产品说明书
Instructions for Use

CelluPro 赛普生物

CelliMax® MetaCHO™培养基
CelliMax® MetaCHO™ Medium

Cat. No.: CPDP050 (Powder)

Issued on August 1, 2024

产品简介：

Introduction

- 适用于 CHO 细胞的培养
  For CHO cell culture
- 化学成分确定
  CD (Chemically Defined)
- 无动物源性成分
  ADCF (Animal Derived Component Free)
- 不含血清
  Serum free
- 不含有酚红
  Without Phenol Red
- 不含有次黄嘌呤和胸苷
  Without Hypoxanthine and Thymidine
- 不含有 L-谷氨酰胺
  Without L-Glutamine
- 不含有水解物和重组蛋白
  Without Hydrolysates and Recombinant Protein
- 含有 5.6g/L 葡萄糖
  With 5.6g/L Glucose

存储条件：

Storage

1. 干粉培养基密封保存在 2~8℃的避光条件下。
   Powder medium should be sealed at 2 to 8°C, away from light.
2. 配制成的液体培养基密封保存在 2~8℃的避光条件下。
   Liquid medium formulated from powder should be sealed dry at 2 to 8°C, away from light.

有效期*：

Shelf Life*

1. 干粉培养基未开封情况下有效期 2 年，开封后请尽快使用。详细信息请见标签。
   Powder medium is valid for 2 years without opening. Please use as soon as possible after opening. Please refer to the label for details.

**上述有效期的制定，均基于赛普生物的通用检测方法。客户可针对不同的使用用途或项目，进行单独的有效期研究。*

**The shelf life is based on the general testing method of CelluPro. It is suggested to study on validity for different uses or projects.*

配制前建议：

Preparation Recommendations

- 洁净的配液容器。
  Clean vessel.
- 高纯度水，如注射用水。
  High purity water (HPW) such as water for injection (WFI).
- 搅拌效率充足的配液系统。
  Liquid mixing system with sufficient mixing efficiency.
- 校准的 pH 计（建议校准点：4.01、7.00、9.21）。
  Calibrated pH meter (Recommended calibration points: 4.01, 7.00, 9.21).
- 校准的渗透压计（建议校准点：0mOsmol/kg、300mOsmol/kg、700mOsmol/kg）。
  Calibrated osmometer (Recommended calibration points: 0, 300, and 700mOsmol/kg).
- 校准的浊度计（建议校准点：0.02 NTU、20.0NTU、100NTU、800NTU）。

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Calibrated turbidimeter (Recommended calibration points: 0.02 NTU, 20.0NTU, 100NTU, 800NTU).

- 储液系统。
  Liquid storage system.
- 除菌过滤系统。
  Sterile filtration system.
- 为防止误差，不建议进行3升以下的小规模配制。
  Small-scale preparation less than 3 liters is not recommended to prevent errors.
- 为确保产品质量，所有与培养基接触的器具或耗材，需保证无支原体和细菌内毒素污染。
  All utensils or consumables in contact with the medium shall be mycoplasma and bacterial endotoxin contamination risk free for product quality.
- 与过滤后的液体培养基接触的过滤系统和储液系统需无菌。
  Filtration system and liquid storage system in contact with the filtered liquid medium should be kept sterile.
- 建议增加 0.8μm 或 0.45μm 的预过滤，以加快过滤速度并提高过滤载量。
  Pre filtration at 0.8μm or 0.45μm is recommended to improve filtration speed and filtration load.
- 搅拌溶解时间与配制规模和搅拌效率相关，本文中所有提及的搅拌时间仅为小规模配制时的参考值。若配制规模大或搅拌系统效率低，则需适当延长各搅拌步骤的时间，以确保可以达到充分的混合及溶解效果。
  Dissolution time varies with preparation scales and mixing efficiency. All the stirring time herein is a reference for small-scale preparation. For larger preparation scale or lower mixing efficiency, each mixing time needs to extend appropriately to ensure sufficient mixing and dissolution effect.
- 过长的配制时间会带来更高的微生物负荷及细菌内毒素污染的风险，因此配制总时长不建议超过12小时。
  Total preparation time is recommended not to exceed 12 hours, for long preparation time will pose higher risk of bioburden and endotoxin contamination.

配制方法：

Preparation Method

1. 在洁净容器中加入终体积 **80~85%**的高纯度水，水温 **20 至 30℃***。
   Fill a clean mixing vessel to **80 to 85%** of the final volume with HPW at ambient temperature (**20 to 30℃**)*.
   **配制温度仅为参考值，过低的温度会影响溶解效率，过高的温度会加大微生物污染的风险，超过 37℃会影响产品质量。*
   **The preparation temperature is for reference only. Low temperature will reduce dissolution efficiency, high temperature will increase the risk of microbial contamination, and over 37℃ will damage the quality.*
2. 开始搅拌。搅拌速度调整为可使粉末快速地完全浸没在溶液中，但**不会产生大量气泡**。
   Start stirring. Mix at a suitable speed until completely dissolved **without many bubbles generated**.
3. **缓慢**加入培养基干粉 **21.55g/L***，避免大块干粉直接加入水中，搅拌**不少于 30 分钟**至完全溶解，此时溶液**仍有浑浊**为正常现象。
   While stirring, **slowly** add **21.55g/L*** powder medium to the vessel, avoiding formation of clumps. Mix **at least 30 minutes** until dissolved. The solution will **remain cloudy** in this step.
   **本文中涉及的所有物料重量，应尽可能保证最小的误差。若误差无法避免，应结合实际情况进行研究。*
   **The weight error should be kept in minimum for all materials involved herein. If the error is unavoidable, it should be studied based on the actual situation.*
4. **缓慢**加入 6mol/L 氢氧化钠溶液*，调整培养基溶液 pH 至 **6.00~6.30**，溶液变**澄清透明**，继续搅拌 **15~30** 分钟。
   Slowly add 6mol/L NaOH solution*, adjust the pH to **6.00 to 6.30** until the solution is clear, and stir for **15 to 30** minutes.
   **可按照比例折算使用其他浓度的氢氧化钠溶液，但不建议使用氢氧化钠粉末，因为局部过高的 pH 可能会产生损伤。*
   **Other concentrations of NaOH solution can be converted in proportion. NaOH powder is not recommended in case local high pH causes damage.*
5. **缓慢**加入 **2.00g/L** 碳酸氢钠粉末，继续搅拌 **15~30** 分钟。
   Slowly add **2.00g/L** sodium bicarbonate powder and stir for **15 to 30** minutes.
6. 搅拌时间结束后，检测培养基溶液 pH。**缓慢**加入

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6mol/L 氢氧化钠溶液，调整培养基溶液 pH 至 **7.00~7.30***。
After stirring, test the pH and **slowly** add 6mol/L NaOH solution to adjust the pH to **7.00 to 7.30***.
**pH 调整时应注意控制氢氧化钠溶液的使用量，避免过度调整导致培养基最终渗透压超出标准范围。*
**The addition amount of NaOH solution shall be controlled to adjust the pH, avoiding out-of-specification osmolality caused by excessive adjustment.*

7. 使用高纯度水定容至终体积（ρ=1.008kg/L，仅供参考），继续搅拌 **10~30** 分钟。
Add HPW to the final volume (ρ=1.008kg/L, for reference only) and mix for **10 to 30** minutes.
8. 此时检测渗透压应为 **270~330mOsmol/kg**，浊度应 **<3.0NTU**。
At this time, expected osmolality is **270 to 330mOsmol/kg**, and expected turbidity is **<3.0NTU**.
9. 使用除菌滤器（**≤0.22μm**）过滤除菌*。
Sterilize with sterile filter (**≤0.22μm**)*.
**建议使用低结合类型滤膜，如聚偏二氟乙烯 PVDF、聚醚砜 PES 或醋酸纤维素 CA。*
**It is recommended to use a low-binding filter membrane type, such as PVDF, PES or CA.*
10. 立即使用，或密封后在 **2 至 8°C**条件下**避光**保存。
Use the prepared medium immediately or seal and store at **2 to 8°C away from light**.

注意事项：
Precautions

CelliMax® MetaCHO™为无蛋白成分的 CD 基础培养基，如原培养基中含有蛋白成分（如胰岛素，IGF 等），更换至 CelliMax® MetaCHO™培养基时，可考虑添加相应物质以缩短细胞适应时间。
CelliMax® MetaCHO™ Medium is a protein-free CD basal medium. If the original medium with protein components (e.g. insulin and IGF) is replaced with CelliMax® MetaCHO™ Medium, corresponding substances can be added to shorten the cell adaptation time.

质量标准*：
Quality Standards*

检测项目 Test Item	标准 Specification
外观 Appearance	淡粉色或淡黄色粉末，含有少量可见微粒 Light pink or light yellow powder with few visible particles
水分 Moisture	<5.0%
渗透压 Osmolality	270-330mOsmol/kg
细菌内毒素 Endotoxin	<10EU/ml
微生物限度 Bioburden	需氧菌总数<1000CFU/g Aerobe<1000CFU/g 霉菌及酵母菌总数<100CFU/g Mold & Yeast<100CFU/g

**实际情况以 CoA 为准*
**Refer to CoA for actual results.*

订购信息*：
Ordering Information*

产品 Product	订单参考号 Order Reference No.	形式 Format
CelliMax® MetaCHO™培养基 CelliMax® MetaCHO™ Medium	CPDP050-10L	干粉 Powder
	CPDP050-100L	

**有关其他信息，请访问 www.cellupro.cn 或详询 sales@cellupro.cn*
**Please visit www.cellupro.cn for more information or contact sales@cellupro.cn.*

**除工艺变更外，其他变更将不另行通知*
** Except for process changes, other changes will not be notified.*

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