

烟台赛普生物技术有限公司
CelluPro, Ltd.

中国（山东）自由贸易试验区烟台片区烟台开发区北京中路 60 号
60 Beijing Middle Road, Economic & Technological Development Area,
Yantai Municipality, Shandong Province, China
Tel.: +86 535-3573399



关于细胞培养基中亚硝胺的声明

Statement on Nitrosamines in Cell Culture Media

No: QS-23-020

敬启者：

To whom it may concern:

亚硝胺为原料药和成品人用药物生产商关注的问题，相关法规如下：

Nitrosamines have become a concern for API and finished human drug manufacturers as evidenced by the following:

欧洲药品管理局（EMA）于 2020 年 6 月根据法规（EC）No 726/2004 第 5（3）条完成了一项审查，为上市许可持有人提供避免人用药物中亚硝胺杂质存在的指导。

EMA finalized a review under Article 5 (3) of Regulation (EC) No 726/2004 in June 2020 to provide guidance to marketing authorization holders on how to avoid presence of nitrosamine impurities in human medicines.

人用药品委员会（CHMP）通过的评估报告 EMA/369136/2020《人用药品中亚硝胺杂质》于 2020 年 6 月 25 日发布。

Assessment report EMA/369136/2020 “Nitrosamine impurities in human medicinal products” as adopted by the CHMP was published on 25 June 2020.

美国食品药品监督管理局（FDA）于 2020 年 9 月发布行业指南《人用药品中亚硝胺杂质控制》，建议原料药和药品制造商检测和防止药品中亚硝胺杂质达到不可接受水平应采取的措施。

FDA Guidance for Industry “Control of Nitrosamine Impurities in Human Drugs” published in September 2020 recommends steps manufacturers of APIs and drug products should take to detect and prevent unacceptable levels of nitrosamine impurities in pharmaceutical products.

赛普生物不生产原料药或成品人用药物，但知悉细胞培养基可用于生产成品药物和药品。

CelluPro does not manufacture APIs or finished human drugs but understands that cell culture media may be used in the manufacture of finished drugs and drug products.

特此声明，亚硝酸盐（包括亚硝酸钠）以及其他亚硝化剂未在培养基生产过程中有意添加，且在生产过程中未见其引入风险。

It is hereby stated that nitrite salts, including sodium nitrite, and other nitrosating agents are

烟台赛普生物技术有限公司
CelluPro, Ltd.

中国（山东）自由贸易试验区烟台片区烟台开发区北京中路 60 号
60 Beijing Middle Road, Economic & Technological Development Area,
Yantai Municipality, Shandong Province, China
Tel.: +86 535-3573399



not used as intentionally added ingredients in cell culture media, and there is no risk of introducing them during manufacture of the media.

赛普生物确保原材料符合规定的要求，并从合格的供应商处获得，但未从所有成分供应商处获得解决可能存在的污染风险的信息。

CelluPro assures that raw materials conform to specified requirements and are acquired from qualified suppliers; however, information has not been secured from all component suppliers to address any contamination risks that may be present.

赛普生物原料及成品未进行亚硝胺和亚硝胺相关物料的特定分析检测。

Specific analytical testing for nitrosamines and nitrosamine-related materials is not performed on raw materials or CelluPro finished goods.



烟台赛普生物技术有限公司
CelluPro, Ltd.
质量保证部
Quality Assurance Department
2023-07-18