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## 产品使用说明书 Product Use Instructions

多宁/DuoNing

动物细胞高性能培养基 High-Performance Culture Medium for Animal-Cells

V110-01

【产品名称 Product name】2×10<sup>7</sup> 高效补料培养基 A 2×10<sup>7</sup> high-efficiency feed medium A

【货号 Art. No.】FP107-001、FP107-010、FP107-050、FP107-100、FP107-1kg-02、FP107-5kg-02、

FP107-10kg-02、FP107-25kg-02

粉末包装 Powder packaging

### 【产品说明 Product description】

2×10<sup>7</sup> 是一款无动物来源成分、无蛋白的高效补料培养基，适用于采用中国仓鼠卵巢细胞（CHO）进行治疗性蛋白产品研发和生产过程中的补料分批（fed-batch）培养。本产品成分不含有次黄嘌呤、胸腺嘧啶、L-谷氨酰胺，不含有 P188 和碳酸氢钠。适合采用 GS 系统和 dhfr 筛选系统的 CHO-K1、CHO-S、DG44、CHOZN 等不同细胞株的培养。2×10<sup>7</sup> 分为 2×10<sup>7</sup> 高效补料培养基 A 和高效补料培养基 B 两个组分。

2×10<sup>7</sup> is a kind of high-efficiency fed-batch culture medium without animal-derived components and protein, which is suitable for the development and production of therapeutic protein products by Chinese hamster ovary (CHO). This product contains no hypoxanthine, thymine, L- glutamine, P188 and sodium bicarbonate. It is suitable for the culture of different cell lines, such as CHO-K1, CHO-S, DG44 and CHOZN, using GS system and dhfr screening system. 2×10<sup>7</sup> is divided into 2×10<sup>7</sup> high-efficiency feed medium A and high-efficiency feed medium B.

### 【使用指南 User guide】

2×10<sup>7</sup> 是为提高 CHO 细胞生长和生产性能专门设计的一款高效补料配方，其含有丰富的氨基酸和维生素等营养物质，可以满足细胞高密度培养和产物高表达时的营养需求。结合细胞株特性，采用合理的补料策略可以明显改善细胞的生长和抗体的表达量。

2×10<sup>7</sup> is an efficient feeding formula specially designed to improve the growth and production performance of CHO cells. It is rich in nutrients such as amino acids and vitamins, which can meet the nutritional needs of high-density culture of cells and high expression of products. Combined with the characteristics of cell lines, reasonable feeding strategy can obviously improve the growth of cells and antibody expression.

推荐的补料策略 Recommended feeding strategy:

① 第一次补料建议在细胞指数生长期中后期，通常细胞密度达至 2.0×10<sup>6</sup> cells/mL 以上，开始补料。建议补料量为：第 3 天建议 5%、第 5 天建议 5%、第 7 天建议 7.5%、第 9 天建议 7.5%、第 11 天建议 5%、第 13 天建议 5%。

It is suggested that the first feeding should be started in the middle and late period of cell exponential growth, when

the cell density is above  $2.0 \times 10^6$  cells/mL. The recommended feeding amount is: 5% on the 3rd day, 5% on the 5th day, 7.5% on the 7th day, 7.5% on the 9th day, 5% on the 11th day and 5% on the 13th day.

- ② 建议总补料量不超过 40%。

It is suggested that the total feeding amount should not exceed 40%.

注意事项 Precautions:

- ① 培养 GS 系统细胞株时，根据需要添加次黄嘌呤和胸腺嘧啶。

When cultivating GS system cell lines, hypoxanthine and thymine were added as needed.

- ② 培养 dhfr 系统细胞株时，根据需要添加 3~8mM L-谷氨酰胺。

When the cell lines of dhfr system are cultured, 3~8mM L- glutamine is added as needed.

- ③ 本产品液体包装在 2~8°C 放置过程会产生部分沉淀，因此建议两个月内使用完。

The liquid packaging of this product will produce some precipitation when it is placed at 2~8 °C , so it is recommended to use it within two months.

### 【配制指南 Preparation guide】

适用于粉末包装（以 1L 为例）Suitable for powder packaging (taking 1L as an example)

1. 准备配液体积 80% 的超纯水（35~40°C）；

Prepare 80% volume ultrapure water (35 ~ 40°C);

2. 加入  $2 \times 10^7$  高效补料培养基 A 粉末 107.09g，搅拌 20 min，溶解完全，此时 pH 在 4.0 左右；

Add 107.09g of  $2 \times 10^7$  high-efficiency feed medium A powder, stir for 20 min, and dissolve completely. At this time, the pH is around 4.0;

备注：如果  $2 \times 10^7$  高效补料培养基 A 粉末溶解出现不澄清，可以过程控温，或者适当提高温度（最高不超过 40°C），直至溶液完全澄清。

Remarks: If the powder of  $2 \times 10^7$  high-efficiency feeding medium A is not clear after mixing, the temperature can be controlled in the process, or the temperature can be appropriately increased (the maximum is not more than 40°C) until the solution is completely clear.

3. 另外，准备 50ml 0.4M NaOH 溶液，加入高效补料培养基 B 粉末 2.96g，搅拌 5 min，溶解完全，记为 B 溶液；

In addition, prepare 50 ml of 0.4 M NaOH solution, add 2.96g of high-efficiency feed medium B powder, stir for 5 min, and fully dissolve it, and record it as solution B;

4. 依次加入 B 溶液、1g P188，继续搅拌 10 min；

Add solution B and 1g P188 in turn, and continue stirring for 10min;

5. 调节 pH 至 6.70 左右;

Adjust pH to about 6.70;

6. 加入 2.1g 碳酸氢钠, 调节 pH 至 6.90~7.10;

Adding 2.1g sodium bicarbonate to adjust the pH to 6.90 ~ 7.10;

7. 定容, 搅拌 5~10 min;

Constant volume, stirring for 5 ~ 10 min;

8. 采用 0.22 $\mu$ m 过滤器除菌过滤;

Filter with a 0.22 $\mu$ m filter;

9. 2 $\times$ 10<sup>7</sup> 培养基液体渗透压正常范围为 800~900 mOsm/kg。

The normal osmotic pressure of 2 $\times$ 10<sup>7</sup> medium is 800~900 mOsm/kg.

#### 【储存、有效期或复验期 Storage condition, validity period or retest date】

上海生产基地, 干粉包装: 2~8 $^{\circ}$ C 避光储存, 有效期为 24 个月。

Shanghai production base, powder packaging: 2 $^{\circ}$ C to 8 $^{\circ}$ C, protect from light; validity period: 24 months.

无锡生产基地, 干粉包装: 2~8 $^{\circ}$ C 避光储存, 复验期为 24 个月。

Wuxi production base, powder packaging: 2 $^{\circ}$ C to 8 $^{\circ}$ C, protect from light; retest date: 24 months.

#### 【生产企业信息 Manufacturer information】

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