***Welcome to Stillman Translations preliminary onboarding assessment!***

*This assessment has 5 sections. Make sure to follow the instructions and complete all the information needed.*

*The goal of this request is to analyze your performance and your potential.*

*Breathe in and out, and do your best. Hope we can count on you soon!*

**SECTION 1. INSTRUCTIONS**

Below you will find a special instruction for section 3:

\*Please make sure target text mirrors source format.

\*Normalize spaces.

**SECTION 2. GLOSSARY**

*In this section, you are required to complete this task:*

*\*Extract four terms (cells 1 to 4) from the text in Section 3 that you consider are worth being in the glossary.*

|  |  |  |
| --- | --- | --- |
|  | **Source** | **Target** |
| 1 | drug product | medicamento |
| 2 | emergency supply | suministro de emergencia |
| 3 | shelf life | periodo de validez |
| 4 | storage | almacenamiento |

**SECTION 3. TRANSLATION**

Please, add your sample translation below (between 300-500 words). Bear in mind this should be the best sample of your work!

|  |  |
| --- | --- |
| **Source** | **Target** |
| Discussion of the ChangesAddition of Drug Product Storage Condition of -20±5 °C Drug product stability data at -20±5 °C are updated in Section 3.2.P.8.1 Stability Summary and Conclusions and Section 3.2.P.8.3 Stability Data – Accelerated in support of an additional storage condition of -20±5 °C for up to 2 weeks. Updates include results at the accelerated condition of -20±5 °C for emergency supply and/or process performance qualification lots EL7834, EK4242, EJ1688, EJ1686, EK1768, EJ1685, EJ0553 EE8492, and EE8493. Current available data at the accelerated condition of -20±5 °C include up to 3 months of data from two emergency supply lots (pre-process performance qualification lots EE8492 and EE8493) and 1 month of data for all other lots. All data generated to date (15-JAN-2021) at the -20±5 °C storage condition are within the specifications stated for drug product lots and support an additional storage at -20±5 °C for up to 2 weeks. As additional stability data is obtained on the process performance qualification lots that will be enrolled in formal stability programs after they are manufactured, extensions for shelf life at the long-term storage condition as well as short-term durations at alternate temperatures may be considered. Information to Fulfill Recommendations As noted in Table 2.3-1, the information presented in this submission partially fulfills Recommendation REC 22. The additional storage at -20±5 °C for up to 2 weeks, supported by stability data from multiple drug product lots at -20±5 °C, fulfills the recommendation to investigate opportunities for storage conditions for the finished product at -20 °C. As additional data are obtained, the possibilities of prolonging the in-use storage time (before dilution) at 2-8 °C and extending the claims for transport conditions at 2-8 °C will be evaluated. Conclusion In order to support an additional storage condition of -20±5 °C for up to 2 weeks, up to 3 months of stability data at the -20±5 °C storage condition is provided from multiple drug product lots. | Análisis de los CambiosAdición de la Condición de Almacenamiento del Producto a -20 ± 5 °C Los datos de estabilidad del medicamento a -20 ± 5 °C se actualizaron en la Sección 3.2.P.8.1 Resumen de Estabilidad y Conclusiones y en la Sección 3.2.P.8.3 Datos de Estabilidad: Acelerada para respaldar una condición de almacenamiento adicional de -20 ± 5 °C durante hasta 2 semanas. Las actualizaciones incluyen los resultados en las condiciones aceleradas a -20 ± 5 °C de lotes de suministro de emergencia y/o de lotes de la calificación de rendimiento del proceso EL7834, EK4242, EJ1688, EJ1686, EK1768, EJ1685, EJ0553 EE8492 y EE8493. Los datos disponibles actuales en la condición acelerada a -20 ± 5 °C incluyen hasta 3 meses de datos de dos lotes de suministro (lotes EE8492 y EE8493 de la calificación de rendimiento del preproceso) y 1 mes de datos de todos los otros lotes. Todos los datos generados hasta el momento (2021-01-15) en la condición de almacenamiento a -20 ± 5 °C se encuentran dentro de las especificaciones establecidas para los lotes del medicamento y respaldan un almacenamiento adicional a -20 ± 5 °C durante hasta 2 semanas. En cuanto se obtengan los datos de los lotes de la calificación de rendimiento del proceso que se inscribirán en programas de estabilidad formal después de su fabricación, se pueden considerar extensiones del periodo de validez en la condición de almacenamiento a largo plazo y en duraciones a corto plazo en temperaturas alternativas. Información para Completar las Recomendaciones Como se señaló en la Tabla 2.3-1, la información que se exhibe en esta presentación cumple parcialmente la Recomendación REC 22. El almacenamiento adicional a -20 ± 5 °C durante hasta 2 semanas, respaldado por los datos de estabilidad de varios lotes del medicamento a -20 ± 5 °C, cumple la recomendación de investigar oportunidades de condiciones de almacenamiento a -20 °C. En cuanto se obtengan datos adicionales, se evaluarán las posibilidades de prolongar el tiempo de almacenamiento en uso (antes de la dilución) a 2 °C–8 °C y de extender las afirmaciones a las condiciones de transporte a 2 °C–8 °C. Conclusión Con el fin de respaldar una condición de almacenamiento adicional a -20 ± 5 °C durante hasta 2 semanas, se presentan hasta 3 meses de datos de estabilidad en la condición de almacenamiento a -20 ± 5 °C de varios lotes del medicamento. |

**SECTION 4. QUESTIONS AND COMMENTS**

We also need to check your capacity to spot potential issues beforehand.

In the table below, please list your questions and comments in relation with this test:

1. Challenging sections from the source text or sections you are unsure of should be copied or inserted into the **Source Text** column.

2. Write your translation in the **Target Text** column.

3. Doubts and comments should be written in English.

|  |  |  |
| --- | --- | --- |
| Source Text | Target Text | Question / Comment  (in English) |
| 2-8 °C | 2 °C–8 °C | In Spanish, ranges can be expressed with a hyphen (–) or with prepositions. I would like to know the client’s preference to be consistent. |
| (15-JAN-2021) | (2021-01-15) | For dates, descending order recommended by the International Organization for Standardization. However, the client may have their own preferences. I would like to know which format I should follow. |
| 2.3.1. Discussion of the Changes | 2.3.3. Análisis de los Cambios | Although this is not the normalized capitalization usage for Spanish, some clients prefer English capitalization. I would ask the client for their preferences. |

**SECTION 5. REFERENCES**

In the table below, please list the reference material you have consulted to carry out this test.

1. Please introduce the **Reference source** (including publisher and full title as appropriate) in the first column.
2. Specify if your reference source is general or specific. If specific, clarify which term or section the reference covers.

|  |  |
| --- | --- |
| Reference Source | General / Specific (Term) |
| Diccionario de términos médicos de la RAE (2011) | General |
| Libro rojo: Diccionario de dudas y dificultades de traducción del inglés médico (3.ª edición) de Fernando A. Navarro  (Versión 3.17; marzo de 2021) | General |
| **ISO 8601** Data elements and interchange formats – Information interchange – Representation of dates and times (2019 Update) | General |

Thanks!