

10/01/2022

METAPHARMACEUTICAL

N DE LOTE:

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PORTON



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## 检验报告书 CERTIFICATE OF ANALYSIS

|                               |                   |                                                                                                 |                  |
|-------------------------------|-------------------|-------------------------------------------------------------------------------------------------|------------------|
| 品 名<br>Product Name           | 硫普罗宁<br>Tiopronin |                                                                                                 |                  |
| 产品代码<br>Product Code          | D57/101009        | 批 号<br>Batch No.                                                                                | 101009-102-00007 |
| 批 量<br>Batch Size             | 81.056Kg          | 生产日期<br>Manufacture date                                                                        | 12 Apr., 2021    |
| 检验依据<br>Testing Reference     | 3-001300/02       | <input checked="" type="checkbox"/> 复检期 Retest Date<br><input type="checkbox"/> 有效期 Expiry Date | 11 Apr., 2023    |
| 放行标准<br>Release Specification | N/A               |                                                                                                 |                  |

| 检验项目 Test Item                            | 检验标准 Acceptance Criteria            |                                   | 检验结果 Result                         |
|-------------------------------------------|-------------------------------------|-----------------------------------|-------------------------------------|
| 外观<br>Appearance                          | 白色结晶性粉末<br>White crystalline powder |                                   | 白色结晶性粉末<br>White crystalline powder |
| 鉴别<br>Identification                      | 红外分光光度法 (IR)                        | 与对照品图谱一致<br>Conforms to reference | 与对照品图谱一致<br>Conforms                |
|                                           | 化学反应 1<br>Chemical Reaction 1       | 应呈正反应<br>Positive                 | 呈正反应 Positive                       |
|                                           | 化学反应 2<br>Chemical Reaction 2       | 应呈正反应<br>Positive                 | 呈正反应 Positive                       |
| 溶液澄清度<br>Clarity                          | 应澄清<br>Clear                        |                                   | 澄清 Clear                            |
| 硫酸盐 (%w/w)<br>Sulfates (%w/w)             | 不得过 0.048<br>NMT 0.048              |                                   | <0.048                              |
| 干燥失重 (%w/w)<br>Loss on drying (%w/w)      | 不得过 0.50<br>NMT 0.50                |                                   | 0.04                                |
| 炽灼残渣 (%w/w)<br>Residue on ignition (%w/w) | 不得过 0.10<br>NMT 0.10                |                                   | 0.01                                |
| 铁盐 (ppm)<br>Iron (ppm)                    | 不得过 5<br>NMT 5                      |                                   | <5                                  |
| 锌 (ppm)<br>Zinc (ppm)                     | 不得过 1000<br>NMT 1000                |                                   | <50                                 |
| 砷盐 (ppm)<br>Arsenic (ppm)                 | 不得过 2<br>NMT 2                      |                                   | <2                                  |
| 含量 (%w/w, HPLC)<br>Assay (%w/w, HPLC)     | 不得小于 98.0<br>NLT 98.0               |                                   | 99.8                                |

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|--------------------------------------------------------------|------------------------------------------------------------------|----------------------|-------------|
| 有关物质<br>(%,Area,HPLC)<br>Related substances<br>(%,Area,HPLC) | 杂质 1 (丙酰甘氨酸)<br>N-(1-oxopropyl)-Glycine                          | 不得过 0.15<br>NMT 0.15 | 0.06        |
|                                                              | 杂质 2 (D57-A)<br>2-Chloropropionylglycine                         | 不得过 0.10<br>NMT 0.10 | 未检出 N.D.    |
|                                                              | 杂质 3 (D57-B)<br>Oxidized tiopronin                               | 不得过 0.50<br>NMT 0.50 | 0.10        |
|                                                              | 未知最大单个杂质<br>Max. single unspecified<br>impurity                  | 不得过 0.10<br>NMT 0.10 | <0.05       |
|                                                              | 杂质总量<br>Total impurities                                         | 不得过 1.0<br>NMT 1.0   | 0.2         |
| 残留溶剂(ppm)<br>Residual Solvents(ppm)                          | 丙酮<br>Acetone                                                    | 不得过 5000<br>NMT5000  | 258         |
|                                                              | 乙酸乙酯<br>Ethyl acetate                                            | 不得过 5000<br>NMT5000  | 未检出 N.D.    |
|                                                              | 环己烷<br>Cyclohexane                                               | 不得过 3880<br>NMT3880  | 295         |
| 甘氨酸(%,w/w,HPLC)<br>Glycine(%,w/w,HPLC)                       | 不得大于 0.30<br>NMT0.30                                             |                      | 0.16        |
| 异亚丙基丙酮 (ppm)<br>Mesityl Oxide (ppm)                          | 不得过 50<br>NMT50                                                  |                      | <50         |
| 结论 Conclusion                                                | 本品按 3-001300/02 检验, 结果符合规定。<br>Conforms to 3-001300/02 Standard. |                      |             |
| 备注 Remark                                                    | N/A                                                              |                      |             |



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### 修订历史 Revision History

| 修订编号<br>Revision No. | 主要变更描述<br>Major Changes from Previous Version                                                                                                                                                                                                                                                        | 日期<br>Date    |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| 01                   | 新建<br>Newly established                                                                                                                                                                                                                                                                              | 14 May, 2021  |
| 02                   | 质量标准升级版, 根据现行版 3-001300/02 质量标准出具报告书。<br>Specification upgrade, update the COA according to current specification (Document NO.: 3-001300/02).<br>使用现行版 SOP-CO-QC3014A5 /04 报告书模板出具检验报告书。<br>Use the current version of the report template to update the COA ( Document NO.: SOP-CO-QC3014A5 /04) . | 15 Sep., 2021 |

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|--------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|
| 报告人: <br>Issued by: | 复核人: <br>Reviewed by: | QA 批准人: <br>Approved by QA: |
| 日 期 Date: 2021.09.15                                                                                   | 日 期 Date: 2021.09.17                                                                                     | 日 期 Date: 2021.09.17                                                                                             |

