产品说明书
Instructions for Use

CelliMax® CHO FGb 培养基
CelliMax® CHO FGb Medium

Cat. No.: CPDP064 (Powder)

Issued on October 30, 2024

产品简介：

Introduction

- 适用于 CHO 细胞培养的补料
  Feed medium 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 L-谷氨酰胺
  Without L-Glutamine
- 不含有水解物和重组蛋白
  Without Hydrolysates and Recombinant Protein
- 不含有葡萄糖
  Without 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℃, 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 at 2 to 8℃, away from light.

有效期*：

Shelf Life*

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、超纯水。
  High purity water (HPW) such as water for injection (WFI), ultrapure water (UPW), etc.
- 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：6.86、9.18、12.46）。
  Calibrated pH meter (Recommended calibration points: 6.86, 9.18, 12.46).
- 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 1 升以下的小规模配制。
  Small-scale preparation less than 1 liter 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 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.

定容方式：

Q.S. Method

1. **体积定容：**培养基配制的定容阶段，将配制溶液以定容至终体积（$V_{最终}$）的方式完成培养基的定容，建议小规模配制时选择此定容方式。
   Q.S. to final volume: q.s. the preparation solution to the final volume (V_{final}), which is recommended for small-scale preparation.
2. **重量定容：**培养基配制的定容阶段，将配制溶液以定容至终重量（$m_{最终}=\rho \times V_{理论}$）的方式完成培养基的定容，建议大规模配制时选择此定容方式。
   Q.S. to final weight: q.s. the preparation solution to the final weight ($m_{final} = \rho \times V_{theoretical}$), which is recommended for large-scale preparation.
3. CelliMax® CHO FGb 培养基的推荐密度：**ρ=1.052kg/L**。（重量定容法使用*）
   Recommended density of CelliMax® CHO FGb Medium: **ρ=1.052kg/L**. (Applied to q.s. to the final weight*)
   **以重量定容法配制1000L（$V_{理论}$）规模的CelliMax® CHO FGb 培养基为例：定容时的终重量（$m_{最终}$）计算过程如下：$m_{最终}=\rho \times V_{理论}=1.052kg/L \times 1000L=1052kg$，则在培养基定容时，应将培养基溶液定容至1052kg 的终重量，此时配制溶液的终体积即为1000L。*
   **Take the method of q.s. to the final weight to prepare 1000L ($V_{theoretical}$) scale of CelliMax® CHO FGb Medium as an example: the final weight (m_{final}) is calculated as: $m_{final} = \rho \times V_{theoretical} = 1.052kg/L \times 1000L = 1052kg$. Then q.s. the medium solution to the final weight of 1052kg, at this time, the final volume of the preparation solution is 1000L.*
4. 培养基配制开始前，请根据配制的目标体积和可提供的定容装置（标准体积量具或称重设备），确定最适合的定容方式。
   Before the preparation of the medium, please determine the most suitable q.s. method according to the target preparation volume and the available q.s. device (standard volume measuring instruments or weighing equipment).

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配制方法：

Preparation Method

1. 在洁净容器中加入终体积 **70~75%**的高纯度水，水温 **20 至 30℃***。
   Fill a clean mixing vessel to **70 to 75 %** 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。*
   **The preparation temperature is for reference only. Very low temperature will reduce dissolution efficiency.*
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 **88.00g/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 **88.00g/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(1%以内**)。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 (within 1%**) 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 **11.00~11.40**，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 **11.00 to 11.40** 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.*
   **随搅拌时间延长，培养基溶液 pH 会略有下降。*
   The media solution pH decreases slightly by the mixing time.
5. 搅拌时间结束后，检测培养基溶液 pH。若溶液 pH 低于 **11.00**，则**缓慢**加入 6mol/L 氢氧化钠溶液调整 pH 至 **11.00~11.40** 范围*。
   After stirring, test the pH of the medium solution. If the solution pH is below **11.00**, **slowly** add 6 mol/L NaOH solution to adjust the pH to the range of **11.00 to 11.40***.
   **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.*
6. 根据配制开始前确定的定容方式，使用高纯度水定容至终体积或终重量*，继续搅拌 **10~15** 分钟。
   Add HPW to the final volume or final weight* according to the determined q.s. method before preparation and stir for **10 to 15** minutes.
   **培养基定容的具体操作和注意事项详见本说明书中“定容方式”部分的相关描述。*
   **Specific q.s. operations and precautions are described in the “Q.S. Method” section.*
7. 此时检测渗透压应为 **200~260mOsmol/kg**（5 倍稀释后检测），浊度应**＜3.0NTU**。
   At this time, expected osmolality is **200 to 260mOsmol/kg** (tested at 5-fold dilution), and expected turbidity is **<3.0NTU**.
8. 使用 **0.22μm 或 0.2μm** 除菌滤器*过滤除菌。
   Sterilize with **0.22μm** or **0.2μm** sterile filter*.
   **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.*
9. 立即使用，或密封后在 **2 至 8℃**条件下**避光**保存。
   Use the prepared medium immediately or seal and store at **2 to 8℃ away from light**.

质量标准*：

Quality Standards*

检测项目 Test Item	标准 Specification
外观 Appearance	白色粉末 White powder
水分 Moisture	＜5.0%
渗透压（1→5） Osmolality (1→5)	200-260mOsmol/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.*

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订购信息*：

Ordering Information*

产品 Product	订单参考号 Order Reference No.	形式 Format
CelliMax® CHO FGb 培养基 CelliMax® CHO FGb Medium	CPDP064-1L	干粉 Powder
	CPDP064-10L	

** 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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