

SOLUTIONS TAILORED TO YOUR NEEDS

We are a significant European API producer with a cGMP-compliant and FDA-approved manufacturing site. Our products are available on 6 continents in more than 60 countries. We are a well-known supplier of high quality products and a trustworthy business partner of leading pharmaceutical companies worldwide.

In addition to a diverse and broad product portfolio of superior quality, excellent customer service and efficient supply chain, Polpharma B2B offers custom-made synthesis service for clients looking for a European manufacturing site for their active pharmaceutical substances.

The entire process is led by a professional project management team coordinating for you all the project activities performed by the R&D, RA, QA and other Operational departments of Polpharma. All of this with the sole purpose of you maintaining full control over your product.

WE GUARANTEE FULL SUPPORT IN THE AREA OF:

- Process optimization
- Analytical method development & validation
- Process scale-up from lab to pilot plant kg scale and multi-tons synthesis in EU cGMP, FDA (US), Anvisa (Brasil), PMDA (Japan) & KFDA (Korea) - approved facility
- Preparation of comprehensive regulatory documentation in an eCTD format
- Professional project management
- IP protection and confidentiality



PRODUCT LIST

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Your European B2B Partner

PRODUCT LIST

CARDIOVASCULAR SYSTEM	EU DMF	US DMF No.	CEP	OTHER DOCUMENTATION
1. Acenocoumarol*	✓			
2. Acetazolamide	✓	010383	✓	
3. Carvedilol	✓	017060	✓	Korean DMF
4. Carvedilol phosphate hemihydrate	✓	020633		
5. Clopamide*	✓			
6. Hydrochlorothiazide	✓	017599	✓	Japanese DMF, Korean DMF
7. Pentoxifylline	✓	020976	✓	Chinese DMF - under registration
8. Prasugrel hydrochloride	✓	030765		
9. Prasugrel maleate	✓	030764		
NERVOUS SYSTEM	EU DMF	US DMF No.	CEP	OTHER DOCUMENTATION
10. Aniracetam	✓			
11. Aripiprazole	✓	023314	✓	
12. Carbamazepine	✓	026266	✓	Korean DMF - under registration
13. Chlorpromazine hydrochloride* NEW!	✓	033203		
14. Lamotrigine	✓	020548	✓	Chinese DMF, Korean DMF
15. Opipramol dihydrochloride	✓			
16. Piracetam	✓		✓	
17. Topiramate	✓	020581		Korean DMF
GENITO-URINARY SYSTEM & SEX HORMONES	EU DMF	US DMF No.	CEP	OTHER DOCUMENTATION
18. Avanafil	✓	029689		
19. Sildenafil base	✓	028319		
20. Sildenafil citrate	✓	023930	✓	Chinese DMF, Japanese DMF
21. Tadalafil NEW!	✓	024590	✓	Chinese DMF
22. Tolterodine tartrate	✓	024345	✓	
23. Vardenafil hydrochloride NEW!	✓	025174		Chinese DMF - under registration Korean DMF
MUSCULO-SKELETAL SYSTEM	EU DMF	US DMF No.	CEP	OTHER DOCUMENTATION
24. Alendronate sodium	✓	016962	✓	Japanese DMF, Korean DMF
25. Baclofen	✓	018014	✓	Japanese DMF, Korean DMF
26. Bazedoxifene acetate	✓	031793		
27. R-baclofen NEW!	✓	031824		

PRODUCT LIST

28. R-baclofen hydrochloride NEW!	✓	033383		
29. Cyclobenzaprine hydrochloride	✓	018317		
30. Etodolac	✓	011405	✓	Japanese DMF Korean DMF - under registration
31. Ibandronate sodium	✓	025638		Chinese DMF, Korean DMF
32. Risedronate sodium	✓	020384	✓	Japanese DMF, Korean DMF
33. Zoledronic acid	✓	024306	CEP application submitted	Japanese DMF Chinese DMF - under registration
RESPIRATORY SYSTEM	EU DMF	US DMF No.	CEP	OTHER DOCUMENTATION
34. Xylometazoline hydrochloride*	✓		✓	
ALIMENTARY TRACT & METABOLISM	EU DMF	US DMF No.	CEP	OTHER DOCUMENTATION
35. Repaglinide	✓	021149	✓	
ANTI-INFECTIVES FOR SYSTEMIC USE	EU DMF	US DMF No.	CEP	OTHER DOCUMENTATION
36. Metronidazole	✓			
ANTIPYRETIC, ANALGESIC AND ANTI-IN-FLAMMATORY	EU DMF	US DMF No.	CEP	OTHER DOCUMENTATION
37. Phenyl salicylate	✓			
38. Salicylamide	✓			
39. Sodium salicylate	✓	026873		Japanese DMF
INJECTABLE FORMS	EU DMF	US DMF No.	CEP	OTHER DOCUMENTATION
1. Acetazolamide	✓	010383	✓	
2. Aripiprazole	✓	023314	✓	
3. Aripiprazole monohydrate (non-sterile) NEW!	✓	033204		
4. Baclofen	✓	018014	✓	Japanese DMF, Korean DMF
5. Ibandronate sodium	✓	025638		Chinese DMF, Korean DMF
6. Metronidazole	✓			
7. Pentoxifylline	✓	020976	✓	Chinese DMF - under registration
8. Piracetam	✓		✓	
9. Zoledronic acid	✓	024306		Japanese DMF

*Polfa Warsaw API Manufacturing Site

DISCLAIMER

Products protected by valid patents are not offered for commercial sale in countries where the sale of such products constitutes patent infringement but are offered solely for uses reasonably related to the development and submission of information under a law regulating the manufacture, use or sale of drugs. It is within the buyer's responsibility and liability to check the patent situation of the product in the imported market(s).

LIST OF APIs IN PIPELINE

ADVANCED STAGE	THERAPEUTIC AREA	EU DMF readiness	US DMF readiness	Other Documentation
1. Apixaban	Blood & blood forming organs	✓	031166	
2. Apremilast	Musculo-skeletal system	✓	031141	
3. Baricitinib	Antineoplastic & immunomodulating agents		early development	
4. Brexpiprazole	Nervous system	✓	032347	
5. Dabigatran etexilate mesylate	Blood & blood forming organs	✓	027620	Chinese DMF - under registration
6. Dapagliflozin	Alimentary tract & metabolism	✓	030555	Korean DMF - under registration
7. Dapagliflozin Propanediol Monohydrate NEW!	Alimentary tract & metabolism	✓	033387	
8. Elagolix sodium NEW!	Genito-urinary system & sex hormones		early development	
9. Empagliflozin	Alimentary tract & metabolism	✓	033180	Chinese DMF - under registration
10. Linagliptin	Alimentary tract & metabolism	✓	029844	Chinese DMF
11. Oxcarbazepine NEW!	Nervous system	Q3 2019	Q3 2019	
12. Pimavanserin tartrate	Nervous system	✓	033385	
13. Rivaroxaban	Blood & blood forming organs	✓	027661	Chinese DMF - under registration
14. Sacubitril NEW!	Cardiovascular system		early development	
15. Sacubitril/Valsartan complex	Cardiovascular system	✓	032337	
16. Safinamide methanesulfonate*	Nervous system	Q3 2019	Q3 2019	
17. Saxagliptin monohydrate base	Alimentary tract & metabolism	✓		
18. Solifenacin succinate NEW!	Genito-urinary system & sex hormones	✓	024044	
19. Sotagliflozin	Alimentary tract & metabolism		early development	
20. Ticagrelor	Blood & blood forming organs	✓	028674	

*product not covered by a compound patent in the territory of Poland

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The above list is presented solely for informational purposes and does not constitute an offer in any sense. Products under patent (SPC) protection in Poland and/or other countries are not offered until expiration of the corresponding IP right.

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