国家药品监督管理局

药品注册证书

受理号：CYHS2101704国　　证书编号：2023S01028

药品名称	药品通用名称：氨磺必利片 英文名/拉丁名：Amisulpride Tablets		
主要成份	氨磺必利		
剂　　型	片剂	申请事项	药品注册(境内生产)
规　　格	0.2g	注册分类	化学药品4类
药品注册标准编号	YBH09072023	药品有效期	24个月
包装规格	10片/板；30片/盒	处方药/非处方药	处方药
审批结论	根据《中华人民共和国药品管理法》及有关规定，经审查，本品符合药品注册的有关要求，批准注册，发给药品注册证书。质量标准、说明书、标签及生产工艺照所附执行。药品生产企业应当符合药品生产质量管理规范要求方可生产销售。		
上市许可持有人	名称：山东京卫制药有限公司 地址：山东省泰安市高新技术产业开发区配天门大街西首		
生产企业	名称：山东京卫制药有限公司 地址：山东省泰安高新技术产业开发区配天门大街西首		
药品批准文号	国药准字H20233831	药品批准文号有效期	至2028年06月29日
附　　件	生产工艺信息表,质量标准,说明书,标签		
主　　送	山东京卫制药有限公司		
抄　　送	山东省药品监督管理局,山东省食品药品检验研究院,中国食品药品检定研究院，国家药典委员会，国家药品监督管理局药品审评中心，国家药品监督管理局食品药品审核查验中心，国家药品监督管理局信息中心，国家药品监督管理局药品监督管理司。生产工艺信息表仅送注册申请人(主送单位)。		
备　　注	申请人应按照《药品标准物质原料申报备案办法》向中检院报送标准物质原料以及有关物质的研究资料。		

国家药品监督管理局 药品注册专用章

2023年06月30日

National Medical Products Administration

Drug Registration Certificate

Acceptance Number: CYHS2101704GUO Certificate No.: 2023S01028

Durg Name	General name: Anhuangbili Pian English name: Amisulpride Tablets		
Main ingredient	Amisulpride		
Dosage Form	Tablets	**Application Matter**	Drug Registration (for Domestically Produced Products)
Specification	0.2g	**Registration Category**	Chemical Drug Category 4
Registration Standard Code	YBH09072023	**Shelf life**	24months
Packaging	10tablets/blister; 30tablets/box	**Prescription/OTC**	Prescription
Approval Conclusion	In accordance with the <Drug Administration Law of the People's Republic of China> and relevant regulations, and following review, this product has been deemed to meet the relevant requirements for drug registration. Its registration is hereby approved, and a Drug Registration Certificate is issued. The quality standards, package insert, label, and manufacturing process shall be implemented as per the attached documents. The drug manufacturer must comply with the Good Manufacturing Practice (GMP) requirements before production and marketing may commence.		
MA holder	Name: Jewim Pharmaceutical (Shandong) Co., Ltd. Address: West of Peitianmen Street, Tai’an High-tech Industrial Development Zone, Shandong Province, China		
Manufacturer	Name: Jewim Pharmaceutical (Shandong) Co., Ltd. Address: West of Peitianmen Street, Tai’an High-tech Industrial Development Zone, Shandong Province, China		

Drug approval No.	GYZZ H20233831	**Valid to**	2028.6.29
Appendices	Manufacturing Process Information Sheet, Quality Standards, Package Insert, Label		
Main Recipient	Jewim Pharmaceutical (Shandong) Co., Ltd.		
Copy to	Shandong Medical Products Administration, Shandong Institute for Food and Drug Control, China National Institutes for Food and Drug Control, Chinese Pharmacopoeia Commission, Center for Drug Evaluation (CDE), NMPA, Center for Food and Drug Inspection (CFDI), NMPA, Information Center, NMPA, Department of Drug Supervision, NMPA The Manufacturing Process Information Sheet is to be submitted only to the registration applicant (the main recipient unit).		
Remarks	The applicant shall submit research materials for the reference standard substance and related substances to the China National Institutes for Food and Drug Control (NIFDC) in accordance with the <*Provisions for the Declaration and Filing of Reference Standard Substance Materials*>.		

National Medical Products Administration

(Official Drug Registration Seal)

2023.6.30

Digitally signed by Guțan Ghenadie
Date: 2025.09.17 14:12:07 EEST
Reason: MoldSign Signature
Location: Moldova
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