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Paper Title: Sterility and Endotoxin of Thai Silk Fibroin Solution in a Production Conformed to ISO13485 Standard

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Abstract

This is the first report of sterile Thai silk fibroin (SF) solution (2-4% (w/v) in water) production at semi-commercial scale under the medical device management system conforming to standard ISO13485:2016. Thai silk cocoons (Bombyx mori, local strain named Nangnoi Srisaket 1) was maintained, cultured and produced in controlled conditions at The Queen Sirikit Sericulture Center Nakhon Ratchasima, Thailand. The GMP (Medical Device) conformed protocol was optimized. The degummed silk fibers were dissolved in concentrated ionic liquid and purified in the clean room facility of the Department of Medical Sciences, Ministry of Public Health, Thailand. With minimal sterilization of the end product, sterility and endotoxin test of the product indicated that the purified proteins were negative for bacteria, mycobacteria, yeast and fungi. The endotoxin levels of all inputs, intermediates and the product was <0.01 - 0.20 EU/ml conforming to the USP standard (for water for injection at the endotoxin level limits <0.25 EU/ml). This indicated that the Thai SF solution can be used for medical and health applications.