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RATI CHOORAKS : PHYSICOCHEMICAL CHARACTERISTICS AND
STABILITY OF FREEZE-DRIED CEPHALEXIN SODIUM POWDER.

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Freeze-drying is a technique employed for preparing sterile powder for reconstitution. In this study, freeze-dried cephalexin sodium of three strengths (250 mg/vial, 500 mg/vial and 1 g/vial) was prepared by freezing the solution of cephalexin in sodium bicarbonate at -80 °C and then vacuum drying in a freeze-dryer. The subambient differential scanning calorimetry (DSC) revealed that the collapse temperature of frozen solution of cephalexin/sodium bicarbonate was around -25 °C and no crystallization of cephalexin was observed during freezing. Well-formed cakes were obtained in all freeze-dried preparations. Powder X-ray diffraction, DSC and thermogravimetric analysis were used to investigate the physicochemical characteristics of the freeze-dried powder. All freeze-dried preparations had partial crystalline characteristics. The stability study at 45 °C indicated that the 250 mg/vial preparation was less stable due to the higher activity of water contained in the freeze-dried cake. Ibilex[®], a commercial sterile cephalexin sodium used as the comparison product in this study, was a free flowing powder with high crystallinity. The stability of Ibilex[®] was higher than the freeze-dried preparations which could be attributed to the higher crystallinity. In addition, the stability study of cephalexin in the reconstitution solutions with Sterile Water for Injection, 5% Dextrose Injection and 0.9% Sodium Chloride Injection suggested that the reconstitution solutions should be used within 8 h and 2 days when stored at 25 °C and 5 °C respectively.