薬食審査発1125第1号
平成２５年11月25日

各 都道府県 保健所設置市 特別区 衛生主管部（局）長　殿

厚生労働省医薬食品局審査管理課長
（公　印　省　略）

抗インフルエンザウイルス薬リレンザの有効期間の延長等について

抗インフルエンザウイルス薬であるリレンザについては、リレンザの製造販売業者であるグラクソ・スミスクライン株式会社より、リレンザの安定性に係る試験成績を添付した報告書が別添のとおり提出されたことから、その内容を確認し、次回以降製造分よりリレンザの有効期間を１０年間に延長することは差し支えないものと考えますのでお知らせします。

また、報告書の別紙「リレンザ安定性試験結果報告書」において、リレンザについて、「室温下において適切に保管される場合、製造後１０年間は承認規格から逸脱しないものと考えます。」とされており、その内容についても差し支えないものと考えますのでお知らせします。

つきましては、貴管下関係医療機関に対し周知されるようお取り計らい願います。

受付
第　号
25.12.-2
熊本市保健所
医療政策課

平成25年11月21日

厚生労働省医薬食品局
審査管理課長 佐藤 岳幸　　殿

グラクソ・スミスクライン株式会社
代表取締役社長 フィリップ・フォシェ

# リレンザ 使用期限延長に関する報告書

抗インフルエンザウイルス薬であるリレンザはその貯蔵方法及び有効期間欄を空欄（有効期間3年以上）として平成11年12月27日に承認されました。当初は使用期限を3年としておりましたが、その後、安定性試験の結果に基づき、平成17年11月出荷分より使用期限を5年とし、さらに平成21年6月以降製造分より使用期限を7年に延長して供給しております。

今般、10年の使用期限の延長が可能と判断できる安定性試験結果が新たに得られましたので、この結果に基づき、次回以降製造分より、使用期限を10年と設定することとしましたので、安定性試験報告書（別紙）を添えて報告いたします。

別紙　「リレンザ安定性試験結果報告書」

## 序論

グラクソ・スミスクライン社はリレンザの有効期間を７年から１０年に延長するための安定性試験を実施し、その結果を評価しましたので報告いたします。

## 安定性試験結果及び考察

表１に安定性試験に用いたロットの詳細を示します。また、表２－１から表２－６に安定性試験の実施計画、表３～表１４に安定性試験結果の詳細を示します。

なお、30℃/65%RHと記載した保存条件は試験開始時には30℃/60%RHで保存を開始し、ICHQ1Aの改訂後の[redacted]年[redacted]月から30℃/65%RHに変更しております（ロット[redacted], [redacted], [redacted]及び[redacted]を除く）。

（１）[redacted]工場の製造ロット

ロット[redacted],[redacted],[redacted],[redacted],[redacted],[redacted]はそれぞれ[redacted]ヶ月、[redacted]ヶ月、[redacted]ヶ月、[redacted]ヶ月、[redacted]ヶ月及び[redacted]ヶ月までの結果が得られ、全ての試験項目で承認規格に適合し、経時的変化もほとんど認められず、10年保存後も承認規格に適合することを確認しました。

ロット[redacted]は試験開始時、[redacted]ヶ月及び[redacted]ヶ月のポイントのみで試験を行い、全ての試験項目で承認規格に適合し、経時的変化もほとんど認められませんでした。

ロット[redacted]は試験開始時及び25℃/60%RHにおいて[redacted]ヶ月のポイントと30℃/65% RHにおいて[redacted]ヶ月までの試験を行い、全ての試験項目で承認規格に適合し、経時的変化もほとんど認められませんでした。

（２）[redacted]工場の製造ロット

ロット[redacted],[redacted],[redacted]は30℃/65%RHにおいて[redacted]ヶ月までの試験結果が得られており、全ての試験項目で承認規格に適合し、経時的変化もほとんど認められないことから、[redacted]工場の製造ロットと同等以上の安定性を有すると判断いたしました。

類縁物質は承認規格には設定しておりませんが、安定性評価の指標として試験を実施しており、製造工場にかかわらず全てのロットにおいて経時的な変化はほとんど認められませんでした。

以上の結果から、[redacted] 工場で製造された、ロット[redacted],[redacted],[redacted] は 120 ヶ月以上安定であることが確認されました。また [redacted] 工場で製造されたロット[redacted],[redacted],[redacted]については[redacted] ヶ月まで安定であることが確認されました。

なお、ロット[redacted],[redacted] はそれぞれ微粒子量試験結果、含量の試験結果が全ロット中で最も規格限度値に近かったため、95%信頼区間を求めたところ、図１及び図２に示しましたように、予測された有効期間は 120 ヶ月以上を示しました。

以上より製造工場にかかわらず、リレンザは120ヶ月の期間安定であると考えられます。なお、本品のデバイスは長期間保存しても安定であることを確認しています。

## 結論

表３～表１４に示した安定性試験結果から、リレンザは長期保存後も承認規格を満たすこと、さらに図１及び図２に示した有効期間の予測からも長期間安定であることを確認しました。これらの結果は、有効期間を 7 年から 10 年に延長することを支持すると考え、リレンザを室温で保存する場合の有効期間を 10 年に延長することが可能であると判断いたしました。

なお、本安定性試験の結果から、室温下において適切に保管される場合、製造後 10 年間は承認規格から逸脱しないものと考えます。

## 表1 ロットの詳細

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| ロット番号 | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 製造スケール | 実生産 | | | | | | | | | | |
| 製造場所 | [redacted] | | | | | | | | [redacted] | | |
| 包装形態 | アルミニウム　ブリスター | | | | | | | | | | |
| 製造年月 | [redacted]年[redacted]月 | [redacted]年[redacted]月 | [redacted]年[redacted]月 | [redacted]年[redacted]月 | [redacted]年[redacted]月 | [redacted]年[redacted]月 | [redacted]年[redacted]月 | [redacted]年[redacted]月 | [redacted]年[redacted]月 | [redacted]年[redacted]月 | [redacted]年[redacted]月 |
| 試験開始年月 | [redacted]年[redacted]月 | [redacted]年[redacted]月 | [redacted]年[redacted]月 | [redacted]年[redacted]月 | [redacted]年[redacted]月 | [redacted]年[redacted]月 | [redacted]年[redacted]月 | [redacted]年[redacted]月 | [redacted]年[redacted]月 | [redacted]年[redacted]月 | [redacted]年[redacted]月 |

## 表2－1 安定性試験の実施計画

| 保存条件 | ロット番号 | 保存期間（ヶ月） | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 0 | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted]℃/[redacted]%RH | [redacted] | [redacted] | | | | | | | |
| [redacted]℃/[redacted]%RH | [redacted] | | | | | | | | |
| [redacted]℃/[redacted]%RH | [redacted] | | | | | | | | |
| [redacted]℃/[redacted]%RH | [redacted] | | | | | | | | |
| [redacted]℃/[redacted]%RH | [redacted] | | | | | | | | |
| [redacted]℃/[redacted]%RH | [redacted] | | | | | | | | |

## 表2－2 安定性試験の実施計画（続き）

| 保存条件 | ロット番号 | 保存期間（ヶ月） |
|---|---|---|
| [redacted]℃/[redacted]%RH | [redacted] | [redacted] |
| [redacted]℃/[redacted]%RH | [redacted] | |
| [redacted]℃/[redacted]%RH | [redacted] | |
| [redacted]℃/[redacted]%RH | [redacted] | |
| [redacted]℃/[redacted]%RH | [redacted] | |
| [redacted]℃/[redacted]%RH | [redacted] | |

測定項目[redacted]：[redacted]
測定項目[redacted]：[redacted]
測定項目[redacted]：[redacted]
測定項目[redacted]：[redacted]
－：実施せず

**表2－3 安定性試験の実施計画**

| 保存条件 | ロット番号 | 保存期間（ヶ月） | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 0 | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted]℃/[redacted]%RH | [redacted] | [redacted] | | | | | | | |
| [redacted]℃/[redacted]%RH | [redacted] | | | | | | | | |
| [redacted]℃/[redacted]%RH | [redacted] | | | | | | | | |

**表2－4 安定性試験の実施計画（続き）**

| 保存条件 | ロット番号 | 保存期間（ヶ月） |
|---|---|---|
| | | [redacted] |
| [redacted]℃/[redacted]%RH | [redacted] | |
| [redacted]℃/[redacted]%RH | [redacted] | |
| [redacted]℃/[redacted]%RH | [redacted] | |

測定項目[redacted]：[redacted]
測定項目[redacted]：[redacted]
測定項目[redacted]：[redacted]
測定項目[redacted]：[redacted]
－：実施せず
[redacted]ヶ月後の試験ポイントにおいては検体残量に応じ下記の試験項目を実施する。
測定項目[redacted]：[redacted]
測定項目[redacted]：[redacted]
－：実施せず

**表2－5 安定性試験の実施計画**

| 保存条件 | ロット番号 | 保存期間（ヶ月） | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 0 | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted]℃/[redacted]%RH | [redacted] | [redacted] | | | | | | | |
| [redacted]℃/[redacted]%RH | [redacted] | | | | | | | | |
| [redacted]℃/[redacted]%RH | [redacted] | | | | | | | | |

**表2－6 安定性試験の実施計画（続き）**

| 保存条件 | ロット番号 | 保存期間（ヶ月） |
|---|---|---|
| | | [redacted] |
| [redacted]℃/[redacted]%RH | [redacted] | |
| [redacted]℃/[redacted]%RH | [redacted] | |
| [redacted]℃/[redacted]%RH | [redacted] | |

測定項目[redacted]：[redacted]
測定項目[redacted]：[redacted]
－：実施せず

## 表3 リレンザ(ロット[redacted])の安定性試験結果

保存条件:[redacted]℃/[redacted]%RH

| 測定項目 | 規格 | 保存期間（ヶ月） | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0 | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 性状 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 |
| 含量（mg/ブリスター） | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 類縁物質(% w/w) | [redacted] | | | | | | | | | | | | | |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

－：実施せず

*：保存条件は[redacted]年[redacted]月[redacted]日より[redacted]℃/[redacted]%RHから[redacted]℃/[redacted]%RHに変更

## 表4 リレンザ(ロット[redacted])の安定性試験結果

保存条件:[redacted]℃/[redacted]%RH

| 測定項目 | 規格 | 保存期間（ヶ月） | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0 | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 性状 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 |
| 含量（mg/ブリスター） | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 類縁物質(% w/w) | [redacted] | | | | | | | | | | | | | |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

－：実施せず

ND：検出せず

*：保存条件は[redacted]年[redacted]月[redacted]日より[redacted]℃/[redacted]%RHから[redacted]℃/[redacted]%RHに変更

## 表5 リレンザ(ロット[redacted])の安定性試験結果

保存条件:[redacted]℃/[redacted]RH

| 測定項目 | 規格 | 保存期間（ヶ月） | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0 | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 性状 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 |
| 含量（mg/ブリスター） | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 類縁物質(% w/w) | [redacted] | | | | | | | | | | |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

－：実施せず

ND：検出せず

*：保存条件は[redacted]年[redacted]月[redacted]日より[redacted]℃/[redacted]%RHから[redacted]℃/[redacted]%RHに変更

## 表6 リレンザ(ロット[redacted])の安定性試験結果

保存条件:[redacted]℃/[redacted]%RH

| 測定項目 | 規格 | 保存期間（ヶ月） | | |
|---|---|---|---|---|
| | | 0 | [redacted] | [redacted] |
| 性状 | 適合 | 適合 | 適合 | 適合 |
| 含量（mg/ブリスター） | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 類縁物質(% w/w) | [redacted] | | | |
| [redacted] | | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

－：実施せず

*：保存条件は[redacted]年[redacted]月[redacted]日より[redacted]℃/[redacted]%RHから[redacted]℃/[redacted]%RHに変更

## 表7 リレンザ(ロット[redacted])の安定性試験結果

保存条件:[redacted]℃/[redacted]%RH

| 測定項目 | 規格 | 保存期間（ヶ月） | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0 | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 性状 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 |
| 含量（mg/ブリスター） | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 類縁物質(% w/w) | [redacted] | | | | | | | | | | | |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

－：実施せず

*：保存条件は[redacted]年[redacted]月[redacted]日より[redacted]℃/[redacted]%RHから[redacted]℃/[redacted]%RHに変更

## 表8 リレンザ(ロット[redacted])の安定性試験結果

保存条件:[redacted]℃/[redacted]%RH

| 測定項目 | 規格 | 保存期間（ヶ月） | |
|---|---|---|---|
| | | 0 | [redacted] |
| 性状 | 適合 | 適合 | 適合 |
| 含量（mg/ブリスター） | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] |
| 類縁物質(% w/w) | [redacted] | | |
| [redacted] | | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] |

－：実施せず

## 表9 リレンザ(ロット[redacted])の安定性試験結果

保存条件:[redacted]℃/[redacted]%RH

| 測定項目 | 規格 | 保存期間（ヶ月） | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0 | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 性状 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 |
| 含量（mg/ブリスター） | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 類縁物質(% w/w) | [redacted] | | | | | | | | | | | | | | | | |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

－：実施せず

*：保存条件は[redacted]年[redacted]月[redacted]日より[redacted]℃/[redacted]%RHから[redacted]℃/[redacted]%RHに変更

## 表10 リレンザ(ロット[redacted])の安定性試験結果

保存条件:[redacted]℃/[redacted]%RH

| 測定項目 | 規格 | 保存期間（ヶ月） | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0 | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 性状 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 |
| 含量（mg/ブリスター） | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 類縁物質(% w/w) | [redacted] | | | | | | | | | | | | | | | | |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

－：実施せず

*：保存条件は[redacted]年[redacted]月[redacted]日より[redacted]℃/[redacted]%RHから[redacted]℃/[redacted]%RHに変更

## 表11 リレンザ(ロット[redacted])の安定性試験結果

保存条件:[redacted]℃/[redacted]%RH

| 測定項目 | 規格 | 保存期間（ヶ月） | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0 | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 性状 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 |
| 含量（mg/ブリスター） | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 類縁物質(% w/w) | [redacted] | | | | | | | | | | | | | | | |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

－：実施せず

## 表12 リレンザ(ロット[redacted])の安定性試験結果

保存条件:[redacted]℃/[redacted]%RH

| 測定項目 | 規格 | 保存期間（ヶ月） | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0 | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 性状 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 |
| 含量（mg/ブリスター） | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 類縁物質(% w/w) | [redacted] | | | | | | | | | | | | | |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

－：実施せず

ND：検出せず

## 表13 リレンザ(ロット[redacted])の安定性試験結果

保存条件:[redacted]℃/[redacted]%RH

| 測定項目 | 規格 | 保存期間（ヶ月） | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0 | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 性状 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 |
| 含量（mg/ブリスター） | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 類縁物質(% w/w) | [redacted] | | | | | | | | | | | | | |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

－：実施せず

ND：検出せず

## 表14 リレンザ(ロット[redacted])の安定性試験結果

保存条件:[redacted]℃/[redacted]%RH

| 測定項目 | 規格 | 保存期間（ヶ月） | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0 | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 性状 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 | 適合 |
| 含量（mg/ブリスター） | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 類縁物質(% w/w) | [redacted] | | | | | | | | | | | | | |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

－：実施せず

ND：検出せず

図1 リレンザ(ロット[redacted])の安定性試験結果[redacted]の 95%信頼区間

[redacted]

図2 リレンザ(ロット[redacted])の安定性試験結果[redacted]の 95%信頼区間

[redacted]