

| 製品名  | オロパタジン塩酸塩OD錠2.5mg「AA」  |   |           |           |            |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
|------|--|---|-----------|-----------|------------|------|-----|------|--|--|--|-----|-----|-----|-----|----|---------------|---|------|------|------|------|----------------|-------|-------|-------|-------|------|-------------------------|-------|-------|-------|-------|-------|-------|-------|-------|------|-------------|--------|-------|-------|-------|----|-----|-------|-------|-------|-------|------|-----|------|--|--|--|-----|-----|-----|-----|----|---------------|---|------|------|------|------|----------------|-------|-------|-------|-------|------|-------------------------|-------|-------|-------|-------|-------|-------|-------|-------|------|-------------|--------|-------|-------|-------|----|-----|-------|-------|-------|-------|------|-----|------|--|--|--|-----|-----------|-----------|------------|----|---------------|---|------|------|------|------|----------------|-------|-------|-------|-------|------|-------------------------|-------|-------|-------|-------|-------|-------|-------|-------|------|-------------|--------|-------|-------|-------|----|-----|-------|-------|-------|-------|
| 試験名  | 安定性試験(無包装)   |   |           |           |            |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
| 試験方法 | 試験製剤   | オロパタジン塩酸塩OD錠2.5mg「AA」   |           |           |            |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
|      | 有効成分   | オロパタジン塩酸塩   |           |           |            |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
|      | 保存形態   | 無包装品  |           |           |            |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
|      | ロット番号  | 1408201   |           |           |            |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
|      | 保存条件   | ①温度(40°C±1°C・75%RH±5%RH、遮光・気密容器)<br>②湿度(25°C±2°C・75%RH±5%RH、開放)<br>③光(2500Lux、25°C±2°C・45%RH±5%RH、開放) |           |           |            |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
|      | 実施期間   | 2012年11月26日～2013年03月14日   |           |           |            |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
|      | 試験項目   | 性状、純度試験、溶出試験、定量試験及び硬度   |           |           |            |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
| 試験結果 | <p>オロパタジン塩酸塩OD錠2.5mg「AA」を無包装状態における各種条件下での安定性を検討した。その結果、すべての条件下において類縁物質の増加とわずかな含量の低下が認められたが、規格の範囲内であり品質の低下は認められず安定であった。また湿度条件では吸湿により硬度の低下が認められた。従って、本剤は湿度による品質の劣化を防ぐため、高湿度下を避けた保存が好ましいと考えられた。</p> <p>①温度</p> <table border="1"> <thead> <tr> <th rowspan="2">試験項目</th> <th rowspan="2">規格値</th> <th colspan="4">保存期間</th> </tr> <tr> <th>開始時</th> <th>1ヵ月</th> <th>2ヵ月</th> <th>3ヵ月</th> </tr> </thead> <tbody> <tr> <td>性状</td> <td>ごくうすい黄色の円形の素錠</td> <td>適</td> <td>変化なし</td> <td>変化なし</td> <td>変化なし</td> </tr> <tr> <td>純度試験</td> <td>総類縁物質質量:1.0%以下</td> <td>0.35%</td> <td>0.36%</td> <td>0.48%</td> <td>0.57%</td> </tr> <tr> <td rowspan="2">溶出試験</td> <td rowspan="2">最小値<br/>15分 85%以上<br/>平均値</td> <td>96.6%</td> <td>97.7%</td> <td>96.8%</td> <td>98.0%</td> </tr> <tr> <td>97.3%</td> <td>98.4%</td> <td>98.5%</td> <td>98.5%</td> </tr> <tr> <td>定量試験</td> <td>95.0～105.0%</td> <td>100.1%</td> <td>98.2%</td> <td>99.3%</td> <td>99.1%</td> </tr> <tr> <td>硬度</td> <td>参考値</td> <td>27.0N</td> <td>30.0N</td> <td>22.2N</td> <td>24.1N</td> </tr> </tbody> </table> <p>②湿度</p> <table border="1"> <thead> <tr> <th rowspan="2">試験項目</th> <th rowspan="2">規格値</th> <th colspan="4">保存期間</th> </tr> <tr> <th>開始時</th> <th>1ヵ月</th> <th>2ヵ月</th> <th>3ヵ月</th> </tr> </thead> <tbody> <tr> <td>性状</td> <td>ごくうすい黄色の円形の素錠</td> <td>適</td> <td>変化なし</td> <td>変化なし</td> <td>変化なし</td> </tr> <tr> <td>純度試験</td> <td>総類縁物質質量:1.0%以下</td> <td>0.35%</td> <td>0.33%</td> <td>0.31%</td> <td>0.42%</td> </tr> <tr> <td rowspan="2">溶出試験</td> <td rowspan="2">最小値<br/>15分 85%以上<br/>平均値</td> <td>96.6%</td> <td>96.2%</td> <td>97.3%</td> <td>96.9%</td> </tr> <tr> <td>97.3%</td> <td>98.0%</td> <td>99.1%</td> <td>98.0%</td> </tr> <tr> <td>定量試験</td> <td>95.0～105.0%</td> <td>100.1%</td> <td>99.7%</td> <td>99.3%</td> <td>98.8%</td> </tr> <tr> <td>硬度</td> <td>参考値</td> <td>27.0N</td> <td>15.9N</td> <td>15.8N</td> <td>14.4N</td> </tr> </tbody> </table> <p>③光</p> <table border="1"> <thead> <tr> <th rowspan="2">試験項目</th> <th rowspan="2">規格値</th> <th colspan="4">保存期間</th> </tr> <tr> <th>開始時</th> <th>30万Lux・hr</th> <th>60万Lux・hr</th> <th>120万Lux・hr</th> </tr> </thead> <tbody> <tr> <td>性状</td> <td>ごくうすい黄色の円形の素錠</td> <td>適</td> <td>変化なし</td> <td>変化なし</td> <td>変化なし</td> </tr> <tr> <td>純度試験</td> <td>総類縁物質質量:1.0%以下</td> <td>0.35%</td> <td>0.26%</td> <td>0.30%</td> <td>0.55%</td> </tr> <tr> <td rowspan="2">溶出試験</td> <td rowspan="2">最小値<br/>15分 85%以上<br/>平均値</td> <td>96.6%</td> <td>98.0%</td> <td>96.8%</td> <td>95.9%</td> </tr> <tr> <td>97.3%</td> <td>98.7%</td> <td>97.7%</td> <td>97.8%</td> </tr> <tr> <td>定量試験</td> <td>95.0～105.0%</td> <td>100.1%</td> <td>99.6%</td> <td>98.1%</td> <td>96.6%</td> </tr> <tr> <td>硬度</td> <td>参考値</td> <td>27.0N</td> <td>27.2N</td> <td>30.3N</td> <td>31.7N</td> </tr> </tbody> </table> |   |           |           |            | 試験項目 | 規格値 | 保存期間 |  |  |  | 開始時 | 1ヵ月 | 2ヵ月 | 3ヵ月 | 性状 | ごくうすい黄色の円形の素錠 | 適 | 変化なし | 変化なし | 変化なし | 純度試験 | 総類縁物質質量:1.0%以下 | 0.35% | 0.36% | 0.48% | 0.57% | 溶出試験 | 最小値<br>15分 85%以上<br>平均値 | 96.6% | 97.7% | 96.8% | 98.0% | 97.3% | 98.4% | 98.5% | 98.5% | 定量試験 | 95.0～105.0% | 100.1% | 98.2% | 99.3% | 99.1% | 硬度 | 参考値 | 27.0N | 30.0N | 22.2N | 24.1N | 試験項目 | 規格値 | 保存期間 |  |  |  | 開始時 | 1ヵ月 | 2ヵ月 | 3ヵ月 | 性状 | ごくうすい黄色の円形の素錠 | 適 | 変化なし | 変化なし | 変化なし | 純度試験 | 総類縁物質質量:1.0%以下 | 0.35% | 0.33% | 0.31% | 0.42% | 溶出試験 | 最小値<br>15分 85%以上<br>平均値 | 96.6% | 96.2% | 97.3% | 96.9% | 97.3% | 98.0% | 99.1% | 98.0% | 定量試験 | 95.0～105.0% | 100.1% | 99.7% | 99.3% | 98.8% | 硬度 | 参考値 | 27.0N | 15.9N | 15.8N | 14.4N | 試験項目 | 規格値 | 保存期間 |  |  |  | 開始時 | 30万Lux・hr | 60万Lux・hr | 120万Lux・hr | 性状 | ごくうすい黄色の円形の素錠 | 適 | 変化なし | 変化なし | 変化なし | 純度試験 | 総類縁物質質量:1.0%以下 | 0.35% | 0.26% | 0.30% | 0.55% | 溶出試験 | 最小値<br>15分 85%以上<br>平均値 | 96.6% | 98.0% | 96.8% | 95.9% | 97.3% | 98.7% | 97.7% | 97.8% | 定量試験 | 95.0～105.0% | 100.1% | 99.6% | 98.1% | 96.6% | 硬度 | 参考値 | 27.0N | 27.2N | 30.3N | 31.7N |
| 試験項目 | 規格値  | 保存期間  |           |           |            |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
|      |  | 開始時   | 1ヵ月       | 2ヵ月       | 3ヵ月        |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
| 性状   | ごくうすい黄色の円形の素錠  | 適   | 変化なし      | 変化なし      | 変化なし       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
| 純度試験 | 総類縁物質質量:1.0%以下   | 0.35%   | 0.36%     | 0.48%     | 0.57%      |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
| 溶出試験 | 最小値<br>15分 85%以上<br>平均値  | 96.6%   | 97.7%     | 96.8%     | 98.0%      |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
|      |  | 97.3%   | 98.4%     | 98.5%     | 98.5%      |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
| 定量試験 | 95.0～105.0%  | 100.1%  | 98.2%     | 99.3%     | 99.1%      |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
| 硬度   | 参考値  | 27.0N   | 30.0N     | 22.2N     | 24.1N      |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
| 試験項目 | 規格値  | 保存期間  |           |           |            |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
|      |  | 開始時   | 1ヵ月       | 2ヵ月       | 3ヵ月        |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
| 性状   | ごくうすい黄色の円形の素錠  | 適   | 変化なし      | 変化なし      | 変化なし       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
| 純度試験 | 総類縁物質質量:1.0%以下   | 0.35%   | 0.33%     | 0.31%     | 0.42%      |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
| 溶出試験 | 最小値<br>15分 85%以上<br>平均値  | 96.6%   | 96.2%     | 97.3%     | 96.9%      |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
|      |  | 97.3%   | 98.0%     | 99.1%     | 98.0%      |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
| 定量試験 | 95.0～105.0%  | 100.1%  | 99.7%     | 99.3%     | 98.8%      |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
| 硬度   | 参考値  | 27.0N   | 15.9N     | 15.8N     | 14.4N      |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
| 試験項目 | 規格値  | 保存期間  |           |           |            |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
|      |  | 開始時   | 30万Lux・hr | 60万Lux・hr | 120万Lux・hr |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
| 性状   | ごくうすい黄色の円形の素錠  | 適   | 変化なし      | 変化なし      | 変化なし       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
| 純度試験 | 総類縁物質質量:1.0%以下   | 0.35%   | 0.26%     | 0.30%     | 0.55%      |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
| 溶出試験 | 最小値<br>15分 85%以上<br>平均値  | 96.6%   | 98.0%     | 96.8%     | 95.9%      |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
|      |  | 97.3%   | 98.7%     | 97.7%     | 97.8%      |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
| 定量試験 | 95.0～105.0%  | 100.1%  | 99.6%     | 98.1%     | 96.6%      |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |
| 硬度   | 参考値  | 27.0N   | 27.2N     | 30.3N     | 31.7N      |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |     |     |     |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |      |     |      |  |  |  |     |           |           |            |    |               |   |      |      |      |      |                |       |       |       |       |      |                         |       |       |       |       |       |       |       |       |      |             |        |       |       |       |    |     |       |       |       |       |