-28-7 | ✓ | | ✓ | | | | | |
| 12. | Risdiplam | Amorphous<br>Crystalline Form A<br>Crystalline Form E | 1825352-65-5 | 2027 | | 2027 | | 2027 | | | 2027 |
| 13. | Sacubitril/Valsartan complex | Crystalline | 936623-90-4 | ✓ | | ✓ | | | | | |
| 14. | Safinamide methanesulfonate | Crystalline anhydrous form A1 | 202825-46-5 | ✓ | | ✓ | | | P | | |
| 15. | Ticagrelor | Form II | 274693-27-5 | ✓ | ✓ | ✓ | | | ✓ | ✓ | P |

P - pending

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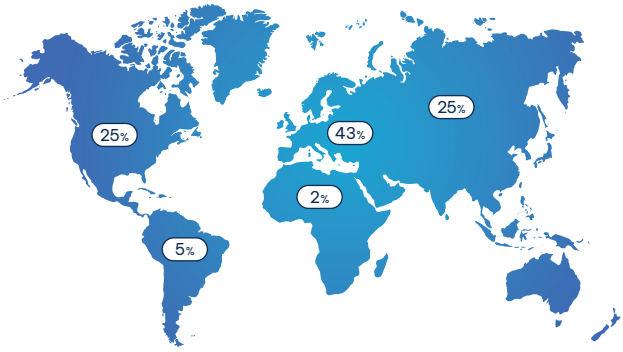
Based on exemption under art. 5(2) of the Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products Apixaban, Dapagliflozin (amorphous), Linagliptin, Rivaroxaban and Ticagrelor, which are protected by SPCs in Poland, can be manufactured and offered only for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

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

SILVER | Top 15%
ecovadis
Sustainability Rating
OCT 2025

## Hybrid Business Model

- **75 years of experience in API business**
- **Generics and CDMO** From development to commercial
- **European location** R&D and 2 manufacturing plants
- **Agile organisation** Fast decision making, top execution
- **Project management excellence**
- **Global market presence**




## Key Facts

**>70** Products

**>70** Countries

**~500** (R&D **~70, ~16** PhD) Employees

### Regulatory

### Full value chain

R&D, commercial production, supply chain, PMO

## Main Technologies

### High Potent

- **PDL R&D:** OEB ≤ 6 (OEL>10ng/m³)
- **GMP PP/KL:** OEB ≤ 5 (OEL > 200ng/m³)
- **GMP Commercial:** OEB ≤ 6 (OEL > 10ng/m³)

### Cryogenic

- **PP:** Reactor capacity range: 0.1 to 0.5 m³ Operational temperature: down to -80°C
- **COMMERCIAL:** reactor capacity range: 2.5 to 6.3m³ Total reactors vol: 23.5m³

### Oligonucleotides

- GMP small scale production line available
- First product validated by Q2 2026

# EU-based CDMO and API manufacturer, trusted by customers and business partners around the world for 75 years

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Technical Capabilities Video

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Save the API product list