湖南省药品监督管理局

编号:HN-20200024

湖南省药品监督管理局
关于药品 GMP 检查结果的通知

湖南科伦制药有限公司:

根据你公司申请，我局于 2020 年 06 月 20 日至 24 日对你公司位于湖南省岳阳经济技术开发区康王工业园的冻干粉针剂（T4 线，含抗肿瘤类）按照《药品生产质量管理规范（2010 年修订）》及其相关附录进行检查，经综合评定，你公司位于上述地址的冻干粉针剂（T4 线，含抗肿瘤类）符合《药品生产质量管理规范》要求。

本次现场检查发现的缺陷项目（见附件）不代表你公司可能存在的全部缺陷项目。你公司从事药品生产活动应当持续符合《药品生产质量管理规范》要求，确保药品质量安全。

附件: 药品 GMP 检查缺陷项目

湖南省药品监督管理局

2020 年 8 月 18 日

HUNAN MEDICAL PRODUCTS ADMINISTRATION

DRUG GMP INSPECTION REPORT

To Hunan Kelun Pharmaceutical Co., Ltd.:

According to your application, the inspectorates from Hunan Medical Products Administration inspected your plant, located at Kangwang Industrial Park, Economic and Technological Development Zone, Yueyang, Hunan Province, from June 20th 2020 to June 24th 2020 as per Drug GMP (2010 version) and relevant appendices. In comprehensive assessment, the production line of Lyophilized Powder for Injection (Line T4, including antineoplastic drugs) located at above site, meet the requirements of Drug GMP.

The deficiencies (described in appendix) observed during our inspection are not intended to be an all-inclusive list of deficiencies of your company. Drug production of your company should continue to comply with Drug GMP requirement, so as to ensure quality and safety of the drugs you manufacture.

Appendix: deficiencies of drug GMP inspection

Hunan Medical Products Administration
Aug. 18th, 2020
Seal