

試験成績書

製品名 ブロスマック NTM

Lot No. BBZOAV01

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判定 合格

極東製薬工業株式会社

茨城県高萩市上手綱朝山3333-26

| 試験項目 | 規格 | 結果/判定 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------|--|---------------------------------------|---------------------------------|---------------------------------------|---------------------------------|----|------|---------|---|----|------|-------|---|----|------|---------|---|-----|---|--------|----------|------|-----|---------|---|-----|---------|--------|---|----|----|----|---|-----|------|----|---|-----|-------|------------|------------|--|
| 包装 | 異常を認めない | 適合 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 性状 | 異常を認めない | 適合 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 無菌試験 | 陰性 | 適合 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 感度・正確性試験 | MICが規格内であること | 適合 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <table><thead><tr><th>薬剤名</th><th><i>M. avium</i> ATCC25291</th><th><i>M. intracellulare</i> ATCC13950</th><th><i>M. kansasii</i> ATCC12478</th></tr></thead><tbody><tr><td>SM</td><td>2~16</td><td>0.125~1</td><td>—</td></tr><tr><td>EB</td><td>4~32</td><td>0.5~4</td><td>—</td></tr><tr><td>KM</td><td>2~16</td><td>0.125~1</td><td>—</td></tr><tr><td>RFP</td><td>—</td><td>≤0.125</td><td>0.06~0.5</td></tr><tr><td>LVFX</td><td>1~8</td><td>0.125~1</td><td>—</td></tr><tr><td>CAM</td><td>0.125~1</td><td>≤0.125</td><td>—</td></tr><tr><td>TH</td><td>4≤</td><td>8≤</td><td>—</td></tr><tr><td>AMK</td><td>2~16</td><td>≤2</td><td>—</td></tr><tr><td>RBT</td><td>0.5~2</td><td>0.008~0.06</td><td>0.008~0.06</td></tr></tbody></table> | 薬剤名 | <i>M. avium</i> ATCC25291 | <i>M. intracellulare</i> ATCC13950 | <i>M. kansasii</i> ATCC12478 | SM | 2~16 | 0.125~1 | — | EB | 4~32 | 0.5~4 | — | KM | 2~16 | 0.125~1 | — | RFP | — | ≤0.125 | 0.06~0.5 | LVFX | 1~8 | 0.125~1 | — | CAM | 0.125~1 | ≤0.125 | — | TH | 4≤ | 8≤ | — | AMK | 2~16 | ≤2 | — | RBT | 0.5~2 | 0.008~0.06 | 0.008~0.06 | |
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| SM | 2~16 | 0.125~1 | — | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| EB | 4~32 | 0.5~4 | — | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| KM | 2~16 | 0.125~1 | — | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| RFP | — | ≤0.125 | 0.06~0.5 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| LVFX | 1~8 | 0.125~1 | — | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CAM | 0.125~1 | ≤0.125 | — | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| TH | 4≤ | 8≤ | — | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| AMK | 2~16 | ≤2 | — | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| RBT | 0.5~2 | 0.008~0.06 | 0.008~0.06 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 同時再現性試験 | 感度・正確性試験を3回繰り返す時、全て規格に適合する | 適合 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

判定者 工藤