

动态光散射技术在静脉注射亚微乳剂粒径评价中的应用

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摘要

目的 用动态光散射技术分析粒径大小及分布, 为静脉注射乳剂的制备提供指导。方法 制备3种不同的维生素E烟酸酯静脉注射亚微乳剂 (I, II和III), 用Nicomp-380激光粒度测定仪分别测定3种制剂的光子相关光谱, 并用离心法测定乳剂的稳定常数 (KE)。结果 3种制剂的光子相关光谱有显著差别。制剂I的Nicomp多波形分布图为双峰, 制剂II和III的Nicomp多波形分布图为单峰, 但制剂III的Gaussian粒径分布图比制剂II的Gaussian粒径分布图明显窄, 且PSDI, PSDV和PSDN重合性很好。得到3个不同的KE值, 分别为0.72, 0.64, 0.51。结论 用Nicomp多波形分布图和Gaussian粒径分布图可以指导制剂的制备。

关键词 [静脉注射乳剂](#) [Gaussian粒径分布图](#) [Nicomp多波形分布图](#) [稳定常数](#) [药物稳定性](#)

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Application of dynamic light scattering on the evaluation of the particles size and distribution of submicroemulsion for injection.

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Abstract

Objective To direct the preparation of submicroemulsion for injection, with the technology of dynamic light scattering being widely used to analyze the size and distribution of particles. Methods Three kinds of α -tocopherol nicotinate (TN) submicroemulsion were prepared. Their dynamic light scattering data were measured by Nicomp-380 laser particle sizing systems and stability constants (KE) were measured by centrifugation method. Results There were significant dissimilarities in the data of three emulsions. Preparation I had two peak values in Nicomp chart, however, preparation II and III had single peak value. The range of distribution of preparation III, with nearly same PSDI, PSDV and PSDN, was much narrower than that of preparation II. The values of KE of three emulsions were 0.72, 0.64 and 0.51, respectively. Conclusions Nicomp chart and Gaussian chart can direct the preparation of submicroemulsion.

Key words [submicroemulsion](#) [Gaussian chart](#) [Nicomp chart](#) [stability constant](#) [drug stability](#)

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