|  |  |
| --- | --- |
| **VIGENCIA ESTABLECIDA POR:** | **FECHA DE VIGENCIA:** |
|  |  |

1. **AUTORIZACIONES**

* 1. AUTORIZACIÓN LABORATORIOS – PROCAPS

| **AUTORIZACIONES** | NOMBRE: | CARGO: | ÁREA: | FIRMA/ FECHA: |
| --- | --- | --- | --- | --- |
| **ELABORADO POR:** |  |  |  |  |
| **REVISADO POR:** |  |  |  |  |

* 1. AUTORIZACIÓN CALIDAD – CUMPLIMIENTO

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AUTORIZACIONES** | **NOMBRE:** | **CARGO:** | **ÁREA:** | **FIRMA/ FECHA:** |
| **APROBADO POR:** |  |  |  |  |

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1. **INTRODUCCIÓN**
2. **ALCANCE**

Aplica para la validación del método analítico de Valoración del producto terminado HIDROCODONA 10mg + ACETAMINOFEN 325mg y/o productos equivalentes. Código: 400002770.

1. **RESPONSABILIDADES**
   1. **COORDINADORES DE CALIDAD I Y II Y/O ANALISTA ENCARGADO (CC I Y II Y/O AN)**
      1. Verificar que, durante el desarrollo de la validación, los analistas y/o técnicos de laboratorio siguieron lo establecido en el protocolo de validación, así como los demás procedimientos que se considere que apliquen.
      2. Revisar toda la información generada por los analistas y/o técnicos de laboratorio.
      3. Elaborar el reporte de validación.
   2. **JEFE DE DESARROLLO ANALÍTICO (JDA)**
      1. Revisar el reporte de validación.
   3. **JEFE DE CUMPLIMIENTO O JEFE DE TÉCNICO Y DE CALIDAD**
      1. Aprobar el reporte de validación.
2. **DESCRIPCIÓN DEL MÉTODO**

El método analítico utilizado durante la validación se encuentra descrito en el protocolo de validación *.*

1. **RESUMEN**

Para la evaluación de los parámetros , se siguió lo establecido en los protocolos de validación .

* 1. **RESUMEN DE RESULTADOS**

Ver **Tabla 1**.

Tabla 1 Resumen de resultados

| **No.** | **Parámetro** | **Criterio de aceptación** | **Resultado** | **Cumple**  **(SI/NO)** |
| --- | --- | --- | --- | --- |
| 1 | Selectividad del Método |  |  |  |
| 2 | Linealidad |  | |  |  | | --- | --- | | **Activo** | **R** | | Activo\_1 | 1.000 | | Activo\_2 | 1.000 |   **Diagrama de residuales:** La distribución de los puntos es aleatoria y no refleja tendencia.   |  |  | | --- | --- | | **Activo** | **RSD Factores de respuesta** | | Activo\_1 | 0.89% | | Activo\_2 | 0.23% | |  |
| 3 | Exactitud del Método (recuperación) |  | Activo\_1   |  |  | | --- | --- | | **Nivel** | **Recuperación (%)** | | I (50%) | 101.3% | | II (100%) | 99.5% | | III (150%) | 98.2% |   Activo\_2   |  |  | | --- | --- | | **Nivel** | **Recuperación (%)** | | I (50%) | 101.2% | | II (100%) | 101.0% | | III (150%) | 99.3% | |  |
| 4 | Precisión del Sistema |  | |  |  | | --- | --- | | **Activo** | **RSD** | | Activo\_1 | 0.2% | | Activo\_2 | 0.3% | |  |
| 5 | Precisión del Método (repetibilidad) |  | |  |  | | --- | --- | | **Activo** | **RSD** | | Activo\_1 | 0.9% | | Activo\_2 | 0.9% | |  |
| 6 | Precisión Intermedia |  | |  |  | | --- | --- | | **Activo** | **RSD** | | Activo\_1 | 1.3% | | Activo\_2 | 1.5% | |  |
| 7 | Rango (intervalo) |  | El método analítico se considera validado en el rango de 50% - 150% de la concentración nominal de trabajo (Activo\_1: 0.78 mg/mL; Activo\_2: 0.024 mg/mL). |  |
| 8 | Estabilidad analítica de las soluciones |  | **Solución estándar:** Cumple para 8 días, almacenada en volumétricas a temperatura ambiente, y 5 días en viales HPLC.  **Solución muestra:** Cumple para 7 días, almacenada en volumétricas a temperatura ambiente, y 4 días en viales HPLC.  Ver resultados en las **Tablas 17 – 18.** |  |
| 9 | Estabilidad analítica de la fase móvil |  | Cumple para 6 días, almacenada en el laboratorio de análisis a temperatura ambiente.  Ver resultados en la **Tabla 19.** |  |
| 10 | Robustez del método |  | Cumple para pequeñas variaciones de Flujo de fase móvil, volumen de inyección, composición de fase móvil y temperatura de la columna.  Ver resultados en la **Tabla 21.** |  |

1. **MATERIALES Y EQUIPOS USADOS**
   1. **DESCRIPCIÓN DE LAS MUESTRAS**

Ver **Tabla 2**.

**Tabla 2.** Muestras utilizadas durante la validación

| Nombre | Código | Lote | Código interno (CIM) |
| --- | --- | --- | --- |

* 1. **ESTÁNDARES**

Ver **Tabla 3**.

**Tabla 3**. Estándares utilizados durante la validación

| Nombre | Fabricante | Lote | Número de parte o Catálogo | Código de Identificación | Concentración | Fecha de vencimiento  (aa-mm-dd) |
| --- | --- | --- | --- | --- | --- | --- |

* 1. **REACTIVOS**

Ver **Tabla 4.**

**Tabla 4.** Reactivos utilizados durante la validación.

| Nombre | Fabricante | Número de lote | Número de parte | Fecha de vencimiento  (aa-mm-dd) |
| --- | --- | --- | --- | --- |

* 1. **MATERIALES**

Ver **Tabla 5.**

**Tabla 5.** Materiales utilizados durante la validación

| Nombre | Fabricante | Numero de parte | Número de lote |
| --- | --- | --- | --- |

* 1. **EQUIPOS**

Ver **Tabla 6**.

**Tabla 6.** Equipos utilizados durante la validación

| Equipo | Consecutivo interno | Fabricante | Modelo | Serial | Próxima actividad  (aa\_mm) |
| --- | --- | --- | --- | --- | --- |

* 1. **COLUMNA**

Ver **Tabla 7.**

**Tabla 7.** Columna usada durante el análisis

| Descripción | Fabricante | Número de parte | Serial | Número interno |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |

1. **ANÁLISIS DE RESULTADOS**
   1. **SELECTIVIDAD DEL MÉTODO** 
      1. **Resultados**

Ver **Tabla 8**.

**Tabla 8.** Soluciones evaluadas durante la selectividad

| **Solución y/o solventes** | **¿Presenta interferencia?** | | **Criterio de aceptación** | **Conclusión** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |

**Conclusión**

Los solventes, soluciones y/o placebos evaluados no generan picos que interfieran con la identificación y cuantificación de los picos principales de . Parámetro validado.

* + 1. **Referencia analítica**

Ver reporte en .

* 1. **LINEALIDAD** 
     1. **Resultados**

Ver resultados en las **Tabla 9 – 10.**

* + 1. **Conclusión**

Los resultados obtenidos demuestran que el método analítico es lineal en **95% - 105%** de la concentración nominal de trabajo .

El método es lineal dentro del rango aceptable. Parámetro validado.

* + 1. **Referencia analítica**

Ver reporte en **.**

* 1. **EXACTITUD DEL MÉTODO (RECUPERACIÓN)** 
     1. **Resultados**

Ver resultados en las **siguientes tablas.**

* + 1. **Conclusión**

Los resultados indican que la recuperación de a diferentes niveles está dentro del límite aceptable, por lo que el método es exacto. Parámetro validado.

* + 1. **Referencia analítica**

Ver reporte en **.**

* 1. **PRECISIÓN DEL SISTEMA** 
     1. **Resultados**

Ver resultados en la **Tabla 13.**

* + 1. **Conclusión**

La precisión del sistema está dentro del límite aceptable. Parámetro validado.

* + 1. **Referencia analítica**

Ver reporte en **.**

* 1. **PRECISIÓN DEL MÉTODO (REPETIBILIDAD)** 
     1. **Resultados**

Ver resultados en la **Tabla 14.**

* + 1. **Conclusión**

De acuerdo con los resultados obtenidos, la Precisión del Método está dentro del límite aceptable. Parámetro validado.

* + 1. **Referencia analítica**

Ver reporte en **.**

* 1. **PRECISIÓN INTERMEDIA** 
     1. **Resultados**

Ver resultados en la **Tabla 15.**

* + 1. **Conclusión**

De acuerdo con los resultados obtenidos, la Precisión Intermedia del Método está dentro del límite aceptable. Parámetro validado.

* + 1. **Referencia analítica**

Ver reporte en **.**

* 1. **RANGO** 
     1. **Conclusión**

Dado que los parámetros de Linealidad, Exactitud del Método y Precisión del método cumplen los criterios de aceptación establecidos, se concluye que el método presenta adecuada linealidad, exactitud, y precisión en el siguiente rango de concentración:

* 1. **ESTABILIDAD ANALÍTICA DE LAS SOLUCIONES** 
     1. **Resultados**

Ver resultados en las **Tablas 16 – 18.**

**Tabla 16.** Condiciones de almacenamiento

|  |  |
| --- | --- |
| **Condición 1** | Soluciones en volumétricas, almacenadas en el laboratorio a temperatura ambiente. |
| **Condición 2** | Soluciones en viales, almacenados en el Automuestreador del equipo temperatura ambiente. |

**Tabla 17.** Resultados de estabilidad de la solución estándar de **ACETAMINOFEN - Solucion Estandar**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Condición de estabilidad** | **Tiempo de estabilidad** | **Conclusión** | **|di| (%)** | **Promedio de Áreas** | **Réplica** | **Áreas** |
| Condicion 1 | Tiempo Inicial | Cumple | 0.0 | 3119.185 | 13113.64|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  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| | Condicion 1 | Sample Stability Time 1 | Cumple | -1.8769 | 3061.754 | 13062.14|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  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--- | --- | --- | |  |  |  |  |  | 2941.336|  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | | Condicion 2 | Tiempo Inicial | Pendiente | 0.6002 | 938.372 | 1943.981|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  | 2929.206|  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | | Condicion 2 | Sample Stability Time 1 | Cumple | -0.2098 | 939.346 | 1936.926|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 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17.** Resultados de estabilidad de la solución estándar de **ACETAMINOFEN - Solucion Estandar**   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **Condición de estabilidad** | **Tiempo de estabilidad** | **Réplica** | **Áreas** | **Promedio de Áreas** | **|di| (%)** | **conclusion** | |  |  |  |  |  |  |  | | Condicion 1 | Tiempo Inicial |  |  | 3119.185 | 0.0 | Cumple | | 1 | 3113.64 | |  |  | 3119.185 | 0.0 | Cumple | | 2 | 3124.73 | |  |  | |  |  |  |  |  |  |  | | Condicion 1 | Sample Stability Time 1 |  |  | 3061.754 | -1.8769 | Cumple | | 1 | 3062.14 | |  |  | 3061.754 | -1.8769 | Cumple | | 2 | 3061.367 | |  |  | |  |  |  |  |  |  |  | | Condicion 2 | Tiempo Inicial |  |  | 3087.756 | -0.0784 | Pendiente | | 1 | 3090.263 | |  |  | 3087.756 | -0.0784 | Pendiente | | 2 | 3085.249 | |  |  | |  |  |  |  |  |  |  | | **Criterio de aceptación** |  | | | | | |   **Tabla 17.** Resultados de estabilidad de la solución estándar de **HIDROCODONA - Solucion Estandar**   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **Condición de estabilidad** | **Tiempo de estabilidad** | **Réplica** | **Áreas** | **Promedio de Áreas** | **|di| (%)** | **conclusion** | |  |  |  |  |  |  |  | | Condicion 1 | Tiempo Inicial |  |  | 935.013 | 0.6826 | Pendiente | | 1 | 928.691 | |  |  | 935.013 | 0.6826 | Pendiente | | 2 | 941.336 | |  |  | |  |  |  |  |  |  |  | | Condicion 2 | Tiempo Inicial |  |  | 938.372 | 0.6002 | Pendiente | | 1 | 943.981 | |  |  | 938.372 | 0.6002 | Pendiente | | 2 | 932.763 | |  |  | |  |  |  |  |  |  |  | | Condicion 1 | Sample Stability Time 1 |  |  | 928.355 | -0.1269 | Cumple | | 1 | 927.505 | |  |  | 928.355 | -0.1269 | Cumple | | 2 | 929.206 | |  |  | |  |  |  |  |  |  |  | | Condicion 2 | Sample Stability Time 1 |  |  | 939.346 | -0.2098 | Cumple | | 1 | 936.926 | |  |  | 939.346 | -0.2098 | Cumple | | 2 | 941.766 | |  |  | |  |  |  |  |  |  |  | | **Criterio de aceptación** |  | | | | | |  * + 1. **Conclusión**     2. **Referencia analítica**   Ver reporte en **.**  Ver reporte en **.**   * 1. **ESTABILIDAD ANALÍTICA DE LA FASE MOVIL**       1. **Resultados**   Ver resultados en las **Tabla 19.**   * + 1. **Conclusión**     2. **Referencia analítica**   Ver reporte en   * 1. **ROBUSTEZ DEL MÉTODO**       1. **Resultados**   Ver resultados en las **Tablas 20 – 21.**  **Tabla 20.** Condiciones de robustezevaluadas   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **Factores evaluados** | | | | | **No. Experimentos** | **Temperatura de la columna (°C)** | **Flujo (mL/min)** | **Volumen de inyección (μL)** | **Fase móvil** |  * + 1. **Conclusión**     2. **Referencia analítica**   Ver reporte en   1. **CONCLUSIONES GENERALES** 2. **RELACIÓN DE OOS Y DESVIACIONES**   Ninguna.   1. **RELACIÓN DE ANEXOS**  | **ANEXOS** | **DESCRIPCIÓN** | | --- | --- | | 1 |  | | 2 |  | | 3 |  | | 4 |  | | 5 |  | | 6 |  | | 7 |  | | 8 |  | | 9 |  | | 10 |  | | 11 |  |  1. **DOCUMENTOS RELACIONADOS**  | **CÓDIGO** | **DESCRIPCIÓN** | | --- | --- | | PRO-ID-0404 |  |  1. **HISTÓRICO DE CAMBIOS**  | **CÓDIGO** | **VERSIÓN** | **FECHA DE MODIFICACIÓN** | **DESCRIPCIÓN** | | --- | --- | --- | --- | | REP-ID-0710 | 00 | No aplica. Primera versión del documento. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |