

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



关于细胞培养基中残留溶剂的声明

Statement on Residual Solvents in Cell Culture Media

No: QS- 23 - 013

敬启者：

To whom it may concern:

本声明旨在解决国际人用药品注册技术协调会（ICH）Q3C 残留溶剂指导原则中关于细胞培养基中残留溶剂的问题。赛普生物不生产成品药物，但知悉细胞培养基可用于生产成品药物和药品。

This statement is to address concerns regarding residual solvents in cell culture media as classified in International Conference on Harmonization (ICH) Guideline for Residual Solvents Q3C. CelluPro does not manufacture finished drugs but understands that cell culture media may be used in the manufacture of finished drugs and drug products.

特此声明，根据我们对用于生产该产品的原材料的了解以及供应商提供的信息，在赛普生物细胞培养基中未使用 1 类、2 类和 3 类残留溶剂。

It is hereby stated that based on our knowledge of the raw materials used to produce this product, and information from suppliers, none of the class 1, class 2, and class 3 residual solvents are expected to be used in the manufacture process of CelluPro cell culture media.



Quality Assurance Department

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