



付茂琦, 余祥彬, 王龙坤, 袁建华. TC-1静脉脂肪乳剂的制备[J]. 中国现代应用药学, 2013, 30(12):127-1276

## TC-1静脉脂肪乳剂的制备

Preparation of TC-1 Intravenous Fat Emulsion

投稿时间: 2013-08-28 最后修改时间: 2013-07-24

DOI:

中文关键词: [TC-1](#) [静脉脂肪乳剂](#) [稳定性](#)

英文关键词: [TC-1](#) [intravenous fat emulsion](#) [stability](#)

基金项目:福建省区域科技重大项目(2010Y3001)

作者	单位	E-mail
<a href="#">付茂琦</a>	<a href="#">福建医科大学, 福州 350004</a>	<a href="mailto:fumaoqi@sina.com">fumaoqi@sina.com</a>
<a href="#">余祥彬*</a>	<a href="#">福州辰星药业有限公司, 福州 350007</a>	<a href="mailto:13905004666@139.com">13905004666@139.com</a>
<a href="#">王龙坤</a>	<a href="#">福州辰星药业有限公司, 福州 350007</a>	
<a href="#">袁建华</a>	<a href="#">上海惠同贸易有限公司, 上海 210000</a>	

摘要点击次数: 110

全文下载次数: 123

中文摘要:

目的 研制和生产TC-1静脉脂肪乳剂, 以期为临床提供解救高血压危象的新型药物制剂。方法 方配比为TC-1  $0.5 \text{ mg} \cdot \text{mL}^{-1}$ 、精制蛋黄卵磷脂1.2%、甘油2.2%。注射用大豆油20%; 通过初乳制备高压匀化、灌装封口、热压灭菌等工序制得TC-1静脉脂肪乳注射液, 并在 $(5 \pm 2)^\circ\text{C}$ 条件下考察制剂6月内的稳定性。结果 3批小批量试验的检验结果, 用动态光散射法测定平均粒径 $<0.3 \mu\text{m}$ 、粒度分布均匀、无 $>1 \mu\text{m}$ 粒子, 稳定性均符合中国药典2010年版及日本药局方的要求。结论 确定了超高压微射均质机-MiniDeBEE制备含药静脉脂肪乳的关键设备条件、工艺参数, 解决了工程配套问题, 所取得的结果有利于脂肪乳剂的生产。TC-1静脉脂肪乳注射液的成功研制, 为含药静脉脂肪乳的制备及稳定性研究提供了一套切实可行的方法。

英文摘要:

OBJECTIVE To prepare fat emulsion of TC-1 for treatment of hypertensive crisis. METHODS The formula consisted of  $0.5 \text{ mg} \cdot \text{mL}^{-1}$  TC-1, 1.2% purified lecithin, 2.2% glycerol and 20% soybean oil. The procedure included coarse emulsion production, high pressure homogenization, filling and sealing, autoclaving, quality tests, etc; and stability of the preparation in 6 months under  $(5 \pm 2)^\circ\text{C}$  was tested. RESULTS The quality test results of the 3 batches of products showed that the average diameters was  $<0.3 \mu\text{m}$  measured by DLS, the distributions of particles were uniform, and there was no  $>1 \mu\text{m}$  particles, and the stability were found according to CP and JP.

CONCLUSION The study focuses on the latest homogenizer named MiniDeBEE applying in production of an intravenous fat emulsion in order to find out the machinery terms, operating data and solve the engineering problems. The results of this study are go for improving the production equipment of fat emulsion. The practical method of the study is useful to other intravenous fat emulsion containing drugs in production or