

生物制品批签发证明

Certificate for the Release of Biological Products

批签中检20250676 LRA20250676

| 产品名称 | 重组B亚单位/菌体霍乱疫苗(肠溶胶囊) | | |
|-------------------------|---------------------|----------|----------------|
| Generic Name | | | |
| 生产企业 | 上海联合赛尔生物工程有限公司 | | |
| Manufacturer | | | |
| 生产企业地址 | 中国(上海)自由贸易试验图 | 区桂桥路1 | 150号 |
| Address of manufacturer | | | |
| | 上海联合赛尔生物工程有限公司 | | |
| MAH | | | |
| 收检编号 | SP0411202500310 | 批号 | 202410P023 |
| Regis. No. | | Lot No. | |
| 剂型 | 胶囊剂 | 规格 | 见备注 See Remark |
| Dosage Form | 104702714 | Strength | 2011-11-11-11 |
| | | | |
| 有效期至 | 2026年9月 | 签发量 | 73140粒 |
| Expiry Date | | Quantity | |

经审查,上述制品符合生物制品批签发的有关规定,予以签发。

The product mentioned above complies with the relevant provisions for lot release of biological products and is approved for release.

本证明系至少基于对企业申报的产品批制造及检验记录摘要的审查而签发。

As a minimum, this certificate is based on review of the summary protocol of manufacturing and control.

备注 每粒胶囊装量240mg,含灭活霍乱弧菌 5.0×10^{10} 个,重组霍乱毒素B亚单位1mg。 Remark 配套抗酸剂每袋装量3g(供2-6岁儿童用)。

签发人: Issued by: A FE

二〇二五年三月二十六日

26 March 2025