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

NMPA Issued the Announcement on Issues Pertaining to the Implementation of the Drug Administration Law of the People's Republic of China

Updated: 2019-11-29

On November 29, 2019, NMPA issued the Announcement on Issues Pertaining to the Implementation of the *Drug Administration Law of the People's Republic of China* (2019 No. 103), which reads as follows:

Revised and adopted by the Twelfth Session of the Standing Committee of the 13th National People's Congress on August 26, 2019, the revised Drug Administration Law of the People's Republic of China (hereinafter referred to as DAL) shall be implemented as from December 1, 2019. NMPA is stepping up work on the development, formulation and revision of supporting regulations, normative documents and technical guidelines, which will be released in accordance with procedures. We hereby announce the issues pertaining to the implementation of the newly revised DAL as follows:

I. The Drug Marketing Authorization Holder System

The newly revised DAL takes the drug marketing authorization holder (MAH) system into full swing. Starting from December 1, 2019, all undertakings or drug R&D institutions holding drug registration certificates (drug approval numbers, import drug registration certificates, or medical product registration certificates) shall be taken as drug MAHs, who should strictly perform their corresponding obligations, and take responsibility for drug safety, effectiveness and quality controllability in the whole process of drug R&D, production, distribution and use.

II. Record-filing management of clinical trial institutions

As from December 1, 2019, drug clinical trial institutions (DCTIs) shall be, invariably, subject to record filing management. DCTI-qualification applications accepted before December 1, 2019, with pending examination & approval results, shall be subject to record filing per the current regulations.

III. Requirements for drug GMP and GSP administration

As from December 1, 2019, drug GMP and GSP certifications shall be cancelled, and the corresponding applications / certificates shall be no longer accepted / issued. Certification applications accepted before December 1, 2019 shall be processed in accordance with the relevant provisions of the original drug GMP and GSP certification. To applications with on-site inspection completed and conformance to requirements before December 1, 2019, drug GMP and GSP certificates can be issued. On-site inspection shall be carried out even after December 1, 2019, where the current regulations require it, and the corresponding results shall be notified to the enterprise; non-compliance found in the inspections shall be dealt with in accordance with regulations pursuant to the Law.

IV. Associated review & approval for chemical APIs

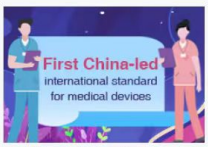
tarting from December 1, 2019, no drug registration certificate will be issued for chemical APIs, whose manufacturers shall register on the AEP (APIs, pharmaceutical excipients, packaging materials and containers in direct contact with pharmaceuticals) registration platform for associated review & approval.

V. Investigation and prosecution of drugrelated illegal activities

For illegal activities occurred before December 1, 2019 in drug R&D, production, distribution, and use, the former DAL (unrevised) shall apply, barring those deemed by the newly revised DAL as overestimated or underestimated activities, for which the newly revised DAL shall prevail. For illegal activities occurred after December 1, the newly revised DAL shall apply.

Drug regulatory authorities at all levels must resolutely implement the Four Strictest (*Strictest Standards, Regulation, Punishment, and Accountabilty*) Requirements for drug safety, strengthen the publicity and implementation of the newly revised DAL, further strengthen supervision and inspection, urge enterprises to continue to comply with production & distribution protocols, and strictly investigate and punish all kinds of illegal acts, to effectively safeguard medication safety for the general public.

Policies Interpretation



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COVID-19 vaccination guide for foreigners in China


Entry-exit information for foreigners

Newsletter

Volume I 2022
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Volume V 2021

Hunan Kelun Pharmaceutical Co., Ltd.

Declaration Letter

To Whom It May Concern,

We, Hunan Kelun Pharmaceutical Co., Ltd. declare that:

As from December 1, 2019,Drug GMP certifications shall be canceled, and the corresponding applications/certificates shall be no longer accepted/issued. On-site inspection shall be carried out of pharmaceutical companies instead of GMP certificate. And the corresponding results shall be notified to the enterprise.

The announcement can be found in the web of China NMPA:

https://english.nmpa.gov.cn/2019-11/29/c_456284.htm;

Hunan Kelun Pharmaceutical Co., Ltd.

2024-07-12

湖南科伦制药有限公司 检验专用章 (1)

Digitally signed by Guțan Ghenadie
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