THE IMPACT OF ETHYLENE OXIDE STERILIZATION ON MULTIFUNCTIONAL MICROSTRUCTURED CARDIAC PATCHES

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This study examines the effects of Ethylene Oxide (EtO) sterilization on the surface characteristics, physico-chemical properties, mechanical integrity, and biological performance of a biodegradable microstructured cardiac patch intended for myocardial infarction treatment. Preliminary studies were performed to first identify the optimal EtO sterilization parameters, ensuring both effective sterilization and minimal impact on the polymeric scaffold's properties and drug release behavior. Tests such as dynamic mechanical analysis (DMA), tensile strength, suture retention, and burst strength were conducted on sterilized patches following ISO guidelines. The degradation behavior was analyzed using FT-IR spectroscopy, HPLC, GPC, and SEM. Cytocompatibility assessments were performed on H9c2 cardiomyoblasts utilizing MTT assays and Annexin V/PI flow cytometry, while transwell assays were used to evaluate the chemoattractive properties of the patches post-sterilization. Sterility tests according to UNI EN ISO 11138-1:2017 verified the efficacy of the EtO sterilization method. Findings from DMA, tensile tests, and SEM indicated that EtO sterilization did not significantly alter the mechanical properties or structure of the biodegradable polymeric scaffold. Furthermore, GPC and HPLC analyses showed no substantial changes in degradation or drug release behavior. The cytocompatibility and chemoattractive properties of the scaffold were fully preserved. These results demonstrate that EtO sterilization is a safe and effective method for preparing innovative biodegradable polymeric implantable medical devices.

Keywords: *Ethylene Oxide Sterilization; Biodegradable Cardiac Patch; Myocardial Infarction Treatment; Polymeric Scaffold; Cytocompatibility*

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