



Fecha: 13/05/2019

**PATRON SECUNDARIO**Materia Prima: **Mupirocina Cálcica**

|                                |                                    |
|--------------------------------|------------------------------------|
| Código: <b>25341</b>           | Nº informe: <b>146676</b>          |
| Lote: <b>180501MC-WF</b>       | Cantidad: <b>20</b>                |
| Vencimiento: <b>may-20</b>     | Nº Bultos: <b>4</b>                |
| Análisis: <b>61704 (PS062)</b> | Proveedor: <b>90039 (CONDERCO)</b> |

| Parámetro               | Especificaciones                                                                                                                                                      | Resultado | Analista    |
|-------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|-------------|
| Aspecto                 | Polvo blanco o casi blanco.                                                                                                                                           | cumple    | PG C496 F21 |
| Solubilidad             | Muy poco soluble en agua. Moderadamente soluble en etanol anhidro y cloruro de metileno                                                                               | cumple    | PG C496 F21 |
| Tamaño de partícula     | El 90 % menor a 25 µm.                                                                                                                                                | 12 µm     | PG C496 F21 |
| Identificación          | <b>A- Espectro I.R.:</b> El gráfico obtenido por la solución Test presenta similitud con el obtenido por la solución Standard.                                        | cumple    | PG C496 F21 |
|                         | <b>B- Test para Calcio:</b> La solución cumple con el test de identificación para calcio.                                                                             | cumple    | PG C496 F21 |
|                         | <b>C- H.P.L.C.:</b> El pico principal obtenido por la solución Test presenta similar tiempo de retención que el pico principal desarrollado por la solución Standard. | cumple    | PG C496 F21 |
| Rotación óptica         | Entre -16 ° y -20 °.                                                                                                                                                  | - 19°     | PG C496 F21 |
| Cloruros                | Máximo 0,5%.                                                                                                                                                          | <0,5 %    | PG C496 F21 |
| Agua                    | Entre 3,0 % y 4,5 %.                                                                                                                                                  | 4,1%      | PG C496 F21 |
| Solventes residuales    | Acetona: maximo 5000 ppm                                                                                                                                              | cumple    | PG C496 F21 |
|                         | Acetato de isobutilo: maximo 5000 ppm                                                                                                                                 | cumple    |             |
|                         | Acetato de etilo: maximo 5000 ppm                                                                                                                                     | cumple    |             |
|                         | Heptano: maximo 5000 ppm                                                                                                                                              | cumple    |             |
| Sustancias Relacionadas | Acido Pseudomónico D: No mayor a 2,5 %.                                                                                                                               | 0,8%      | PG C496 F21 |
|                         | Impurezas Individuales: No mayor a 1,0 %.                                                                                                                             | 0,3%      |             |
|                         | Impurezas Totales: No mayor a 4,5 %.                                                                                                                                  | 1,9%      |             |
| Valoración              | Entre 865 µg y 936 µg de Mupirocina por mg de Mupirocina Cálcica                                                                                                      | 910 µg    | PG C496 F21 |
|                         | % de mupirocina Ca expresado sobre droga seca                                                                                                                         | 98,5%     |             |

Observaciones:

Método TCC1/194/07  
Conservacion: Heladera

Resolución

**APROBADO**

Control de Calidad

Firma:

Jefe de Control de Calidad

Fecha: 13/05/2019

杭州中美华东制药有限公司  
HANGZHOU ZHONGMEI HUADONG PHARMACEUTICAL CO., LTD

检验报告单

CERTIFICATE OF ANALYSIS

地址: 莫干山路866号 Address NO. 866 MOGANSAN ROAD HANGZHOU CHINA

电话: Tel 86-0571-89903388

传真: Fax 86-0571-89903366



检验编号: Analysis Sequence No. 18ZM06080011

| 品名:                     | 莫匹罗星钙(MUPIROCIN CALCIUM) | 检验目的:          | 全检(Total Analysis) |
|-------------------------|--------------------------|----------------|--------------------|
| Product Name            |                          | Analysis Scope |                    |
| 批号:                     | 180501 MC WF             | 数量:            | 44.5kg             |
| Batch No.               |                          | Quantity       |                    |
| 规格:                     | 5kg/桶                    | 送检日期:          | 2018-05-14         |
| Packaging Specification |                          | Anal. Date     |                    |
| 来源:                     | 102车间(102 Workshop)      | 报告日期:          | 2018-06-20         |
| Source                  |                          | Report Date    |                    |
| 生产日期:                   | 2018-05-03               | 有效期至:          | 2020-05-02         |
| MFG Date                |                          | Exp. Date      |                    |

| 检验项目                                | 单位   | 标准规定                                                                                                                                                                                                            | 检验数据                       |
|-------------------------------------|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Items                               | Unit | Specifications                                                                                                                                                                                                  | Results                    |
| 性状:<br>(Description)                | ---  | 应为白色或类白色粉末(White or almost white powder)                                                                                                                                                                        | 类白色粉末(Almost white powder) |
| 【鉴别】<br>(Identification)            | ---  |                                                                                                                                                                                                                 |                            |
| 鉴别A:<br>(Identification A)          | ---  | 供试品红外光谱应与对照品图谱相一致<br>(The IR spectrum of sample should be identical with that of reference standard.)                                                                                                           | IR 符合规定(IR conforms)       |
| 鉴别B:<br>(Identification B)          | ---  | 含量项下, 供试品的主峰保留时间应与对照品主峰保留时间一致(The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay.) | 符合规定(Conforms)             |
| 鉴别C:<br>(Identification C)          | ---  | 钙盐鉴别反应应符合规定(It meets the requirements for calcium)                                                                                                                                                              | 呈正反应(Positive)             |
| 比旋度:<br>(Specific optical rotation) | °    | -20- -16                                                                                                                                                                                                        | -18                        |
| 水分:<br>(Water)                      | %    | 3.0-4.5                                                                                                                                                                                                         | 3.7                        |
| 氯化物:<br>(Chlorides)                 | %    | ≤0.5                                                                                                                                                                                                            | <0.5                       |
| 【有关物质】<br>(Impurities)              | ---  |                                                                                                                                                                                                                 |                            |
| 假单胞菌D:<br>(Pseudomonas D)           | %    | ≤2.5                                                                                                                                                                                                            | 0.8                        |

检验结论: 符合USP41 (QA-SMP-J067-11) 标准的规定 [Complies with USP41 (QA-SMP-J067-11)]

Conclusion

备注:

Note

QC经理: 徐芳 2018.06.20  
(QC Manager)

检验人: 张华 2018.06.20  
(Analyst)

复核人: 张华 2018.06.20  
(Checker)

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| Items                       | Unit                     | Specifications      | Results            |
| 除根单孢菌D外, 其他单个杂质:            | %                        | ≤1                  | 0                  |
| (Other impurity)            |                          |                     |                    |
| 总杂质:                        | %                        | ≤4.5                | 1.6                |
| (Total impurities)          |                          |                     |                    |
| [残留溶剂]                      | ---                      |                     |                    |
| (Residual Solvent)          |                          |                     |                    |
| 丙酮:                         | ppm                      | ≤500                | 3                  |
| (Acetone Residual)          |                          |                     |                    |
| 乙酸异丁酯:                      | ppm                      | ≤500                | 未检出 (Not detected) |
| (Isobutyl acetate Residual) |                          |                     |                    |
| 乙酸乙酯:                       | ppm                      | ≤500                | 未检出 (Not detected) |
| (Ethyl acetate Residual)    |                          |                     |                    |
| 正庚烷:                        | ppm                      | ≤500                | 未检出 (Not detected) |
| (N-heptane Residual)        |                          |                     |                    |
| 含量 (按莫匹罗星计):                | %                        | 86.5-93.6           | 92.7               |
| (Assay)                     |                          |                     |                    |
| [微生物限度]                     | ---                      |                     |                    |
| (Microbial limits)          |                          |                     |                    |
| 需氧菌:                        | cfu /g                   | ≤1000               | <10                |
| (Aerobic bacteria)          |                          |                     |                    |
| 霉菌和酵母菌:                     | cfu /g                   | ≤100                | <1                 |
| (Mold & yeast)              |                          |                     |                    |
| 大肠埃希菌:                      | ---                      | 不得检出 (Not detected) | 未检出 (Not detected) |
| (E.coli)                    |                          |                     |                    |

检验结论: 符合USP41 (QA-SMP-J067-11) 标准的规定 (Complies with USP41 (QA-SMP-J067-11))

Conclusion

备注:

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(QC Manager)

检验人:

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复核人:

(Checker)

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| Items                   | Unit                      | Specifications   | Results             |
| [粒度分布]                  |                           |                  |                     |
| (Particle Size)         |                           |                  |                     |
| 粒径 (<15um)              | %                         | >90.0            | 100.0               |
| (Particle Size <15um)   |                           |                  |                     |
| 粒径 (<30um)              | %                         | 100.0            | 100.0               |
| (Particle Size <30um)   |                           |                  |                     |
| 包装外观                    | —                         | 应符合规定 (Conforms) | 符合规定 (Conforms)     |
| (Package exterior)      |                           |                  |                     |

检验结论: 符合USP41 (QA-SMP-J067-11) 标准的规定 (Complies with USP41 (QA-SMP-J067-11))

Conclusion

备注:

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(QC Manager)

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(Analyst)

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(Checker)

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