

# 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 | BRASILIAN DMF |
|-----|--|--|-------------------------------|-------------|--------|---------|--------|-------------|--------------|------------|--------------|---------------|
| 1.  | Acenocumarol*                          | Cardiovascular system                        |                               | 152-72-7    | ●      |         |        |             |              |            |              |               |
| 2.  | Acetazolamide                          | Cardiovascular system                        | Form II                       | 59-66-5     | ●      | ●       | ●      |             |              | ●          |              |               |
| 3.  | Alendronate sodium                     | Musculo-skeletal system                      | Trihydrate                    | 121268-17-5 | ●      | ●       | ●      |             | ●            | ●          | ●            |               |
| 4.  | Aniracetam                             | Nervous system                               | Monoclinic form               | 72432-10-1  | ●      |         |        |             |              |            |              |               |
| 5.  | Aripiprazole                           | Nervous system                               | Type I                        | 129722-12-9 | ●      | ●       | ●      |             |              |            |              |               |
| 6.  | Aripiprazole monohydrate (non-sterile) | Nervous system                               | Monohydrate                   | 851220-85-4 | ●      |         | ●      |             |              |            |              |               |
| 7.  | Baclofen                               | Musculo-skeletal system                      | Form B                        | 1134-47-0   | ●      | ●       | ●      |             | ●            | ●          | ●            | ●             |
| 8.  | Carbamazepine                          | Nervous system                               | Form III                      | 298-46-4    | ●      | ●       | ●      |             |              | ●          |              |               |
| 9.  | Carvedilol                             | Cardiovascular system                        | Form II                       | 72956-09-3  | ●      | ●       | ●      |             | ●            | ●          |              |               |
| 10. | Carvedilol phosphate hemihydrate       | Cardiovascular system                        | Form I                        | 610309-89-2 | ●      |         | ●      |             |              |            |              |               |
| 11. | Clopidamide*                           | Cardiovascular system                        | Polymorphic form              | 636-54-4    | ●      |         |        |             |              |            |              |               |
| 12. | Etodolac                               | Musculo-skeletal system                      | Crystalline racemate, none    | 41340-25-4  | ●      | ●       | ●      |             | ●            | ●          | ●            | ●             |
| 13. | Hydrochlorothiazide                    | Cardiovascular system                        | Form I                        | 58-93-5     | ●      | ●       | ●      | ●           | ●            | ●          | ●            | ●             |
| 14. | Ibandronate sodium                     | Musculo-skeletal system                      | Monohydrate Form B            | 138926-19-9 | ●      | pending | ●      | ●           | ●            | ●          |              | pending       |
| 15. | Lamotrigine                            | Nervous system                               | Anhydrous monoclinic          | 84057-84-1  | ●      | ●       | ●      | ●           | ●            | ●          |              |               |
| 16. | Nefopam Hydrochloride*                 | Nervous system                               |                               | 23327-57-3  | ●      |         |        |             |              |            |              |               |
| 17. | Opipramol dihydrochloride              | Nervous system                               | Amorphous                     | 909-39-7    | ●      |         |        |             |              |            |              |               |
| 18. | Oxcarbazepine                          | Nervous system                               | Form A                        | 28721-07-5  | ●      | pending | ●      |             |              |            |              |               |
| 19. | Pentoxifylline                         | Cardiovascular system                        | Form I                        | 1677687     | ●      | ●       | ●      | ●           |              |            |              |               |
| 20. | Phenyl salicylate                      | Antipyretic, analgesic and anti-inflammatory | Crystalline orthorhombic form | 118-55-8    | ●      |         |        |             |              |            |              |               |
| 21. | Piracetam                              | Nervous system                               | Form II                       | 7491-74-9   | ●      | ●       |        |             |              |            |              | ●             |
| 22. | R-Baclofen                             | Musculo-skeletal system                      | Form B                        | 69308-37-8  | ●      |         | ●      |             |              |            |              |               |
| 23. | R-Baclofen hydrochloride               | Musculo-skeletal system                      | Crystalline HCl form          | 63701-55-3  | ●      |         | ●      |             |              |            |              |               |
| 24. | Risedronate sodium                     | Musculo-skeletal system                      | Form A                        | 115436-72-1 | ●      | ●       | ●      |             | ●            | ●          | ●            | ●             |

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|     | PRODUCT                   | Therapeutic Category                         | Polymorphic form                      | CAS No.     | EU DMF | CEP | US DMF | CHINESE DMF | JAPANESE DMF | KOREAN DMF | CANADIAN DMF | BRASILIAN DMF |
|-----|---------------------------|--|---------------------------------------|-------------|--------|-----|--------|-------------|--------------|------------|--------------|---------------|
| 25. | Salicylamide              | Antipyretic, analgesic and anti-inflammatory | Monoclinic form with space group 12/a | 65-45-2     | ●      |     |        |             |              |            |              |               |
| 26. | Sildenafil citrate        | Genito-urinary system & sex horm             | Anhydrous Form                        | 171599-83-0 | ●      | ●   | ●      | ●           | ●            |            | ●            |               |
| 27. | Sitagliptin hydrochloride | Alimentary tract & metabolism                | Polymorphic form III                  | 486459-71-6 | ●      |     | ●      |             |              |            |              |               |
| 28. | Sodium salicylate         | Antipyretic, analgesic and anti-inflammatory | Monoclinic form (space group P21/m)   | 54-21-7     | ●      |     | ●      |             | ●            |            |              |               |
| 29. | Solifenacin succinate     | Genito-urinary system & sex hormones         | Form I                                | 242478-37-1 | ●      | ●   | ●      |             |              |            |              |               |
| 30. | Tadalafil                 | Genito-urinary system & sex hormones         | Form A (form I)                       | 171596-29-5 | ●      | ●   | ●      | ●           | ●            |            |              | ●             |
| 31. | Tolterodine tartrate      | Genito-urinary system & sex hormones         | Crystalline Form I                    | 124937-52-6 | ●      | ●   |        |             |              |            | ●            |               |
| 32. | Topiramate                | Nervous system                               | Orthorhombic structure                | 97240-79-4  | ●      |     | ●      |             |              | ●          |              |               |
| 33. | Vardenafil hydrochloride  | Genito-urinary system & sex hormones         | Trihydrate form                       | 330808-88-3 | ●      | ●   | ●      | ●           | ●            | ●          | ●            | ●             |
| 34. | Xylometazoline HCl*       | Respiratory system                           |                                       | 1218-35-5   | ●      | ●   |        |             |              |            |              |               |
| 35. | Zoledronic acid           | Musculo-skeletal system                      | Monohydrate                           | 165800-06-6 | ●      | ●   | ●      |             | ●            |            | ●            | ●             |

\* IPOCHEM API manufacturing site

## INJECTABLE GRADE

|     | PRODUCT             | Therapeutic Category    | Polymorphic form   | CAS No.     | EU DMF | CEP     | US DMF | CHINESE DMF | JAPANESE DMF | KOREAN DMF | CANADIAN DMF | BRASILIAN DMF |
|-----|---------------------|-------------------------|--------------------|-------------|--------|---------|--------|-------------|--------------|------------|--------------|---------------|
| 1.  | Acetazolamide       | Cardiovascular system   | Form II            | 59-66-5     | ●      | ●       | ●      |             |              | ●          |              |               |
| 2.  | Alendronate sodium  | Musculo-skeletal system | Trihydrate         | 121268-17-5 | ●      | ●       | ●      |             | ●            | ●          | ●            |               |
| 3.  | Aripiprazole        | Nervous system          | Type I             | 129722-12-9 | ●      | ●       | ●      |             |              |            |              |               |
| 4.  | Baclofen            | Musculo-skeletal system | Form B             | 1134-47-0   | ●      | ●       | ●      |             | ●            | ●          | ●            | ●             |
| 5.  | Hydrochlorothiazide | Cardiovascular system   | Form I             | 58-93-5     | ●      | ●       | ●      | ●           | ●            | ●          | ●            | ●             |
| 6.  | Ibandronate sodium  | Musculo-skeletal system | Monohydrate Form B | 138926-19-9 | ●      | pending | ●      | ●           | ●            | ●          |              | pending       |
| 7.  | Pentoxifylline      | Cardiovascular system   | Form I             | 1677687     | ●      | ●       | ●      | ●           |              |            |              |               |
| 8.  | Piracetam           | Nervous system          | Form II            | 7491-74-9   | ●      | ●       |        |             |              |            |              | ●             |
| 9.  | Risedronate sodium  | Musculo-skeletal system | Form A             | 115436-72-1 | ●      | ●       | ●      |             | ●            | ●          | ●            | ●             |
| 10. | Zoledronic acid     | Musculo-skeletal system | Monohydrate        | 165800-06-6 | ●      | ●       | ●      |             | ●            |            | ●            | ●             |

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# API PIPELINE

|     | PRODUCT                               | Therapeutic Category                     | Polymorphic form              | CAS No.      | EU DMF  | CEP     | US DMF  | CHINESE DMF | JAPANESE DMF | KOREAN DMF | CANADIAN DMF | BRASILIAN DMF |
|-----|---------------------------------------|--|-------------------------------|--------------|---------|---------|---------|-------------|--------------|------------|--------------|---------------|
| 1.  | Apixaban                              | Blood & blood forming organs             | Crystalline form N-1          | 503612-47-3  | ●       |         | ●       |             |              | ●          |              | ●             |
| 2.  | Apremilast                            | Musculo-skeletal system                  | Form B                        | 608141-41-9  | ●       |         | ●       |             |              |            |              |               |
| 3.  | Baricitinib                           | Antineoplastic & immunomodulating agents | Form I                        | 1187594-09-7 |         |         |         |             |              |            |              |               |
| 4.  | Brexipiprazole                        | Nervous system                           | Polymorphic form I            | 913611-97-9  | ●       |         | ●       |             |              |            |              |               |
| 5.  | Dapagliflozin                         | Alimentary tract & metabolism            | Amorphous                     | 461432-26-8  | ●       |         | ●       |             |              | ●          | ●            | ●             |
| 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  | pending |         | pending |             |              |            |              |               |
| 8.  | Empagliflozin                         | Alimentary tract & metabolism            | Crystalline anhydrous         | 864070-44-0  | ●       |         | ●       | ●           |              | ●          |              |               |
| 9.  | Enzalutamide                          | Oncology                                 | Anhydrous form R1             | 915087-33-1  |         |         |         |             |              |            |              |               |
| 10. | Isavuconazonium sulfate               | Antifungal agent                         | Amorphous                     | 742049-41-8  |         |         |         |             |              |            |              |               |
| 11. | Linagliptin                           | Alimentary tract & metabolism            | Form: mix A&B                 | 668270-12-0  | ●       |         | ●       | ●           |              | ●          | ●            |               |
| 12. | Pimavanserin tartrate                 | Nervous system                           | Crystalline anhydrous form C  | 389574-19-0  | ●       |         | ●       |             |              |            |              |               |
| 13. | Rivaroxaban                           | Blood & blood forming organs             | Modification I                | 366789-02-8  | ●       |         | ●       | ●           |              | ●          |              |               |
| 14. | Sacubitril/Valsartan complex          | Cardiovascular system                    | Crystalline                   | 171599-83-0  | ●       |         | ●       |             |              |            |              |               |
| 15. | Safinamide methanesulfonate           | Nervous system                           | Crystalline anhydrous form A1 | 202825-46-5  | ●       |         | ●       |             |              |            |              |               |
| 16. | Ticagrelor                            | Blood & blood forming organs             | Form II                       | 274693-27-5  | ●       | 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, 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.

No product of the above list is offered for sale or made available in Germany due to patent (SPC) protection.



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