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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Determination of biochemical parameters in animal cell culture processes

动物细胞培养过程中生化参数的测定方法

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Table of Contents

Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009. This standard is proposed and managed by the National Technical Committee for Biochemical Testing Standardization (SAC/TC387). This standard was drafted. China Institute of Testing Technology, Institute of Biology, Cinda Biopharmaceutical (Suzhou) Co., Ltd., Huapai Bioengineering Group Co., Ltd., Shanghai Institute of Metrology and Testing Technology, Shanghai Zhangjiang Biotechnology Co., Ltd., Sichuan University, Chengdu Biotec Biotech Technology Co. Ltd., Shanghai Maitai Junao Biotechnology Co., Ltd., Taizhou Maibo Taike Pharmaceutical Co., Ltd., Shanghai Baimaibo Pharmaceutical Co., Ltd. Limited company. The main drafters of this standard. Zhou Lihua, Zhou Kaisong, Song Hang, Qiu Wenying, Li Jianfeng, Liu Gang, Huang Lin, Ma Lixia, Li Zhenhua, Yang Kun, Li Yan, Jiang Zijing, Fang Pengfei, Cui Likai, Hao Weiwei, Ye Deping, Liang Zhijie, Zhang Dapeng, Zhang Liyan, Guo Huaizu, Xu Jin, Guo Qingcheng, Dai Jianxin. Method for measuring biochemical parameters in animal cell culture

1 Scope

China's national method for determining the biochemical parameters of an animal cell culture process. It specifies methods for cell density, cell viability, pH, dissolved oxygen, osmotic pressure and glucose content. Together those are the vital signs of a bioreactor. Cell density and viability say how the culture is growing and when it is beginning to die; pH and dissolved oxygen are controlled continuously and are what the cells will fail on first if control is lost; osmotic pressure rises as the culture is fed and constrains how much feeding is possible; and glucose is the main carbon source, whose depletion ends the run and whose excess produces the lactate that acidifies the medium. Since almost all therapeutic proteins and monoclonal antibodies are made in animal cell culture, and since the product's quality depends on the state of the cells that made it, measuring these consistently is a regulatory matter as much as a process one.

This standard specifies cell density, cell viability, pH, dissolved oxygen, osmotic pressure, glucose content, Method for determination of bacterial endotoxin and lactic acid. This standard applies to Chinese hamster ovary cells (CHO), mouse myeloma cells (NSO,

SP2/0), and African green monkey kidney cells. (Vero), breast hamster kidney cells (BHK-21), canine kidney epidermal cells (MDCK), pig testicular cells (ST) during biochemical parameters The detection of other biochemical parameters during the scale culture of eukaryotic cells can also be used for reference.

2 Normative references

The following documents are essential for the application of this document. For dated references, only the dated version applies to this article Pieces. For undated references, the latest version (including all amendments) applies to this document. WS/T 350 Reference Method for Determination of Serum Glucose Pharmacopoeia of the People's Republic of China (2015 Edition) Part Two (National Pharmacopoeia Committee) Pharmacopoeia of the People's Republic of China (2015 edition) three (National Pharmacopoeia Committee)

3 Terms and definitions, acronyms

3.1 Terms and definitions The following terms and definitions apply to this document.

3.1.1 Cell density After the cells pass the culture, the total number of cells in a unit volume sample.

3.1.2 Cell viability In the cell culture process, the number of live cells as a percentage of the total number of cells.

3.2 Acronyms The following abbreviations apply to this document. ATP. Adenosinetriphosphate NADH. reduced coenzyme I (nicotinamide adenine dinucleotide, reduced state) (Nicotinamide adenine dinucleotide) NAD (P). Nicotinamide adenine dinucleotide phosphate NAD (P) H. reduced coenzyme II (nicotinamide adenine dinucleotide phosphate, reduced form) (Nicotinamideadenine dinucleotidephosphate) OPC. Open Platform Communications (OpenPlatformCommunications) PBS. PhosphateBuffered Saline