

SYNOPSIS

Gamma Sterilization in Products Containing Metal Components¹ 包含金属元素产品的γ射线灭菌



Introduction

介绍

Gamma sterilization is used on various materials and products manufactured for the medical and pharmaceutical industries. It is routinely used for products containing both plastic and metal components. There has been industry speculation when using gamma sterilization for products containing metallic components over plastics that a shadow effect or non-sterile areas could occur beneath the metal. ASI has performed sterility testing on various products it manufactures that contain both metal and plastic components to verify the sterility of the designs.

伽马射线灭菌常用于各种医疗和制药行业生产的各种材料和产品。它通常用于包含塑料和金属部件的产品。有业内人士猜测，当材料中含有金属时，金属下面的塑料位置可能产生阴影或产生漏灭菌区域。ASI对其生产的各种包含金属和塑料部件的产品进行了无菌测试，以验证产品的无菌性。

Representative sampling at ASI

ASI典型样品

ASI has performed sterility testing on tubing sets containing multiple stainless steel clamps. The test samples consisted of various types of tubing (silicone, TPE) and connectors (polycarbonate polypropylene) that were connected using 0.024" stainless steel clamps. (Typically, when metal clamps are required in the design, ASI will use clamps with a wall thickness of 0.024".) The tubing sets were approximately 5 feet in length, with metal clamps spaced every 2-3 inches along the design. The samples were sterilized using gamma radiation at 27.5 kGy – 45 kGy, and then tested for fluid path sterility. Of the thirty units assembled, all units were confirmed to be sterile, post gamma sterilization.

ASI已经对包含多个不锈钢夹具的管路组装进行了灭菌测试。测试样品由使用0.024英寸不锈钢卡箍连接的各种类型的管（硅胶，TPE）和连接器（聚碳酸酯/聚丙烯）组成。（通常，当设计中需要金属卡箍时，ASI将使用壁厚为0.024英寸的卡箍）。这些管路组装的长度大约为5英尺，沿产品每隔2-3英寸配有金属卡箍。样品使用27.5 kGy - 45 kGy γ射线灭菌，然后测试流体灭菌路径。三十套装配管路组装经过伽马灭菌后，产品确认为无菌。

Additional studies were performed using TPE tubing enshrouded in various metal layers. In one sample, the tubing was wrapped in

12 layers of stainless steel wrap totaling .024" in thickness. Another TPE tubing sample was covered in metal clamps of 0.024" thickness. Bacillus pumilus indicators were strategically placed in all the samples, which were then gamma irradiated at a minimum allowable dose of 27.5 kGy – 33 kGy. All indicators confirmed to be sterility, post gamma sterilization.

我们又做了另外的研究，使用TPE管材，包裹在不同的金属层中。一个样品管子被包裹在总厚度为0.024英寸的12层不锈钢包装中。另一个TPE管样品被覆盖在0.024英寸厚的金属卡箍中。将短小芽孢杆菌指示剂放置在所有样品中，然后以最低27.5kGy-33kGy剂量进行γ照射。伽马射线灭菌后，所有指标均确认为无菌。

Representative sampling was also performed on metallic foil bags using ASI's PL-01079 film. Bacillus pumilus indicators were placed in three bags, which were then gamma sterilized at 27.5 kGy – 33 kGy. All indicators were confirmed to be sterile.

我们还在含有ASIPL-01079薄膜的金属箔袋上进行了试验，将短小芽孢杆菌指示物放入三个袋中，然后以27.5kGy-33kGy进行γ射线灭菌，所有灭菌指示剂确认无菌。

Gamma sterilization Vs. Alternate methods

伽马射线与Vs. 其它方法

The use of gamma irradiation has benefits over other methods of sterilization for medical and pharmaceutical devices. Dry heat and steam autoclave can have negative effects on packaging and products that are heat sensitive. Ethylene Oxide sterilization (EO) has longer cycle development and validation requirements and leaves unwanted residuals that need to be monitored. EO requires gas permeable packaging therefore limits packaging methods. Gamma sterilization is recommended for plastics and heat sensitive materials, as well as metallic components as it has shorter processing times, allows for non-permeable packaging, and does not leave residuals.

伽马射线辐射在医疗和制药器械的灭菌方法上，与其他灭菌方法相比具有优势。干热和蒸汽高压灭菌器可能对包装和对热敏感的产品产生负面影响。环氧乙烷灭菌（EO）具有较长的开发和验证要求，并产生其他残留物，需额外验证，同时还要要求透气包装，因此限制了包装方法。伽马射线灭菌推荐用于塑料和热敏性材料以及以及金属部件，因为它具有更短的加工时间，可接受的非渗透性包装，并且不会留下残留物。

Conclusion

结论

Gamma sterilization is a widely utilized method of terminal sterilization used for medical and pharmaceutical products containing a variety of materials. It has many advantages over other methods of sterilization and has been determined to be effective in sterilizing product containing plastics and metallic components. Most of ASI's products are irradiated at 27.5 kGy – 45 kGy. ASI performed testing at nominal (27.5 – 45 kGy) and minimal (27.5 – 33 kGy) sterilization dose ranges to verify that the irradiation

process was not inhibited by the use of stainless steel clamps in the design.

伽玛灭菌是一种广泛使用的终端灭菌方法，用于各种材料的医疗和制药产品。与其他灭菌方法相比，它具有许多优点，并且已经确定它可以有效地对含有塑料和金属成分的产品进行灭菌。ASI的大部分产品都以27.5 kGy - 45 kGy辐照。ASI在标称（27.5 – 45 kGy）和最小（27.5 - 33 kGy）灭菌剂量范围内进行了测试，已验证辐照过程中使用不锈钢卡箍，不会对辐射工艺造成限制。

1. 本文主要内容来源于ASI公司技术文件翻译
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