

Characterization of bovine insulin microcrystals prepared by the Seed Zone Method

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Abstract

A novel bovine insulin microcrystals (<5 μm almost 90% in volume) preparation process was developed for pulmonary delivery using the seed zone method. The stability of bovine insulin microcrystals produced was investigated by the chromatographic analysis. The percentage of high molecular weight proteins (%HMWP) and other insulin related compounds (%OIRC) of the insulin microcrystals were almost same compared with its raw material, while the percentage of A-21 desamido insulin (%D) was significantly low ($P<0.001$). The physicochemical properties of the bovine insulin microcrystals were measured using X-ray diffraction (XRD) and differential scanning calorimetry (DSC). The physicochemical properties of the produced microcrystals were similar to those of the commercial insulin powder and milled crystalline form. Therefore, the bovine insulin microcrystals which were produced by the seed zone method maintain their physicochemical properties sufficiently good for the pulmonary delivery in terms of product-related impurities.

References

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