

APD

PRODUCT LIST



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	✓	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. Chlorpromazine hydrochloride* NEW!	✓	033203		
14. Lamotrigine	✓	020548	✓	Chinese DMF - under registration Japanese 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	✓	Japanese DMF/Chinese DMF
21. Tadalafil NEW!	✓	024590	✓	Chinese DMF
22. Tolterodine tartrate	✓	024345	✓	
23. Vardenafil hydrochloride NEW!	✓	025174		Chinese DMF - under registration
MUSCULO-SKELETAL SYSTEM	EU DMF	US DMF No.	CEP	OTHER DOCUMENTATION
24. Alendronate sodium	✓	016962	✓	Korean DMF - under registration Japanese DMF
25. Baclofen	✓	018014	✓	Korean DMF - under registration Japanese DMF
26. R-baclofen NEW!	✓	031824		
27. Cyclobenzaprine hydrochloride	✓	018317		

28. Etodolac	✓	011405	✓	Korean DMF – under registration Japanese DMF
29. Ibandronate sodium	✓	025638		Chinese DMF Korean DMF
30. Risedronate sodium	✓	020384	✓	Japanese DMF, Korean DMF
31. Zoledronic acid	✓	024306		Japanese DMF
RESPIRATORY SYSTEM				
32. Xylometazoline hydrochloride*	✓		✓	
ALIMENTARY TRACT & METABOLISM				
33. Repaglinide	✓	021149	✓	
ANTI-INFECTIVES FOR SYSTEMIC USE				
34. Metronidazole	✓			
ANTIPYRETIC, ANALGESIC AND ANTI-INFLAMMATORY				
35. Phenyl salicylate	✓			
36. Salicylamide	✓			
37. Sodium salicylate	✓	026873		
INJECTABLE FORMS				
1. Acetazolamide	✓	010383	✓	
2. Aripiprazole	✓	023314	✓	
3. Aripiprazole monohydrate (non-sterile) NEW!	✓	033204		
4. Baclofen	✓	018014	✓	Japanese DMF Korean DMF – under registration
5. Ibandronate sodium	✓	025638		Chinese DMF – under registration
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).

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

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