LEPURE乐纯生物

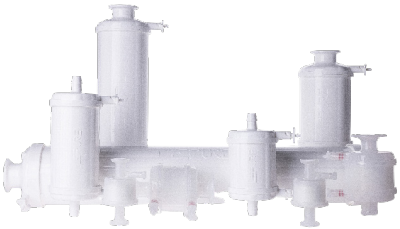
LeSiever® 囊式除菌级过滤器

伽马辐照版

使用说明

LeSiever® Sterilizing Capsule Filter
Gamma irradiation

User Guide



简介

安装和使用 LeSiever®PES 囊式除菌级过滤器需要遵循以下流程，操作指南中有详细的操作流程介绍，建议用户对文档中信息进行仔细阅读。本操作指南基于大量实验操作总结，为工艺应用设计与风险评估中的一部分，对关键工艺步骤有指导作用。若部分操作无法匹配您的需求，请咨询乐纯生物相关技术支持人员。如有人为不当操作造成的囊式过滤器的损坏，乐纯生物不予以承担责任。

说明

产品单页、化学兼容性以及验证指南中涉及到产品的应用参数，需要在实际操作过程中确认细节信息。

伽马辐照灭菌

警示：伽马辐照版的囊式过滤器不能进行高温蒸汽灭菌或在线蒸汽灭菌。

LeSiever® 囊式除菌级过滤器的灭菌参数如下：

伽马辐照灭菌	25-40 kGy

注：

1. **使用超出验证范围的工艺参数进行灭菌，需要进行独立验证。**
2. **经伽马辐照预灭菌后产品不能进行二次灭菌。**

安装

在实际应用当中需要调整囊式过滤器的方向，使液体流动方向符合囊式过滤器标签上箭头指示方向，按照囊式过滤器进出口的连接方式以及接口尺寸与生产管路进行连接，将压力表连接在管路上，用以进行实时压力的检测。

过滤器润湿

将囊式过滤器垂直于地面（箭头方向指向地面），关闭囊式过滤器的出口阀门，在 2 psi 的压力下，缓慢向囊式腔体中注入液体（WFI、缓冲液或料液），打开上端的排气阀，排空囊式过滤器中的气体，直到液体流出排气阀，关闭排气阀。打开囊式滤器的出口阀门，以 2 LPM/10 inch 流速冲洗至少 5 分钟。

过滤器预冲洗

过滤器预冲洗是一个关键步骤，建议在伽马辐照灭菌后进行预冲洗，从而有效降低滤器中的可提取物质。

建议过滤最小预冲洗量如下表所示：

囊式过滤器的型号	最小冲洗量
Size 1	0.4 L
Size 5	1 L
2 英寸	2 L
4 英寸	4 L
5 英寸	5 L
10 英寸	10 L
20 英寸	20 L

完整性测试

过滤器使用后需要进行完整性测试，使用前灭菌后的完整性测试需要依据各地法规来判定是否需要进行。在完整性测试过程中，膜润湿是一个至关重要的步骤，完整性测试失败需要进行问题排查，在测试过程中出现问题，可咨询乐纯生物相关技术支持人员。

更换囊式过滤器

囊式过滤器的更换应符合工艺的 GMP 要求，对于生物制药过程中使用的囊式过滤器，由于清洗验证复杂且验证成本较高，建议一次性使用。若囊式过滤器用于多个生产批次，建议达到最大允许压差或验证过滤载量前更换。

最大压差如下表所示：

	Size1	Size5/2"/4"/5"/10"/20"
最大正向压差	4.0 bar	5.0 bar
最大反向压差	2 bar	2.5 bar

Introduction

The following procedures should be followed for the installation and use of LePure LeSiever® Sterilizing Capsule Filter. These instructions and the information contained within the product document includes brochure, datasheet, validation guide must be read thoroughly. It is critical to follow these instructions to ensure optimal filter performance. If some of the procedures do not suit your needs, please consult LePure Biotech. LePure Biotech shall not be held accountable for any damage to the capsule filters caused by improper operation by any person.

Specification

Please check the brochure, chemical compatibility chart, datasheet and validation guide for details, or contact LePure Biotech.

Sterilization

⚠ Caution: Neither Autoclave nor Steam-in-place[SIP] is applicable for gamma irradiation capsule filters.

The LeSiever® Sterilizing capsule Filter should only be sterilized as follows:

Gamma	25-40 kGy

Notes:

1. **Sterilization using process parameters outside the validation range should be independently validated.**
2. **LeSiever® Sterilizing Capsule Filter cannot be autoclaved after gamma irradiation.**

Installation

LeSiever® capsules must be oriented in the process so that process flow follows the flow indicated by the flow direction arrow on the capsule,and the pressure gauge is connected to the production pipeline according to the connection mode of the inlet and outlet of the capsule filter and the nozzle size for real-time detection of pressures.

Filter Wetting

Filters should be installed in an appropriate orientation, which follows the flow indicated by the flow direction arrow,close the outlet valve of the capsule filter, slowly inject liquid (WFI, buffer or material solution) into the filter chamber at a pressure of 2 psi. Open the upper vent valve until the liquid flows out of the vent valve,then close the vent valve. Open the downstream drain valve of capsule, and adjust water flow to approximately 2 LPM/10 inch of filtration area for a minimum 5 minutes.

Filter Flushing

Flushing the filter after gamma irradiation is highly recommended.Flushing is beneficial to filtrate quality and will reduce leachables from the filter.
Recommended Flush Volume (Liters) per LeSiever® Filters:

Model of Capsule Filter	Minimum flushing volume
Size 1	0.4 L
Size 5	1 L
2 Inch	2 L
4 Inch	4 L
5 Inch	5 L
10 Inch	10 L
20 Inch	20 L

Integrity Testing

Sterilizing Capsule Filter should be integrity tested post-use, according to a GMP requirement for many applications. Pre-use, post-sterilization integrity testing is recommended to ensure that the filter is capable of performing its stated function.Contact LePure Biotech for recommended integrity test procedures and integrity test values.

Capsule Filter Replacement

Filter capsules should be replaced in line with the GMP requirements of the process. LeSiever® capsules are disposable. No attempt should be made to clean disposable filter capsules. Where filter capsules are used for more than one manufacturing batch, replacements are recommended when the maximum allowable differential Capsule Filter pressure has been reached, if the flow rate has become unacceptable or if the cumulative steam life has been reached, whichever occurs first. Discard Capsule Filter in accordance with local environmental procedures. The maximum allowable differential pressure is shown in the table below:

	Size1	Size5/2"/4"/5"/10"/20"
Maximum upward pressure differential	4.0 bar	5.0 bar
Maximum downward pressure differential	2 bar	2.5 bar

LEPURE

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版本号 :AC20230543V1