

Accelerated *In Vitro* Drug Release Method Development for Implantable Medical Device †

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Abstract: Drug-eluting stent (DES) has been a revolutionary change in the treatment of coronary artery disease because of its outstanding ability to reduce restenosis. Active pharmaceutical ingredient (API) present in the DES is one of the key responsible components for its clinical safety and efficacy, measured by pharmacodynamic and pharmacokinetic properties. Sirolimus (SRL) is a macrolide immunosuppressant that inhibits in-stent restenosis when released in a controlled manner. Pharmacokinetic characteristic is assessed by *in vitro* real-time drug release testing during development, which is time-consuming and expensive. Hence, an accelerated *in vitro* release method is developed for a rapid formulation assessment. The release characteristics mainly depend on the drug release medium that solubilizes and improves the stability of drugs. Different surfactants were evaluated in an aqueous buffer to create drug release media (DRM) for the DES that releases SRL. The DRM accelerated the *in vitro* drug release in 48 hours which correlated well with the real-time drug release of 48 days. This newly developed accelerated *in vitro* drug release method can be used during formulation development and quality control for commercial manufacturing of DES, which will save lots of time, energy, resources, and money.

Keywords: drug-eluting stent; real-time *in vitro* release; accelerated *in vitro* release; drug release media.

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Conflicts of Interest

The authors declare no conflict of interest.