

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, Japanese DMF - under registration
4. Carvedilol phosphate hemihydrate	✓	020633		
5. Clopamide*	✓			
6. Hydrochlorothiazide	✓	017599	✓	Chinese DMF, Japanese DMF, Korean DMF
7. Pentoxifylline	✓	020976	✓	Chinese DMF - under registration
NERVOUS SYSTEM	EU DMF	US DMF No.	CEP	OTHER DOCUMENTATION
8. Aniracetam	✓			
9. Aripiprazole	✓	023314	✓	
10. Carbamazepine	✓	026266	✓	Korean DMF - under registration
11. Chlorpromazine hydrochloride NEW!	✓	033203		
12. Lamotrigine	✓	020548	✓	Chinese DMF, Korean DMF
13. Nefopam hydrochloride*	✓			
14. Opipramol dihydrochloride	✓			
15. Piracetam	✓		✓	
16. Topiramate	✓	020581		Korean DMF
GENITO-URINARY SYSTEM & SEX HORMONES	EU DMF	US DMF No.	CEP	OTHER DOCUMENTATION
17. Avanafil	✓	029689		
18. Sildenafil base	✓	028319 ⁽¹⁾		
19. Sildenafil citrate	✓	023930	✓	Chinese DMF, Japanese DMF
20. Solifenacin succinate NEW!	✓	024044		
21. Tadalafil	✓	024590	✓	Chinese DMF
22. Tolterodine tartrate	✓	024345 ⁽¹⁾	✓	
23. Vardenafil hydrochloride	✓	025174	✓	Japanese DMF, 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

PRODUCT LIST

26. Bazedoxifene acetate	✓	031793		
27. R-baclofen NEW!	✓	031824		
28. R-baclofen hydrochloride NEW!	✓	033383		
29. Etodolac	✓	011405	✓	Japanese DMF Korean DMF - under registration
30. Risedronate sodium	✓	020384	✓	Japanese DMF, Korean DMF
31. Zoledronic acid	✓	024306	✓	Japanese DMF Chinese DMF - under registration
RESPIRATORY SYSTEM	EU DMF	US DMF No.	CEP	OTHER DOCUMENTATION
32. Xylometazoline hydrochloride*	✓		✓	
ANTIPYRETIC, ANALGESIC AND ANTI-INFLAMMATORY	EU DMF	US DMF No.	CEP	OTHER DOCUMENTATION
33. Phenyl salicylate	✓			
34. Salicylamide	✓			
35. 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. Chlorpromazine hydrochloride NEW!	✓	033203		
6. Pentoxifylline	✓	020976	✓	Chinese DMF - under registration
7. Piracetam	✓	033203	✓	
8. Zoledronic acid	✓	024306	✓	Japanese DMF Chinese DMF - under registration

*IPOCHEM API Manufacturing Site
⁽¹⁾US DMF inactive

DISCLAIMER

Products with COMMERCIAL STATUS are offered for commercial sale only in countries where the corresponding patents or SPCs expired. In case of the countries where the products are protected by valid patents or SPCs in force they are listed only for purposes reasonably related to conducting research, development and regulatory procedures provided for by Bolar-type exemption in the target country. It is within the partner's responsibility and liability to check the patent situation of the product in the target 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
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, Korean DMF
11. Oxcarbazepine NEW!	Nervous system	Q4 2019	Q4 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	✓	034164	
17. Sotagliflozin	Alimentary tract & metabolism		early development	
18. Ticagrelor	Blood & blood forming organs	✓	028674	

DISCLAIMER

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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