

安定性試験(長期保存条件)に関する資料

共和薬品工業株式会社

| 製品名   | エバスチンOD錠10mg「アメル」  |                     |                     |                     |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
|-------|--|---------------------|---------------------|---------------------|------|-----|-----|-----|------|----|-----------|------------|------|------|------|------------|---|---|---|------|-------------|---|---|---|-------------|---|---|---|----|--------------|---------|---------|---------|-------|---------------------------|-----|---|---|-----|---------------------------|------|------|------|------|-----------------------|---------------------|---------------------|---------------------|------|-------------|-------|------|------|------|------|------|------|----|------|------|------|------|---|---|---|------|---|---|---|---|---|---|----|---------|---------|---------|-------|---|---|-----|-----|------|------|------|------|---------------------|---------------------|---------------------|------|------|------|------|
| 試験名   | 安定性試験(長期)  |                     |                     |                     |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
| 試験方法  | 試験製剤 エバスチンOD錠10mg「アメル」<br>有効成分 エバスチン<br>検体 PTP包装品(ポリ塩化ビニルフィルム+アルミニウム箔、アルミニウム袋)<br>保存条件 25°C60%RH、36ヶ月間<br>試験項目 性状、確認試験、純度試験、硬度、製剤均一性、崩壊性、溶出試験及び定量試験  |                     |                     |                     |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
| 試験結果  | 市販包装品を用いた長期保存試験(25±2°C、60±5%RH、36ヶ月間)の結果、エバスチンOD錠10mg「アメル」は通常の市場流通下において3年間安定であることが確認された。<br><br><div style="text-align: right;">(n=9)</div> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>試験項目</th> <th>規格値</th> <th>開始時</th> <th>6ヶ月</th> <th>12ヶ月</th> </tr> </thead> <tbody> <tr> <td>性状</td> <td>白色の素錠である。</td> <td>白色の素錠であった。</td> <td>変化なし</td> <td>変化なし</td> </tr> <tr> <td>確認試験</td> <td>紫外可視吸光度測定法</td> <td>適</td> <td>適</td> <td>適</td> </tr> <tr> <td rowspan="2">純度試験</td> <td>各縁物質:0.5%以下</td> <td>適</td> <td>適</td> <td>適</td> </tr> <tr> <td>総縁物質:1.0%以下</td> <td>適</td> <td>適</td> <td>適</td> </tr> <tr> <td>硬度</td> <td>20N(2.0kg)以上</td> <td>34(3.5)</td> <td>37(3.8)</td> <td>36(3.7)</td> </tr> <tr> <td>製剤均一性</td> <td>日局 含量均一性試験<br/>判定値:15.0%以下</td> <td>0.9</td> <td>—</td> <td>—</td> </tr> <tr> <td>崩壊性</td> <td>日局 崩壊試験法<br/>即放性製剤(秒)60秒以内</td> <td>29.3</td> <td>32.7</td> <td>27.3</td> </tr> <tr> <td>溶出試験</td> <td>日局 溶出試験法<br/>15分間80%以上</td> <td>92.0<br/>(87.0~95.0)</td> <td>89.8<br/>(87.0~92.0)</td> <td>87.0<br/>(84.0~92.0)</td> </tr> <tr> <td>定量試験</td> <td>95.0~105.0%</td> <td>100.1</td> <td>98.3</td> <td>99.5</td> </tr> </tbody> </table><br><table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>試験項目</th> <th>18ヶ月</th> <th>24ヶ月</th> <th>36ヶ月</th> </tr> </thead> <tbody> <tr> <td>性状</td> <td>変化なし</td> <td>変化なし</td> <td>変化なし</td> </tr> <tr> <td>確認試験</td> <td>適</td> <td>適</td> <td>適</td> </tr> <tr> <td rowspan="2">純度試験</td> <td>適</td> <td>適</td> <td>適</td> </tr> <tr> <td>適</td> <td>適</td> <td>適</td> </tr> <tr> <td>硬度</td> <td>36(3.7)</td> <td>32(3.3)</td> <td>31(3.2)</td> </tr> <tr> <td>製剤均一性</td> <td>—</td> <td>—</td> <td>2.2</td> </tr> <tr> <td>崩壊性</td> <td>24.7</td> <td>24.7</td> <td>24.3</td> </tr> <tr> <td>溶出試験</td> <td>83.2<br/>(80.0~85.7)</td> <td>82.8<br/>(80.0~88.0)</td> <td>85.1<br/>(82.1~91.0)</td> </tr> <tr> <td>定量試験</td> <td>98.7</td> <td>98.8</td> <td>99.5</td> </tr> </tbody> </table> |                     |                     |                     | 試験項目 | 規格値 | 開始時 | 6ヶ月 | 12ヶ月 | 性状 | 白色の素錠である。 | 白色の素錠であった。 | 変化なし | 変化なし | 確認試験 | 紫外可視吸光度測定法 | 適 | 適 | 適 | 純度試験 | 各縁物質:0.5%以下 | 適 | 適 | 適 | 総縁物質:1.0%以下 | 適 | 適 | 適 | 硬度 | 20N(2.0kg)以上 | 34(3.5) | 37(3.8) | 36(3.7) | 製剤均一性 | 日局 含量均一性試験<br>判定値:15.0%以下 | 0.9 | — | — | 崩壊性 | 日局 崩壊試験法<br>即放性製剤(秒)60秒以内 | 29.3 | 32.7 | 27.3 | 溶出試験 | 日局 溶出試験法<br>15分間80%以上 | 92.0<br>(87.0~95.0) | 89.8<br>(87.0~92.0) | 87.0<br>(84.0~92.0) | 定量試験 | 95.0~105.0% | 100.1 | 98.3 | 99.5 | 試験項目 | 18ヶ月 | 24ヶ月 | 36ヶ月 | 性状 | 変化なし | 変化なし | 変化なし | 確認試験 | 適 | 適 | 適 | 純度試験 | 適 | 適 | 適 | 適 | 適 | 適 | 硬度 | 36(3.7) | 32(3.3) | 31(3.2) | 製剤均一性 | — | — | 2.2 | 崩壊性 | 24.7 | 24.7 | 24.3 | 溶出試験 | 83.2<br>(80.0~85.7) | 82.8<br>(80.0~88.0) | 85.1<br>(82.1~91.0) | 定量試験 | 98.7 | 98.8 | 99.5 |
| 試験項目  | 規格値  | 開始時                 | 6ヶ月                 | 12ヶ月                |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
| 性状    | 白色の素錠である。  | 白色の素錠であった。          | 変化なし                | 変化なし                |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
| 確認試験  | 紫外可視吸光度測定法   | 適                   | 適                   | 適                   |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
| 純度試験  | 各縁物質:0.5%以下  | 適                   | 適                   | 適                   |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
|       | 総縁物質:1.0%以下  | 適                   | 適                   | 適                   |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
| 硬度    | 20N(2.0kg)以上   | 34(3.5)             | 37(3.8)             | 36(3.7)             |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
| 製剤均一性 | 日局 含量均一性試験<br>判定値:15.0%以下  | 0.9                 | —                   | —                   |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
| 崩壊性   | 日局 崩壊試験法<br>即放性製剤(秒)60秒以内  | 29.3                | 32.7                | 27.3                |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
| 溶出試験  | 日局 溶出試験法<br>15分間80%以上  | 92.0<br>(87.0~95.0) | 89.8<br>(87.0~92.0) | 87.0<br>(84.0~92.0) |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
| 定量試験  | 95.0~105.0%  | 100.1               | 98.3                | 99.5                |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
| 試験項目  | 18ヶ月   | 24ヶ月                | 36ヶ月                |                     |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
| 性状    | 変化なし   | 変化なし                | 変化なし                |                     |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
| 確認試験  | 適  | 適                   | 適                   |                     |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
| 純度試験  | 適  | 適                   | 適                   |                     |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
|       | 適  | 適                   | 適                   |                     |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
| 硬度    | 36(3.7)  | 32(3.3)             | 31(3.2)             |                     |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
| 製剤均一性 | —  | —                   | 2.2                 |                     |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
| 崩壊性   | 24.7   | 24.7                | 24.3                |                     |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
| 溶出試験  | 83.2<br>(80.0~85.7)  | 82.8<br>(80.0~88.0) | 85.1<br>(82.1~91.0) |                     |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |
| 定量試験  | 98.7   | 98.8                | 99.5                |                     |      |     |     |     |      |    |           |            |      |      |      |            |   |   |   |      |             |   |   |   |             |   |   |   |    |              |         |         |         |       |                           |     |   |   |     |                           |      |      |      |      |                       |                     |                     |                     |      |             |       |      |      |      |      |      |      |    |      |      |      |      |   |   |   |      |   |   |   |   |   |   |    |         |         |         |       |   |   |     |     |      |      |      |      |                     |                     |                     |      |      |      |      |