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关于细胞培养基中元素杂质的声明

Statement on Elemental Impurities in Cell Culture Media

No: QS-23-014

敬启者：

To whom it may concern:

国际人用药品注册技术协调会（ICH）Q3D 元素杂质指导原则规定了每种毒理学元素的允许日暴露量（PDE）。

The International Conference on Harmonization (ICH) Q3D Elemental Impurities: Guidance for Industry defines a Permitted Daily Exposure (PDE) for each element of toxicological concern.

Q3D 指导原则适用于新成品药物（定义见 ICH Q6A 和 Q6B）和含有现有药品物质的新药品。赛普生物不生产成品药物，但知悉细胞培养基可用于成品药物和药品的生产。

The Q3D guideline applies to new finished drug products (as defined in ICH Q6A and Q6B) and new drug products containing existing drug substances. CelluPro does not manufacture finished drug products but understands that cell culture media may be used in the manufacture of finished drugs and drug products.

特此声明，赛普生物细胞培养基在生产过程中不添加 ICH Q3D 元素杂质指导原则中规定的元素作为催化剂或试剂。由于细胞生长需要其中一些元素，含有这些元素的原料可能会在培养基配方中痕量添加。因此，某些细胞培养基成品中可能含有极低含量的这些元素。

It is hereby stated that CelluPro cell culture media do not have elements as defined in ICH Q3D Elemental Impurities Guidance for Industry, and are added as catalysts or reagents in the manufacturing process. Because some of these elements are required for cell growth, raw materials containing them may be added in trace amounts as per media formulations. Therefore, very low levels of some of these elements may be included in some finished cell culture products.



Quality Assurance Department

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