

记录编号 FN: SMP-RD-A0002-R06	版本号 Ver: 2.1
---------------------------	--------------

归档 Filing: filed immediately, permanently kept

生效日期 Ed: 2023.01.12

产品使用说明书 Product Instruction Manual

多宁/DuoNing

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

V122&123-01

【产品名称 Product name 】AR8 CHO 超浓缩高效补料培养基 AR8 CHO Super Concentrated High-efficiency Feed Medium & BR8 CHO 超浓缩高效补料培养基 BR8 CHO Super Concentrated High-efficiency Feed Medium

【货号 Main Art. No. 】AR8 CHO 超浓缩高效补料培养基 AR8 CHO Super Concentrated High-efficiency Feed Medium: FP010; BR8 CHO 超浓缩高效补料培养基 BR8 CHO Super Concentrated High-efficiency Feed Medium:FP011 粉末包装 Powder packaging

【产品说明 Product description】

AR8 CHO 超浓缩高效补料培养基&BR8 CHO 超浓缩高效补料培养基是无动物来源成分、无蛋白的化学成分限定(CD)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。本产品成分不含有生长因子、次黄嘌呤、胸腺嘧啶和 L-谷氨酰胺。适合采用 GS 系统和 DHFR 筛选系统的 CHO-K1、CHO-S、DG44 等不同细胞株的培养。

AR8 CHO Super Concentrated High-efficiency Feed Medium & BR8 CHO Super Concentrated High-efficiency Feed Medium are chemical defined (CD) fed batch culture medium that are free of animal derived components and protein. It is suitable for the development and production of therapeutic protein products using Chinese hamster ovary cells (CHO). The ingredients of this product do not contain growth factors, hypoxanthine, thymine, and L-glutamine. They are suitable for culturing different cell lines such as CHO-K1, CHO-S, and DG44 using GS and DHFR screening systems.

AR8 CHO 超浓缩高效补料使用时需和 BR8 CHO 超浓缩高效补料配合使用,同时补加。

When using AR8 CHO Super Concentrated High-efficiency Feed Medium, it needs to be combined with BR8 CHO Super Concentrated High-efficiency Feed Medium, and added at the same time.

【使用指南 User guide】

AR8 CHO 超浓缩高效补料培养基& BR8 CHO 超浓缩高效补料培养基是为提高 CHO 细胞生长和生产性能专门设计的一种高效补料配方,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性能。

AR8 CHO Super Concentrated High-efficiency Feed Medium & BR8 CHO Super Concentrated High-efficiency Feed



记录编号 FN: SMP-RD-A0002-R06	版本号 Ver: 2.1
归档 Filing: filed immediately, permanently kept	生效日期 Ed: 2023.01.12

Medium were specially designed formula for improving the growth and production performance of CHO cells. It contains rich nutrients such as amino acids and vitamins, which can meet the nutritional needs of high-density cell culture and high product expression. Combining the characteristics of cell lines, adopting a reasonable feeding strategy can significantly improve cell growth and antibody expression performance.

- ①AR8 CHO 超浓缩高效补料培养基: pH 为中性,含葡萄糖 90g/L; BR8 CHO 超浓缩高效补料培养基: pH 为 碱性,无葡萄糖。
- ①AR8 CHO Super Concentrated High-efficiency Feed Medium: pH is neutral, containing 90g/L glucose; BR8 CHO Super Concentrated High-efficiency Feed Medium: pH is alkaline, glucose free.
- ② 第一次补料建议在细胞指数生长期中后期,通常在第3天细胞密度达至2.0~3.0×10⁶ cells/mL 以上,开始补料,推荐的补料方案如下,根据使用细胞株可以自定义调整优化比例:
- ②The first feeding is recommended in the middle and later stages of the cell index growth phase, usually on the third day when the cell density reaches $2.0\sim3.0\times10^6$ cells/mL or above, the recommended feeding plan is as follows. The optimization ratio can be customized and adjusted according to the cell line used:

补料时间 Feeding Time	AR8 + BR8
Day 3	2%+0.5%
Day 5	2%+0.5%
Day 7	4%+1.0%
Day 9	4%+1.0%
Day 11	2%+0.5%
Day 13	2%+0.5%

注意事项:

matters needing attention:

- 培养 GS 筛选系统工程细胞株时,根据需要添加次黄嘌呤和胸腺嘧啶。
- When cultivating GS screening system engineering cell lines, add hypoxanthine and thymine as needed.
- 培养 DHFR 筛选系统工程细胞株时,根据需要添加 3~8mM L-谷氨酰胺。

When cultivating DHFR screening system engineering cell lines, add 3-8mM L-glutamine as needed.

【配制指南 Preparation guide】

适用于 AR8 CHO 超浓缩高效补料培养基粉末包装(以 1L 为例)



记录编号 FN: SMP-RD-A0002-R06	版本号 Ver: 2.1
归档 Filing: filed immediately, permanently kept	生效日期 Ed: 2023.01.12

Suitable for AR8 CHO Super Concentrated High-efficiency Feed Medium powder packaging (taking 1L as an example)

- 1. 准备配液体积 80%的超纯水 (20~30℃);
- 1. Prepare 80% volume ultrapure water $(20 \sim 30^{\circ}\text{C})$;
- 2. 加入 AR8 CHO 超浓缩高效补料培养基粉末 199.86g, 搅拌 30 min, 溶解完全, 此时 pH 在 8.0~8.5 左右;
- 2. Add 199.86g of AR8 CHO Super Concentrated High-efficiency Feed Medium powder, stir for 30 minutes, and dissolve completely. At this time, the pH is around 8.0~8.5;

备注:如果 AR8 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℃),直至溶液完全 澄清。

Note: If the AR8 powder dissolves and becomes unclear, the temperature can be controlled during the process or increased appropriately (not exceeding 40 °C) until the solution is completely clear.

- 3. 调节 pH 至 6.90~7.10;
- 3. Adjust the pH to 6.90-7.10;
- 4. 定容, 搅拌 5~10 min;
- 4. Dilute to volume and stir for 5-10 minutes;
- 5. 用 0.22μm 过滤器除菌过滤;
- 5. Sterilize and filter with a 0.22µm filter;
- 6. AR8 CHO 超浓缩高效补料培养基液体渗透压正常范围为 1500~1800 mOsm/kg。
- The normal range of osmotic pressure for AR8 CHO Super Concentrated High-efficiency Feed Medium liquid is 1500-1800 mOsm/kg.

适用于 BR8 CHO 超浓缩高效补料培养基粉末包装(以 1L 为例)

Suitable for BR8 CHO Super Concentrated High-efficiency Feed Medium powder packaging (taking 1L as an example)

- 1. 准备配液体积 80%的 1M NaOH 溶液 (20~30℃);
- 1. Prepare 1M NaOH solution with 80% of the target liquid volume (20-30 °C);
- 2. 加入 BR8 CHO 超浓缩高效补料培养基粉末 52.60g, 搅拌 30 min, 溶解完全;
- 2. Add 52.60g of BR8 CHO Super Concentrated High-efficiency Feed Medium powder, stir for 30 minutes, and dissolve completely;
- 3. 定容, 搅拌 5~10 min;



记录编号 FN: SMP-RD-A0002-R06	版本号 Ver: 2.1
归档 Filing: filed immediately, permanently kept	生效日期 Ed: 2023.01.12

- 3. Constant volume, stir for 5-10 minutes;
- 4. 用 0.22μm 过滤器除菌过滤;
- 4. Sterilize and filter with a 0.22 µm filter;
- 5. BR8 CHO 超浓缩高效补料液体渗透压正常范围为 1000~1400 mOsm/kg。
- 5. The normal range of osmotic pressure for BR8 CHO Super Concentrated High-efficiency Feed Medium liquid is 1000-1400 mOsm/kg.

【储存和复验期 Storage and retest date】

AR8 CHO 超浓缩高效补料培养基(粉末包装): 2~8℃ 避光储存,复验期为2年。

AR8 CHO Super Concentrated High-efficiency Feed Medium (powder packaging): stored in a dark place at 2-8 °C, with a retest date of 2 years.

BR8 CHO 超浓缩高效补料培养基(粉末包装): 2~8℃ 避光储存,复验期为2年。

BR8 CHO Super Concentrated High-efficiency Feed Medium (powder packaging): stored in a dark place at 2-8 °C, with a retest date of 2 years.

【生产企业信息 Manufacturer information】

名称 Name: 无锡多宁生物科技有限公司 Wuxi Duoning Biotechnology co.,Ltd

地址 Address: 无锡新加坡工业园新集路 2-1、2-2 号厂房 No.2-1, No.2-2, Xinji Road, Singapore Industrial Park, Wuxi

电话 Tel: 0510-85956600 网址 Website: www.duoningbio.com

Controlled document. Unauthorized use, disclosure or copying is prohibited. All copyright violations will be prosecuted.

4 of 4 Shanghai Duoning Biotechnology Co., Ltd.

Wuxi Duoning Biotechnology Co., Ltd.