

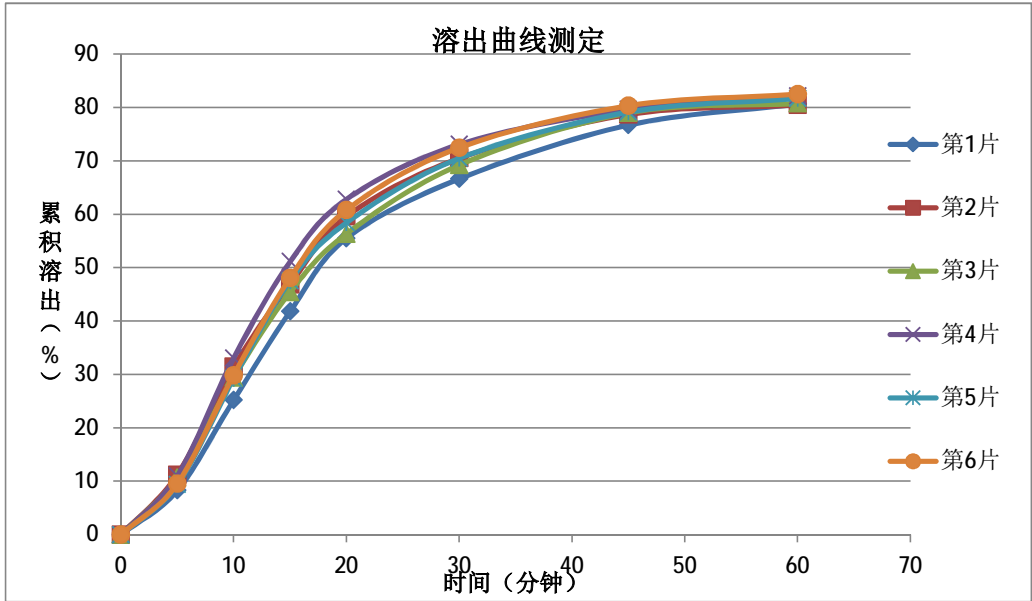
SMF-4109自制品溶出曲线[含0.1%吐温80的pH6.8磷酸盐缓冲液]-24112901批

编号: RC-SMF-4109-0005 打印时间: 2024/12/6
 电脑名称: WLPC08
 路径: E:\RC\SMF-4109\2024-12\20241205\[SMF-4109-0005-rcqx-FX273-274.xlsm]zpz1-6.8+tw

| | | | | |
|----------|-------------|---------|--------|--------|
| 信息区 | 介质体积 | 900 | 补液体积 | 10 |
| 对照品批号 | 61123040205 | | 防伪码 | 600829 |
| 对照品水分 | 0.14% | 系数 | 1.0000 | |
| 对照品含量 | 100.5% | 对照品稀释倍数 | 4000 | |
| 是否计算累计溶出 | 是 | | | |
| 规格 (mg) | 8 | 供试品稀释倍数 | 2 | |

| 对照品溶液 | | | | | | | | |
|-------|----------|--------|--------|--------|--------|--------|--------|------|
| 序号 | 称样量 (mg) | A1 | A2 | A3 | A4 | A5 | A平均 | RSD% |
| 1 | 16.23 | 193638 | 193762 | 193948 | 193548 | 194019 | 193783 | 0.11 |
| 2 | 16.23 | 194584 | 194344 | - | - | - | 194464 | 0.09 |
| 响应值 | RSD% | 判断 | | | | | | |
| 11940 | 0.25 | 数据可信 | | | | | | |
| 11982 | | | | | | | | |

SMF-4109自制品溶出曲线[含0.1%吐温80的pH6.8磷酸盐缓冲液]-24112901批



试验结论: 本品在含0.1%吐温80的pH6.8磷酸盐缓冲液介质中坎地沙坦酯溶出曲线测定结果, 溶出量随时间延长有增加趋势, 最终累积溶出未达100%。

操作者:

复核者:

日期:

日期:

SMF-4109自制品溶出曲线[含0.1%吐温80的pH6.8磷酸盐缓冲液]-24112901批

| 时间(min) | 样品 | A | 溶出量(%) | 累积(%) | 平均累积(%) | RSD% |
|------------------------|----|--------|--------|-------|---------|-------|
| 0 | \ | 0 | 0 | 0 | 0 | 0 |
| 5 | 1 | 17571 | 8.293 | 8.29 | 10.03 | 11.47 |
| | 2 | 23833 | 11.249 | 11.25 | | |
| | 3 | 22682 | 10.705 | 10.70 | | |
| | 4 | 23351 | 11.021 | 11.02 | | |
| | 5 | 19876 | 9.381 | 9.38 | | |
| | 6 | 20219 | 9.543 | 9.54 | | |
| 10 | 1 | 53264 | 25.139 | 25.23 | 29.73 | 8.90 |
| | 2 | 66441 | 31.359 | 31.48 | | |
| | 3 | 62120 | 29.319 | 29.44 | | |
| | 4 | 69866 | 32.975 | 33.10 | | |
| | 5 | 61782 | 29.160 | 29.26 | | |
| | 6 | 63047 | 29.757 | 29.86 | | |
| 15 | 1 | 87814 | 41.446 | 41.82 | 46.83 | 6.61 |
| | 2 | 98346 | 46.417 | 46.89 | | |
| | 3 | 95358 | 45.007 | 45.45 | | |
| | 4 | 107348 | 50.666 | 51.15 | | |
| | 5 | 99808 | 47.107 | 47.54 | | |
| | 6 | 101015 | 47.677 | 48.11 | | |
| 20 | 1 | 115887 | 54.696 | 55.53 | 58.94 | 4.66 |
| | 2 | 124216 | 58.627 | 59.62 | | |
| | 3 | 117433 | 55.426 | 56.37 | | |
| | 4 | 130923 | 61.793 | 62.84 | | |
| | 5 | 121803 | 57.488 | 58.44 | | |
| | 6 | 126812 | 59.852 | 60.82 | | |
| 30 | 1 | 138194 | 65.225 | 66.66 | 70.42 | 3.31 |
| | 2 | 145936 | 68.879 | 70.52 | | |
| | 3 | 143420 | 67.691 | 69.25 | | |
| | 4 | 151209 | 71.367 | 73.11 | | |
| | 5 | 146002 | 68.910 | 70.50 | | |
| | 6 | 150152 | 70.868 | 72.50 | | |
| 45 | 1 | 157979 | 74.563 | 76.73 | 78.94 | 1.56 |
| | 2 | 161645 | 76.293 | 78.70 | | |
| | 3 | 162501 | 76.697 | 79.01 | | |
| | 4 | 163447 | 77.143 | 79.67 | | |
| | 5 | 162723 | 76.802 | 79.16 | | |
| | 6 | 165113 | 77.930 | 80.35 | | |
| 60 | 1 | 164587 | 77.681 | 80.67 | 81.40 | 1.06 |
| | 2 | 163707 | 77.266 | 80.52 | | |
| | 3 | 164475 | 77.629 | 80.79 | | |
| | 4 | 167012 | 78.826 | 82.21 | | |
| | 5 | 166358 | 78.517 | 81.73 | | |
| | 6 | 167839 | 79.216 | 82.50 | | |
| 极限250转/ 分钟-10分 钟 | 1 | 167331 | 78.977 | 82.83 | 83.62 | 1.33 |
| | 2 | 165878 | 78.291 | 82.40 | | |
| | 3 | 170223 | 80.342 | 84.37 | | |
| | 4 | 171984 | 81.173 | 85.44 | | |
| | 5 | 167983 | 79.284 | 83.37 | | |
| | 6 | 167732 | 79.166 | 83.33 | | |

操作者：
日期：

复核者：
日期：

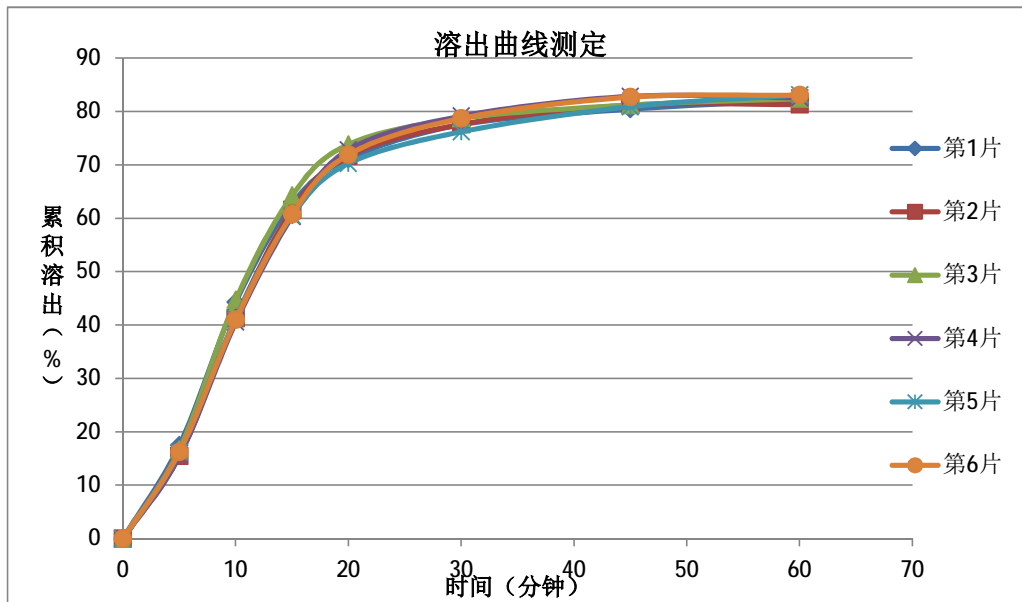
SMF-4109自制品溶出曲线[含0.35%吐温20的pH6.5磷酸盐缓冲液]-24112901批

编号: RC-SMF-4109-0005 打印时间: 2024/12/6
 电脑名称: WLPC08
 路径: E:\RC\SMF-4109\2024-12\20241205\[SMF-4109-0005-rcqx-FX273-274.xlsm]zpz1-6.5+tw

| | | | | |
|----------|-------------|---------|--------|--------|
| 信息区 | 介质体积 | 900 | 补液体积 | 10 |
| 对照品批号 | 61123040205 | | 防伪码 | 611747 |
| 对照品水分 | 0.14% | 系数 | 1.0000 | |
| 对照品含量 | 100.5% | 对照品稀释倍数 | 4000 | |
| 是否计算累计溶出 | 是 | | | |
| 规格 (mg) | 8 | 供试品稀释倍数 | 2 | |

| 对照品溶液 | | | | | | | | |
|-------|----------|--------|--------|--------|--------|--------|--------|------|
| 序号 | 称样量 (mg) | A1 | A2 | A3 | A4 | A5 | A平均 | RSD% |
| 1 | 16.23 | 195197 | 194706 | 195029 | 195194 | 194755 | 194976 | 0.13 |
| 2 | 16.23 | 199034 | 198930 | - | - | - | 198982 | 0.04 |
| 响应值 | RSD% | 判断 | | | | | | |
| 12013 | 1.44 | 数据可信 | | | | | | |
| 12260 | | | | | | | | |

SMF-4109自制品溶出曲线[含0.35%吐温20的pH6.5磷酸盐缓冲液]-24112901批



试验结论: 本品在含0.35%吐温20的pH6.5磷酸盐缓冲液介质中坎地沙坦酯溶出曲线测定结果, 溶出量随时间延长有增加趋势, 最终累积溶出未达100%。

操作者:

复核者:

日期:

日期:

SMF-4109自制品溶出曲线[含0.35%吐温20的pH6.5磷酸盐缓冲液]-24112901批

| 时间(min) | 样品 | A | 溶出量(%) | 累积(%) | 平均累积(%) | RSD% |
|------------------------|----|--------|--------|-------|---------|------|
| 0 | \ | 0 | 0 | 0 | 0 | 0 |
| 5 | 1 | 37561 | 17.473 | 17.47 | 16.25 | 4.72 |
| | 2 | 33257 | 15.471 | 15.47 | | |
| | 3 | 35842 | 16.673 | 16.67 | | |
| | 4 | 33196 | 15.442 | 15.44 | | |
| | 5 | 34754 | 16.167 | 16.17 | | |
| | 6 | 34955 | 16.260 | 16.26 | | |
| 10 | 1 | 94869 | 44.131 | 44.33 | 42.20 | 4.32 |
| | 2 | 88353 | 41.100 | 41.27 | | |
| | 3 | 95743 | 44.538 | 44.72 | | |
| | 4 | 86894 | 40.422 | 40.59 | | |
| | 5 | 88390 | 41.118 | 41.30 | | |
| | 6 | 87743 | 40.817 | 41.00 | | |
| 15 | 1 | 133328 | 62.022 | 62.71 | 61.69 | 2.51 |
| | 2 | 131040 | 60.958 | 61.59 | | |
| | 3 | 136722 | 63.601 | 64.28 | | |
| | 4 | 128245 | 59.657 | 60.28 | | |
| | 5 | 128721 | 59.879 | 60.52 | | |
| | 6 | 129261 | 60.130 | 60.76 | | |
| 20 | 1 | 150004 | 69.779 | 71.15 | 71.97 | 1.75 |
| | 2 | 151376 | 70.418 | 71.72 | | |
| | 3 | 155798 | 72.475 | 73.86 | | |
| | 4 | 153798 | 71.544 | 72.83 | | |
| | 5 | 148302 | 68.988 | 70.29 | | |
| | 6 | 151873 | 70.649 | 71.95 | | |
| 30 | 1 | 162073 | 75.394 | 77.54 | 78.00 | 1.40 |
| | 2 | 162364 | 75.529 | 77.62 | | |
| | 3 | 164557 | 76.549 | 78.74 | | |
| | 4 | 165683 | 77.073 | 79.15 | | |
| | 5 | 159425 | 74.162 | 76.23 | | |
| | 6 | 164758 | 76.643 | 78.73 | | |
| 45 | 1 | 166563 | 77.482 | 80.47 | 81.58 | 1.21 |
| | 2 | 168289 | 78.285 | 81.21 | | |
| | 3 | 168120 | 78.207 | 81.25 | | |
| | 4 | 171815 | 79.925 | 82.86 | | |
| | 5 | 167755 | 78.037 | 80.93 | | |
| | 6 | 171529 | 79.792 | 82.73 | | |
| 60 | 1 | 168425 | 78.348 | 82.20 | 82.46 | 0.82 |
| | 2 | 166651 | 77.523 | 81.32 | | |
| | 3 | 168724 | 78.488 | 82.40 | | |
| | 4 | 169352 | 78.780 | 82.60 | | |
| | 5 | 170678 | 79.396 | 83.16 | | |
| | 6 | 170388 | 79.262 | 83.09 | | |
| 极限250转/ 分钟-10分 钟 | 1 | 172227 | 80.117 | 84.84 | 84.42 | 1.41 |
| | 2 | 167144 | 77.753 | 82.41 | | |
| | 3 | 171815 | 79.925 | 84.71 | | |
| | 4 | 171674 | 79.860 | 84.56 | | |
| | 5 | 170546 | 79.335 | 83.98 | | |
| | 6 | 174805 | 81.316 | 86.02 | | |

操作者：
日期：

复核者：
日期：

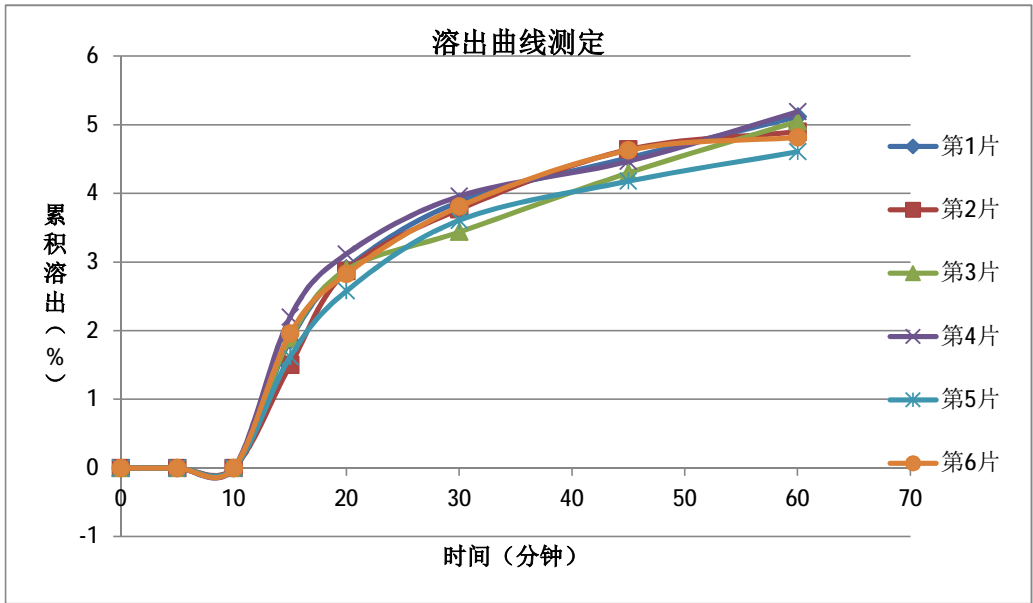
SMF-4109自制品溶出曲线[pH6.8磷酸盐缓冲液]-24112901批

编号: RC-SMF-4109-0005 打印时间: 2024/12/6
 电脑名称: WLPC08
 路径: E:\RC\SMF-4109\2024-12\20241205\[SMF-4109-0005-rcqx-FX273-274.xlsm]zpz1-6.8

| | | | | |
|----------|-------------|---------|--------|--------|
| 信息区 | 介质体积 | 900 | 补液体积 | 10 |
| 对照品批号 | 61123040205 | | 防伪码 | 620000 |
| 对照品水分 | 0.14% | 系数 | 1.0000 | |
| 对照品含量 | 100.5% | 对照品稀释倍数 | 4000 | |
| 是否计算累计溶出 | 是 | | | |
| 规格 (mg) | 8 | 供试品稀释倍数 | 2 | |

| 对照品溶液 | | | | | | | | |
|-------|----------|--------|--------|--------|--------|--------|--------|------|
| 序号 | 称样量 (mg) | A1 | A2 | A3 | A4 | A5 | A平均 | RSD% |
| 1 | 16.23 | 201208 | 200240 | 202320 | 200937 | 202651 | 201471 | 0.50 |
| 2 | 16.23 | 203677 | 197418 | - | - | - | 200548 | 2.21 |
| 响应值 | RSD% | 判断 | | | | | | |
| 12413 | 0.32 | 数据可信 | | | | | | |
| 12357 | | | | | | | | |

SMF-4109自制品溶出曲线[pH6.8磷酸盐缓冲液]-24112901批



试验结论: 本品在pH6.8磷酸盐缓冲液介质中坎地沙坦酯溶出曲线测定结果, 溶出量随时间延长有增加趋势, 最终累积溶出未达100%。

操作者:

复核者:

日期:

日期:

SMF-4109自制品溶出曲线[pH6.8磷酸盐缓冲液]-24112901批

| 时间(min) | 样品 | A | 溶出量(%) | 累积(%) | 平均累积(%) | RSD% |
|------------------------|----|-------|--------|-------|---------|---------|
| 0 | \ | 0 | 0 | 0 | 0 | 0 |
| 5 | 1 | 0 | 0.000 | 0.00 | 0.00 | #DIV/0! |
| | 2 | 0 | 0.000 | 0.00 | | |
| | 3 | 0 | 0.000 | 0.00 | | |
| | 4 | 0 | 0.000 | 0.00 | | |
| | 5 | 0 | 0.000 | 0.00 | | |
| | 6 | 0 | 0.000 | 0.00 | | |
| 10 | 1 | 0 | 0.000 | 0.00 | 0.00 | #DIV/0! |
| | 2 | 0 | 0.000 | 0.00 | | |
| | 3 | 0 | 0.000 | 0.00 | | |
| | 4 | 0 | 0.000 | 0.00 | | |
| | 5 | 0 | 0.000 | 0.00 | | |
| | 6 | 0 | 0.000 | 0.00 | | |
| 15 | 1 | 4075 | 1.857 | 1.86 | 1.84 | 13.57 |
| | 2 | 3294 | 1.501 | 1.50 | | |
| | 3 | 4141 | 1.888 | 1.89 | | |
| | 4 | 4838 | 2.205 | 2.20 | | |
| | 5 | 3556 | 1.621 | 1.62 | | |
| | 6 | 4288 | 1.955 | 1.96 | | |
| 20 | 1 | 6347 | 2.893 | 2.91 | 2.87 | 6.05 |
| | 2 | 6262 | 2.854 | 2.87 | | |
| | 3 | 6298 | 2.871 | 2.89 | | |
| | 4 | 6792 | 3.096 | 3.12 | | |
| | 5 | 5614 | 2.559 | 2.58 | | |
| | 6 | 6158 | 2.807 | 2.83 | | |
| 30 | 1 | 8395 | 3.827 | 3.88 | 3.74 | 5.08 |
| | 2 | 8167 | 3.723 | 3.77 | | |
| | 3 | 7433 | 3.388 | 3.44 | | |
| | 4 | 8570 | 3.906 | 3.96 | | |
| | 5 | 7821 | 3.565 | 3.61 | | |
| | 6 | 8250 | 3.760 | 3.81 | | |
| 45 | 1 | 9715 | 4.428 | 4.52 | 4.46 | 4.13 |
| | 2 | 9990 | 4.554 | 4.64 | | |
| | 3 | 9231 | 4.208 | 4.30 | | |
| | 4 | 9589 | 4.371 | 4.47 | | |
| | 5 | 8981 | 4.094 | 4.18 | | |
| | 6 | 9951 | 4.536 | 4.63 | | |
| 60 | 1 | 10926 | 4.980 | 5.12 | 4.95 | 4.35 |
| | 2 | 10443 | 4.760 | 4.90 | | |
| | 3 | 10786 | 4.916 | 5.05 | | |
| | 4 | 11059 | 5.041 | 5.19 | | |
| | 5 | 9815 | 4.474 | 4.61 | | |
| | 6 | 10253 | 4.673 | 4.82 | | |
| 极限250转/ 分钟-10分 钟 | 1 | 10840 | 4.941 | 5.14 | 5.16 | 3.10 |
| | 2 | 11017 | 5.022 | 5.22 | | |
| | 3 | 11070 | 5.046 | 5.24 | | |
| | 4 | 11270 | 5.137 | 5.34 | | |
| | 5 | 10295 | 4.693 | 4.87 | | |
| | 6 | 10824 | 4.934 | 5.13 | | |

操作者：
日期：

复核者：
日期：

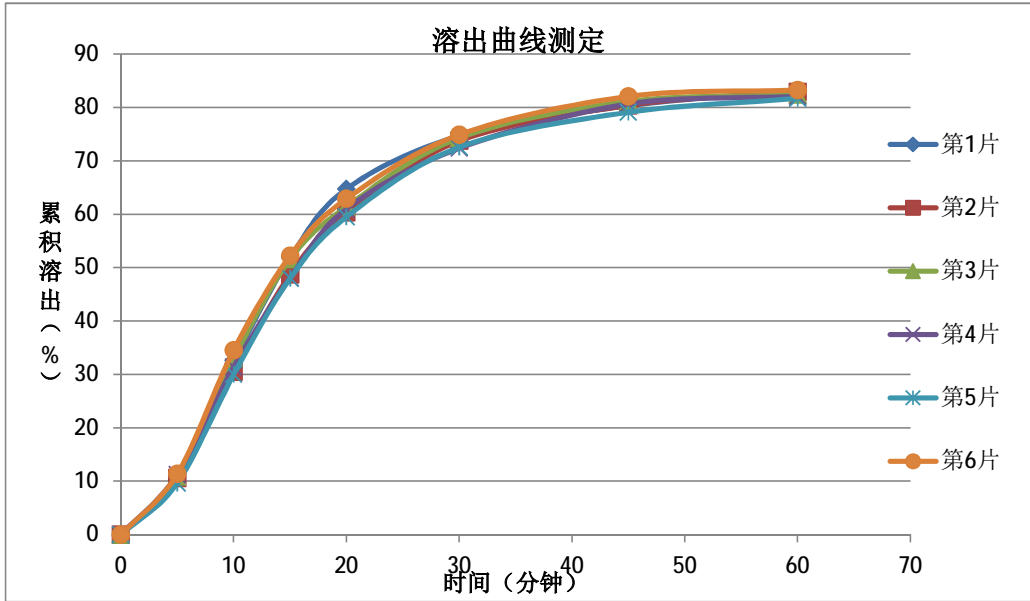
SMF-4109自制品溶出曲线[含0.1%吐温80的pH6.8磷酸盐缓冲液]-24112902批 (4mg投2片)

编号: RC-SMF-4109-0005 打印时间: 2024/12/6
 电脑名称: WLPC08
 路径: E:\RC\SMF-4109\2024-12\20241205\[SMF-4109-0005-rcqx-FX273-274.xlsm]zpz2-6.8+tw

| | | | | |
|----------|-------------|---------|--------|--------|
| 信息区 | 介质体积 | 900 | 补液体积 | 10 |
| 对照品批号 | 61123040205 | | 防伪码 | 611061 |
| 对照品水分 | 0.14% | 系数 | 1.0000 | |
| 对照品含量 | 100.5% | 对照品稀释倍数 | 4000 | |
| 是否计算累计溶出 | 是 | | | |
| 规格 (mg) | 8 | 供试品稀释倍数 | 2 | |

| 对照品溶液 | | | | | | | | |
|-------|----------|--------|--------|--------|--------|--------|--------|------|
| 序号 | 称样量 (mg) | A1 | A2 | A3 | A4 | A5 | A平均 | RSD% |
| 1 | 16.23 | 186416 | 187040 | 187350 | 188038 | 188278 | 187424 | 0.41 |
| 2 | 16.23 | 190761 | 191142 | - | - | - | 190952 | 0.15 |
| 响应值 | RSD% | 判断 | | | | | | |
| 11548 | 1.32 | 数据可信 | | | | | | |
| 11765 | | | | | | | | |

SMF-4109自制品溶出曲线[含0.1%吐温80的pH6.8磷酸盐缓冲液]-24112902批 (4mg投2片)



试验结论: 本品在含0.1%吐温80的pH6.8磷酸盐缓冲液介质中坎地沙坦酯溶出曲线测定结果, 溶出量随时间延长有增加趋势, 最终累积溶出未达100%。

操作者:

复核者:

日期:

日期:

SMF-4109自制品溶出曲线[含0.1%吐温80的pH6.8磷酸盐缓冲液]-24112902批（4mg投2片）

| 时间(min) | 样品 | A | 溶出量(%) | 累积(%) | 平均累积(%) | RSD% |
|------------------------|----|--------|--------|-------|---------|------|
| 0 | \ | 0 | 0 | 0 | 0 | 0 |
| 5 | 1 | 21907 | 10.610 | 10.61 | 10.73 | 5.82 |
| | 2 | 21794 | 10.556 | 10.56 | | |
| | 3 | 22542 | 10.918 | 10.92 | | |
| | 4 | 23160 | 11.217 | 11.22 | | |
| | 5 | 19933 | 9.654 | 9.65 | | |
| | 6 | 23551 | 11.406 | 11.41 | | |
| 10 | 1 | 67117 | 32.507 | 32.62 | 32.04 | 5.35 |
| | 2 | 62722 | 30.378 | 30.50 | | |
| | 3 | 68139 | 33.002 | 33.12 | | |
| | 4 | 64624 | 31.299 | 31.42 | | |
| | 5 | 61754 | 29.909 | 30.02 | | |
| | 6 | 71072 | 34.422 | 34.55 | | |
| 15 | 1 | 106085 | 51.380 | 51.86 | 50.09 | 4.00 |
| | 2 | 99673 | 48.275 | 48.73 | | |
| | 3 | 105511 | 51.102 | 51.59 | | |
| | 4 | 98356 | 47.637 | 48.11 | | |
| | 5 | 98242 | 47.582 | 48.02 | | |
| | 6 | 106806 | 51.730 | 52.24 | | |
| 20 | 1 | 131592 | 63.734 | 64.78 | 61.69 | 3.07 |
| | 2 | 122569 | 59.364 | 60.36 | | |
| | 3 | 124658 | 60.376 | 61.43 | | |
| | 4 | 124001 | 60.058 | 61.06 | | |
| | 5 | 120963 | 58.586 | 59.55 | | |
| | 6 | 127723 | 61.860 | 62.94 | | |
| 30 | 1 | 150587 | 72.934 | 74.69 | 73.78 | 1.46 |
| | 2 | 148884 | 72.109 | 73.76 | | |
| | 3 | 149887 | 72.595 | 74.32 | | |
| | 4 | 146057 | 70.740 | 72.41 | | |
| | 5 | 146509 | 70.959 | 72.58 | | |
| | 6 | 151042 | 73.154 | 74.93 | | |
| 45 | 1 | 160628 | 77.797 | 80.37 | 80.64 | 1.22 |
| | 2 | 161026 | 77.990 | 80.44 | | |
| | 3 | 162329 | 78.621 | 81.15 | | |
| | 4 | 161516 | 78.227 | 80.68 | | |
| | 5 | 158415 | 76.725 | 79.13 | | |
| | 6 | 164169 | 79.512 | 82.10 | | |
| 60 | 1 | 164529 | 79.687 | 83.12 | 82.60 | 0.76 |
| | 2 | 164477 | 79.661 | 82.98 | | |
| | 3 | 163109 | 78.999 | 82.41 | | |
| | 4 | 162649 | 78.776 | 82.10 | | |
| | 5 | 162000 | 78.462 | 81.72 | | |
| | 6 | 164804 | 79.820 | 83.29 | | |
| 极限250转/ 分钟-10分 钟 | 1 | 166037 | 80.417 | 84.74 | 84.61 | 0.91 |
| | 2 | 164609 | 79.725 | 83.93 | | |
| | 3 | 164140 | 79.498 | 83.78 | | |
| | 4 | 165768 | 80.287 | 84.49 | | |
| | 5 | 166513 | 80.648 | 84.78 | | |
| | 6 | 168435 | 81.578 | 85.93 | | |

操作者：
日期：

复核者：
日期：

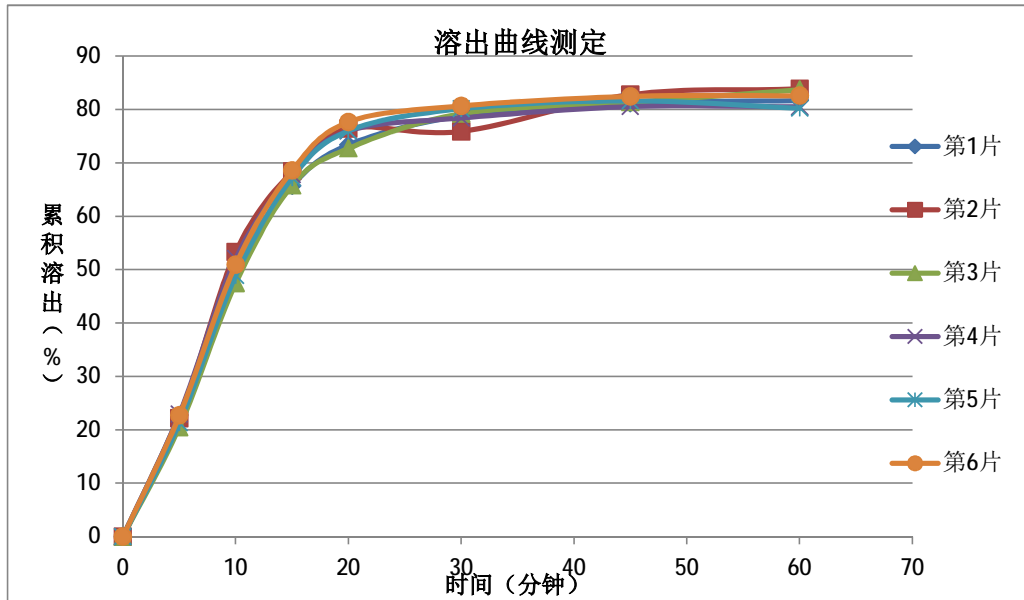
SMF-4109自制品溶出曲线[含0.35%吐温20的pH6.5磷酸盐缓冲液]-24112902批 (4mg投2片)

编号: RC-SMF-4109-0005 打印时间: 2024/12/6
 电脑名称: WLPC08
 路径: E:\RC\SMF-4109\2024-12\20241205\SMF-4109-0005-rcqx-FX273-274.xlsm\zpz2-6.5+tw

| | | | | |
|----------|-------------|---------|--------|--------|
| 信息区 | 介质体积 | 900 | 补液体积 | 10 |
| 对照品批号 | 61123040205 | | 防伪码 | 602276 |
| 对照品水分 | 0.14% | 系数 | 1.0000 | |
| 对照品含量 | 100.5% | 对照品稀释倍数 | 4000 | |
| 是否计算累计溶出 | 是 | | | |
| 规格 (mg) | 8 | 供试品稀释倍数 | 2 | |

| 对照品溶液 | | | | | | | | |
|-------|----------|--------|--------|--------|--------|--------|--------|------|
| 序号 | 称样量 (mg) | A1 | A2 | A3 | A4 | A5 | A平均 | RSD% |
| 1 | 16.23 | 192947 | 192758 | 192749 | 192793 | 192453 | 192740 | 0.10 |
| 2 | 16.23 | 192513 | 192543 | - | - | - | 192528 | 0.02 |
| 响应值 | RSD% | 判断 | | | | | | |
| 11876 | 0.09 | 数据可信 | | | | | | |
| 11862 | | | | | | | | |

SMF-4109自制品溶出曲线[含0.35%吐温20的pH6.5磷酸盐缓冲液]-24112902批 (4mg投2片)



试验结论: 本品在含0.35%吐温20的pH6.5磷酸盐缓冲液介质中坎地沙坦酯溶出曲线测定结果, 溶出量随时间延长有增加趋势, 最终累积溶出未达100%。

操作者:

复核者:

日期:

日期:

SMF-4109自制品溶出曲线[含0.35%吐温20的pH6.5磷酸盐缓冲液]-24112902批（4mg投2片）

| 时间(min) | 样品 | A | 溶出量(%) | 累积(%) | 平均累积(%) | RSD% |
|------------------------|----|--------|--------|-------|---------|------|
| 0 | \ | 0 | 0 | 0 | 0 | 0 |
| 5 | 1 | 47858 | 22.763 | 22.76 | 22.06 | 4.43 |
| | 2 | 46606 | 22.167 | 22.17 | | |
| | 3 | 43084 | 20.492 | 20.49 | | |
| | 4 | 48277 | 22.962 | 22.96 | | |
| | 5 | 44773 | 21.295 | 21.30 | | |
| | 6 | 47721 | 22.697 | 22.70 | | |
| 10 | 1 | 105256 | 50.063 | 50.32 | 50.51 | 4.15 |
| | 2 | 111539 | 53.051 | 53.30 | | |
| | 3 | 99439 | 47.296 | 47.52 | | |
| | 4 | 108922 | 51.806 | 52.06 | | |
| | 5 | 102345 | 48.678 | 48.91 | | |
| | 6 | 106564 | 50.685 | 50.94 | | |
| 15 | 1 | 136501 | 64.923 | 65.73 | 67.26 | 1.86 |
| | 2 | 142079 | 67.577 | 68.41 | | |
| | 3 | 136779 | 65.056 | 65.81 | | |
| | 4 | 140799 | 66.968 | 67.80 | | |
| | 5 | 139703 | 66.446 | 67.22 | | |
| | 6 | 142469 | 67.762 | 68.58 | | |
| 20 | 1 | 151121 | 71.877 | 73.41 | 75.39 | 2.53 |
| | 2 | 157401 | 74.864 | 76.45 | | |
| | 3 | 149823 | 71.260 | 72.74 | | |
| | 4 | 156521 | 74.446 | 76.02 | | |
| | 5 | 156684 | 74.523 | 76.04 | | |
| | 6 | 160036 | 76.117 | 77.69 | | |
| 30 | 1 | 160848 | 76.504 | 78.83 | 78.87 | 2.13 |
| | 2 | 154512 | 73.490 | 75.91 | | |
| | 3 | 161781 | 76.947 | 79.21 | | |
| | 4 | 159853 | 76.030 | 78.43 | | |
| | 5 | 163630 | 77.827 | 80.17 | | |
| | 6 | 164574 | 78.276 | 80.69 | | |
| 45 | 1 | 163987 | 77.997 | 81.18 | 81.68 | 1.03 |
| | 2 | 167305 | 79.575 | 82.81 | | |
| | 3 | 164507 | 78.244 | 81.37 | | |
| | 4 | 162585 | 77.330 | 80.58 | | |
| | 5 | 164926 | 78.443 | 81.65 | | |
| | 6 | 166500 | 79.192 | 82.48 | | |
| 60 | 1 | 163260 | 77.651 | 81.70 | 82.12 | 1.90 |
| | 2 | 167701 | 79.763 | 83.88 | | |
| | 3 | 167674 | 79.750 | 83.74 | | |
| | 4 | 160710 | 76.438 | 80.54 | | |
| | 5 | 160155 | 76.174 | 80.25 | | |
| | 6 | 164923 | 78.442 | 82.61 | | |
| 极限250转/ 分钟-10分 钟 | 1 | 161570 | 76.847 | 81.76 | 82.58 | 1.57 |
| | 2 | 160592 | 76.382 | 81.39 | | |
| | 3 | 167004 | 79.431 | 84.31 | | |
| | 4 | 164017 | 78.011 | 82.97 | | |
| | 5 | 160506 | 76.341 | 81.27 | | |
| | 6 | 165515 | 78.723 | 83.76 | | |

操作者：
日期：

复核者：
日期：

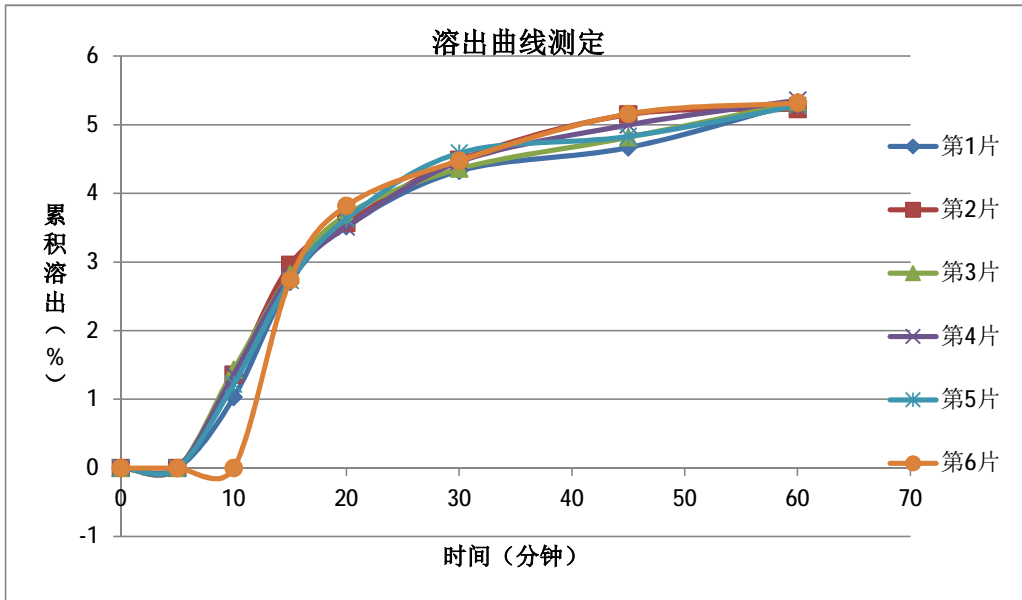
SMF-4109自制品溶出曲线[pH6.8磷酸盐缓冲液]-24112902批（4mg投2片）

编号：RC-SMF-4109-0005 打印时间：2024/12/6
 电脑名称：WLPC08
 路径：E:\RC\SMF-4109\2024-12\20241205\[SMF-4109-0005-rcqx-FX273-274.xlsm]zpz2-6.8

| | | | | |
|----------|-------------|---------|--------|--------|
| 信息区 | 介质体积 | 900 | 补液体积 | 10 |
| 对照品批号 | 61123040205 | | 防伪码 | 600000 |
| 对照品水分 | 0.14% | 系数 | 1.0000 | |
| 对照品含量 | 100.5% | 对照品稀释倍数 | 4000 | |
| 是否计算累计溶出 | 是 | | | |
| 规格（mg） | 8 | 供试品稀释倍数 | 2 | |

| 对照品溶液 | | | | | | | | |
|-------|---------|--------|--------|--------|--------|--------|--------|------|
| 序号 | 称样量（mg） | A1 | A2 | A3 | A4 | A5 | A平均 | RSD% |
| 1 | 16.23 | 192177 | 192694 | 192341 | 191352 | 191855 | 192084 | 0.27 |
| 2 | 16.23 | 191970 | 191669 | - | - | - | 191820 | 0.12 |
| 响应值 | RSD% | 判断 | | | | | | |
| 11835 | 0.10 | 数据可信 | | | | | | |
| 11819 | | | | | | | | |

SMF-4109自制品溶出曲线[pH6.8磷酸盐缓冲液]-24112902批（4mg投2片）



试验结论：本品在pH6.8磷酸盐缓冲液介质中坎地沙坦酯溶出曲线测定结果，溶出量随时间延长有增加趋势，最终累积溶出未达100%。

操作者：

复核者：

日期：

日期：

SMF-4109自制品溶出曲线[pH6.8磷酸盐缓冲液]-24112902批 (4mg投2片)

| 时间(min) | 样品 | A | 溶出量(%) | 累积(%) | 平均累积(%) | RSD% |
|------------------------|----|-------|--------|-------|---------|---------|
| 0 | \ | 0 | 0 | 0 | 0 | 0 |
| 5 | 1 | 0 | 0.000 | 0.00 | 0.00 | #DIV/0! |
| | 2 | 0 | 0.000 | 0.00 | | |
| | 3 | 0 | 0.000 | 0.00 | | |
| | 4 | 0 | 0.000 | 0.00 | | |
| | 5 | 0 | 0.000 | 0.00 | | |
| | 6 | 0 | 0.000 | 0.00 | | |
| 10 | 1 | 2169 | 1.035 | 1.03 | 1.07 | 50.78 |
| | 2 | 2838 | 1.355 | 1.36 | | |
| | 3 | 3001 | 1.432 | 1.43 | | |
| | 4 | 2860 | 1.365 | 1.36 | | |
| | 5 | 2557 | 1.220 | 1.22 | | |
| | 6 | 0 | 0.000 | 0.00 | | |
| 15 | 1 | 5654 | 2.699 | 2.71 | 2.79 | 3.30 |
| | 2 | 6159 | 2.940 | 2.96 | | |
| | 3 | 5881 | 2.807 | 2.82 | | |
| | 4 | 5834 | 2.785 | 2.80 | | |
| | 5 | 5690 | 2.716 | 2.73 | | |
| | 6 | 5739 | 2.739 | 2.74 | | |
| 20 | 1 | 7295 | 3.482 | 3.52 | 3.62 | 3.26 |
| | 2 | 7378 | 3.522 | 3.57 | | |
| | 3 | 7631 | 3.642 | 3.69 | | |
| | 4 | 7261 | 3.466 | 3.51 | | |
| | 5 | 7520 | 3.589 | 3.63 | | |
| | 6 | 7938 | 3.789 | 3.82 | | |
| 30 | 1 | 8899 | 4.248 | 4.33 | 4.45 | 2.13 |
| | 2 | 9236 | 4.408 | 4.49 | | |
| | 3 | 8953 | 4.273 | 4.36 | | |
| | 4 | 9157 | 4.371 | 4.46 | | |
| | 5 | 9438 | 4.505 | 4.59 | | |
| | 6 | 9227 | 4.404 | 4.48 | | |
| 45 | 1 | 9527 | 4.547 | 4.67 | 4.94 | 4.01 |
| | 2 | 10514 | 5.019 | 5.15 | | |
| | 3 | 9819 | 4.687 | 4.82 | | |
| | 4 | 10200 | 4.869 | 5.00 | | |
| | 5 | 9832 | 4.693 | 4.83 | | |
| | 6 | 10565 | 5.043 | 5.16 | | |
| 60 | 1 | 10777 | 5.144 | 5.32 | 5.31 | 0.86 |
| | 2 | 10548 | 5.035 | 5.23 | | |
| | 3 | 10772 | 5.142 | 5.33 | | |
| | 4 | 10845 | 5.176 | 5.36 | | |
| | 5 | 10669 | 5.092 | 5.28 | | |
| | 6 | 10769 | 5.140 | 5.32 | | |
| 极限250转/ 分钟-10分 钟 | 1 | 11628 | 5.550 | 5.79 | 5.48 | 3.03 |
| | 2 | 10622 | 5.070 | 5.32 | | |
| | 3 | 10902 | 5.204 | 5.45 | | |
| | 4 | 10762 | 5.137 | 5.38 | | |
| | 5 | 10848 | 5.178 | 5.42 | | |
| | 6 | 11060 | 5.279 | 5.51 | | |

操作者：
日期：

复核者：
日期：