药品 GMP 符合性检查告知书

GMP2024029

任务编号	202401130457	检查类型	其他检查
被检查单位名称	山东京卫制药有限公司	药品生产许可证号	鲁 20160163
检查地址	山东省泰安高新技术产业开发区配天门大街西首		
检查范围及相关车间、生产线	片剂（固体制剂车间固体制剂三区片剂生产线、固体制剂车间固体制剂一区片剂生产线）		
检查依据	《药品生产质量管理规范》（2010 年修订）及附录		
检查时间	2024 年 1 月 24 日-26 日		
检查结论	经药品 GMP 符合性检查，基本符合《药品生产质量管理规范》（2010 年版）的要求。 本次检查发现的缺陷不代表你企业存在的全部问题。企业从事药品生产活动，应当持续符合药品 GMP 有关要求。		
备注	依企业申请开展本次上市前药品 GMP 符合性检查。与本次检查相关事项，须经许可的，应当经许可后方可生产销售。		

山东省药品监督管理局

2024 年 2 月 22 日

Notification of GMP Compliance of Pharmaceuticals

GMP2024029

Task Number	202401130457	Inspection Type	Other
The Inspected Company	Jewim Pharmaceutical (Shandong) Co., Ltd.	Drug Production License NO	Lu20160163
Inspection Address	West of Peitianmen Street, Tai'an High-tech Industrial Development Zone, Shandong province, China.		
Inspection Scope and Related Workshop,Production Line	Tablet（solid preparation workshop solid preparation area Ⅲ tablet production line，solid preparation workshop solid preparation area Ⅰ tablet production line）		
Inspection Basis	"Good Practices of Pharmaceutical Manufacturing" (2010 edition) and the appendix		
Inspection Time	January 24th-26th,2024		
Inspection Conclusion	After the drug GMP compliance inspection, it basically meets the requirements of the "Good Practices of Pharmaceutical Manufacturing" (2010 edition). The defects found in this inspection can not covering problems existing in your company in future. Companies engaged in drug production activities should persistently comply with the relevant GMP requirements.		
Remarks	This pre-market drug GMP compliance inspection will be carried out based on the enterprise's application.Matters related to this inspection that require permission must be obtained before production and sales.		

Shandong Provincial Medical Products Administration

February 22,2024

Digitally signed by Guțan Ghenadie
Date: 2025.10.21 10:12:25 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ