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论文

共溶剂冻干法制备环糊精包合物中叔丁醇残留量影响因素考察

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摘要：

为考察共溶剂冻干法制备环糊精包合物中叔丁醇残留量影响因素，优化处方和工艺，有效控制叔丁醇残留量，本文采用气相色谱法测定冻干样品中叔丁醇残留量，通过调整共溶剂中叔丁醇浓度、环糊精种类、样品分装量、冷冻方式及二次干燥时间，以确定影响叔丁醇残留量的主要因素。结果表明，无定形的包合材料、低的叔丁醇浓度和快速的冷冻方式是导致残留量高的主要因素，而退火是一种很好的降低叔丁醇残留量的技术，二次干燥时间对叔丁醇残留量无明显影响。因此，为保证较低的叔丁醇残留量，制备时宜选择适宜的包合材料、共溶剂浓度和冻干工艺。

关键词： 共溶剂冻干法 环糊精包合物 叔丁醇 残留量

Factors influencing the content of residual *tert*-butyl alcohol in cyclodextrin complex prepared by lyophilization cosolvent system

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Abstract:

In order to minimize the residual *tert*-butyl alcohol (TBA) level in cyclodextrin complex prepared by freeze drying TBA/water cosolvent system, the formulation and lyophilization procedure that may influence the residual TBA was studied. Residual TBA in freeze dried cyclodextrin complex was determined by gas chromatography. The significant formulation and processing factors that influence residual TBA were identified by adjusting the initial TBA concentration in cosolvent, selecting cyclodextrin type (*β*-cyclodextrin or hydroxypropyl *β*-cyclodextrin), changing sample volume in flasket, altering freezing mode (fast freezing or slow freezing) and modifying the duration of secondary drying. The results show that the amorphous cyclodextrin material (hydroxypropyl *β*-cyclodextrin), initial low TBA concentration in cosolvent and fast freezing would lead to high TBA residue in cyclodextrin complex, annealing was effective in reducing the residual TBA. The duration of secondary drying had no distinct effect on residual TBA. It is concluded that in order to reduce residual TBA in cyclodextrin complex prepared by lyophilization monophase solution, the initial TBA concentration in cosolvent should be higher than the crystal formation concentration, the appropriate cyclodextrin type and freeze drying processing should be choosen.

Keywords: cyclodextrin complex *tert*-butyl alcohol residue lyophilization cosolvent system

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