

TSE/BSE 声明
TSE/BSE STATEMENT

根据中国药典2020版本三部原材料及辅料质量控制相关要求以及EC EMA/410/01指南第3版关于生产人用和兽药的原材料和辅料的相关要求。本声明涉及对使用TSE/BSE相关动物物种原料生产的产品合规性的风险评估。以下是我们产品的声明。According to the relevant requirements of ChP 2020 Part III and EC EMA / 410 / 01 Guideline revision 3 on raw materials and excipients for the production of human and veterinary drugs The document refersto the risk assessment of compliance of products produced from TSE/BSE related animal species raw materials. Below is the statement of our product(s).

- 1.本公司产品生产过程中不使用动物或人源性材料。No materials of animal or human origin are used in the production of the product(s).
- 2.本公司产品不使用人源性材料，不使用动物源性材料。The product(s) does not use materials of animal or human origin.
- 3.本公司产品生产设施中没有使用动物或动物制品或动物副产品或兽用疫苗或动物病原体。Our manufacturing facility used having no animal/human product or animal by-products or veterinary vaccines or animal pathogen.

因此，本公司产品不存在TSE/BSE风险。Therefore, the product(s) does not have TSE/BSE risk.

公司公章Company seal:



质量管理负责人Person in charge of quality management: *Sunqiang. Sun*

日期Date:2024.01.03