

Abstract

Development of mesenchymal stem cell (MSC) derived secretomes that aid in skin regeneration and aging has recently been on the rise. However, biologic products are prone to denaturation thus it becomes a challenge for their long-term storage stability. To solve this issue, a freeze drying method is often used. Nonetheless, this process is expensive, time consuming, and energy intensive. Therefore, to increase product development and manufacturing efficiency, a quality by design (QbD) approach to MSC-secretome lyophilization was done to see the effect of different primary drying temperatures towards the physicochemical characteristics of the freeze-dried MSC-secretomes. The results showed that MSC-secretomes with homogeneously white partially collapsed cake and sufficient moisture level were obtained after freeze drying at -30°C (T30) and -25°C (T25) primary drying temperatures. Reconstitution time, solution appearance, and pH of the reconstituted freeze-dried product were within acceptable limits and were not impacted by different primary drying temperature settings. In terms of secretome particle size and protein profile, this study's data suggests that T25 settings is better in conserving particle size compared to T30 settings which showed an overall increase in size, yet both had similar SDS-PAGE protein profiles. Therefore, freeze-dried MSC-secretomes with acceptable physicochemical characteristics could be produced using the Huaihai Freeze-dryer, and this data suggests that primary drying temperature of -30°C and -25°C only impacts the particle size of the reconstituted product.

Keywords: Mesenchymal stem cell; freeze drying; QbD; MSC-secretome; primary drying temperature