

论文

混悬型多相脂质体139静脉输注液粒径及异物检查方法

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摘要:

关键词: 多相脂质体 139

THE DETERMINATION METHODS ON SIZE AND DISTRIBUTION OF PARTICLES AND PARTICULATE MATTER IN INTRAVENOUS INJECTION. OF POLYPHASE LIPOSOME (139) IN THE FORM OF SUSPENSION

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Abstract:

The methods on observation of the pattern of polyphase liposome and on determination of size and distribution of particles and particulate matter of intravenous injection of polyphase liposome (139) in the form of suspension are presented in this paper. Microscopic photographs of the injection of polyphase liposome (139) demonstrated the structure of artificial cell of polyphase liposome. With Coulter counter (TA II) and microscope-micrometer the size and distribution of particles in the injection of polyphase liposome (139) in the form of suspension is shown. The results of measurement by the two methods are the same, especially the results on size of the large particles in the injection (139). Moreover, the membrane filter-microscope method described in USP XX for measuring the particulate matter in large-volume injection for single dose infusion was improved. The improved method was used in the determination of particulate matter in the intravenous injection of polyphase liposome (139) in the form of suspension. This method is not only more accurate but also more simple and convenient than the original USP XX method.

Keywords: Polyphase liposome (139)

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