

## CytoSinct™ CD8 Nanobeads, human (GMP)

### 产品描述

CytoSinct™ CD8 Nanobeads, human (GMP) 用于从新鲜的或冻存的外周血单个核细胞 (PBMCs)、单采血或单细胞悬液中分离或去除表达 CD8 蛋白的细胞。CytoSinct™ CD8 Nanobeads, human (GMP) 具有纳米结构, 多余的磁珠可通过离心或常规上清置换进行去除。

货号	L00933-7.5	L00933-2.5
规格	7.5 ml	2.5 ml
分选能力	可用于从最多 $4 \times 10^{10}$ 总细胞数的样本中标记最多 $4 \times 10^9$ 细胞数的靶细胞	可用于从最多 $1.3 \times 10^{10}$ 总细胞数的样本中标记最多 $1.3 \times 10^9$ 细胞数的靶细胞
产品成分	生物相容性材料包覆的纳米颗粒, 偶联有抗人 CD8 抗体, 储存在磷酸盐缓冲液 (PBS) 中, 含有人血白蛋白 (HSA) 作为稳定剂, pH 值在 6.5-7.5 范围	
内毒素	<2 EU/ml (凝胶限度法, USP <85>)	
无菌	符合规定 (USP <71>)	
储存	2-8°C 储存	

### 法规声明

#### 📌 声明

根据 USP<1043>, CytoSinct™ CD8 Nanobeads, human (GMP) 被归类为辅助材料; 根据中国国家药品监督管理局发布的免疫细胞治疗产品药学研究与评价技术指导原则, CytoSinct™ CD8 Nanobeads, human (GMP) 被归类为其他原材料。CytoSinct™ CD8 Nanobeads, human (GMP) 的生产和检测参照相关 GMP 规范的指导, 以提高高质量的磁珠产品。

#### ♥️ 保证

本产品仅保证在交付给客户时不存在工艺和材料上的缺陷。对于某一特定用途的产品的适用性, GenScript 不作任何明示或暗示的保证或陈述。不提供超出产品说明书范围的任何明示或暗示的保证。GenScript 的责任仅限于更换产品或退还购买价格。GenScript 不承担任何因产品而造成的财产损失、人身伤害或经济损失。

### 警告和注意事项

1. 不要冷冻。
2. CytoSinct™ CD8 Nanobeads, human (GMP) 仅用于体外细胞处理, 不可用于任何体内应用。
3. 本产品不可直接用于任何治疗用途, 或直接注射入病人体内。
4. 使用时须遵循使用说明书的指导。
5. 使用此产品时, 必须遵守当地的法律法规。任何针对靶细胞的应用均属于使用者的责任范围。
6. 本产品应为一次性使用, 请勿重复使用。
7. 若瓶子出现破损或密封被破坏, 请勿使用。
8. 超过产品标签上标示的有效期后, 请勿使用。
9. 若病人对鼠免疫球蛋白或葡聚糖-氧化铁复合物有过敏反应, 不建议使用本产品。
10. 病人可能会产生人抗小鼠抗体 (HAMA)。

### 使用说明

1. 细胞准备和标记的步骤需在室温下进行。
2. 所有操作步骤须在无菌条件下进行。
3. 使用手工或机器将磁珠从容器内取出均可。
4. 可选: 使用适当的染色试剂后, 可以通过流式细胞术或荧光显微镜评估标记效率。应使用碘化丙啶或 7-AAD 对死细胞进行排除。

## CytoSinct™ CD8 Nanobeads, human (GMP)

### Product Description

The CytoSinct™ CD8 Nanobeads, human (GMP) is used for *in vitro* isolation or depletion CD8+ cells from fresh or frozen peripheral blood mononuclear cells (PBMCs), leukapheresis products or single cell suspension based on the surface expression of human CD8. Due to the nanoscale structure of the CytoSinct™ CD8 Nanobeads, human (GMP), the excess reagent can be removed by centrifugation or conventional supernatant replacement.

<b>Cat. No.</b>	L00933-7.5	L00933-2.5
<b>Size</b>	7.5 mL	2.5 mL
<b>Capacity</b>	sufficient for up to $4 \times 10^9$ target cells from up to $4 \times 10^{10}$ total cells	sufficient for up to $1.3 \times 10^9$ target cells from up to $1.3 \times 10^{10}$ total cells
<b>Composition</b>	Bio-degradable matrix coated nanoparticles conjugated with anti-CD8 antibodies supplied in phosphate buffered-saline (PBS), containing Human Serum Albumin (HSA), pH 6.5-7.5	
<b>Endotoxin content</b>	<2 EU/mL as determined by Limulus Amebocyte Lysate (LAL) limit assay (USP <85>)	
<b>Sterility</b>	Sterility is tested and confirmed according to USP <71>	
<b>Storage</b>	Store at 2-8 °C	

### Regulatory and legal notes

#### Disclaimer

The CytoSinct™ CD8 Nanobeads, human (GMP) is regulatory classified as ancillary materials as per USP <1043> and the Guidelines for CMC Studies and Assessment for Immune Cell Therapy Products published by the National Medical Products Administration in China. The CytoSinct™ CD8 Nanobeads, human (GMP) is manufactured and tested according to relevant GMP guidelines to render the Nanobeads of high quality.

#### Warranty

The products sold hereunder are warranted only to be free from defects in workmanship and material at the time of delivery to the customer. GenScript makes no warranty or representation, either expressed or implied, with respect to the fitness of a product for a particular purpose. There are no warranties, expressed or implied, which extend beyond the manual of the products. GenScript's

liability is limited to either replacement of the products or refund of the purchase price. GenScript is not liable for any property damage, personal injury or economic loss caused by the products.

### Warnings and precautions

1. Do not freeze.
2. The CytoSinct™ CD8 Nanobeads, human (GMP) is for *ex vivo* cell processing only, and are not intended for human *in vivo* applications.
3. The product is not designated for therapeutic use or direct infusion into patients.
4. The instructions for use must be followed.
5. When using this product, the national legislation and regulations must be followed. Any application of *ex vivo* processed target cells is exclusively within the responsibility of the user.
6. For single use only. Do not re-use.
7. Use only if vials are undamaged and sealed.
8. Do not use after the expiry date indicated on product label.
9. The product is not recommended for use with patients known or suspected to have sensitivity against mouse immunoglobulins or iron-dextran.
10. Patients may develop human anti-mouse antibodies (HAMA).

### Instructions for use

1. All cell preparation and labeling steps should be performed at room temperature.
2. Work under sterile conditions.
3. Remove the reagent from the vial manually or use an automated process.
4. Optional: The efficiency of the labeling can be evaluated by flow cytometry or fluorescence microscopy using appropriate staining reagents. Propidium iodide or 7-AAD should be used for flow-cytometric exclusion of dead cells.

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