

|                                                                                  |                      |                                                   |
|----------------------------------------------------------------------------------|----------------------|---------------------------------------------------|
|  | BOLETIN DE ANALISIS  | Código: 90000863-01                               |
|                                                                                  | LEVONORGESTREL MICRO | Fecha Emisión: abr-18<br>Fecha Expiración: abr-23 |
| CONTROL DE CALIDAD                                                               |                      | Reemplaza a: PO-MP-100185-05                      |

Lote de Inspección: 010000482818

Lote de MM: N0001

Código = 90000863  
 Lote Proveedor = ZLVNY17002  
 Cantidad = 500 G  
 Embalaje = TACHO PLASTICO

Fecha de recepción = 18-04-2018  
 Fecha de muestreo = 24-04-2018  
 Muestreado por = G.P.G  
 Cant. Muestra = 36 G  
 N° Bultos = 1  
 N° Bultos teóricos a muestrear = 1  
 N° Bultos muestreados = 1

Fecha Informe = 20/06/18  
 Fecha inicio = 19/05/18  
 Fecha término = 30/05/18  
 Analizado por = Sebastian Calderon  
 Cuaderno = NA  
 Folio N° = N0001  
 Vence = 30/11/22  
 Reanálisis = NA

Proveedor = PROTOPHARM AG  
 Procedimiento de muestreo = CL-QC-968-0010-02

Bibliografía: EA-MP-22400421-01

| PARAMETROS                        | RESULTADO                                                                                                                                                                                                                               | LIMITES                                                                                    |
|-----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| DESCRIPCION                       | Polvo Fino de color Blanco                                                                                                                                                                                                              | Polvo fino de color blanco o prácticamente blanco.                                         |
| SOLUBILIDAD                       | Prácticamente insoluble en agua<br>soluble en cloroformo<br>ligeramente soluble en alcohol                                                                                                                                              | Prácticamente insoluble en agua<br>Soluble en cloroformo<br>Ligeramente soluble en alcohol |
| IDENTIFICACION                    | cumple IR: 97,59%<br>cumple R.E.: -33,228°; P.F.: 233°C<br>cumple HPLC: TR similar                                                                                                                                                      | A: IR<br>B: Cumple Rotación específica y Punto de fusión.<br>C: HPLC                       |
| PUNTO DE FUSION                   | 233°C                                                                                                                                                                                                                                   | 232 - 238°C                                                                                |
| ROTACION ESPECIFICA               | -33,228°                                                                                                                                                                                                                                | -30° a -36°                                                                                |
| PERDIDA POR DESECACION            | 0,2 %                                                                                                                                                                                                                                   | Máximo 0,5%                                                                                |
| RESIDUO DE IGNICION               | 0,1 %                                                                                                                                                                                                                                   | Máximo 0,3%                                                                                |
| LIMITE DE GRUPO ETINIL            | 8,0 %                                                                                                                                                                                                                                   | 7,81 - 8,18%                                                                               |
| PUREZA CROMATOGRAFIA              | ≤ 0,5% . cumple individual<br>≤ 2% . cumple total                                                                                                                                                                                       | Máximo 0,5%, impureza individual<br>Máximo 2%, impurezas totales                           |
| LIMITE DE SOLVENTE RESIDUALES (%) |                                                                                                                                                                                                                                         |                                                                                            |
| Tetrahidrofurano                  | <del>720</del> <u>ND</u> <small>SL 20/06/18</small>                                                                                                                                                                                     | 720 ppm                                                                                    |
| Diclorometano                     | <del>600</del> <u>0,003 ppm</u> <small>SL 20/06/18</small>                                                                                                                                                                              | 600 ppm                                                                                    |
| Acetona                           | <u>ND</u>                                                                                                                                                                                                                               | 5000 ppm                                                                                   |
| Acetato de etilo                  | <u>ND</u>                                                                                                                                                                                                                               | 5000 ppm                                                                                   |
| VALORACION                        | 99,9 % t.c.<br>100,1 % b.s.                                                                                                                                                                                                             | 98,0 a 102,0%, calculado en base seca.                                                     |
| REQUERIMIENTO INTERNO (M)         |                                                                                                                                                                                                                                         |                                                                                            |
| TAMAÑO PARTICULAS                 | 23,4 μm<br>13,0 μm                                                                                                                                                                                                                      | 100% ≤ 20 μm.<br>90% ≤ 10 μm.                                                              |
| OBSERVACIONES:                    | (M) Control de Cambio: 86351 Asociado al Cambio de Partícula Ag<br>ADD: 8/6/2018<br>Solventes Residuales: NA 06/5<br>26/06/18                                                                                                           |                                                                                            |
| INGRESO POTENCIA A SAP:           | Porcentaje tal cual                                                                                                                                                                                                                     |                                                                                            |
| FECHA CALIFICACION                | 26/06/18                                                                                                                                                                                                                                |                                                                                            |
| EMBALAJE:                         | Guardar en recipientes bien cerrados, resistentes a la luz.                                                                                                                                                                             |                                                                                            |
| CALIFICACION                      | <div style="text-align: center;"> <br/> <b>APROBADO</b><br/>         Juan Luis Arriagada<br/>         Q.F. Gerente Control de Calidad       </div> |                                                                                            |

| Original                     |                 | Recepción      |               | Materia prima   |                     |
|------------------------------|-----------------|----------------|---------------|-----------------|---------------------|
| <b>LEVONORGESTREL MICRO.</b> |                 |                |               | <b>90000863</b> |                     |
| Grupo HR (CG)                | LXB204KG (3)    | Cantidad       | 500 G         | Lote            | <b>N0001</b>        |
| Fe. entrada m.               | (ST) 18.04.2018 | Pedido         | 4500486230    | Lote insp.      | <b>010000482818</b> |
| Fe. fabricación              | 31.12.2017      | Fabricante     | ---           |                 |                     |
| Fe. sig. verific.            | 17.02.2019      | Lote Proveedor | ZLVNY17002    |                 |                     |
| Fe. caducidad                | 30.11.2022      | Proveedor      | PROTOPHARM AG |                 |                     |

Nombre del material en la nota de entrega y/o contenedor (si es que difiere del nombre interno)

Fecha entrada de mercancía 18.04.2018  
Pedido 4500486230  
Proveedor PROTOPHARM AG  
Fabricante ---  
Número de lote del proveedor ZLVNY17002  
Cantidad total 500 G  
Número de contenedores 1  
Número de lote interno N0001  
Fecha de caducidad 30.11.2022

|                                    |                                        |                             |       |
|------------------------------------|----------------------------------------|-----------------------------|-------|
| Integridad de los contenedores     | <input checked="" type="checkbox"/> Si | <input type="checkbox"/> No | _____ |
| Integridad de los sellos           | <input checked="" type="checkbox"/> Si | <input type="checkbox"/> No | _____ |
| Datos de etiqueta correctos        | <input checked="" type="checkbox"/> Si | <input type="checkbox"/> No | _____ |
| Limpieza de contenedores           | <input checked="" type="checkbox"/> Si | <input type="checkbox"/> No | _____ |
| Revisión vehículo                  | <input checked="" type="checkbox"/> Si | <input type="checkbox"/> No | _____ |
| Certificado de análisis disponible | <input checked="" type="checkbox"/> Si | <input type="checkbox"/> No | _____ |

Este material ha sido revisado para verificar que cumple con los criterios adecuados para identificación, etiquetado, integridad, limpieza y transporte; así mismo su documentación ha sido revisada para determinar si todos los documentos necesarios han sido entregados para mantener trazabilidad.

Comentarios

\_\_\_\_\_  
Fecha - Firma del Operador

|                |                                     |                                                                           |
|----------------|-------------------------------------|---------------------------------------------------------------------------|
| Lista-ID: QP04 | <b>010000482818</b><br>010000482818 | Impresión: 23.04.2018 11:25:37<br>(Hora del sistema: 23.04.2018 16:25:37) |
|----------------|-------------------------------------|---------------------------------------------------------------------------|

|                       |                 |                    |               |               |              |
|-----------------------|-----------------|--------------------|---------------|---------------|--------------|
| Original              |                 | Instr. de Muestreo |               | Materia prima |              |
| LEVONORGESTREL MICRO. |                 |                    |               | 90000863      |              |
| Grupo HR (CG)         | LXB204KG (3)    | Cantidad           | 500 G         | Lote          | N0001        |
| Fe. entrada m.        | (ST) 18.04.2018 | Pedido             | 4500486230    | Lote insp.    | 010000482818 |
| Fe. fabricación       | 31.12.2017 ✓    | Fabricante         | ---           |               |              |
| Fe. sig. verific.     | 17.02.2019      | Lote Proveedor     | ZLVNY17002 ✓  |               |              |
| Fe. caducidad         | 30.11.2022 ✓    | Proveedor          | PROTOPHARM AG |               |              |

## Advertencias

Instr. de Almacenaje

Instr. de Seguridad

Usar mascarilla con filtros!, Usar ropa de trabajo, cofia, gafas y guantes!, Muestrear únicamente bajo flujo laminar!

## Contenedor externo

Número

Tipo de empaque

Emp. sin coment

Etiquetado

Sellado

Farmacopéico

1  
✓ si ☐ no  
✓ si ☐ no  
✓ si ☐ no

## Contenedor interno

Número

Tipo de empaque

Limpio

Etiquetado

Cierre adecuado

36/501 NEOMA.  
2 Bolsas transparentes.  
✓ si ☐ no  
✓ si ☐ no  
✓ si ☐ no

## Muestreo

WCent.

Número (Et.)

Cant. UM

RLS

1

(00)

500,000 G

## Nota

Total: Cant. esperada 500,000 G Cant. tomada 36. G

Muestra para Ident. del cont:

Muestra Pool del contenedor:

Comentario de Muestreo:

1g  
7g  
CONTRAMUESTRA: 7g; ANALISIS DE ARMONIO: 1g.  
+ 20g para homogeneización.

Muestreo realizado el:

24/04/18

Muestreado por (Firma):

676

Página verificada el:

26/06/18

Verificado por (Firma):

005

|                |                              |                                                                           |
|----------------|------------------------------|---------------------------------------------------------------------------|
| Lista-ID: QP01 | 010000482818<br>010000482818 | Impresión: 23.04.2018 11:25:48<br>(Hora del sistema: 23.04.2018 16:25:47) |
|----------------|------------------------------|---------------------------------------------------------------------------|

90000863

11/0001

## CERTIFICATE OF ANALYSIS

SYMBIOTEC

PHARMALAB PVT. LIMITED

Formerly Known as Symbiotec Pharmed Ltd

|                  |                                                   |             |               |
|------------------|---------------------------------------------------|-------------|---------------|
| Product Name     | LEVONORGESTREL EP (MICRONISED) (CAS No. 797-63-7) |             |               |
| Batch No.        | ZLVNy17002                                        | Mfg. Date   | December 2017 |
| A. R. No.        | P2FP17483                                         | Retest Date | November 2022 |
| Date of Sampling | 31/12/2017                                        |             |               |

| S. No. | Test                                                                                                | Results                                                                                                            | Specification                                                                                                                              |
|--------|-----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
|        | Character: Appearance                                                                               | Almost white (micronised) crystalline powder                                                                       | White or almost white, crystalline powder                                                                                                  |
|        | Solubility                                                                                          | Practically insoluble in water, sparingly soluble in methylene chloride, slightly soluble in ethanol (96 per cent) | Practically insoluble in water, sparingly soluble in methylene chloride, slightly soluble in ethanol (96 per cent).                        |
| 1      | Identification<br>A. $\text{KOR}$<br>B. IR                                                          | -32.89°<br>Concordant                                                                                              | Between -35° to -30°<br>The IR Spectrum of sample should be concordant with the IR spectrum obtained from Levonorgestrel working standard. |
| 2      | Specific optical rotation<br>(C = 1%, Methylene chloride, at 20°C)                                  | -32.89°                                                                                                            | Between -35° to -30°                                                                                                                       |
|        | Related substances (by HPLC)                                                                        |                                                                                                                    |                                                                                                                                            |
|        | Impurity A                                                                                          | BRL                                                                                                                | NMT 0.3 %                                                                                                                                  |
|        | Impurity B                                                                                          | BLD                                                                                                                | NMT 0.3 %                                                                                                                                  |
|        | Impurity C                                                                                          | 0.09 %                                                                                                             | NMT 0.3 %                                                                                                                                  |
|        | Impurity M                                                                                          | 0.19 %                                                                                                             | NMT 0.3 %                                                                                                                                  |
|        | Impurity S                                                                                          | BRL                                                                                                                | NMT 0.2 %                                                                                                                                  |
|        | Impurity U                                                                                          | BLQ                                                                                                                | NMT 0.2 %                                                                                                                                  |
|        | Impurity H                                                                                          | BLD                                                                                                                | NMT 0.2 %                                                                                                                                  |
|        | Unspecified impurities                                                                              | BRL                                                                                                                | NMT 0.2 %                                                                                                                                  |
|        | Total impurities other than impurity Q                                                              | 0.04 %                                                                                                             | NMT 0.15 %                                                                                                                                 |
|        | Method B                                                                                            | 0.33 %                                                                                                             | NMT 1.0 %                                                                                                                                  |
|        | Impurity V                                                                                          |                                                                                                                    |                                                                                                                                            |
|        | Impurity W                                                                                          | 0.004 %                                                                                                            | NMT 0.15 %                                                                                                                                 |
|        | Loss on drying (At 105°C)                                                                           | Not Detected                                                                                                       | NMT 0.3 %                                                                                                                                  |
|        | Sulfated ash                                                                                        | 0.29 % w/w                                                                                                         | NMT 0.5 % w/w                                                                                                                              |
|        | Assay (By Potentiometrically)                                                                       | 0.08 % w/w                                                                                                         | NMT 0.1 % w/w                                                                                                                              |
|        | Additional Test<br>Residual Solvents (by GC)<br>Methylene Dichloride<br>Tetrahydrofuran<br>Methanol | 99.53 %<br>55 ppm<br>< 10 ppm<br>367 ppm                                                                           | Between 98.0 % to 102.0 % (dried substance)<br>NMT 600 ppm<br>NMT 720 ppm<br>NMT 3000 ppm                                                  |
|        | Particle Size<br>Malvern<br>(By dry method)                                                         | 5.15 $\mu\text{m}$<br>9.51 $\mu\text{m}$                                                                           | 90.0 % < 10 $\mu\text{m}$<br>99.5 % < 20 $\mu\text{m}$                                                                                     |

Opinion: The above material complies with the prescribed EP 9.0 specification  
 BRL = Below reporting limit, BLD = Below limit of detection, BLQ = Below limit of quantification  
 Date of Release: 02/01/2018  
 Reprint on: 11/01/2018

Prepared by  
Uma Sahu  
(Chemist - QC)

Checked by  
Rajshree Dubey  
(Executive - QC)

Approved by  
Nitesh Pal  
(Asst. Manager - QC)

Manufacturing Site: Plot No. 5, 6, 7 & 8 SEZ Phase - II, Pharma Zone  
 Pithampur Dist. Bhar - 454774 (M.P.) India  
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 Email: symbiotec@symbiotec.in



## REPORTE ANALÍTICO DE MATERIA PRIMA

Página 1 de 8

|                        |                  |                              |             |                        |          |                |            |
|------------------------|------------------|------------------------------|-------------|------------------------|----------|----------------|------------|
| NOMBRE MATERIA PRIMA:  |                  | LEVONOR Gestrrel MICRONIZADO |             |                        |          |                |            |
| CODIGO MATERIA PRIMA   | 90000863         | LOTE INSPECCION              | 10000482818 | LOTE MM                | N0001    | LOTE PROVEEDOR | 22VNY17002 |
| METODOLOGIA UTILIZADA: | EA-MP-22400421-0 | FECHA INICIO ANALISIS        | 18/05/18    | FECHA TERMINO ANALISIS | 30/05/18 |                |            |

## CALCULOS

\* DESCRIPCIÓN: POLVO FINO DE COLOR BLANCO, LIBRE DE PARTICULAS EXTRAÑAS. CUMPLE.

\* SOLUBILIDAD: Pesar 100 mg de muestra y disolver en el volumen apropiado de solvente.

Cumple Prácticamente insoluble en AGUA: 71000 ~L

Cumple soluble en cloroformo: 10-30 ~L

Cumple ligeramente soluble en Alcohol: 10,0-100,0 ~L AL 66%.

28-May-2018 12:57:18

|       |   |          |
|-------|---|----------|
| 001:N | + | 100.0 mg |
| 002:N | + | 100.0 mg |
| 003:N | + | 100.0 mg |

SCL  
28/05/18

|      |            |
|------|------------|
| 001: | AGUA       |
| 002: | CLOROFORMO |
| 003: | ALCOHOL    |

## \* IDENTIFICACIÓN

a) IR: ESP-010 : Existe correlación con EL ESTANDAR. CUMPLE.

b) ROTACIÓN ESPECÍFICA: cumple con los requerimientos de ROTACIÓN ESPECÍFICA Y RANGO DE FUSIÓN que lo diferencia del NORGESREL. (VER PÁGINA 2)

c) HPLC: El PEAK PRINCIPAL de la solución muestra, presenta UN TR SIMILAR AL de la solución ESTANDAR.

SCL/CLM

ANALISTA

DCP 05/06/18

PRIMERA REVISION

Rpp 24/06/18

ENCARGADO MATERIAS PRIMAS

**CALCULOS**

\* PUNTO DE FUSIÓN: FUS-002  
 ESPECIFICACIÓN: 232 °C / 239 °C  
 RESULTADO: 233 °C  
 CONCLUSIÓN: cumple

\* ROTACIÓN ESPECÍFICA: POL-003; BAL-099  
 ESPECIFICACIÓN: -30° y -35°  
 RESULTADO:  $\bar{x}$ : -33,22°  
 CONCLUSIÓN: cumple

SOLUCIÓN muestra 20 mg/mL en cloroFORMa.

17-May-2018 15:50:28

001:N + 1000.5 mg  
 002:N + 1001.2 mg

SLC  
 28/05/18

m1: 1000.5 / 50 mL : 20,01 mg/mL  
 m2: 1001.2 / 50 mL : 20,024 mg/mL

\* Pérdida por desecación: BAL-099; EST-015  
 ESPECIFICACIÓN: Máximo 0,5 %  
 Procedimiento: 105 °C x 5 HORAS  
 RESULTADO: 0,2 % MTA 1  $\bar{x}$ : 0,2 %  
 0,2 % MTA 2  
 CONCLUSIÓN: cumple

18-May-2018 10:53:26

MTA 1

001:N 0.0 mg  
 002:N + 28512.9 mg → CAPSULA VACIA  
 003:N + 29547.8 mg → CAPSULA c/MTA

18-May-2018 10:59:53

MTA 2

004:N 0.0 mg  
 005:N + 28412.9 mg → CAPSULA VACIA  
 006:N + 29484.7 mg → CAPSULA c/MTA

SLC  
 28/05/18

18-May-2018 17:14:26

001:N + 29546.2 mg → MTA Desecada  
 MTA 1

18-May-2018 17:15:57

MTA 2  
 002:N + 29483.1 mg → MTA Desecada  
 SLC 28/05/18

SLC/CLM

ANALISTA

D. CP 25/06/18

PRIMERA REVISION

EXP 26/06/18

ENCARGADO MATERIAS PRIMAS

ENCARGADO  
MATERIAS PRIMAS

**CALCULOS**

\* Límite de grupo etinil: BAL-065 / Tit-001 ✓  
 - Especificación: no menos de 7,81% y no más de 8,18% de grupo etinil.

- Cálculo:

$$\% = \frac{h \times F \times 2,503 \times 100}{P_{MTA}}$$

h: mL gastado  
 F: Factor corrección  
 P<sub>MTA</sub>: Peso MTA (mg)

Factor corrección = 1

----- Pesar -----  
 29.May 2018 9:59  
 Nombre de usuario Home  
 ID balanzas BAL- 065  
 ID1  
 199.69 mg

SCL  
 28/05/18

----- Pesar -----  
 29.May 2018 10:04  
 Nombre de usuario Home  
 ID balanzas BAL- 065  
 ID1  
 200.23 mg

Muestra 1 / 40 mL TAF + 10 mL Nitrito Plata (1/10)

Muestra 2 / 40 mL TAF + 10 mL Nitrito de Plata (1/10)

Resultados: Muestra 1: 8,00% ✓  
 Muestra 2: 7,98% ✓  
 $\bar{x} = 8,0\%$  ✓

SCL/CLM

ANALISTA

DOP 05/06/18

PRIMERA REVISION

IPP 26/06/18

ENCARGADO  
 MATERIAS PRIMAS

**CALCULOS**

| BLANCO | MUESTRA 1 | MUESTRA 2 |
|--------|-----------|-----------|
|--------|-----------|-----------|

METTLER TOLEDO T70  
 Versión 3.1.5  
 Núm. de series 5128235222  
 ID del valorador  
 Excellence Titrator  
 29/05/2018 11:46:40  
 Administrator

ID del método MP2061  
 ID serie de muestras --

Resumen  
 Muestras

N° 1  
 ID BLANCO  
 Tamaño de las muestras 0 g  
 R1 (Consumo) NaN mL

Todos los resultados  
 Muestra 1/1

ID BLANCO  
 R1 (Consumo) NaN mL

METTLER TOLEDO T70  
 Versión 3.1.5  
 Núm. de series 5128235222  
 ID del valorador  
 Excellence Titrator  
 29/05/2018 11:53:06  
 Administrator

ID del método MP2061  
 ID serie de muestras --

Resumen  
 Muestras

N° 1  
 ID N0001-1  
 Tamaño de las muestras 0.19969 g  
 R1 (Consumo) 6.37914 mL

Todos los resultados  
 Muestra 1/1

ID N0001-1  
 R1 (Consumo) 6.37914 mL

METTLER TOLEDO T70  
 Versión 3.1.5  
 Núm. de series 5128235222  
 ID del valorador  
 Excellence Titrator  
 29/05/2018 15:26:32  
 Administrator

ID del método MP2061  
 ID serie de muestras --

Resumen  
 Muestras

N° 1  
 ID N0001-2  
 Tamaño de las muestras 0.20023 g  
 R1 (Consumo) 6.38018 mL

Todos los resultados  
 Muestra 1/1

ID N0001-2  
 R1 (Consumo) 6.38018 mL

SL/CLM

**ANALISTA**

DCP 05/06/18

**PRIMERA REVISION**

Rpn 26/06/18

**ENCARGADO  
MATERIAS PRIMAS**

**CALCULOS**

- + VALORACIÓN: HPLC-024 / BAL-065
- ESPECIFICACIÓN: 98,0 / 102,0 % de Levonorgestrel ✓
- CALCULO:  $\frac{\text{Area MTA}}{\text{Area ST}} \times \frac{\text{Peso ST}}{200} \times \frac{15}{100} \times \frac{\text{Potencia}}{100} \times \frac{200}{\text{Peso MTA}} \times \frac{100}{15} \times 100$
- CALCULO:  $\frac{\% \text{ TAL CVA}}{(100 - \% \text{ Humedad})} \times 100$  ✓

STD SECUNDARIO LEVONORGESTREL: 101,0%

----- Pesar -----  
 18.May 2018 20:24  
 Nombre de usuario Home  
 ID balanzas BAL- 065  
 ID1

19.59 mg  
 19.78 mg  
 19.76 mg

SL  
 20/05/18

MTA 1: 19,59 → / 200 × 15/100  
 MTA 2: 19,78 → / 200 × 15/100  
 MTA 3: 19,76 → / 200 < 15/100 ✓

----- Pesar -----  
 18.May 2018 20:51  
 Nombre de usuario Home  
 ID balanzas BAL- 065  
 ID1

19.40 mg  
 19.46 mg

SL  
 20/05/18

ST1: 19,40 → / 200 × 15/100 ✓  
 ST2: 19,46 → / 200 < 15/100 ✓

| ST1                   | ST2                   | MUESTRAS           | % VD                    |
|-----------------------|-----------------------|--------------------|-------------------------|
| 512,90588 ✓           | 509,49292 ✓           | 1.- 523,88135 ✓    | 102,2 % ✓               |
| 514,76190 ✓           | 509,56033 ✓           | 2.- 509,80197 ✓    | 98,5 % ✓                |
| 512,68140 ✓           | 509,97739 ✓           | 3.- 512,93555 ✓    | 99,2 % ✓                |
| 512,74373 ✓           | $\bar{x}$ : 509,67688 | CONTROL: 515,20044 | $\bar{x}$ : 99,9 % ✓ TC |
| 511,414205 ✓          | RSD: 0,1 %            |                    | RSD: 2,0 % ✓            |
| $\bar{x}$ : 512,90695 | RECUBRO: 100,9 %      |                    | $\bar{x}$ : 100,1 % BS  |
| RSD: 0,2 %            |                       |                    |                         |

CONCLUSIÓN: cum Dle

SL/CLM

DCL 05/06/18

TOP 26/06/18

ANALISTA

PRIMERA REVISION

 ENCARGADO  
 MATERIAS PRIMAS

**CALCULOS**

\* RESIDUO DE IGNICION: MVP-003 / BAL-099

ESPECIFICACIÓN: NO MAS DE 0.3-1.

$$\text{Cálculo} = \frac{\text{CRISOL} + \text{RESIDUO}}{\text{CRISOL VACIO}} \times 100$$

$$\frac{\text{CRISOL} + \text{MUESTRA}}{\text{CRISOL VACIO}}$$

- Resultado : MTA 1: 0.08 %  $\bar{X}$ : 0.1-1.  
MTA 2: 0.03 %

28-May-2018 11:35:25

001:N + 27952.0 mg  
002:N + 29011.9 mg  
003:N + 25558.3 mg  
004:N + 26560.9 mg

005:N + 31939.4 mg  
006:N + 33057.2 mg  
007:N + 27687.1 mg  
008:N + 28748.7 mg

28/05/18

001: MTA1 CRISOL VACIO lote N0001  
002: ~~MTA 2~~ <sup>sol</sup> ~~28/05/18~~ MTA1 CRISOL + MTA N0001  
003: MTA2 CRISOL VACIO lote N0001  
004: MTA2 CRISOL + MUESTRA lote N0001

005: MTA1 CRISOL VACIO N0002  
006: MTA1 CRISOL + MTA lote N0002  
007: MTA2 CRISOL VACIO N0002  
008: MTA2 CRISOL + MTA lote N0002

30-May-2018 12:48:44

008:N + 27952.8 mg  
009:N + 25559.1 mg  
010:N + 31939.5 mg  
011:N + 27687.2 mg

30/05/18

008: MTA 1 CRISOL + RESIDUO } lote N0001  
009: MTA 2 CRISOL + RESIDUO }  
010: MTA 1 CRISOL + RESIDUO } lote N0002  
011: MTA 2 CRISOL + RESIDUO }

NOTA: SE ADJUNTAN PESOS DE lote N0002 YA QUE SE IMPRIME 1 SOLO REGISTRADO.

SCL/CHM

ANALISTA

DCP 05/06/18

PRIMERA REVISION

Rop 26/06/18

ENCARGADO MATERIAS PRIMAS

## CALCULOS

\* TAMAÑO DE PARTICULAS : MEDP-0001 / BAL-099  
 ESPECIFICACIÓN : 100%  $\leq 20 \mu m$   
 90%  $\leq 10 \mu m$

CONCENTRACIÓN : 200 g / 50 mL

RESULTADOS : 100% PARTICULAS :  $\bar{x}$  : 23,4  $\mu m$   
 90% PARTICULAS :  $\bar{x}$  : 5,83  $\mu m$

CONCLUSIÓN : NO UMOLÉ 13,0  $\mu m$  25/05/18

25-May-2018 11:35:52

Control de cambio : 863SA ASOCIADO  
 a transición de Partículas

001:N N0001+ 201.7 mg  
 002:N N0002 200.3 mg

n 2  
 $\bar{x}$  201.05 mg  
 s 0.35 mg  
 srel 0.17 %  
 $\Sigma x$  402.1 mg

SCL  
 25/05/18

DP 26/06/18

SCL/CLM

ANALISTA

DP 05/06/18

PRIMERA REVISION

DP 26/06/18

ENCARGADO  
 MATERIAS PRIMAS

**REACTIVOS UTILIZADOS:**

| REACTIVO                | LOTE DEL REACTIVO     | FECHA DE CADUCIDAD | OBSERVACIONES                          |
|-------------------------|-----------------------|--------------------|----------------------------------------|
| cloroformo              | <del>K49554945</del>  | 10/20              | solubilidad / Rot. específica / pureza |
| alcohol (etanol)        | <del>K49572183</del>  | 09/22              | pureza / solubilidad                   |
| ácido sulfúrico         | <del>K49257331</del>  | 06/22              | Residuo iónico $O^-$                   |
| ácido fosfomolibdico    | <del>K48867232</del>  | 03/20              | pureza                                 |
| Acetonitrilo            | <del>10818630</del>   | 10/20              | valoración                             |
| metanol                 | <del>10893507</del>   | 05/20              | valoración                             |
| AGUA                    | <del>3274-S</del>     | 19/05/18           | valoración                             |
| AGUA                    | <del>3278-S</del>     | 26/05/18           | Tamaño Partícula                       |
| AGUA                    | <del>3279-S</del>     | 29/05/18           | solubilidad                            |
| AGUA                    | <del>3279-S</del>     | 29/05/18           | solubilidad                            |
| AGUA                    | <del>3280-S</del>     | 30/05/18           | límite etinil                          |
| Tetrahidropurano        | <del>10933201</del>   | 01/21              | límite etinil                          |
| Nitrato de Plata (1/10) | <del>SCL/01-018</del> | 29/06/18           | límite etinil                          |
| Hidróxido de Sodio      | <del>H470763241</del> | 02/20              | límite etinil                          |
| Fase móvil val.         | <del>SCL/01-016</del> | 18/06/18           | valoración                             |
| ácido fosfomolibdico    | <del>SCL/01-017</del> | 29/06/18           | pureza                                 |
| Nitrato de Plata        | <del>K42507012</del>  | 01/19              | límite etinil                          |
| Alcohol al 96/.         | <del>SCL-01/19</del>  | 28/06/18           | solubilidad                            |
| Fase móvil pureza       | <del>SCL/01/20</del>  | 25/06/18           | pureza                                 |
|                         |                       |                    | SCL<br>30/05/18                        |

SCL

ANALISTA

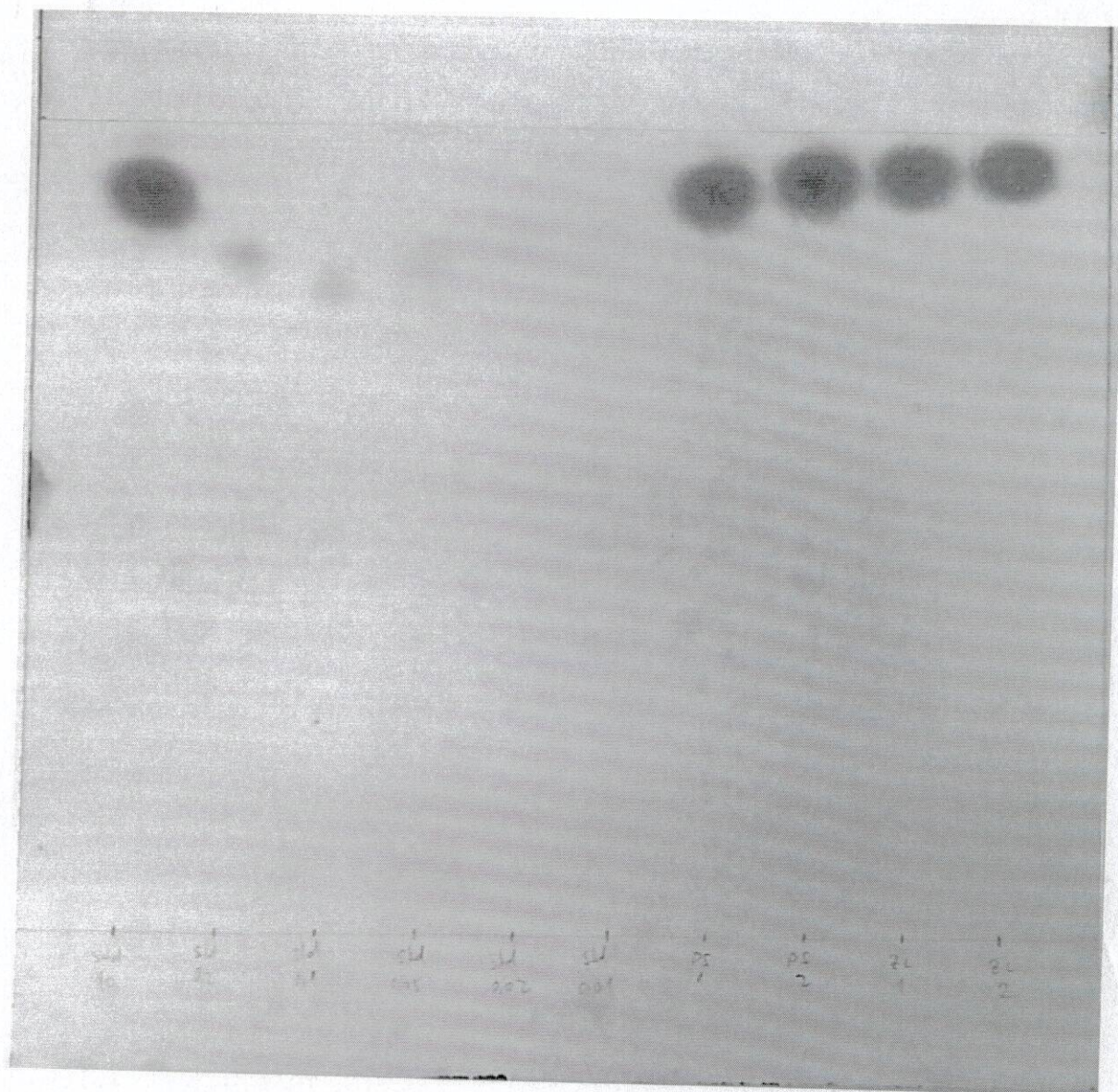
DCP 05/06/18

PRIMERA REVISION

PPP 26/06/18

 ENCARGADO  
MATERIAS PRIMAS

PUREZA CROMATOGRAFICA



N0001

N0002

Kpp 26/06/16

Dcf  
05/06/18

|  | REGISTRO                                             | RE-0461-01                                                                                         |
|-----------------------------------------------------------------------------------|------------------------------------------------------|----------------------------------------------------------------------------------------------------|
|                                                                                   | CHECK LIST CROMATOGRAFIA                             |                                                                                                    |
|                                                                                   | AREA ANALISIS QUIMICO                                | may-16                                                                                             |
| PRODUCTO/MATERIA PRIMA <u>LEVONORGESTREL MICRONIZADO</u>                          |                                                      |                                                                                                    |
| OP/LOTE QM <u>10000482818</u>                                                     |                                                      |                                                                                                    |
| SERIE/LOTE MM <u>20001</u>                                                        |                                                      |                                                                                                    |
| FECHA <u>18/05/18</u>                                                             |                                                      |                                                                                                    |
| VERIFICACION FECHA COMPUTADOR HPLC                                                | <input checked="" type="checkbox"/>                  | <u>[Firma]</u> 18/05/18<br>FIRMA/FECHA                                                             |
| VERIFICACION HORA COMPUTADOR HPLC                                                 | <input checked="" type="checkbox"/>                  | <u>[Firma]</u> 18/05/18<br>FIRMA/FECHA                                                             |
| VALORACION                                                                        | <input checked="" type="checkbox"/>                  | UNIFORMIDAD <input type="checkbox"/> CINETICA <input type="checkbox"/> SR <input type="checkbox"/> |
| CONDICIONES CROMATOGRAFICAS                                                       |                                                      |                                                                                                    |
| HPLC N°                                                                           | <u>HPLC-024</u>                                      |                                                                                                    |
| COLUMNA                                                                           | <u>CB; 15 cm x 4,6 mm; 5 µm (ID-082)</u>             |                                                                                                    |
| FASE MOVIL                                                                        | <u>ACN / MeOH / H<sub>2</sub>O (350 / 150 / 450)</u> |                                                                                                    |
| VELOCIDAD DE FLUJO                                                                | <u>1,0 mL/min</u>                                    |                                                                                                    |
| VOLUMEN INYECCION                                                                 | <u>50 µL</u>                                         |                                                                                                    |
| LONGITUD ONDA                                                                     | <u>215 nm</u>                                        |                                                                                                    |
| TEMPERATURA HORNO                                                                 | <u>25 °C</u>                                         |                                                                                                    |
| VERIFICACION DE LA CONDICIONES CROMATOGRAFICAS<br>INGRESADAS EN EL HPLC           | <input checked="" type="checkbox"/>                  | <u>[Firma]</u> 18/05/18<br>FIRMA/FECHA                                                             |
| VERIFICACION EN EL NOMBRE DE LA SECUENCIA INYECTADA<br>LA SERIE ANALIZADA         | <input checked="" type="checkbox"/>                  | <u>[Firma]</u> 18/05/18<br>FIRMA/FECHA                                                             |
| CODIGO COLUMNA/CUADERNO/FOLIO                                                     | <u>ID-082/03/18</u>                                  |                                                                                                    |
| CUADERNO/FOLIO DE PREPARACION FASE MOVIL                                          | <u>SCL/01-016</u>                                    |                                                                                                    |

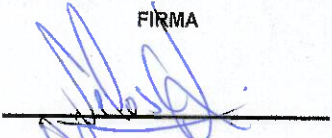
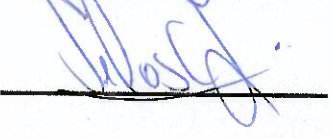
DCP  
05/06/18

|  | REGISTRO                 |      | RE-0461-01 |
|-----------------------------------------------------------------------------------|--------------------------|------|------------|
|                                                                                   | CHECK LIST CROMATOGRAFIA |      |            |
|                                                                                   | AREA ANALISIS QUIMICO    |      | may-16     |
| <b>ESTÁNDAR DE TRABAJO</b>                                                        |                          |      |            |
| PRINCIPIO ACTIVO                                                                  | N° INYECTADAS            | CV   | LIMITE     |
| levonorgestrel                                                                    | 5                        | 0,2% | 2,0%       |
|                                                                                   |                          |      |            |
|                                                                                   |                          |      |            |
|                                                                                   |                          |      |            |
|                                                                                   |                          |      |            |
| sc 18/05/10                                                                       |                          |      |            |
| <b>ESTÁNDAR DE CONTROL</b>                                                        |                          |      |            |
| PRINCIPIO ACTIVO                                                                  | N° INYECTADAS            | CV   | LIMITE     |
| levonorgestrel                                                                    | 3                        | 0,1% | 2,0%       |
|                                                                                   |                          |      |            |
|                                                                                   |                          |      |            |
|                                                                                   |                          |      |            |
|                                                                                   |                          |      |            |
| sc 18/05/18                                                                       |                          |      |            |
| RESOLUCION                                                                        |                          |      |            |
| LIMITE                                                                            |                          |      |            |
|                                                                                   |                          |      |            |
|                                                                                   |                          |      |            |
|                                                                                   |                          |      |            |
| RESOLUCION                                                                        |                          |      |            |
| LIMITE                                                                            |                          |      |            |
|                                                                                   |                          |      |            |
|                                                                                   |                          |      |            |
|                                                                                   |                          |      |            |

Dcd  
05/06/18

|  | REGISTRO                            |             | RE-0461-01               |
|-----------------------------------------------------------------------------------|-------------------------------------|-------------|--------------------------|
|                                                                                   | CHECK LIST CROMATOGRAFIA            |             |                          |
|                                                                                   | AREA ANALISIS QUIMICO               |             | may-16                   |
| PRINCIPIO ACTIVO                                                                  | ASIMETRIA                           | LIMITE      |                          |
| levonorgestrel                                                                    | 0.93949                             | 0.05/2      |                          |
|                                                                                   |                                     |             |                          |
|                                                                                   |                                     |             |                          |
|                                                                                   |                                     |             |                          |
|                                                                                   |                                     |             |                          |
|                                                                                   |                                     |             |                          |
| PRINCIPIO ACTIVO                                                                  | PLATOS TEORICOS                     | LIMITE      |                          |
| levonorgestrel                                                                    | 6324                                | 72000       |                          |
|                                                                                   |                                     |             |                          |
|                                                                                   |                                     |             |                          |
|                                                                                   |                                     |             |                          |
|                                                                                   |                                     |             |                          |
|                                                                                   |                                     |             |                          |
| PRINCIPIO ACTIVO                                                                  | RECUBRO                             | UNIFORMIDAD | DISOLUCION               |
| levonorgestrel                                                                    | 100.9%                              | n/a         | n/a                      |
|                                                                                   |                                     |             |                          |
|                                                                                   |                                     |             |                          |
|                                                                                   |                                     |             |                          |
|                                                                                   |                                     |             |                          |
|                                                                                   |                                     |             |                          |
| CUMPLE                                                                            | <input checked="" type="checkbox"/> | NO CUMPLE   | <input type="checkbox"/> |
| OBSERVACION                                                                       |                                     |             |                          |
|                                                                                   |                                     |             |                          |

DCP  
05/06/18

|                                                                                   |                                                                                    |            |
|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------|------------|
|  | REGISTRO                                                                           | RE-0461-01 |
|                                                                                   | CHECK LIST CROMATOGRAFIA                                                           |            |
|                                                                                   | AREA ANALISIS QUIMICO                                                              | may-16     |
|                                                                                   | FIRMA                                                                              | FECHA      |
| INYECTADO POR                                                                     |  | 18/05/18   |
| CALCULADO POR                                                                     |  | 23/05/18   |
| COORDINADOR HPLC/DEPUTY                                                           |                                                                                    |            |
| SUPERVISOR/JEFE MATERIAS PRIMAS/JEFE ANALISIS QUIMICO                             |  | 26/06/18   |

DCP  
05/06/18

Batch Review Method: C:\CHEM32\1\METHODS\LEVONORGESTREL\_VAL.M

['#' ==> Run has not been reprocessed with Batch Review Method  
['\*' ==> Run has been saved with batch file]

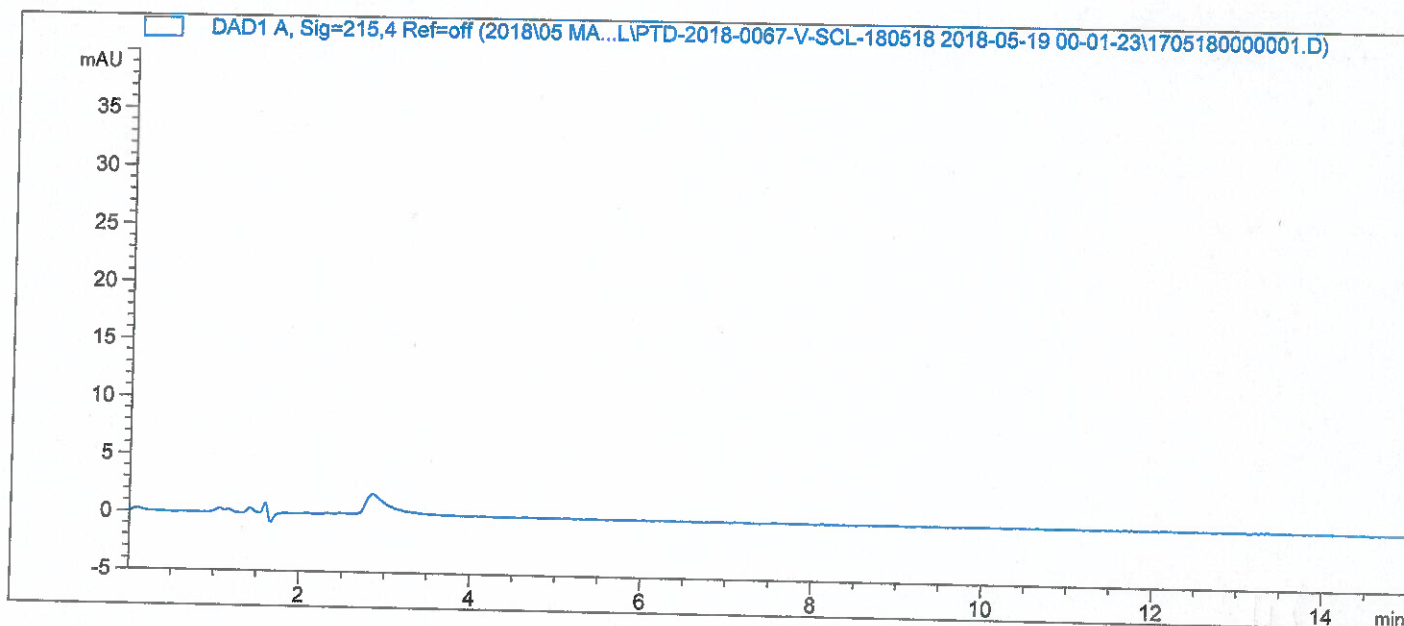
| #* | Location | Sample                     | Levonorg<br>RT | Levonorgestr<br>Area |
|----|----------|----------------------------|----------------|----------------------|
| -- | -----    | -----                      | -----          | -----                |
|    | Vial 1   | Blanco                     | 0.000          | 0.00000              |
|    | Vial 4   | STD 1 Levonorgestrel       | 9.110          | 512.90588            |
|    | Vial 4   | STD 1 Levonorgestrel       | 9.108          | 514.76190            |
|    | Vial 4   | STD 1 Levonorgestrel       | 9.114          | 512.68140            |
|    | Vial 4   | STD 1 Levonorgestrel       | 9.109          | 512.74353            |
|    | Vial 4   | STD 1 Levonorgestrel       | 9.113          | 511.44205            |
|    | Vial 5   | STD 2 Levonorgestrel       | 9.112          | 509.49292            |
|    | Vial 5   | STD 2 Levonorgestrel       | 9.110          | 509.56033            |
|    | Vial 5   | STD 2 Levonorgestrel       | 9.111          | 509.97739            |
|    | Vial 6   | N0001 Levonorgestrel mta_1 | 9.112          | 523.88135            |
|    | Vial 7   | N0001 Levonorgestrel mta_2 | 9.113          | 509.80197            |
|    | Vial 8   | N0001 Levonorgestrel mta_3 | 9.112          | 512.93555            |
|    | Vial 4   | STD control                | 9.115          | 515.70044            |
|    |          | *** End of Report ***      |                |                      |

App 26/06/18

Del  
05/06/18

=====

|                 |                                                                                                                              |            |             |
|-----------------|------------------------------------------------------------------------------------------------------------------------------|------------|-------------|
| Acq. Operator   | : SYSTEM                                                                                                                     | Seq. Line  | : 1         |
| Acq. Instrument | : HPLC-024                                                                                                                   | Location   | : Vial 1    |
| Injection Date  | : 19-May-18 12:02:23 AM                                                                                                      | Inj        | : 1         |
|                 |                                                                                                                              | Inj Volume | : 50.000 µl |
| Acq. Method     | : C:\CHEM32\1\DATA\2018\05 MAYO\LEVONORGESTREL_MP_180518_SCL\PTD-2018-0067-V-SCL-180518 2018-05-19 00-01-23\LEVONORGESTREL.M |            |             |
| Last changed    | : 19-May-18 12:01:23 AM by SYSTEM                                                                                            |            |             |
| Analysis Method | : C:\CHEM32\1\METHODS\LEVONORGESTREL_VAL.M                                                                                   |            |             |
| Last changed    | : 22-May-18 10:49:10 AM by SYSTEM                                                                                            |            |             |
| Method Info     | : LEVONORGESTREL                                                                                                             |            |             |



=====  
Area Percent Report  
=====

Sorted By : Signal  
Calib. Data Modified : 22-May-18 10:39:52 AM  
Multiplier : 1.0000  
Dilution : 1.0000  
Do not use Multiplier & Dilution Factor with ISTDs

Signal 1: DAD1 A, Sig=215,4 Ref=off

| Peak # | RetTime [min] | Type | Width [min] | Area [mAU*s] | Area % | Name           |
|--------|---------------|------|-------------|--------------|--------|----------------|
| 1      | 9.100         |      | 0.0000      | 0.00000      | 0.0000 | Levonorgestrel |

Totals : 0.00000

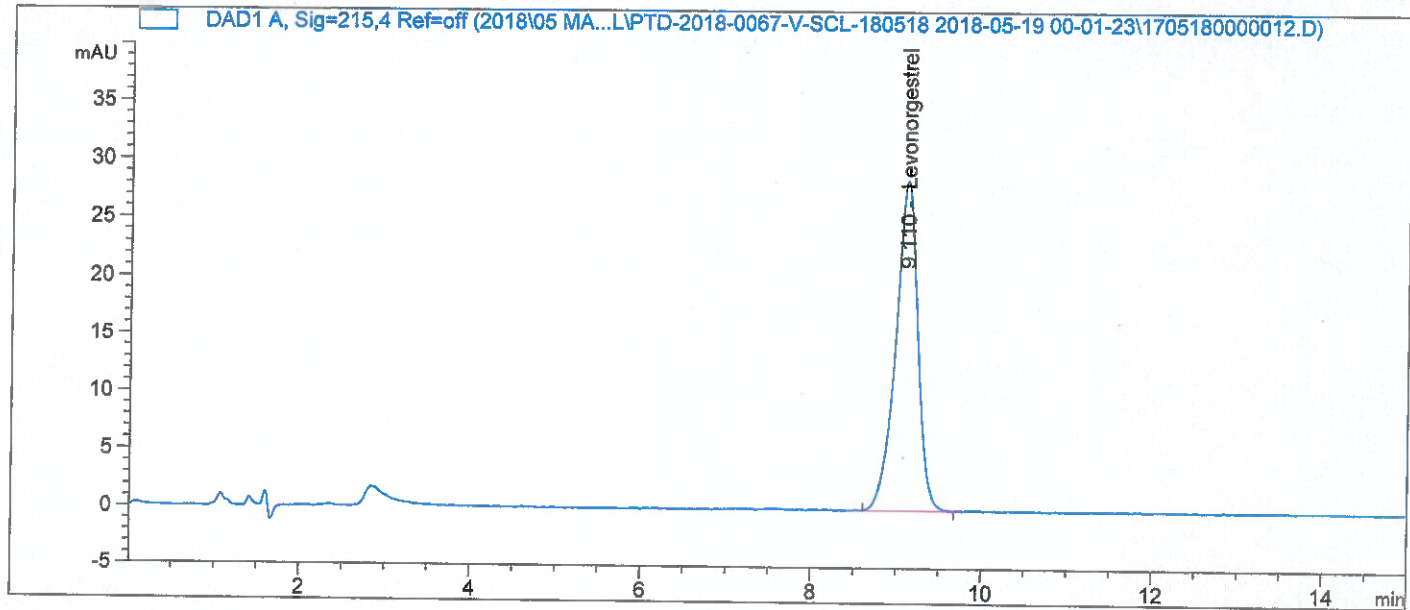
2 Warnings or Errors :

Warning : Calibration warnings (see calibration table listing)  
Warning : Calibrated compound(s) not found

=====  
\*\*\* End of Report \*\*\*

DCP  
05/06/18

```
=====
Acq. Operator   : SYSTEM                      Seq. Line :    4
Acq. Instrument : HPLC-024                   Location  : Vial 4
Injection Date  : 19-May-18 3:01:07 AM        Inj       :    1
                                           Inj Volume: 50.000 µl
Acq. Method     : C:\CHEM32\1\DATA\2018\05 MAYO\LEVONORGESTREL_MP_180518_SCL\PTD-
                                           2018-0067-V-SCL-180518 2018-05-19 00-01-23\LEVONORGESTREL.M
Last changed    : 19-May-18 12:01:23 AM by SYSTEM
Analysis Method : C:\CHEM32\1\METHODS\LEVONORGESTREL_VAL.M
Last changed    : 22-May-18 10:49:10 AM by SYSTEM
Method Info     : LEVONORGESTREL
=====
```



=====  
Area Percent Report  
=====

```
Sorted By      : Signal
Calib. Data Modified : 22-May-18 10:39:52 AM
Multiplier     : 1.0000
Dilution       : 1.0000
Do not use Multiplier & Dilution Factor with ISTDs
```

Signal 1: DAD1 A, Sig=215,4 Ref=off

| Peak # | RetTime [min] | Type | Width [min] | Area [mAU*s] | Area %   | Name           |
|--------|---------------|------|-------------|--------------|----------|----------------|
| 1      | 9.110         | BB   | 0.2745      | 512.90588    | 100.0000 | Levonorgestrel |

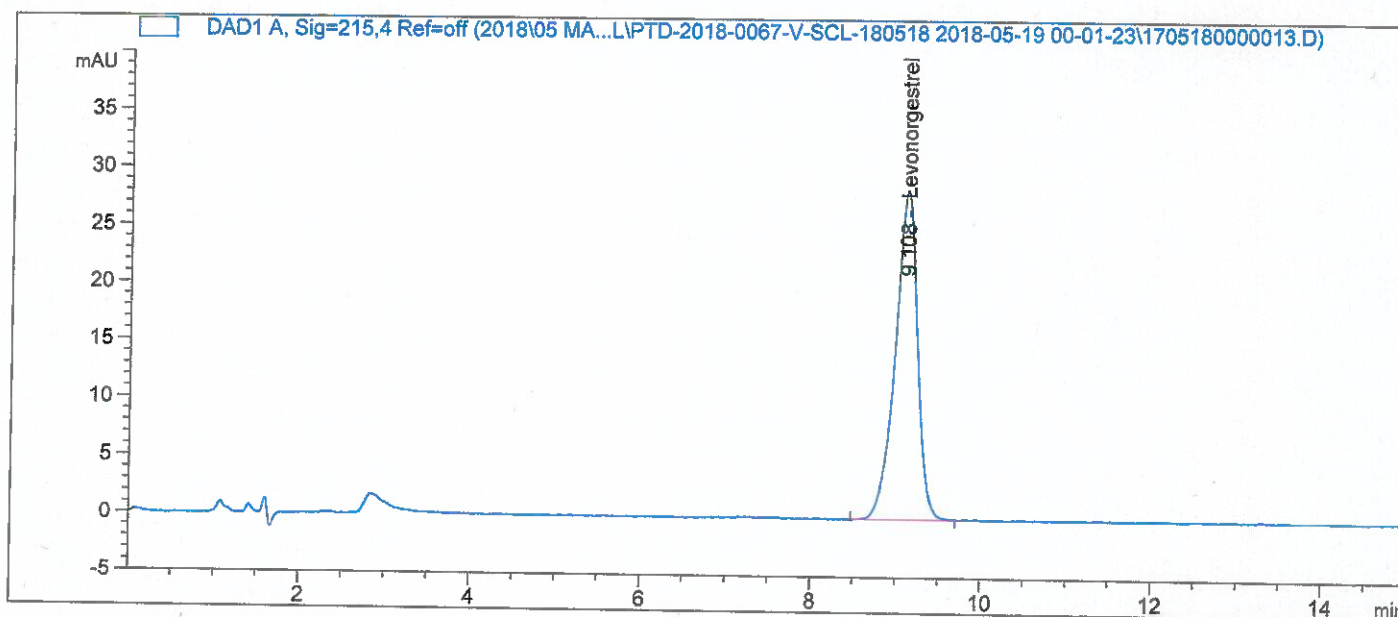
Totals : 512.90588

2 Warnings or Errors :

Warning : Calibration warnings (see calibration table listing)  
Warning : Invalid calibration curve, (Levonorgestrel)

=====  
\*\*\* End of Report \*\*\*

```
=====
Acq. Operator   : SYSTEM                      Seq. Line :    4
Acq. Instrument : HPLC-024                   Location  : Vial 4
Injection Date  : 19-May-18 3:17:23 AM        Inj       :    2
                                           Inj Volume: 50.000 µl
Acq. Method     : C:\CHEM32\1\DATA\2018\05 MAYO\LEVONORGESTREL_MP_180518_SCL\PTD-
                                           2018-0067-V-SCL-180518 2018-05-19 00-01-23\LEVONORGESTREL.M
Last changed    : 19-May-18 12:01:23 AM by SYSTEM
Analysis Method : C:\CHEM32\1\METHODS\LEVONORGESTREL_VAL.M
Last changed    : 22-May-18 10:49:10 AM by SYSTEM
Method Info     : LEVONORGESTREL
=====
```



=====  
Area Percent Report  
=====

Sorted By : Signal  
Calib. Data Modified : 22-May-18 10:39:52 AM  
Multiplier : 1.0000  
Dilution : 1.0000  
Do not use Multiplier & Dilution Factor with ISTDs

Signal 1: DAD1 A, Sig=215,4 Ref=off

| Peak # | RetTime [min] | Type | Width [min] | Area [mAU*s] | Area %   | Name           |
|--------|---------------|------|-------------|--------------|----------|----------------|
| 1      | 9.108         | BB   | 0.2732      | 514.76190    | 100.0000 | Levonorgestrel |

Totals : 514.76190

2 Warnings or Errors :

Warning : Calibration warnings (see calibration table listing)  
Warning : Invalid calibration curve, (Levonorgestrel)

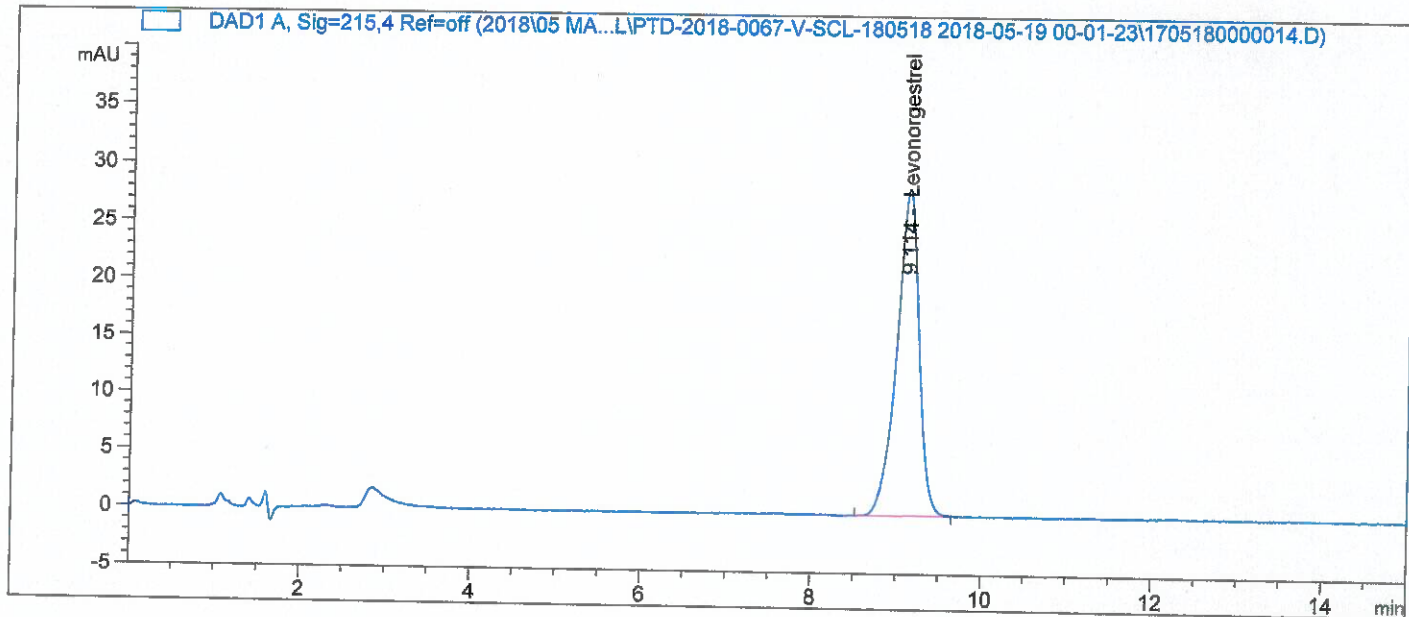
=====  
\*\*\* End of Report \*\*\*

Dep  
05/06/18

=====

|                 |                                                                                                                              |            |             |
|-----------------|------------------------------------------------------------------------------------------------------------------------------|------------|-------------|
| Acq. Operator   | : SYSTEM                                                                                                                     | Seq. Line  | : 4         |
| Acq. Instrument | : HPLC-024                                                                                                                   | Location   | : Vial 4    |
| Injection Date  | : 19-May-18 3:33:39 AM                                                                                                       | Inj        | : 3         |
|                 |                                                                                                                              | Inj Volume | : 50.000 µl |
| Acq. Method     | : C:\CHEM32\1\DATA\2018\05 MAYO\LEVONORGESTREL_MP_180518_SCL\PTD-2018-0067-V-SCL-180518 2018-05-19 00-01-23\LEVONORGESTREL.M |            |             |
| Last changed    | : 19-May-18 12:01:23 AM by SYSTEM                                                                                            |            |             |
| Analysis Method | : C:\CHEM32\1\METHODS\LEVONORGESTREL_VAL.M                                                                                   |            |             |
| Last changed    | : 22-May-18 10:49:10 AM by SYSTEM                                                                                            |            |             |
| Method Info     | : LEVONORGESTREL                                                                                                             |            |             |

=====



=====  
Area Percent Report  
=====

Sorted By : Signal  
Calib. Data Modified : 22-May-18 10:39:52 AM  
Multiplier : 1.0000  
Dilution : 1.0000  
Do not use Multiplier & Dilution Factor with ISTDs

Signal 1: DAD1 A, Sig=215,4 Ref=off

| Peak # | RetTime [min] | Type | Width [min] | Area [mAU*s] | Area %   | Name           |
|--------|---------------|------|-------------|--------------|----------|----------------|
| 1      | 9.114         | BB   | 0.2727      | 512.68140    | 100.0000 | Levonorgestrel |

Totals : 512.68140

2 Warnings or Errors :

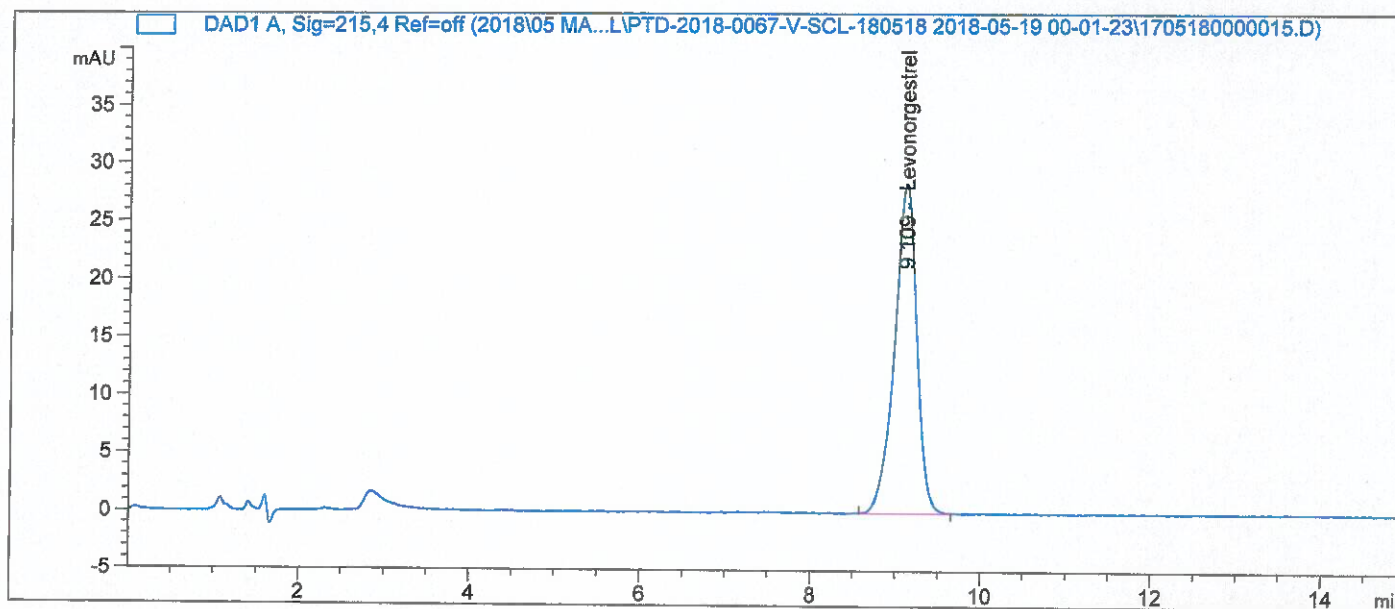
Warning : Calibration warnings (see calibration table listing)  
Warning : Invalid calibration curve, (Levonorgestrel)

=====  
\*\*\* End of Report \*\*\*  
=====

DCP  
05/06/18

Sample Name: STD 1 Levonorgestrel

```
=====
Acq. Operator   : SYSTEM                      Seq. Line :    4
Acq. Instrument : HPLC-024                   Location  : Vial 4
Injection Date  : 19-May-18 3:49:55 AM        Inj       :    4
                                           Inj Volume: 50.000 µl
Acq. Method     : C:\CHEM32\1\DATA\2018\05 MAYO\LEVONORGESTREL_MP_180518_SCL\PTD-
                                           2018-0067-V-SCL-180518 2018-05-19 00-01-23\LEVONORGESTREL.M
Last changed    : 19-May-18 12:01:23 AM by SYSTEM
Analysis Method : C:\CHEM32\1\METHODS\LEVONORGESTREL_VAL.M
Last changed    : 22-May-18 10:49:10 AM by SYSTEM
Method Info     : LEVONORGESTREL
=====
```



```
=====
                          Area Percent Report
=====
```

```
Sorted By           : Signal
Calib. Data Modified : 22-May-18 10:39:52 AM
Multiplier          : 1.0000
Dilution            : 1.0000
Do not use Multiplier & Dilution Factor with ISTDs
```

Signal 1: DAD1 A, Sig=215,4 Ref=off

| Peak # | RetTime [min] | Type | Width [min] | Area [mAU*s] | Area %   | Name           |
|--------|---------------|------|-------------|--------------|----------|----------------|
| 1      | 9.109         | BB   | 0.2732      | 512.74353    | 100.0000 | Levonorgestrel |

Totals : 512.74353

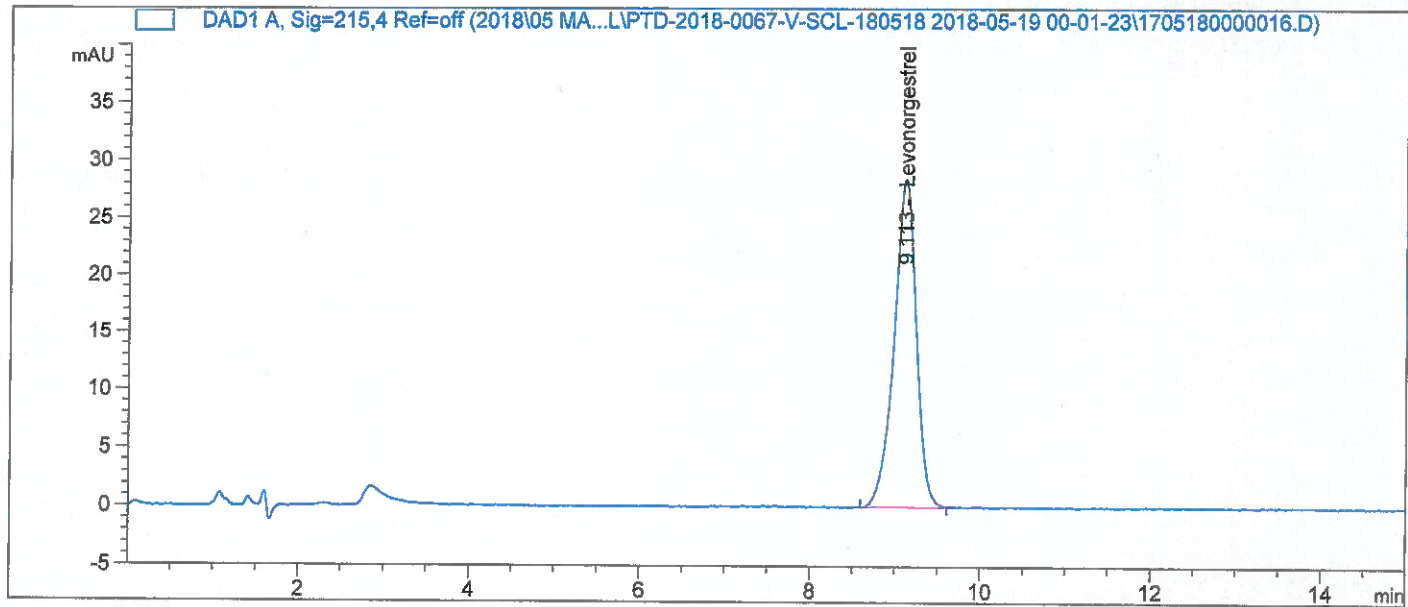
## 2 Warnings or Errors :

Warning : Calibration warnings (see calibration table listing)  
Warning : Invalid calibration curve, (Levonorgestrel)

```
=====
*** End of Report ***
=====
```

DCL  
05/06/18

```
=====
Acq. Operator   : SYSTEM                      Seq. Line :    4
Acq. Instrument : HPLC-024                   Location  : Vial 4
Injection Date  : 19-May-18 4:06:12 AM        Inj       :    5
                                           Inj Volume: 50.000 µl
Acq. Method     : C:\CHEM32\1\DATA\2018\05 MAYO\LEVONORGESTREL_MP_180518_SCL\PTD-
                  2018-0067-V-SCL-180518 2018-05-19 00-01-23\LEVONORGESTREL.M
Last changed    : 19-May-18 12:01:23 AM by SYSTEM
Analysis Method : C:\CHEM32\1\METHODS\LEVONORGESTREL_VAL.M
Last changed    : 22-May-18 10:49:10 AM by SYSTEM
Method Info     : LEVONORGESTREL
=====
```



```
=====
                          Area Percent Report
=====
```

```
Sorted By      :      Signal
Calib. Data Modified : 22-May-18 10:39:52 AM
Multiplier     :      1.0000
Dilution       :      1.0000
Do not use Multiplier & Dilution Factor with ISTDs
```

Signal 1: DAD1 A, Sig=215,4 Ref=off

| Peak # | RetTime [min] | Type | Width [min] | Area [mAU*s] | Area %   | Name           |
|--------|---------------|------|-------------|--------------|----------|----------------|
| 1      | 9.113         | BB   | 0.2744      | 511.44205    | 100.0000 | Levonorgestrel |

Totals : 511.44205

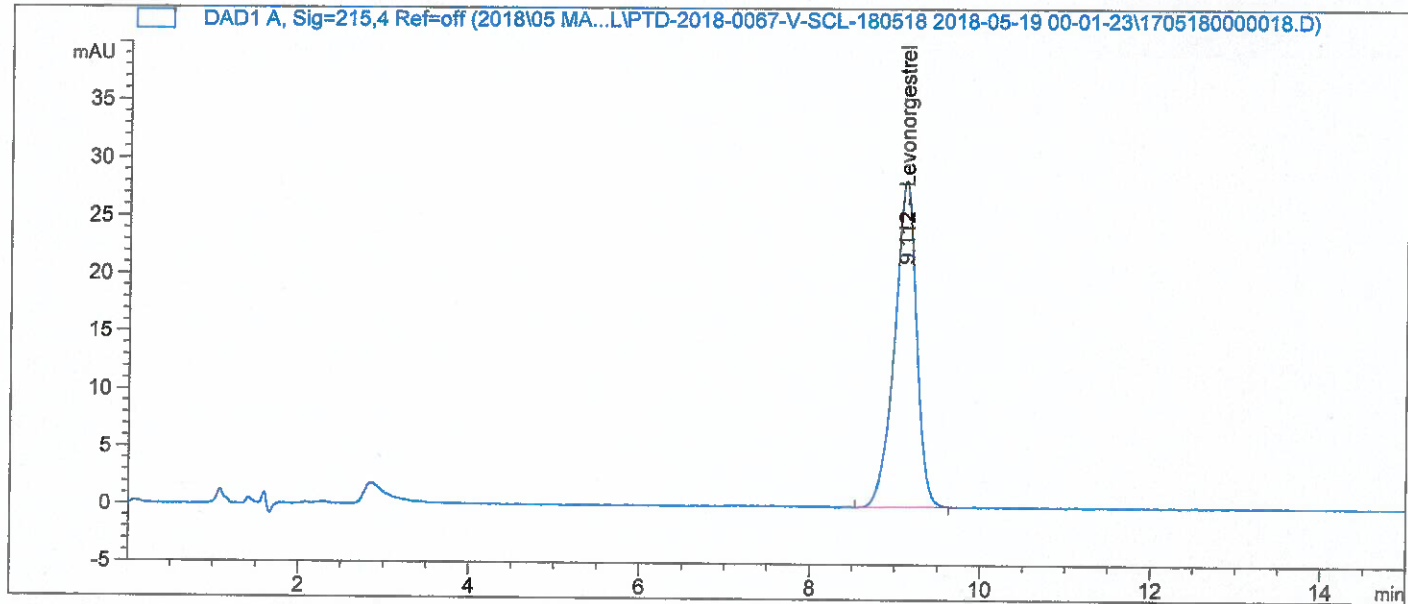
2 Warnings or Errors :

Warning : Calibration warnings (see calibration table listing)  
Warning : Invalid calibration curve, (Levonorgestrel)

```
=====
*** End of Report ***
=====
```

DCP  
05/06/18

```
=====
Acq. Operator   : SYSTEM                      Seq. Line :    5
Acq. Instrument : HPLC-024                   Location  : Vial 5
Injection Date  : 19-May-18 4:38:43 AM        Inj       :    1
                                           Inj Volume: 50.000 µl
Acq. Method     : C:\CHEM32\1\DATA\2018\05 MAYO\LEVONORGESTREL_MP_180518_SCL\PTD-
                                           2018-0067-V-SCL-180518 2018-05-19 00-01-23\LEVONORGESTREL.M
Last changed    : 19-May-18 12:01:23 AM by SYSTEM
Analysis Method : C:\CHEM32\1\METHODS\LEVONORGESTREL_VAL.M
Last changed    : 22-May-18 10:49:10 AM by SYSTEM
Method Info     : LEVONORGESTREL
=====
```



=====  
Area Percent Report  
=====

Sorted By : Signal  
Calib. Data Modified : 22-May-18 10:39:52 AM  
Multiplier : 1.0000  
Dilution : 1.0000  
Do not use Multiplier & Dilution Factor with ISTDs

Signal 1: DAD1 A, Sig=215,4 Ref=off

| Peak # | RetTime [min] | Type | Width [min] | Area [mAU*s] | Area %   | Name           |
|--------|---------------|------|-------------|--------------|----------|----------------|
| 1      | 9.112         | BB   | 0.2728      | 509.49292    | 100.0000 | Levonorgestrel |

Totals : 509.49292

2 Warnings or Errors :

Warning : Calibration warnings (see calibration table listing)  
Warning : Invalid calibration curve, (Levonorgestrel)

=====  
\*\*\* End of Report \*\*\*

DUP  
05/06/18

=====

|                 |                        |            |             |
|-----------------|------------------------|------------|-------------|
| Acq. Operator   | : SYSTEM               | Seq. Line  | : 5         |
| Acq. Instrument | : HPLC-024             | Location   | : Vial 5    |
| Injection Date  | : 19-May-18 4:54:58 AM | Inj        | : 2         |
|                 |                        | Inj Volume | : 50.000 µl |

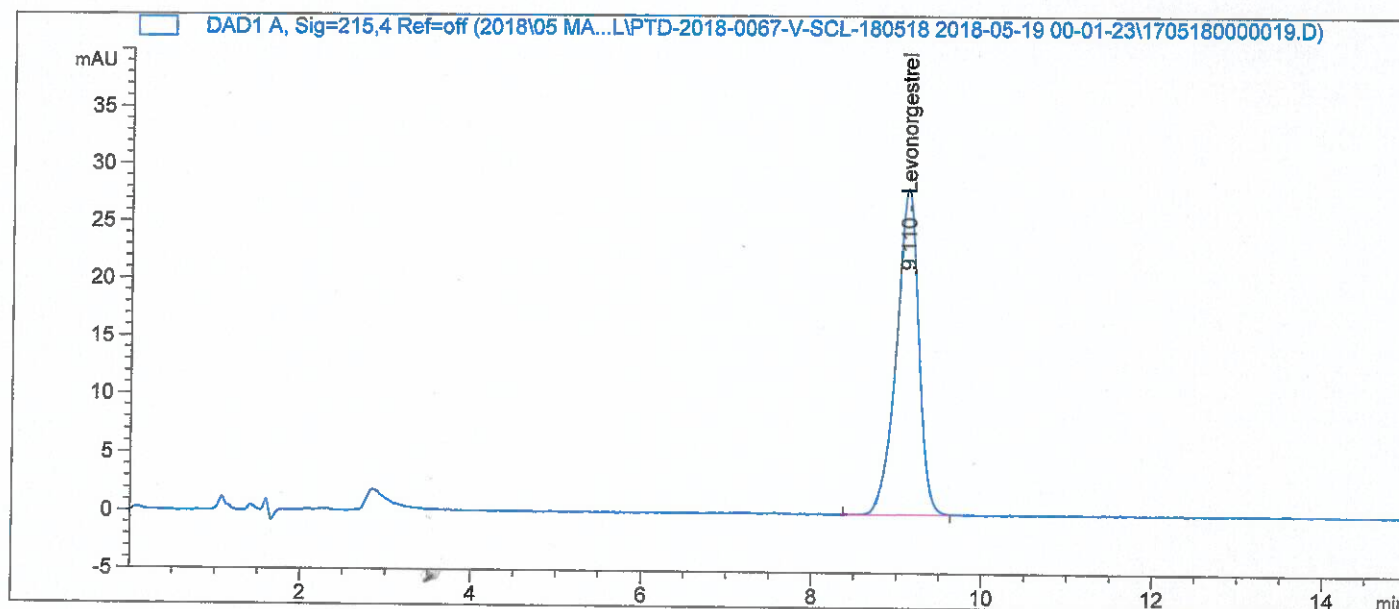
Acq. Method : C:\CHEM32\1\DATA\2018\05 MAYO\LEVONORGESTREL\_MP\_180518\_SCL\PTD-2018-0067-V-SCL-180518 2018-05-19 00-01-23\LEVONORGESTREL .M

Last changed : 19-May-18 12:01:23 AM by SYSTEM

Analysis Method : C:\CHEM32\1\METHODS\LEVONORGESTREL\_VAL .M

Last changed : 22-May-18 10:49:10 AM by SYSTEM

Method Info : LEVONORGESTREL



=====  
Area Percent Report  
=====

Sorted By : Signal  
Calib. Data Modified : 22-May-18 10:39:52 AM  
Multiplier : 1.0000  
Dilution : 1.0000  
Do not use Multiplier & Dilution Factor with ISTDs

Signal 1: DAD1 A, Sig=215,4 Ref=off

| Peak # | RetTime [min] | Type | Width [min] | Area [mAU*s] | Area %   | Name           |
|--------|---------------|------|-------------|--------------|----------|----------------|
| 1      | 9.110         | BB   | 0.2734      | 509.56033    | 100.0000 | Levonorgestrel |

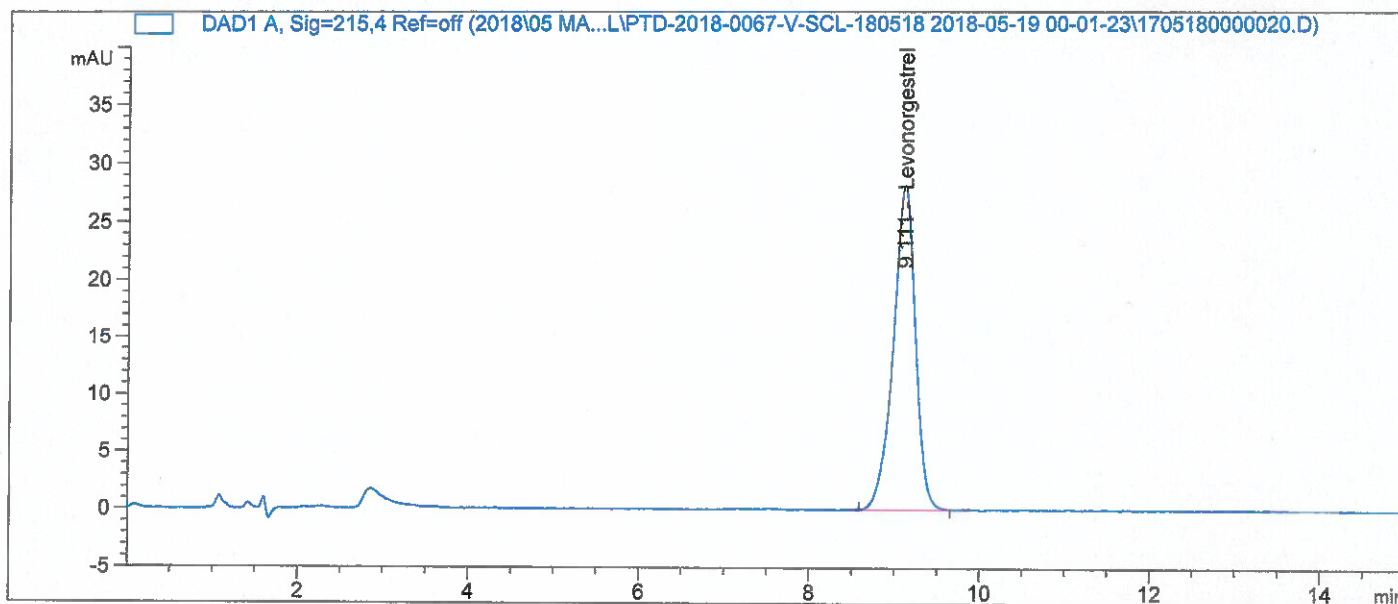
Totals : 509.56033

2 Warnings or Errors :

Warning : Calibration warnings (see calibration table listing)  
Warning : Invalid calibration curve, (Levonorgestrel)

=====  
\*\*\* End of Report \*\*\*

```
=====
Acq. Operator   : SYSTEM                      Seq. Line :    5
Acq. Instrument : HPLC-024                   Location  : Vial 5
Injection Date  : 19-May-18 5:11:12 AM        Inj       :    3
                                           Inj Volume: 50.000 µl
Acq. Method     : C:\CHEM32\1\DATA\2018\05 MAYO\LEVONORGESTREL_MP_180518_SCL\PTD-
                                           2018-0067-V-SCL-180518 2018-05-19 00-01-23\LEVONORGESTREL.M
Last changed    : 19-May-18 12:01:23 AM by SYSTEM
Analysis Method : C:\CHEM32\1\METHODS\LEVONORGESTREL_VAL.M
Last changed    : 22-May-18 10:49:10 AM by SYSTEM
Method Info     : LEVONORGESTREL
=====
```



=====  
Area Percent Report  
=====

```
Sorted By      : Signal
Calib. Data Modified : 22-May-18 10:39:52 AM
Multiplier     : 1.0000
Dilution       : 1.0000
Do not use Multiplier & Dilution Factor with ISTDs
```

Signal 1: DAD1 A, Sig=215,4 Ref=off

| Peak # | RetTime [min] | Type | Width [min] | Area [mAU*s] | Area %   | Name           |
|--------|---------------|------|-------------|--------------|----------|----------------|
| 1      | 9.111         | BB   | 0.2738      | 509.97739    | 100.0000 | Levonorgestrel |

Totals : 509.97739

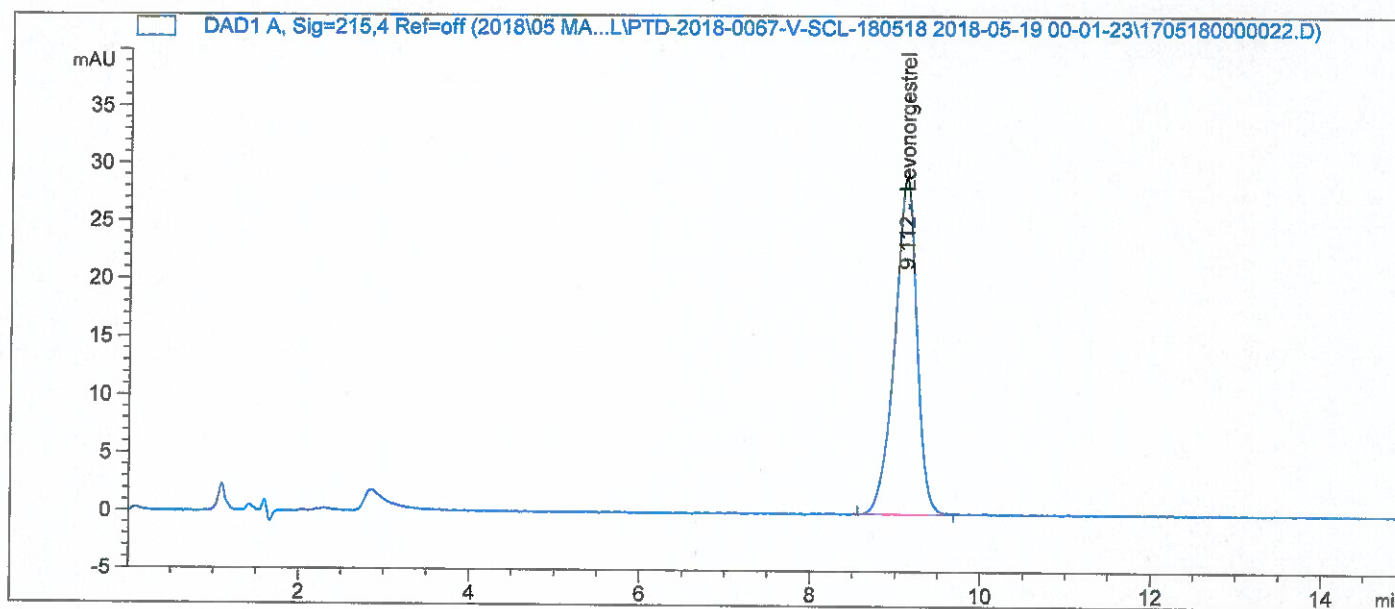
2 Warnings or Errors :

Warning : Calibration warnings (see calibration table listing)  
Warning : Invalid calibration curve, (Levonorgestrel)

=====  
\*\*\* End of Report \*\*\*

Sample Name: N0001 Levonorgestrel mta\_1

```
=====
Acq. Operator   : SYSTEM                      Seq. Line :    6
Acq. Instrument : HPLC-024                   Location  : Vial 6
Injection Date  : 19-May-18 5:43:41 AM        Inj       :    1
                                           Inj Volume: 50.000 µl
Acq. Method     : C:\CHEM32\1\DATA\2018\05 MAYO\LEVONORGESTREL_MP_180518_SCL\PTD-
                                           2018-0067-V-SCL-180518 2018-05-19 00-01-23\LEVONORGESTREL.M
Last changed    : 19-May-18 12:01:23 AM by SYSTEM
Analysis Method : C:\CHEM32\1\METHODS\LEVONORGESTREL_VAL.M
Last changed    : 22-May-18 10:49:10 AM by SYSTEM
Method Info     : LEVONORGESTREL
=====
```



```
=====
                          Area Percent Report
=====
```

```
Sorted By      : Signal
Calib. Data Modified : 22-May-18 10:39:52 AM
Multiplier     : 1.0000
Dilution       : 1.0000
Do not use Multiplier & Dilution Factor with ISTDs
```

Signal 1: DAD1 A, Sig=215,4 Ref=off

| Peak # | RetTime [min] | Type | Width [min] | Area [mAU*s] | Area %   | Name           |
|--------|---------------|------|-------------|--------------|----------|----------------|
| 1      | 9.112         | BB   | 0.2740      | 523.88135    | 100.0000 | Levonorgestrel |

Totals : 523.88135

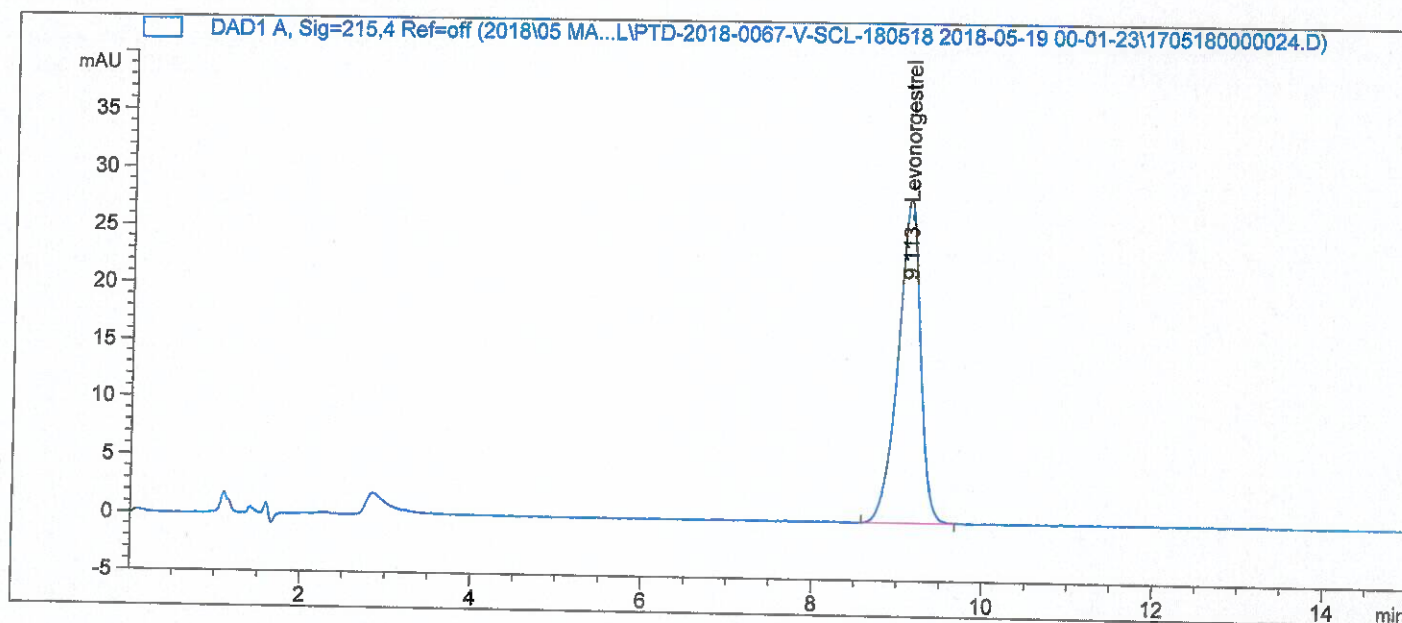
2 Warnings or Errors :

Warning : Calibration warnings (see calibration table listing)  
Warning : Invalid calibration curve, (Levonorgestrel)

```
=====
*** End of Report ***
=====
```

DCP  
05/06/18

```
=====
Acq. Operator   : SYSTEM                      Seq. Line :    7
Acq. Instrument : HPLC-024                   Location  : Vial 7
Injection Date  : 19-May-18 6:16:15 AM        Inj       :    1
                                           Inj Volume: 50.000 µl
Acq. Method     : C:\CHEM32\1\DATA\2018\05 MAYO\LEVONORGESTREL_MP_180518_SCL\PTD-
                                           2018-0067-V-SCL-180518 2018-05-19 00-01-23\LEVONORGESTREL.M
Last changed    : 19-May-18 12:01:23 AM by SYSTEM
Analysis Method : C:\CHEM32\1\METHODS\LEVONORGESTREL_VAL.M
Last changed    : 22-May-18 10:49:10 AM by SYSTEM
Method Info     : LEVONORGESTREL
=====
```



```
=====
Area Percent Report
=====
```

```
Sorted By      : Signal
Calib. Data Modified : 22-May-18 10:39:52 AM
Multiplier     : 1.0000
Dilution       : 1.0000
Do not use Multiplier & Dilution Factor with ISTDs
```

Signal 1: DAD1 A, Sig=215,4 Ref=off

| Peak # | RetTime [min] | Type | Width [min] | Area [mAU*s] | Area %   | Name           |
|--------|---------------|------|-------------|--------------|----------|----------------|
| 1      | 9.113         | BB   | 0.2740      | 509.80197    | 100.0000 | Levonorgestrel |

Totals : 509.80197

2 Warnings or Errors :

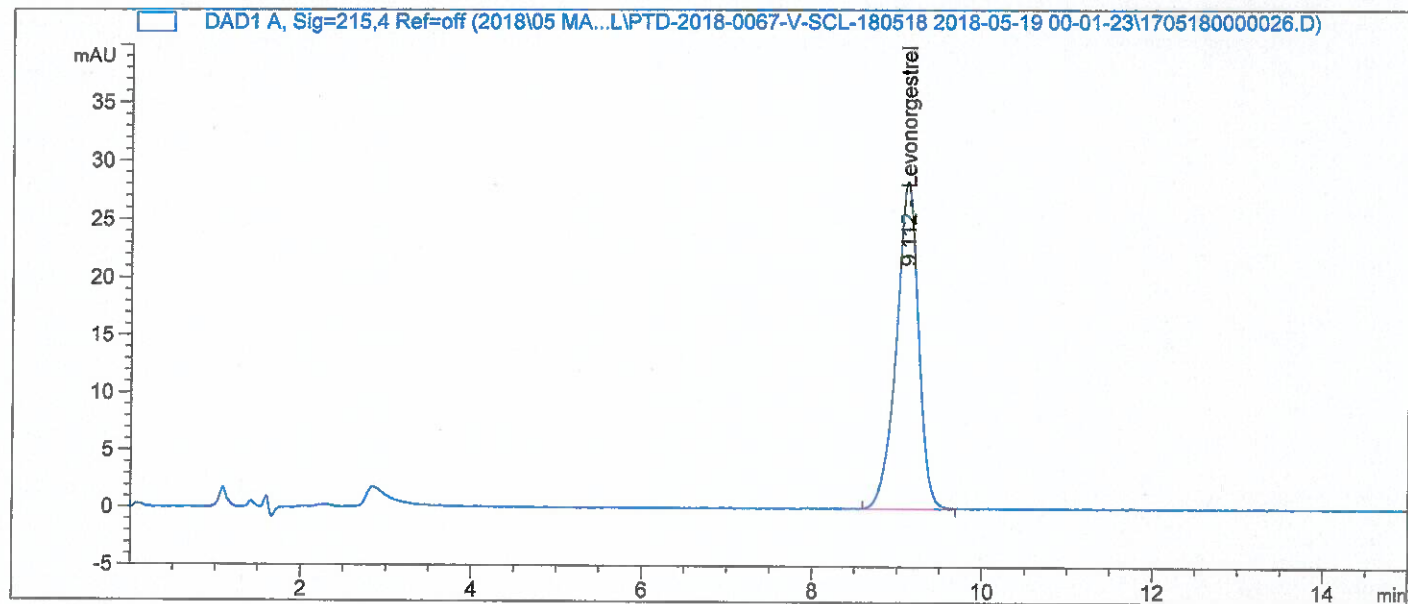
Warning : Calibration warnings (see calibration table listing)  
Warning : Invalid calibration curve, (Levonorgestrel)

```
=====
*** End of Report ***
=====
```

Dcp  
05/06/18

Sample Name: N0001 Levonorgestrel mta\_3

```
=====
Acq. Operator   : SYSTEM                      Seq. Line :    8
Acq. Instrument : HPLC-024                   Location  : Vial 8
Injection Date  : 19-May-18 6:48:49 AM        Inj       :    1
                                           Inj Volume: 50.000 µl
Acq. Method     : C:\CHEM32\1\DATA\2018\05 MAYO\LEVONORGESTREL_MP_180518_SCL\PTD-
                                           2018-0067-V-SCL-180518 2018-05-19 00-01-23\LEVONORGESTREL.M
Last changed    : 19-May-18 12:01:23 AM by SYSTEM
Analysis Method : C:\CHEM32\1\METHODS\LEVONORGESTREL_VAL.M
Last changed    : 22-May-18 10:49:10 AM by SYSTEM
Method Info     : LEVONORGESTREL
=====
```



```
=====
                          Area Percent Report
=====
```

```
Sorted By      :      Signal
Calib. Data Modified : 22-May-18 10:39:52 AM
Multiplier     :      1.0000
Dilution       :      1.0000
Do not use Multiplier & Dilution Factor with ISTDs
```

Signal 1: DAD1 A, Sig=215,4 Ref=off

| Peak # | RetTime [min] | Type | Width [min] | Area [mAU*s] | Area %   | Name           |
|--------|---------------|------|-------------|--------------|----------|----------------|
| 1      | 9.112         | BB   | 0.2741      | 512.93555    | 100.0000 | Levonorgestrel |

Totals : 512.93555

2 Warnings or Errors :

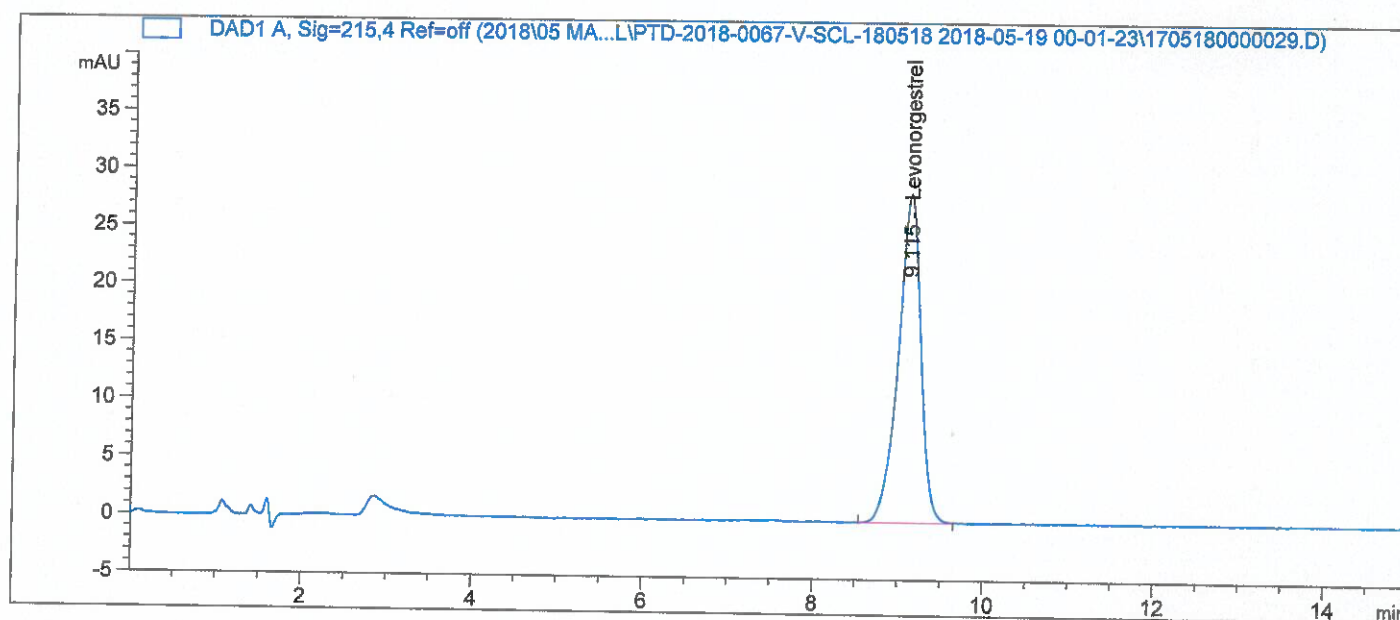
Warning : Calibration warnings (see calibration table listing)  
Warning : Invalid calibration curve, (Levonorgestrel)

```
=====
*** End of Report ***
=====
```

DGP  
05/06/18

Sample Name: STD control

```
=====
Acq. Operator   : SYSTEM                      Seq. Line :   10
Acq. Instrument : HPLC-024                   Location  : Vial 4
Injection Date  : 19-May-18 7:37:38 AM       Inj       :    1
                                           Inj Volume: 50.000 µl
Acq. Method     : C:\CHEM32\1\DATA\2018\05 MAYO\LEVONORGESTREL_MP_180518_SCL\PTD-
                                           2018-0067-V-SCL-180518 2018-05-19 00-01-23\LEVONORGESTREL.M
Last changed    : 19-May-18 12:01:23 AM by SYSTEM
Analysis Method : C:\CHEM32\1\METHODS\LEVONORGESTREL_VAL.M
Last changed    : 22-May-18 10:49:10 AM by SYSTEM
Method Info     : LEVONORGESTREL
=====
```



```
=====
                          Area Percent Report
=====
```

```
Sorted By      : Signal
Calib. Data Modified : 22-May-18 10:39:52 AM
Multiplier     : 1.0000
Dilution       : 1.0000
Do not use Multiplier & Dilution Factor with ISTDs
```

Signal 1: DAD1 A, Sig=215,4 Ref=off

| Peak # | RetTime [min] | Type | Width [min] | Area [mAU*s] | Area %   | Name           |
|--------|---------------|------|-------------|--------------|----------|----------------|
| 1      | 9.115         | BB   | 0.2749      | 515.70044    | 100.0000 | Levonorgestrel |

Totals : 515.70044

2 Warnings or Errors :

Warning : Calibration warnings (see calibration table listing)  
Warning : Invalid calibration curve, (Levonorgestrel)

```
=====
*** End of Report ***
=====
```

DQ  
05/06/18

Extended Performance Report

Instrument: HPLC-024

| Module         | Type   | Firmware rev.  | Serial number |
|----------------|--------|----------------|---------------|
| DAD            | G1315D | B.06.75 [0010] | DEAAX02350    |
| Column Comp. 2 | G1316A | A.06.50 [005]  | DEACN09648    |
| Sampler 3      | G1329B | A.06.54 [003]  | DEAB306862    |
| Quat. Pump 4   | G1311B | A.06.55 [004]  | DEAB703491    |

Specials:  
G1330 B DEBAK06053 THERMOSTAT

Software Revision: Rev. C.01.03 [37] Copyright © Agilent Technologies

Column Description : Zorbax Eclipse XDB-C8  
Serial# : USRK072288  
Product# : 993967-906 Batch# : B13175  
Diameter : 4.6 mm Length : 150.0 mm  
Particle size : 5.0 µm Void time : 1.246 min  
# Injections : 15  
Maximum Pressure : 400.0 bar Maximum pH : 9.0  
Minimum pH : 2.0  
Maximum Temperature: 60.0 °C  
Comment : ID-082

Analysis method:  
Path: C:\CHEM32\1\METHODS\LEVONORGESTREL\_VAL.M  
Name: LEVONORGESTREL\_VAL.M

Sample information for Location: Vial 4

|                   |                  |             |      |
|-------------------|------------------|-------------|------|
| Sample Name:      | STD 1 Levonorges | Multiplier: | 1.00 |
| Injection#:       | 1                | Dilution:   | 1.00 |
| Injection volume: | 50.000 µl        |             |      |

Acquisition information:

Operator: SYSTEM  
Date/Time: 19-May-18 3:01:07 AM  
Data file:  
Path: C:\CHEM32\1\DATA\2018\05 MAYO\LEVONORGESTREL\_MP\_180518\_SCL\PTD-20  
Name: 1705180000012.D  
Method file:  
Path: C:\Chem32\1\DATA\2018\05 MAYO\LEVONORGESTREL\_MP\_180518\_SCL\PTD-20  
Name: LEVONORGESTREL.M

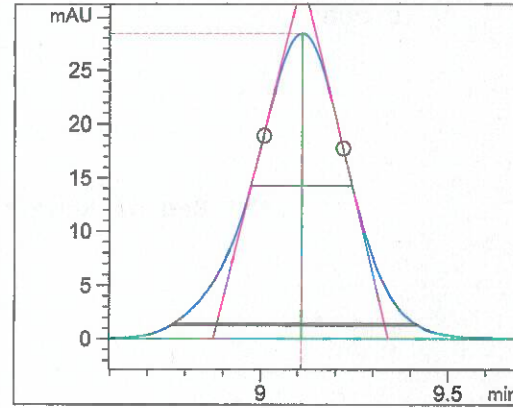
Flow: 1.000 ml/min  
Pressure at start: 114 bar Pressure at end: 116 bar  
Left Temp. at start: 25.0°C Left Temp. at end: 25.0 °C  
Right Temp. at start: 25.0°C Right Temp. at end: 25.0 °C

DCP  
05/06/18

Compound# 1: Levonorgestrel  
Amount [ng/ul]: 0.00000

Peak description [min]:

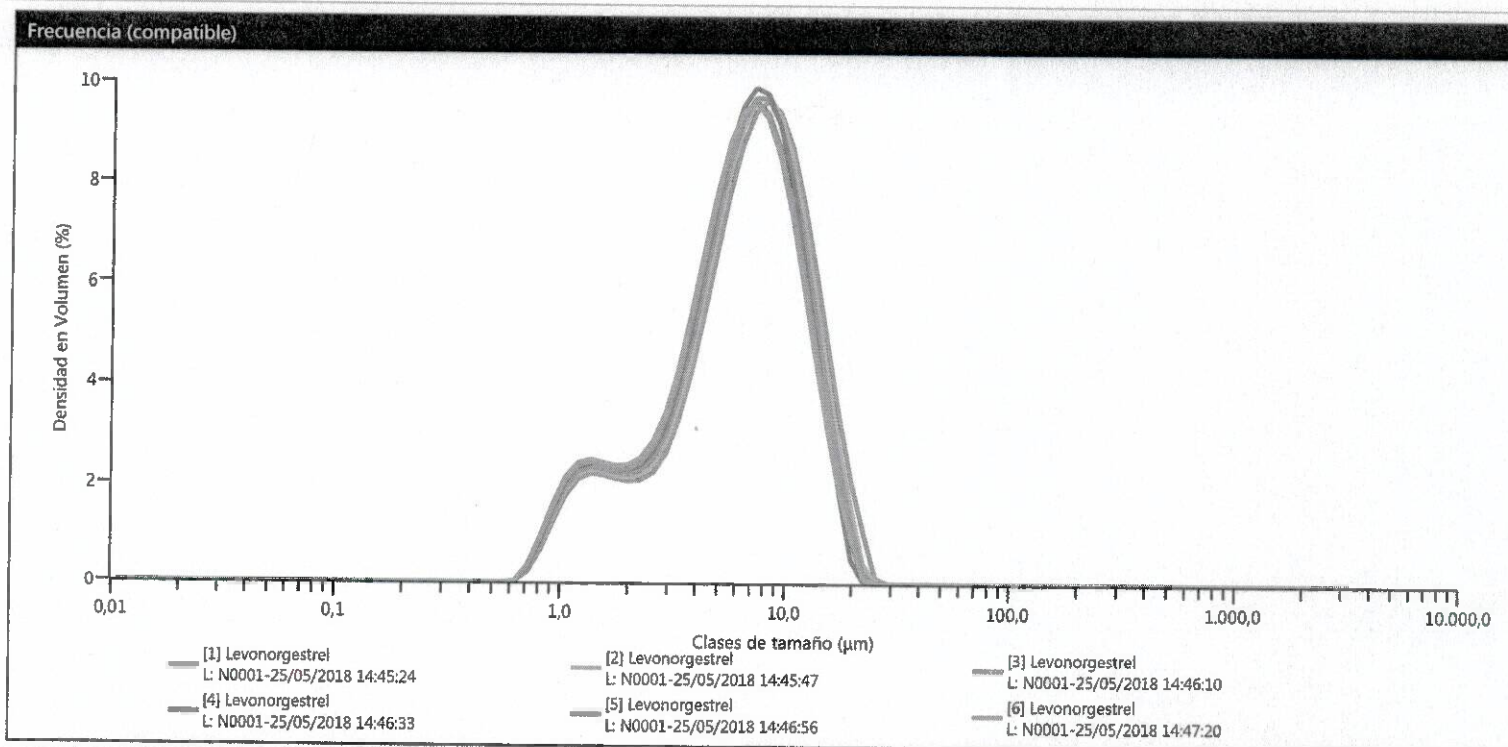
Signal: DAD1 A, Sig=215,4 Ref=off  
RetTime: 9.10967 k': 6.31114  
Height: 28.42624 Area: 512.90588  
Start: 8.60787 End: 9.67594  
Skew: -0.07893 Excess: 0.33222  
Width at half height: 0.26969  
5 sigma: 0.65918  
tangent: 0.46467  
tailing: 0.64446  
Symmetry: 1.05182  
USP Tailing: 0.93949  
Integration type: BB  
Time increment [msec]: 400.00000  
Data points: 218



| Statistical moments (BB peak detection): |            | Efficiency: Plates per .. |            |
|------------------------------------------|------------|---------------------------|------------|
|                                          |            | column                    | meter      |
| M0:                                      | 512.893867 |                           |            |
| M1:                                      | 9.106046   | Tangent method:           | 6152 41016 |
| M2:                                      | 0.016688   | Halfwidth method:         | 6324 42161 |
| M3:                                      | -0.000170  | 5 sigma method:           | 4777 31846 |
| M4:                                      | 0.000928   | Statistical:              | 4969 33125 |

| Relationship to preceeding peak: |                     | Selectivity:        |   |
|----------------------------------|---------------------|---------------------|---|
| Resolution                       | Tangent method: -   | 5 sigma method:     | - |
|                                  | Halfwidth method: - | Statistical method: | - |

Dq  
05/06/18

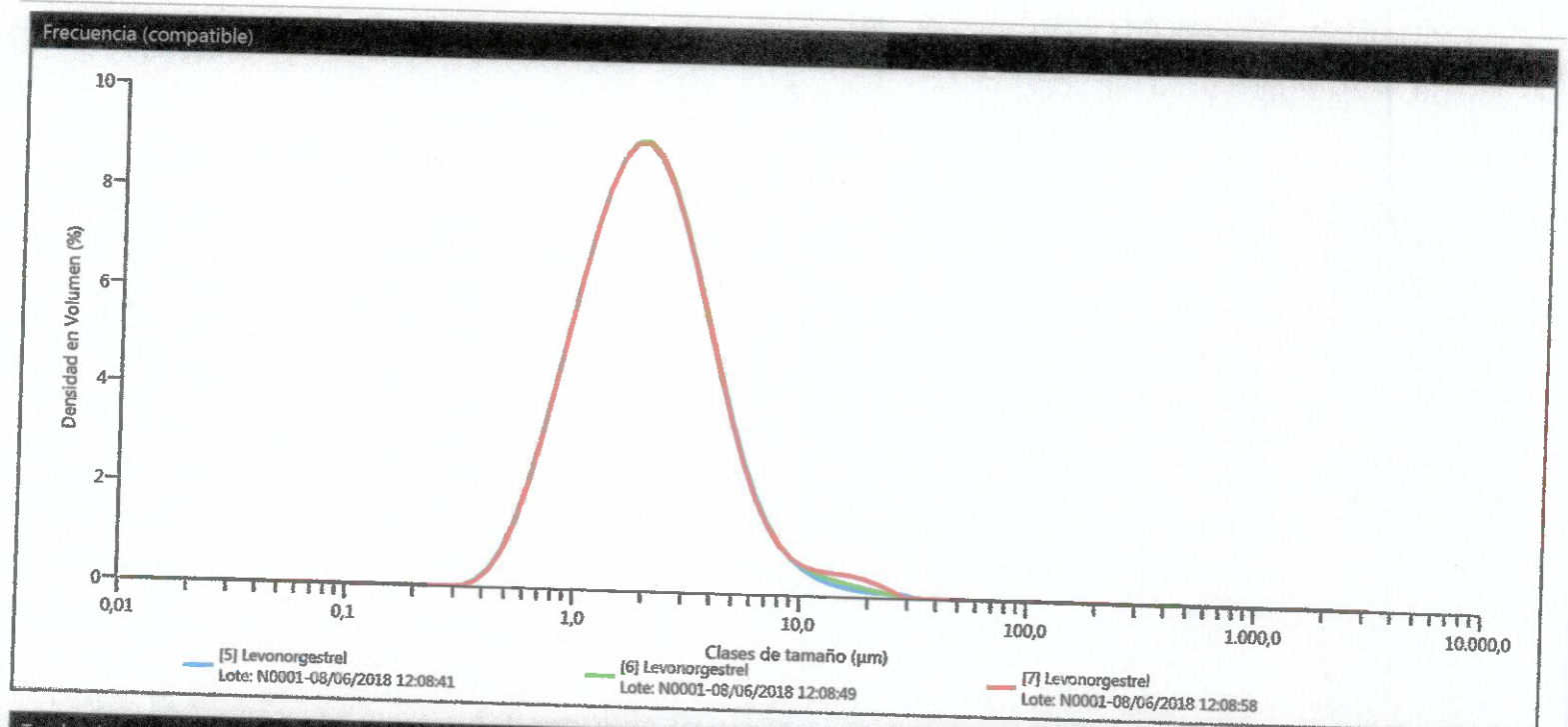


Tendencia

| Número de registro | Nombre de la muestra       | Dx (90) (µm) | Dx (100) (µm) |
|--------------------|----------------------------|--------------|---------------|
| 1                  | Levonorgestrel<br>L: N0001 | 14,2         | 26,4          |
| 2                  | Levonorgestrel<br>L: N0001 | 13,5         | 24,0          |
| 3                  | Levonorgestrel<br>L: N0001 | 13,0         | 24,0          |
| 4                  | Levonorgestrel<br>L: N0001 | 12,3         | 21,2          |
| 5                  | Levonorgestrel<br>L: N0001 | 12,6         | 23,8          |
| 6                  | Levonorgestrel<br>L: N0001 | 12,3         | 21,2          |
| <b>Media</b>       |                            | <b>13,0</b>  | <b>23,4</b>   |
| <b>1XStd dev</b>   |                            | <b>0,757</b> | <b>2,00</b>   |
| <b>1XRSD (%)</b>   |                            | <b>5,83</b>  | <b>8,53</b>   |

Hydro (low medication)

Dcp  
08/06/18



| Tendencia |           | Número de registro | Nombre de la muestra          | Dx (90) (µm) | Dx (99,5) (µm) | Dx (100) (µm) |
|-----------|-----------|--------------------|-------------------------------|--------------|----------------|---------------|
|           |           | 5                  | Levonorgestrel<br>Lote: N0001 | 4,78         | 15,3           | 30,8          |
|           |           | 6                  | Levonorgestrel<br>Lote: N0001 | 4,83         | 16,3           | 27,1          |
|           |           | 7                  | Levonorgestrel<br>Lote: N0001 | 4,96         | 19,8           | 27,3          |
|           | Media     |                    |                               | 4,86         | 17,1           | 28,4          |
|           | 1XStd dev |                    |                               | 0,0936       | 2,34           | 2,10          |
|           | 1XRSD (%) |                    |                               | 1,93         | 13,7           | 7,38          |

Drug Dispersion (2<sup>da</sup> medición)

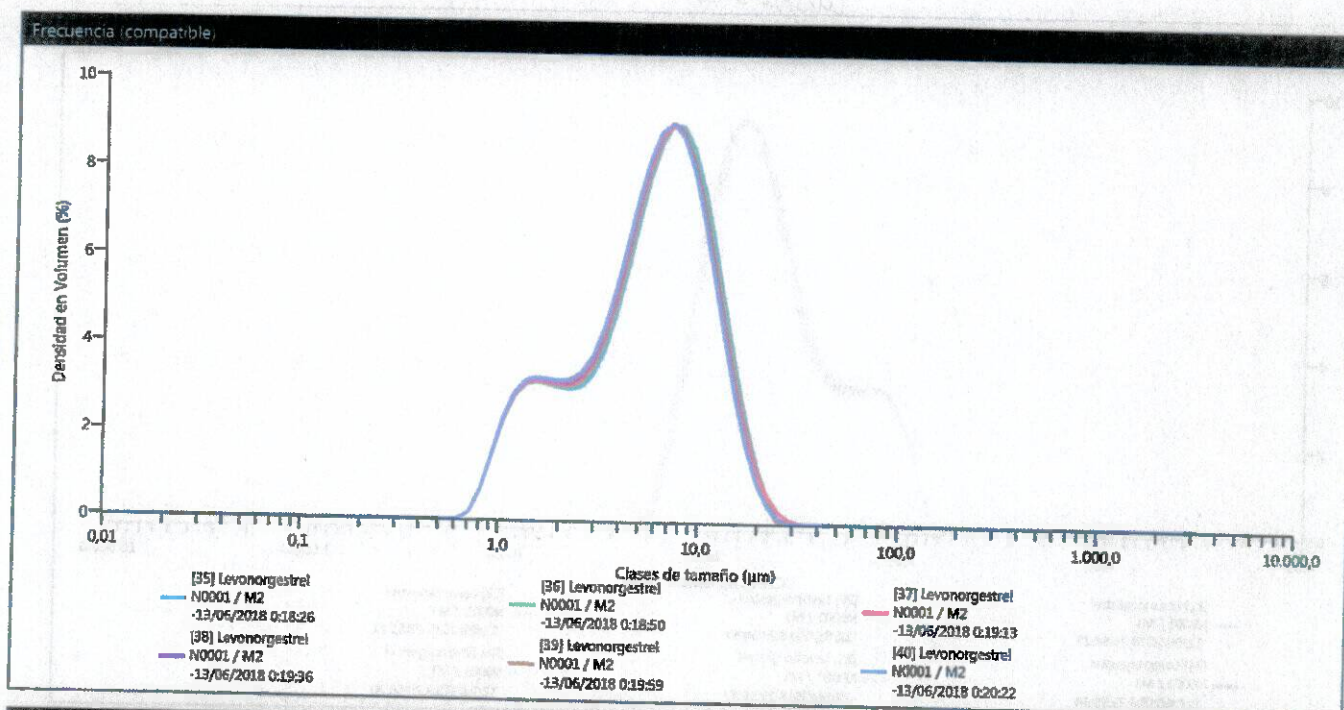


Malvern Instruments Ltd.  
www.malvern.com

Mastersizer - v3.40  
Página 1 de 1

Fichero de medida34

Creado: 18/08/2017  
Impreso: 08/06/2018 13:11



Tendencia

| Número de registro | Nombre de la muestra         | Dx (90) (µm) | Dx (99,5) (µm) | Dx (100) (µm) |
|--------------------|------------------------------|--------------|----------------|---------------|
| 35                 | Levonorgestrel<br>N0001 / M2 | 13,0         | 21,2           | 24,1          |
| 36                 | Levonorgestrel<br>N0001 / M2 | 12,7         | 21,1           | 24,1          |
| 37                 | Levonorgestrel<br>N0001 / M2 | 12,7         | 22,7           | 30,8          |
| 38                 | Levonorgestrel<br>N0001 / M2 | 12,4         | 21,0           | 27,2          |
| 39                 | Levonorgestrel<br>N0001 / M2 | 12,3         | 20,8           | 24,1          |
| 40                 | Levonorgestrel<br>N0001 / M2 | 12,2         | 20,9           | 27,2          |
| Media              |                              | 12,6         | 21,3           | 26,2          |
| 1XStd dev          |                              | 0,293        | 0,731          | 2,73          |
| 1XRSD (%)          |                              | 2,34         | 3,43           | 10,4          |

*Angulo dispersión (30º medición)*

|                                                                                                                                        |                                          |                                 |            |
|----------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|---------------------------------|------------|
| <br>Centro de Servicios de<br>Análisis de Laboratorio | Registro N°01 PG-004 Boletín de Análisis | Código: PG-004                  | Versión: 7 |
|                                                                                                                                        |                                          | Fecha de Aprobación: 02-05-2016 |            |
|                                                                                                                                        |                                          | Página 1 de 1                   |            |

## BOLETÍN DE ANÁLISIS

### N°19392

| IDENTIFICACIÓN DEL CLIENTE |                                |          |                               |
|----------------------------|--------------------------------|----------|-------------------------------|
| Razón Social               | LAB. ANDRÓMACO S.A.            | R.U.T.   | 76.237.266-5                  |
| Dirección                  | Avenida Quilín 5273, Peñalolén | e-mail   | Juan.Arriagada@grunenthal.com |
| Solicitado por             | Q.F. Juan Luis Arriagada       | Teléfono | 25948264                      |

| NOMBRE DEL PRODUCTO        |                   | LEVONORGESTREL MICRO            |                  |
|----------------------------|-------------------|---------------------------------|------------------|
| Lote                       | 010000482818      | Lote Proveedor                  | ZLVNY17002       |
| Lote MM                    | N0001             | Laboratorio Fabricante / Origen | Andrómaco S.A.   |
| Fecha de Elaboración       | No se especifica  | Fecha Vencimiento               | No se especifica |
| Tamaño partida / lote      | No se especifica  | Tipo de muestreo                | Cliente          |
| Presentación               | Materia Prima     | Forma Farmacéutica              | Polvo            |
| Cantidad Recibida          | 1 frasco x 1 g    | Cantidad de contramuestra       | S/C              |
| Metodología Analítica      | EA-MP-22400421-01 | N° Registro                     | No se especifica |
| Fecha Recepción            | 25/04/2018        | Fecha Inicio                    | 26/04/2018       |
| Solicitud N°               | No se especifica  | Fecha Término                   | 02/05/2018       |
| Analista                   | Marcela Flores    | Reg. Datos                      | 04 MF 094        |
| Condiciones Almacenamiento | No se especifica  |                                 |                  |

| RESULTADO DE LA MUESTRA RECIBIDA                                                                                                      |                                                                                        |              |
|---------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|--------------|
| Ensayos                                                                                                                               | Especificación / Límites                                                               | Resultados   |
| SOLVENTE RESIDUAL                                                                                                                     | Tetrahidrofurano: 720 ppm                                                              | No detectado |
|                                                                                                                                       | Diclorometano: 600 ppm                                                                 | 0,003 ppm    |
|                                                                                                                                       | Acetona: 5000 ppm                                                                      | No detectado |
|                                                                                                                                       | Acetato de etilo: 5000 ppm                                                             | No detectado |
| CALIFICACIÓN MUESTRA                                                                                                                  | <ul style="list-style-type: none"> <li>Cumple con los parámetros analizados</li> </ul> |              |
| Observaciones                                                                                                                         |                                                                                        |              |
| Las muestras fueron enviadas por el cliente, quien se responsabiliza de su origen y procedencia. No se especifica método de muestreo. |                                                                                        |              |

  
 Q.F. Cristián Urquiza  
 Director Técnico (S)  
 Centro de Servicios de Análisis de Laboratorio.

  
 Centro de Servicios de  
Análisis de Laboratorio

Santiago, 02 de Mayo de 2018

Este Boletín fue realizado en las instalaciones de Centro de Servicios de Análisis de Laboratorio, bajo norma técnica 139 de Buenas Prácticas de Laboratorio.  
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 Fono: (56-2) 261 785 00  
 Avenida Carrascal 3585, Quinta Normal  
 contacto@cslab.cl

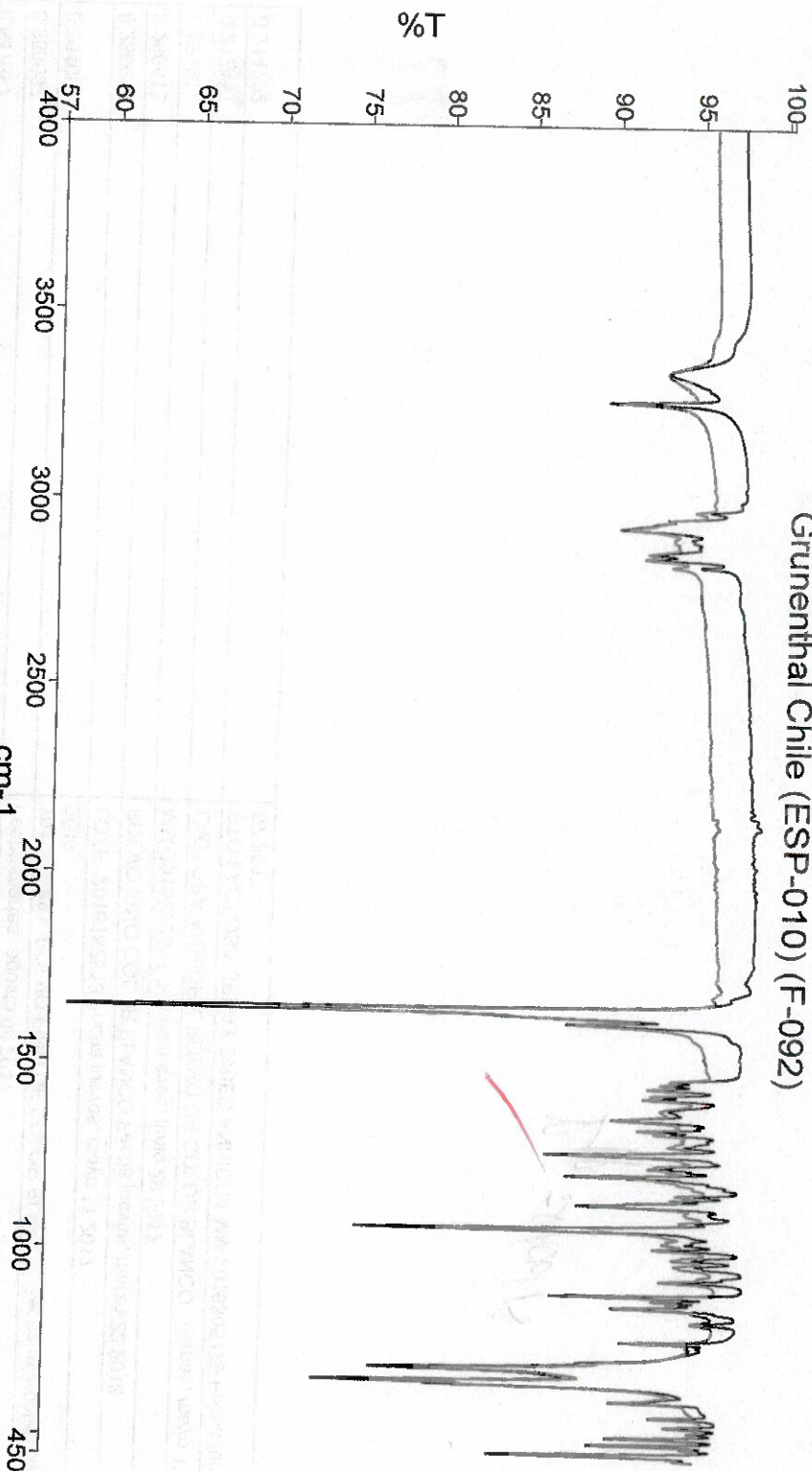
DCP  
05/06/18

Analista  
Fecha

Claudio Leiva  
sábado, mayo 19, 2018 4:36 PM

PerkinElmer Spectrum Version 10.4.4  
sábado, mayo 19, 2018 4:36 PM

### Grunenthal Chile (ESP-010) (F-092)



| Espectros de origen       |                                              |                                                                     |  |
|---------------------------|----------------------------------------------|---------------------------------------------------------------------|--|
| Nombre de la muestra      | Mejor coincidencia de búsqueda               | Descripción de la mejor coincidencia de búsqueda                    |  |
| Levonorgestrel Lote N0001 | C:\pel_data\libreria nueva\LEVONORGESTREL.sp | MM2016162469 Polvo fino de color blanco Fecha jueves, junio 22 2017 |  |

Grupo Grunenthal Chile

Thursday, 17-MAY-2018

This sample was measured on an Autopol IV S2, serial number 82046,  
manufactured by Rudolph Research Analytical, Hackettstown, N.J.

Method Name : Levonorgestrel

Range Limits: -35.000 to -30.000

LotID : N0001

Set Temperature : 25.0

Time Delay : 5

Temp Corr : OFF

| n    | Average   | Std.Dev.    | Maximum | Minimum | OR ° Arc | WL G | Lg. mm | Conc. | Temp. |
|------|-----------|-------------|---------|---------|----------|------|--------|-------|-------|
| 5    | -33.228   | 0.0214      | -33.198 | -33.254 |          |      |        |       |       |
| S.No | Sample ID | Time        | Result  | Scale   | OR ° Arc | WL G | Lg. mm | Conc. | Temp. |
| 1    | M2        | 05:33:33 PM | -33.236 | SR      | -1.329   | 589  | 200.00 | 2.000 | 25.2  |
| 2    | M2        | 05:33:44 PM | -33.236 | SR      | -1.329   | 589  | 200.00 | 2.000 | 25.2  |
| 3    | M2        | 05:33:50 PM | -33.254 | SR      | -1.330   | 589  | 200.00 | 2.000 | 25.2  |
| 4    | M2        | 05:33:57 PM | -33.217 | SR      | -1.329   | 589  | 200.00 | 2.000 | 25.2  |
| 5    | M2        | 05:34:04 PM | -33.198 | SR      | -1.328   | 589  | 200.00 | 2.000 | 25.2  |

Operator : \_\_\_\_\_

Operator Signature : \_\_\_\_\_

*8pp 26/06/18*

*8pp 05/06/18*

8/19/18  
05/06/18

Grupo Grunenthal Chile

Thursday, 17-MAY-2018

This sample was measured on an Autopol IV S2, serial number 82046,  
manufactured by Rudolph Research Analytical, Hackettstown, NJ.

Method Name : Levonorgestrel  
Range Limits: -35.000 to -30.000  
LotID : N0001

Set Temperature : 25.0  
Time Delay : 5  
Temp Corr : OFF

| n    | Average   | Std.Dev.    | Maximum | Minimum | OR %Arc | WLG | Lg.mm  | Conc. | Temp. |
|------|-----------|-------------|---------|---------|---------|-----|--------|-------|-------|
| 5    | -33.215   | 0.0174      | -33.203 | -33.242 |         |     |        |       |       |
| S.No | Sample ID | Time        | Result  | Scale   | OR %Arc | WLG | Lg.mm  | Conc. | Temp. |
| 1    | M1        | 05:24:34 PM | -33.203 | SR      | -1.328  | 589 | 200.00 | 2.000 | 25.2  |
| 2    | M1        | 05:24:41 PM | -33.203 | SR      | -1.328  | 589 | 200.00 | 2.000 | 25.2  |
| 3    | M1        | 05:24:48 PM | -33.203 | SR      | -1.328  | 589 | 200.00 | 2.000 | 25.2  |
| 4    | M1        | 05:24:55 PM | -33.222 | SR      | -1.329  | 589 | 200.00 | 2.000 | 25.2  |
| 5    | M1        | 05:25:01 PM | -33.242 | SR      | -1.330  | 589 | 200.00 | 2.000 | 25.2  |

Operator : \_\_\_\_\_

Operator Signature : VP 26/06/18

| GRUNENTHAL           |                                     | LISTADO DE USO DE EQUIPOS Y VERIFICACION DE BITACORAS |                       |                                                                                 |         |                                            |
|----------------------|-------------------------------------|-------------------------------------------------------|-----------------------|---------------------------------------------------------------------------------|---------|--------------------------------------------|
| NOMBRE MATERIA PRIMA | Levonor Gestrel                     |                                                       | LOTE QM               | 1000098 2818                                                                    | LOTE MM | N0001                                      |
| BALANZAS             | <input checked="" type="checkbox"/> | BAL-225<br>BAL-099<br>scl 20/05/12                    | PARAMETRO INVOLUCRADO | solubilidad, Rotación específica, Perdida por Secado, Pureza, tamaño partícula. |         |                                            |
|                      | <input checked="" type="checkbox"/> | BAL-224<br>BAL-206<br>scl 20/05/12                    | PARAMETRO INVOLUCRADO | Pureza, Valoración.                                                             |         |                                            |
|                      | <input checked="" type="checkbox"/> | BAL-223<br>BAL-065<br>scl 20/05/12                    | PARAMETRO INVOLUCRADO | límite etínic, valoración                                                       |         |                                            |
|                      | <input type="checkbox"/>            | BAL-115                                               | PARAMETRO INVOLUCRADO |                                                                                 |         |                                            |
| IR                   | <input checked="" type="checkbox"/> | ESP-010                                               | BITACORA N°           | 2                                                                               | FOLIO   | 92 ANALISIS identidad                      |
| PUNTO DE FUSION      | <input checked="" type="checkbox"/> | FUS-002                                               | BITACORA N°           | 2                                                                               | FOLIO   | 24 ANALISIS Punto Fusión                   |
| REFRACTOMETRO        | <input type="checkbox"/>            | RFRA-002                                              | BITACORA N°           |                                                                                 | FOLIO   | ANALISIS                                   |
| POLARIMETRO          | <input checked="" type="checkbox"/> | POL-003                                               | BITACORA N°           | 1                                                                               | FOLIO   | 146 ANALISIS Rotación específica           |
| ULTRAVIOLETA         | <input type="checkbox"/>            | ESP-006                                               | BITACORA N°           |                                                                                 | FOLIO   | ANALISIS                                   |
| KARL FISHER          | <input type="checkbox"/>            | KARL-001                                              | BITACORA N°           |                                                                                 | FOLIO   | ANALISIS                                   |
|                      | <input type="checkbox"/>            | KARL-003                                              | BITACORA N°           |                                                                                 | FOLIO   | ANALISIS                                   |
| MUFLAS               | <input type="checkbox"/>            | MUF-002                                               | BITACORA N°           |                                                                                 | FOLIO   | ANALISIS                                   |
|                      | <input checked="" type="checkbox"/> | MUF-003                                               | BITACORA N°           | 07                                                                              | FOLIO   | 22 ANALISIS Residuos ignición              |
| ESTUFAS              | <input checked="" type="checkbox"/> | EST-015                                               | BITACORA N°           | 1                                                                               | FOLIO   | 046/048 ANALISIS Perdida por Secado/pureza |
|                      | <input type="checkbox"/>            | EST-016                                               | BITACORA N°           |                                                                                 | FOLIO   | ANALISIS                                   |
| MEMOTITULADOR        | <input checked="" type="checkbox"/> | TIT-001                                               | BITACORA N°           | 2                                                                               | FOLIO   | 24 ANALISIS límite grupo etínic            |
| PEACHIMETROS         | <input type="checkbox"/>            | PEHC-001                                              | BITACORA N°           |                                                                                 | FOLIO   | ANALISIS                                   |
|                      | <input type="checkbox"/>            | PEHC-002                                              | BITACORA N°           |                                                                                 | FOLIO   | ANALISIS                                   |
| HPLC                 | <input checked="" type="checkbox"/> | HPLC-024                                              | BITACORA N°           | 1                                                                               | FOLIO   | 43 ANALISIS valoración / identidad         |
|                      | <input type="checkbox"/>            | HPLC-                                                 | BITACORA N°           |                                                                                 | FOLIO   | ANALISIS                                   |
| VISCOSIMETROS        | <input type="checkbox"/>            | VIS-006                                               | BITACORA N°           |                                                                                 | FOLIO   | ANALISIS                                   |
|                      | <input type="checkbox"/>            | VIS-007                                               | BITACORA N°           |                                                                                 | FOLIO   | ANALISIS                                   |

Dep  
05/06/18



## LISTADO DE USO DE EQUIPOS Y VERIFICACION DE BITACORAS

|                                  |                          |                          |             |                          |       |                          |          |                   |
|----------------------------------|--------------------------|--------------------------|-------------|--------------------------|-------|--------------------------|----------|-------------------|
| DISOLUTORES                      | <input type="checkbox"/> | DIS-009                  | BITACORA N° | <input type="checkbox"/> | FOLIO | <input type="checkbox"/> | ANALISIS |                   |
|                                  | <input type="checkbox"/> | DIS-010                  | BITACORA N° | <input type="checkbox"/> | FOLIO | <input type="checkbox"/> | ANALISIS |                   |
|                                  | <input type="checkbox"/> | DIS-011                  | BITACORA N° | <input type="checkbox"/> | FOLIO | <input type="checkbox"/> | ANALISIS |                   |
|                                  | <input type="checkbox"/> | DIS-015                  | BITACORA N° | <input type="checkbox"/> | FOLIO | <input type="checkbox"/> | ANALISIS | 36<br>30/05/18    |
| DUROMETRO                        | <input type="checkbox"/> | DUR-007                  | BITACORA N° | <input type="checkbox"/> | FOLIO | <input type="checkbox"/> | ANALISIS |                   |
|                                  | <input type="checkbox"/> | DUR-008                  | BITACORA N° | <input type="checkbox"/> | FOLIO | <input type="checkbox"/> | ANALISIS |                   |
| FRIABILOMETRO                    | <input type="checkbox"/> | FRI-006                  | BITACORA N° | <input type="checkbox"/> | FOLIO | <input type="checkbox"/> | ANALISIS |                   |
| DESINTEGRADOR                    | <input type="checkbox"/> | DES-002                  | BITACORA N° | <input type="checkbox"/> | FOLIO | <input type="checkbox"/> | ANALISIS |                   |
| PIE DE METRO                     | <input type="checkbox"/> | PDM-028                  | BITACORA N° | <input type="checkbox"/> | FOLIO | <input type="checkbox"/> | ANALISIS |                   |
|                                  | <input type="checkbox"/> | PDM-029                  | BITACORA N° | <input type="checkbox"/> | FOLIO | <input type="checkbox"/> | ANALISIS |                   |
|                                  | <input type="checkbox"/> | PDM-030                  | BITACORA N° | <input type="checkbox"/> | FOLIO | <input type="checkbox"/> | ANALISIS |                   |
| MICROSCOPIO                      | <input type="checkbox"/> | MIC-002                  | BITACORA N° | <input type="checkbox"/> | FOLIO | <input type="checkbox"/> | ANALISIS |                   |
| TERMOMETRO                       | C. METROLOGICO           | <input type="checkbox"/> | BITACORA N° | <input type="checkbox"/> | FOLIO | <input type="checkbox"/> | ANALISIS |                   |
| CRONOMETRO                       | C. METROLOGICO           | <input type="checkbox"/> | BITACORA N° | <input type="checkbox"/> | FOLIO | <input type="checkbox"/> | ANALISIS |                   |
| OTROS                            | C. METROLOGICO           | MEP-001                  | BITACORA N° | 01                       | FOLIO | 27                       | ANALISIS | Tamaño Partícula. |
|                                  | C. METROLOGICO           | <input type="checkbox"/> | BITACORA N° | <input type="checkbox"/> | FOLIO | <input type="checkbox"/> | ANALISIS |                   |
| TOTAL EQUIPOS UTILIZADOS         |                          | <input type="checkbox"/> |             |                          |       |                          |          |                   |
| TOTAL BITACORAS LLENADAS         |                          | <input type="checkbox"/> |             |                          |       |                          |          |                   |
| PORCENTAJE CUMPLIMIENTO REGISTRO |                          | <input type="checkbox"/> |             |                          |       |                          |          |                   |
| V°B JEFATURA                     |                          | FIRMA ANALISTA           |             |                          |       |                          |          |                   |

DCP  
05/06/18

| Original                     |                 | Decisión de Uso |               | Materia prima   |              |
|------------------------------|-----------------|-----------------|---------------|-----------------|--------------|
| <b>LEVONORGESTREL MICRO.</b> |                 |                 |               | <b>90000863</b> |              |
| Grupo HR (CG)                | LXB204KG (3)    | Cantidad        | 500 G         | Lote            | N0001        |
| Fe. entrada m.               | (ST) 18.04.2018 | Pedido          | 450048230     | Lote insp.      | 010000482818 |
| Fe. fabricación              | 31.12.2017      | Fabricante      | ---           |                 |              |
| Fe. sig. verific.            | 30.11.2022      | Lote Proveedor  | ZLWY17002     |                 |              |
| Fe. caducidad                | 30.11.2022      | Proveedor       | PROTOPHARM AG |                 |              |

Decisión de Uso**Liberación**

26.06.2018 17:31:19

Graciela Garay, CL06864, Supervisora de Materias Primas  
(Nombre, Numero Personal, Función)Cantidad liberada

en stock libre:

500 G

El documento ha sido creado digitalmente y es válido sin firma.

|               |                                                                                                      |                                                                           |
|---------------|------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| List-ID: QV01 | <br>010000482818 | Impresión: 26.06.2018 17:31:23<br>(Hora del sistema: 26.06.2018 23:31:23) |
|---------------|------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|

| Original                     |                 | Log de verificación |               | Materia prima   |                     |
|------------------------------|-----------------|---------------------|---------------|-----------------|---------------------|
| <b>LEVONORGESTREL MICRO.</b> |                 |                     |               | <b>90000863</b> |                     |
| Grupo HR (CG)                | LXB204KG (3)    | Cantidad            | 500 G         | Lote            | <b>N0001</b>        |
| Fe. entrada m.               | (ST) 18.04.2018 | Pedido              | 4500482830    | Lote insp.      | <b>010000482818</b> |
| Fe. fabricación              | 31.12.2017      | Fabricante          | ---           |                 |                     |
| Fe. sig. verific.            | 30.11.2022      | Lote Proveedor      | ZLWNY17002    |                 |                     |
| Fe. caducidad                | 30.11.2022      | Proveedor           | PROTOPHARM AG |                 |                     |

| No. Param   | Parámetros                       | Especificaciones   | Resultados    |
|-------------|----------------------------------|--------------------|---------------|
| <b>8000</b> | <b>Cumple plan de inspeccion</b> | CUMPLE             | <b>Cumple</b> |
| 8020        | Potencia                         | 97,500 - 102,000 % | <b>99,900</b> |

Lista-ID: QR02



010000482818

Impresión: 26.06.2018 17:33:33  
(Hora del sistema: 26.06.2018 23:33:32)

| Original                     |                 | Documento-UDP  |               | Materia prima   |                     |
|------------------------------|-----------------|----------------|---------------|-----------------|---------------------|
| <b>LEVONORGESTREL MICRO.</b> |                 |                |               | <b>90000863</b> |                     |
| Grupo HR (CG)                | LXB204KG (3)    | Cantidad       | 500 G         | Lote            | <b>N0001</b>        |
| Fe. entrada m.               | (ST) 18.04.2018 | Pedido         | 4500486230    | Lote insp.      | <b>010000482818</b> |
| Fe. fabricación              | 31.12.2017      | Fabricante     | ---           |                 |                     |
| Fe. sig. verific.            | 30.11.2022      | Lote Proveedor | ZLWNY17002    |                 |                     |
| Fe. caducidad                | 30.11.2022      | Proveedor      | PROTOPHARM AG |                 |                     |

## Seguimiento del pedido

Base: 90000863 - N0001

FFIL: 17.05.2018

| Operación | Descripción     | Entrada    | Salida     | Operador        |
|-----------|-----------------|------------|------------|-----------------|
| PNQ       | 1. Confirmación | 18.04.2018 |            |                 |
| PNQ       | 2. Confirmación |            | 26.06.2018 | Garay, Graciela |
| RLS       |                 | 26.06.2018 | 26.06.2018 | Garay, Graciela |

CLAUDIO / ADUANA

Este documento ha sido revisado y se ha verificado su cumplimiento con las normas GMP.

*Kpp 26/06/18*  
(Nombre, fecha, firma)

Lista-ID: QR03



010000482818

Impresión: 26.06.2018 17:33:34  
(Hora del sistema: 26.06.2018 23:33:33)

| Original              |                 | Log de modificaciones |               | Materia prima |
|-----------------------|-----------------|-----------------------|---------------|---------------|
| LEVONORGESTREL MICRO. |                 |                       |               | 90000863      |
| Grupo HR (CG)         | LXB204KG (3)    | Cantidad              | 500 G         | Lote          |
| Fe. entrada m.        | (ST) 18.04.2018 | Pedido                | 4500486230    | N0001         |
| Fe. fabricación       | 31.12.2017      | Fabricante            | ---           | Lote insp.    |
| Fe. sig. verifíc.     | 30.11.2022      | Lote Proveedor        | ZLVNY17002    | 010000482818  |
| Fe. caducidad         | 30.11.2022      | Proveedor             | PROTOPHARM AG |               |

## Modificaciones en lote

| Denominación de modificación                     |            | Fecha / Hora (sistema) | Modificación por |
|--------------------------------------------------|------------|------------------------|------------------|
| Fecha de caducidad o fecha preferente de consumo |            | 18.04.2018 / 18:52:39  | CL16322          |
| valor anterior                                   |            |                        |                  |
| valor nuevo                                      | 30.11.2022 |                        |                  |
| Fecha de producción/fabricación                  |            | 18.04.2018 / 18:52:39  | CL16322          |
| valor anterior                                   |            |                        |                  |
| valor nuevo                                      | 31.12.2017 |                        |                  |
| Lote en stock no libre                           |            | 18.04.2018 / 18:52:39  | CL16322          |
| valor anterior                                   |            |                        |                  |
| valor nuevo                                      | X          |                        |                  |
| Lote en stock no libre                           |            | 26.06.2018 / 23:31:19  | CL06864          |
| valor anterior                                   | X          |                        |                  |
| valor nuevo                                      |            |                        |                  |
| Número de lote de proveedor                      |            | 18.04.2018 / 18:52:39  | CL16322          |
| valor anterior                                   |            |                        |                  |
| valor nuevo                                      | ZLVNY17002 |                        |                  |
| Próxima fecha inspección                         |            | 18.04.2018 / 18:52:39  | CL16322          |
| valor anterior                                   |            |                        |                  |
| valor nuevo                                      | 17.02.2019 |                        |                  |
| Próxima fecha inspección                         |            | 26.06.2018 / 23:31:19  | CL06864          |
| valor anterior                                   | 17.02.2019 |                        |                  |
| valor nuevo                                      | 30.11.2022 |                        |                  |

## Modificaciones en clasificación de lotes

| Denominación de modificación |      | Fecha / Hora (sistema) | Modificación por |
|------------------------------|------|------------------------|------------------|
| LOBM_UDCODE                  |      | 26.06.2018 / 23:31:19  | CL06864          |
| valor anterior               |      |                        |                  |
| valor nuevo                  | QC F |                        |                  |

|                |                                                                                                      |                                                                           |
|----------------|------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| Lista-ID: QR06 | <br>010000482818 | Impresión: 26.06.2018 17:33:35<br>(Hora del sistema: 26.06.2018 23:33:34) |
|----------------|------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|

| Original                     |                 | Reconciliación |               | Materia prima   |              |
|------------------------------|-----------------|----------------|---------------|-----------------|--------------|
| <b>LEVONORGESTREL MICRO.</b> |                 |                |               | <b>90000863</b> |              |
| Grupo HR (CG)                | LXB204KG (3)    | Cantidad       | 500 G         | Lote            | N0001        |
| Fe. entrada m.               | (ST) 18.04.2018 | Pedido         | 450048230     | Lote insp.      | 010000482818 |
| Fe. fabricación              | 31.12.2017      | Fabricante     | ---           |                 |              |
| Fe. sig. verific.            | 30.11.2022      | Lote Proveedor | ZLWY17002     |                 |              |
| Fe. caducidad                | 30.11.2022      | Proveedor      | PROTOPHARM AG |                 |              |

Original

| Descripción          | WCent. | Páginas | Fecha/Hora Sistema |          | Reconciliación ok                   |                          |
|----------------------|--------|---------|--------------------|----------|-------------------------------------|--------------------------|
|                      |        |         |                    |          | Si                                  | No                       |
| Recepción            | -      | 1       | 23.04.2018         | 16:25:37 | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Instr. de Muestreo   | -      | 1       | 23.04.2018         | 16:25:48 | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Etiqueta de Muestreo | -      | 4       | 23.04.2018         | 16:29:39 | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Decision de empleo   | -      | 1       | 26.06.2018         | 23:31:23 | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Log de verificación  | -      | 1       | 26.06.2018         | 23:33:33 | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Documento-UDP        | -      | 1       | 26.06.2018         | 23:33:34 | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Log de modif.        | -      | 1       | 26.06.2018         | 23:33:35 | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

Reimpresión

Sin

Comentarios

|  |
|--|
|  |
|  |
|  |
|  |
|  |

26/06/18  
Fecha - Firma Operador

|                |                                                                                                      |                                                                           |
|----------------|------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| Lista-ID: QR04 | <br>010000482818 | Impresión: 26.06.2018 17:36:58<br>(Hora del sistema: 26.06.2018 23:36:58) |
|----------------|------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|

|                                                                                   |                                                                            |                           |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------|---------------------------|
|  | GERENCIA CONTROL DE CALIDAD                                                | Código:<br>RE-0456-01     |
|                                                                                   | CHECKLIST DE CALIFICACION MATERIAS PRIMAS<br>DEPARTAMENTO ANALISIS QUIMICO | Fecha Vigencia : Abr-2016 |

| NOMBRE MATERIA PRIMA: <u>levonorgestrel puro</u> |                                                       |                                                                                                   |
|--------------------------------------------------|-------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| LOTE: <u>10001</u>                               |                                                       |                                                                                                   |
| CÓDIGO: <u>20000863</u>                          |                                                       |                                                                                                   |
| LOTE INSPECCION QM: <u>10000482818</u>           |                                                       |                                                                                                   |
|                                                  |                                                       | Observaciones                                                                                     |
| <input type="checkbox"/>                         | Presencia desviaciones                                | <input checked="" type="radio"/> N.A.<br><input type="radio"/> Desviaciones:                      |
| <input type="checkbox"/>                         | Presencia OOS/OOT                                     | <input checked="" type="radio"/> N.A.<br><input type="radio"/> OOS:<br><input type="radio"/> OOT: |
| <input checked="" type="checkbox"/>              | Cabecera apropiada AR y adjuntos                      | <input type="radio"/> N.A                                                                         |
| <input checked="" type="checkbox"/>              | Compruebe metodología analítica                       | <input type="radio"/> N.A                                                                         |
| <input checked="" type="checkbox"/>              | Compruebe instrucciones de muestreo (Materias Primas) | <input type="radio"/> N.A                                                                         |
| <input checked="" type="checkbox"/>              | Verificación de término de Análisis Químico           | <input type="radio"/> N.A                                                                         |
| <input type="checkbox"/>                         | Verificación de término de Análisis Microbiológico    | <input checked="" type="radio"/> N.A                                                              |
| <input checked="" type="checkbox"/>              | Verificación de término de Análisis Externo           | <input type="radio"/> N.A                                                                         |
| <input checked="" type="checkbox"/>              | Verificación adjuntos (es. reconciliaciones)          | <input type="radio"/> N.A                                                                         |
| <input checked="" type="checkbox"/>              | Presencia de CoA interno                              | <input type="radio"/> N.A                                                                         |
| <input checked="" type="checkbox"/>              | Presencia de CoA de proveedor                         | <input type="radio"/> N.A                                                                         |
| <input checked="" type="checkbox"/>              | Presencia de CoA de Servicio externo                  | <input type="radio"/> N.A                                                                         |
| <input checked="" type="checkbox"/>              | Verificación de Permiso de uso para MP importadas     | <input type="radio"/> N.A                                                                         |
| <input checked="" type="checkbox"/>              | Llenado completo y una documentación adecuada         | <input type="radio"/> N.A                                                                         |
| <b>CONCLUSIÓN</b>                                |                                                       |                                                                                                   |
| NO CUMPLE <input type="checkbox"/>               |                                                       | <b>RECHAZADO</b>                                                                                  |
| CUMPLE <input checked="" type="checkbox"/>       |                                                       | <b>APROBADO</b> ✓                                                                                 |
| FIRMA REVISOR..... <u>66S</u>                    |                                                       | FECHA..... <u>26/06/18</u>                                                                        |
| FIRMA JEFE AREA..... <u>Rpl</u>                  |                                                       | FECHA..... <u>26/06/18</u>                                                                        |
| FIRMA GERENTE QC..... <u>ep</u>                  |                                                       | FECHA..... <u>26/06/18</u>                                                                        |