**DATOS DEL OFICIO DE REGISTRO SANITARIO DE MEDICAMENTOS**

**(Último oficio emitido en hojas de seguridad y oficios blancos de modificación)**

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| **Rubro del oficio de Registro** | **Dice en Hoja de Seguridad** | **Debe decir** | **Número de oficio en blanco de la modificación /corrección interna** |
| Registros Sanitario: | **XXXMXXXX SSA** |  |  |
| No. de solicitud |  |  |  |
| No. de solicitud anterior |  |  |  |
| Titular:Domicilio:RFC *(nacional)*: |  |  |  |
| Denominación distintiva: |  |  |  |
| Denominación genérica: |  |  |  |
| Clasificación artículo 226 LGS: |  |  |  |
| Forma farmacéutica |  |  |  |
| Fabricante(s) del(os) fármaco(s)Razón social:Domicilio: | *Indicar todos los sitios que estén en el registro* |  |  |
| Fabricante(s) del(os) proceso(s) adicional(es):Razón social:Domicilio: | *Indicar todos los sitios que estén en el registro* |  |  |
| Fabricante(s) del(os) medicamento(s)Razón social:Domicilio: | *Indicar todos los sitios que estén en el registro* |  |  |
| Sitio de Acondicionado primarioRazón social:Domicilio: | *Indicar todos los sitios que estén en el registro* |  |  |
| Sitio de Acondicionado secundarioRazón social:Domicilio: | *Indicar todos los sitios que estén en el registro* |  |  |
| DistribuidorRazón social:Domicilio: | *Indicar todos los sitios que estén en el registro* |  |  |
| ImportadorRazón social:Domicilio: | *Indiciar “No aplica” cuando sea un registro con titular en México* |  |  |
| Unidad de farmacovigilanciaRazón social:Domicilio: | *Indiciar “No aplica” cuando sea un registro con titular en México* |  |  |
| Representante legal:NombreDomicilio: | *Indiciar “No aplica” cuando sea un registro con titular en México* |  |  |
| Otro (Para, Bajo licencia de, Fabricante del diluyente, etcétera; indique): NombreDomicilio: |  |  |  |
| Presentaciones: |  |  |  |
| Envase: |  |  |  |
| Vida útil: |  |  |  |
| Indicación terapéutica: |  |  |  |
| Contraindicaciones: |  |  |  |
| Vía de administración: |  |  |  |
| Consideración de uso: |  |  |  |

**FÓRMULA**

***Replicar cuantas veces sea necesario.***

**DICE:**

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| **Concentración** |  |  |  |
| **Cada xxxxx *(Forma farmacéutica / mL / dosis, xxxx, )* contiene(n):**  |
| **Fármaco(s)** |
|  | *Denominación genérica del fármaco* | *Cantidad*  | *Unidades*  | *Observaciones (si aplica)* |
|  | XXXXXXXXXXXXXXXXXX | XXXXXX | XXXXX | XXXXXXXXXX |
|  | XXXXXXXXXXXXXXXXXX | XXXXXX | XXXXX | XXXXXXXXXX |
|  | XXXXXXXXXXXXXXXXXX | XXXXXX | XXXXX | XXXXXXXXXX |
|  | Equivalente a: ***Cuando se conoce la cantidad de sal del fármaco agregada equivalente a la dosis requerida****, por ejemplo:* *Bromhidrato de citalopram: 26.240 mg* *Equivalente a: Citalopram 20.000 mg;**de lo contrario se coloca de la siguiente forma:* *Dorzolamida 20.000 mg y la observación “Se adiciona como Clorhidrato de dorzolamida equivalente a ...”)* |
|  | XXXXXXXXXXXXXXXXXX | XXXXXX | XXXXX | XXXXXXXXXX |
| **Aditivo(s)** |
|  | *Denominación genérica del aditivo*  | *Cantidad*  | *Unidades*  | *Observaciones (si aplica)* |
|  | XXXXXXXXXXXXXXXXXX | XXXXXX | XXXXX | XXXXXXXXXX |
|  | XXXXXXXXXXXXXXXXXX | XXXXXX | XXXXX | XXXXXXXXXX |
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**DEBE DECIR:**

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| **Concentración** |  |  |  |
| **Cada xxxxx *(Forma farmacéutica / mL / dosis, xxxx, )* contiene(n):**  |
| **Fármaco(s)** |
|  | *Denominación genérica del fármaco* | *Cantidad*  | *Unidades*  | *Observaciones (si aplica)* |
|  | XXXXXXXXXXXXXXXXXX | XXXXXX | XXXXX | XXXXXXXXXX |
|  | XXXXXXXXXXXXXXXXXX | XXXXXX | XXXXX | XXXXXXXXXX |
|  | XXXXXXXXXXXXXXXXXX | XXXXXX | XXXXX | XXXXXXXXXX |
|  | Equivalente a: ***Cuando se conoce la cantidad de sal del fármaco agregada equivalente a la dosis requerida****, por ejemplo:* *Bromhidrato de citalopram: 26.240 mg* *Equivalente a: Citalopram 20.000 mg;**de lo contrario se coloca de la siguiente forma:* *Dorzolamida 20.000 mg y la observación “Se adiciona como Clorhidrato de dorzolamida equivalente a ...”)* |
|  | XXXXXXXXXXXXXXXXXX | XXXXXX | XXXXX | XXXXXXXXXX |
| **Aditivo(s)** |
|  | *Denominación genérica del aditivo*  | *Cantidad*  | *Unidades*  | *Observaciones (si aplica)* |
|  | XXXXXXXXXXXXXXXXXX | XXXXXX | XXXXX | XXXXXXXXXX |
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