

布托啡诺、尼卡地平、乌拉地尔和替罗非班经微量注射泵配伍给药的稳定性与相容性研究[△]

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摘要 目的 考察布托啡诺、尼卡地平、乌拉地尔及替罗非班的配伍稳定性与相容性。方法 采用微量注射泵模拟输注, 分别于4种药物配伍后0、2、4、6、8 h时在针头处实时采样, 考察其外观、pH、不溶性微粒数; 采用超高效液相色谱法测定布托啡诺、尼卡地平、乌拉地尔、替罗非班含量。结果 8 h内, 各配伍溶液的外观均保持澄清透明状态, 无肉眼可见的浑浊、沉淀、颜色变化及气体产生; pH波动幅度为0.02~0.09, 均小于0.1个pH单位; 各配伍溶液中粒径 $\geq 10 \mu\text{m}$ 的不溶性微粒数均未超过9粒, 粒径 $\geq 25 \mu\text{m}$ 的不溶性微粒数均未超过2粒, 均符合2025年版《中国药典》(四部)的相关规定。布托啡诺、尼卡地平、乌拉地尔、替罗非班在配伍后8 h时的相对百分含量为92.38%~113.40%。结论 在模拟临床微量注射泵输注条件下的8 h内, 布托啡诺、尼卡地平、乌拉地尔、替罗非班配伍溶液的稳定性、相容性均较好。

关键词 布托啡诺; 尼卡地平; 乌拉地尔; 替罗非班; 微量注射泵; 联合输注; 稳定性; 相容性

Study on the stability and compatibility of butorphanol, nicardipine, urapidil and tirofiban administered via micro-infusion pump

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ABSTRACT **OBJECTIVE** To investigate the stability and compatibility of butorphanol, nicardipine, urapidil, and tirofiban. **METHODS** A micro-infusion pump was used to simulate the infusion process. Samples were collected in real time from the needle tip at 0, 2, 4, 6, and 8 h after mixing of the four drugs. The appearance, pH, and number of insoluble particles were examined. The contents of butorphanol, nicardipine, urapidil, and tirofiban were determined using the ultra-high-performance liquid chromatography method. **RESULTS** Within 8 hours, all mixed solutions remained clear and transparent, with no visible turbidity, precipitation, color change, or gas generation. The pH fluctuation ranged from 0.02 to 0.09, both within 0.1 pH units. The number of insoluble particles $\geq 10 \mu\text{m}$ in size in each compatibility solution was ≤ 9 , and the number of insoluble particles $\geq 25 \mu\text{m}$ was ≤ 2 , meeting the requirements of the 2025 edition of the *Chinese Pharmacopoeia* (Volume IV). The relative percentage contents of butorphanol, nicardipine, urapidil, and tirofiban at 8 hours after compatibility mixing ranged from 92.38% to 113.40%. **CONCLUSIONS** Within 8 hours under simulated clinical micro-infusion pump infusion conditions, the stability and compatibility of the mixed solution containing butorphanol, nicardipine, urapidil, and tirofiban were satisfactory.

KEYWORDS butorphanol; nicardipine; urapidil; tirofiban; micro-infusion pump; combined infusion; stability; compatibility

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重症监护病房(intensive care unit, ICU)患者常需经有限静脉通路同时输注多种药物, 这会增加药物发生物理或化学不相容的风险。物理不相容可表现为配伍溶液出现沉淀、变色等变化, 而化学不相容则可导致药物出现降解或生成毒性产物, 二者均可引起患者治疗失