

## 紫杉醇（半合成）检验报告

## Certificate of Analysis (Paclitaxel (Semi-synthetic))

|                          |   |                            |   |
|--------------------------|---|----------------------------|---|
| 产品名称<br>Product Name     | 紫杉醇（半合成）<br>Paclitaxel (Semi-synthetic) | 执行标准<br>Executive Standard | USP 43 紫杉醇<br>USP 43 Paclitaxel                               |
| 批号<br>Batch Number       | 20211101                                | 产品数量<br>Product Quantity   | 4975.2g   |
| 生产日期<br>Manufacture Date | 2021年11月01日<br>Nov,01, 2021             | 报告日期<br>Report Date        | 2021年11月10日<br>Nov,10, 2021                                   |
| 有效期至<br>Expiry Date      | 2024年10月31日<br>Oct,31, 2024             | 储存条件<br>Conditions         | 遮光，密封室温条件下保存<br>shading, keep under seal at room temperature. |

| 检验项目<br>TEST   | 检验方法<br>TEST METHOD    | 检验标准<br>SPECIFICATIONS  | 检验结果<br>RESULT   |                   |  |
|--|------------------------|---|------------------|-------------------|--|
| 外观<br>Description  |                        | 本品为白色或类白色结晶型粉末<br>A white or almost white powder  | White powder     |                   |  |
| 溶解性<br>Solubility  |                        | 在二氯甲烷中易溶，在甲醇、乙醇中溶解，在水中几乎不溶<br>Soluble in dichloromethane, soluble in methanol and alcohol, insoluble in water.  | 符合规定<br>Conforms |                   |  |
| 溶液的澄清度与颜色<br>Clarity and color   |                        | 溶液应澄清无色<br>Clarification of colorless   | 符合规定<br>Conforms |                   |  |
| 含量（按干燥品计）（HPLC）<br>ASSAY (calculated on the anhydrous, solvent-free basis) | USP<621>               | 97.0%~102.0%  | 99.8%            |                   |  |
| 比旋度 $[\alpha]_D^{20}$<br>SPECIFIC ROTATION                                 | USP<781S><br>Method Ic | -49.0°~-55.0°   | -51.4°           |                   |  |
| 鉴别<br>IDENTIFICATION   | IR<br>USP<197K>        | 红外光谱定性：样品的红外光吸收图谱应与对照品的图谱一致<br>Infrared Absorption: In accordance with the reference Standard spectrum of paclitaxel  | 符合规定<br>Conforms |                   |  |
|  | HPLC<br>USP<621>       | 高效液相色谱定性：紫杉醇出峰保留时间与标准品对照保留时间应一致<br>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<br>Conforms |                   |  |
| 有关物质<br>(HPLC)<br>RELATED<br>COMPOUNDS                                     | USP<621>Test           | 10-去乙酰基巴卡亭III<br>10-Deacetyl/baccatin III   | NMT 0.1%         | 未检出<br>Undetected |  |
|  |                        | 巴卡亭III<br>Baccatin III  | NMT 0.2%         | 0.04%             |  |
|  |                        | 光学降解产物<br>Photodegradant  | NMT 0.1%         | 未检出<br>Undetected |  |
|  |                        | 10-去乙酰基紫杉醇<br>10-Deacetylpaclitaxel   | NMT 0.5%         | 0.02%             |  |
|  |                        | 2-去苯酰基紫杉醇-2-戊烯酸酯<br>2-Debenzoylpaclitaxel-2-penten oate   | NMT 0.7%         | 未检出<br>Undetected |  |
|  |                        | 开环环丙烷，乙酰基和苯酰基<br>Oxetane ring opened, acetyl and benzoyl migrated   |                  |                   |  |
|  |                        | 10-乙酰乙酰基紫杉醇<br>10-Acetoacetylpaclitaxel   | NMT 0.4%         | 未检出<br>Undetected |  |
|  |                        | 10-去乙酰基-7-表紫杉醇<br>10-Deacetyl-7-epipaclitaxel   |                  |                   |  |
|  |                        | 7-表-紫杉醇<br>7-Epipaclitaxel  | NMT 0.4%         | 0.04%             |  |
|  |                        | 10,13-二支链紫杉醇<br>10,13-Bissidechainpaclitaxel  | NMT 0.5%         | 0.01%             |  |
|  |                        | 7-乙酰基紫杉醇<br>7-Acetylpaclitaxel  | NMT 0.6%         | 未检出<br>Undetected |  |
|  |                        | 13-三甲基硅烷巴卡亭III<br>13-Tes-baccatin III   | NMT 0.1%         | 未检出<br>Undetected |  |
| 7-三甲基硅烷紫杉醇<br>7-Tes-paclitaxel   | NMT 0.3%               | 未检出<br>Undetected   |                  |                   |  |

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|  |   |  |                        |                         |
|--|---|--|------------------------|-------------------------|
|  | 其它单个杂质<br>Others  |  | NMT 0.1% (each)        | 0.048%                  |
|  | 杂质总和<br>Total   |  | NMT 2.0%               | 0.22%                   |
| 有机挥发<br>杂质<br>ORGANIC<br>VOLATILE<br>IMPURITIE | 甲醇<br>Methanol  | USP<621><br>Test   | NMT 3000ppm            | 未检出<br>Undetected       |
|  | 丙酮<br>Acetone   |  | NMT 5000ppm            | 未检出<br>Undetected       |
|  | 正庚烷<br>n-heptane  |  | NMT 5000ppm            | 618ppm                  |
|  | 乙醇<br>Alcohol   |  | NMT 5000ppm            | 未检出<br>Undetected       |
|  | 四氯呋喃<br>Tetrachlorofuran  |  | NMT 720ppm             | 未检出<br>Undetected       |
|  | 乙酸乙酯<br>Ethyl acetate   |  | NMT 5000ppm            | 未检出<br>Undetected       |
|  | 二氯甲烷<br>Dichloromethane   |  | NMT 600ppm             | 未检出<br>Undetected       |
|  | 甲苯<br>Toluene   |  | NMT 890ppm             | 未检出<br>Undetected       |
|  | N, N-二甲基酰胺<br>N, N-dimethylamide  |  | NMT 880ppm             | 未检出<br>Undetected       |
|  | 水分<br>WATER   |  | USP <921><br>Method Ic | NMT 4.0%                |
| 炽灼残渣<br>RESIDUE ON IGNITION                    | USP<281>  | NMT 0.2%   | 0.03%                  |                         |
| 重金属<br>HEAVY METALS                            | USP<231><br>Method II   | NMT 0.002%   | 符合规定<br>Conforms       |                         |
| 细菌内毒素<br>BACTERIAL ENDOTOXINS                  | USP<85>   | NMT 0.4 EU/mg  | 符合规定<br>Conforms       |                         |
| 微生物限度<br>MICROBIAL LIMITS                      | USP<61>   | 总的需氧微生物菌落数不得超过 100 cfu/g<br>Total aerobic microbial count NMT100 cfu/g   | 符合规定<br>Conforms       |                         |
|  | USP<62>   | 不得检出金黄色葡萄球菌，铜绿假单胞杆菌，沙门氏菌和大肠杆菌<br>It meets the requirements of the tests for the absence of Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella species, and Escherichia coli | 符合规定<br>Conforms       |                         |
| 结论<br>CONCLUSION                               | 本品按美国药典 USP43 检验上述项目，结果符合规定。<br>The product is in accordance with USP43 to test the above-mentioned items, the test results conform to the specification. |  |                        |                         |
| 检验者：<br>Tested by QC                           | 单阳军   | 审核者：<br>Checked by QC  | 孙超                     | 质控部经理：<br>QC Manager    |
| 日期：Nov,10, 2021<br>Date                        |   | 日期：Nov,10, 2021<br>Date  |                        | 日期：Nov,10, 2021<br>Date |