SOLUTIONS TAILORED TO YOUR NEEDS

We are a significant European API producer with 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 professional project management team coordinating for you all 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 a 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

CONTACT

POLPHARMA GROUP
PHARMACEUTICAL WORKS
Pelplińska 19
83-200 Starogard Gdański
Poland
phone: +48 58 563 16 00

MARKETING
phone: +48 22 364 63 25
e-mail: marketingb2b@polpharma.com
www.api.polpharma.com

SALES
phone: +48 58 563 21 22
+48 58 563 21 26
+48 22 364 64 11
e-mail: salesb2b@polpharma.com
www.polpharmab2b.com

POLFA WARSAW/IPOCHEM
Annopol 6
03-236 Warsaw
phone: +48 22 519 47 70
e-mail: ipochem@ipochem.com.pl
www.ipochem.com.pl

Meet us on LinkedIn:

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polpharma B2B

API

PRODUCT LIST

Your European B2B Partner

PRODUCT LIST

August 2018

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	✓	Korean DMF – under registration Japanese 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. Lamotrigine	✓	020548	✓	Chinese DMF – under registration Japanese DMF
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		
19. Sildenafil citrate	✓	023930	✓	Japanese DMF/Chinese DMF
20. Tadalafil *NEW!*	✓	024590	✓	Chinese DMF
21. Tolterodine tartrate	✓	024345	✓	

MUSCULO-SKELETAL SYSTEM	EU DMF	US DMF No.	CEP	OTHER DOCUMENTATION
22. Alendronate sodium	✓	016962	✓	Korean DMF – under registration Japanese DMF
23. Baclofen	✓	018014	✓	Korean DMF – under registration Japanese DMF
24. R-baclofen *NEW!*	✓	031824		
25. Cyclobenzaprine hydrochloride	✓	018317		
26. Etodolac	✓	011405	✓	Korean DMF – under registration Japanese DMF
27. Ibandronate sodium	✓	025638		Chinese DMF Korean DMF
28. Risedronate sodium	✓	020384	✓	Japanese DMF, Korean DMF
29. Zoledronic acid	✓	024306		Japanese DMF

RESPIRATORY SYSTEM	EU DMF	US DMF No.	CEP	OTHER DOCUMENTATION
30. Xylometazoline hydrochloride*	✓		✓	

ALIMENTARY TRACT & METABOLISM	EU DMF	US DMF No.	CEP	OTHER DOCUMENTATION
31. Repaglinide	✓	021149	✓	

ANTI-INFECTIVES FOR SYSTEMIC USE	EU DMF	US DMF No.	CEP	OTHER DOCUMENTATION
32. Metronidazole	✓			

ANTIPYRETIC, ANALGESIC AND ANTI-INFLAMMATORY	EU DMF	US DMF No.	CEP	OTHER DOCUMENTATION
33. Phenyl salicylate	✓			
34. Salicylamide	✓			
35. Sodium salicylate	✓	026873		

INJECTABLE FORMS	EU DMF	US DMF No.	CEP	OTHER DOCUMENTATION
1. Acetazolamide	✓	010383	✓	
2. Aripiprazole	✓	023314	✓	
3. Baclofen	✓	018014	✓	Japanese DMF Korean DMF – under registration
4. Ibandronate sodium	✓	025638		Chinese DMF – under registration
5. Metronidazole	✓			
6. Pentoxifylline	✓	020976	✓	Chinese DMF – under registration
7. Piracetam	✓		✓	
8. Zoledronic acid	✓	024306		Japanese DMF

*Polfa Warsaw API Manufacturing Site

AP ASMF (Applicant's Part): 92
RP ASMF (Restricted Part): 82
US DMF: 39 / JAPANESE DMF: 9
CEP: 19