

Wuxi Fortune Pharmaceutical Co., Ltd

无锡福祈制药有限公司

No. 2 Kongyang 1<sup>st</sup> Road, Xishan Economic Zone, Wuxi City, Jiangsu Province, P.R.China 214191  
中国江苏省无锡市锡山经济开发区蓉洋一路2号 Tel: +86-510-83104425 Fax: +86-510-83101257

Certificate of Analysis

检验报告书

CEP No.: RO-CEP 2016-034-Rev 01

Analysis No. (检验编号): Pr20200810

|                       |                   |                      |            |
|-----------------------|-------------------|----------------------|------------|
| Product Name:<br>产品名称 | Mitomycin<br>丝裂霉素 | Specification:<br>规格 | API<br>原料药 |
| Batch No.:<br>批号      | AD200902A         | Quantity:<br>数量      | 755.00 g   |
| MFG. Date:<br>生产日期    | 2020/09/11        | RET. Date:<br>复验期    | 2024/09/10 |
| Test Standard<br>检验依据 | EP10th            | Report Date:<br>报告日期 | 2020/09/25 |

| Test Items<br>检验项目                        | Acceptable Criteria<br>标准规定                                                                                                                                                                                                                                       | Results<br>结果                              |
|-------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Appearance<br>性状                          | Blue-violet crystals or crystalline powder.<br>应为蓝紫色结晶或结晶性粉末                                                                                                                                                                                                      | Blue-violet crystalline powder<br>蓝紫色结晶性粉末 |
| Identification<br>鉴别                      | A: The infrared absorption spectrum is concordant with that of the reference standard<br>应与对照品的红外光吸收图谱一致                                                                                                                                                          | Conform<br>符合规定                            |
| A: Infrared absorption spectrum<br>红外吸收光谱 | B: In the assay, the principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (a).<br>含量测定项下, 供试品溶液与对照品溶液主峰的保留时间和大小与对照溶液 (a) 所获得的图谱类似。 | Conform<br>符合规定                            |
| B: HPLC<br>液相色谱                           |                                                                                                                                                                                                                                                                   |                                            |
| Tests<br>检查                               |                                                                                                                                                                                                                                                                   |                                            |
| pH                                        | 5.5 ~ 7.5                                                                                                                                                                                                                                                         | 7.2                                        |
| Water<br>水分                               | ≤2.5%                                                                                                                                                                                                                                                             | <0.1 %                                     |
| Related substances<br>有关物质                | Impurity 杂质A ≤0.5%<br>Impurity 杂质B ≤0.5%<br>Impurity 杂质C ≤0.5%<br>Impurity 杂质D ≤0.5%<br>Any other impurity 其他<br>单个杂质 ≤0.15 %<br>Total impurities 总杂 ≤2.0%                                                                                                        | ND<br>ND<br>ND<br>ND<br>ND<br>ND           |
| Bacterial endotoxins<br>细菌内毒素             | Less than 10 IU/mg<br>应<10 IU/mg                                                                                                                                                                                                                                  | <10 IU/mg                                  |
| Microbial contamination<br>微生物限度          | TAMC需氧菌总数 ≤10 <sup>3</sup> cfu/g<br>TYMC霉菌和酵母菌总数 ≤10 <sup>2</sup> cfu/g                                                                                                                                                                                           | <10cfu/g<br><10cfu/g                       |
| Assay<br>含量测定                             | 97.0%~102.0% (anhydrous substance)<br>应为97.0%~102.0% (按无水物计算)                                                                                                                                                                                                     | 99.0 %                                     |
| Residual solvents<br>残留溶剂                 | Methanol 甲醇 ≤3000ppm<br>Ethyl ether 乙醚 ≤5000ppm<br>Ethyl acetate 乙酸乙酯 ≤5000ppm                                                                                                                                                                                    | <3000ppm<br><5000ppm<br><5000ppm           |

Conclusion: Conform to the specification of EP10th  
结论: 本品按EP10版标准检验, 结果符合规定

Prepared by:  
制单:

Approved:  
批准:

Wuxi Fortune Pharmaceutical Co., Ltd

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Certificate of Analysis

检验报告书

CEP No.: RO-CEP 2016-034-Rev 08

Analysis No. (检验编号): Pr20200869

|                       |                   |                      |            |
|-----------------------|-------------------|----------------------|------------|
| Product Name:<br>产品名称 | Mitomycin<br>丝裂霉素 | Specification:<br>规格 | API<br>原料药 |
| Batch No.:<br>批号      | AD201004A         | Quantity:<br>数量      | 868.00 g   |
| MFG. Date:<br>生产日期    | 2020/10/15        | RET. Date:<br>复验期    | 2024/10/14 |
| Test Standard<br>检验依据 | EP10th            | Report Date:<br>报告日期 | 2020/11/04 |

| Test Items<br>检验项目                        | Acceptable Criteria<br>标准规定                                                                                                                                                                                                                                       | Results<br>结果                              |
|-------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Appearance<br>性状                          | Blue-violet crystals or crystalline powder.<br>应为蓝紫色结晶或结晶性粉末                                                                                                                                                                                                      | Blue-violet crystalline powder<br>蓝紫色结晶性粉末 |
| Identification<br>鉴别                      |                                                                                                                                                                                                                                                                   |                                            |
| A: Infrared absorption spectrum<br>红外吸收光谱 | A: The infrared absorption spectrum is concordant with that of the reference standard<br>应与对照品的红外光吸收图谱一致                                                                                                                                                          | Conform<br>符合规定                            |
| B: HPLC<br>液相色谱                           | B: In the assay, the principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (a).<br>含量测定项下, 供试品溶液与对照品溶液主峰的保留时间和大小与对照溶液 (a) 所获得的图谱类似。 | Conform<br>符合规定                            |
| Tests<br>检查                               |                                                                                                                                                                                                                                                                   |                                            |
| pH                                        | 5.5 ~ 7.5                                                                                                                                                                                                                                                         | 6.5                                        |
| Water<br>水分                               | ≤2.5%                                                                                                                                                                                                                                                             | 0.1 %                                      |
| Related substances<br>有关物质                | Impurity 杂质A ≤0.5%<br>Impurity 杂质B ≤0.5%<br>Impurity 杂质C ≤0.5%<br>Impurity 杂质D ≤0.5%<br>Any other impurity 其他<br>单个杂质 ≤0.15 %<br>Total impurities 总杂 ≤2.0%                                                                                                        | ND<br>ND<br>ND<br>ND<br>ND<br>ND           |
| Bacterial endotoxins<br>细菌内毒素             | Less than 10 IU/mg<br>应<10 IU/mg                                                                                                                                                                                                                                  | <10 IU/mg                                  |
| Microbial contamination<br>微生物限度          | TAMC需氧菌总数≤10 <sup>3</sup> cfu/g<br>TYMC霉菌和酵母菌总数 ≤10 <sup>2</sup> cfu/g                                                                                                                                                                                            | <10cfu/g<br><10cfu/g                       |
| Assay<br>含量测定                             | 97.0%~102.0% (anhydrous substance)<br>应为97.0%~102.0% (按无水物计算)                                                                                                                                                                                                     | 97.9 %                                     |
| Residual solvents<br>残留溶剂                 | Methanol 甲醇 ≤3000ppm<br>Ethyl ether乙醚 ≤5000ppm<br>Ethyl acetate乙酸乙酯 ≤5000ppm                                                                                                                                                                                      | <3000ppm<br><5000ppm<br>ND                 |

Conclusion: Conform to the specification of EP10th  
结论: 本品按EP10版标准检验, 结果符合规定

Prepared by  
制单:

Approved by  
批准:

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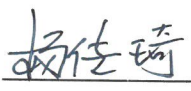
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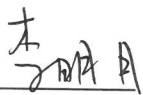
## PARTICLE SIZE STATEMENT

To Whom it May Concern,

Date: April 19, 2021

We, Wuxi Fortune Pharmaceutical Co., Ltd hereby confirm that our *Mitomycin* (Batch No.: AD200902A& AD201004A) are passed 120  $\mu$  m sieve.

Name: Yang Chuanqi Signature:  Position: QA Manager

Name: Li Mingyue Signature:  Position: Production Manager

Wuxi Fortune Pharmaceutical Co., Ltd

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### ZINC CONTENT STATEMENT

To Whom it May Concern,

Date: April 19, 2021

We, Wuxi Fortune Pharmaceutical Co., Ltd hereby confirm that Zinc content of our *Mitomycin* (AD200902A& AD201004A) is not more than 5ppm.

Name: Yang Chuanqi Signature: 杨传琦 Position: QA Manager

Wuxi Fortune Pharmaceutical Co., Ltd

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## Wuxi Fortune Pharmaceutical Co., Ltd

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### QUALIFIED PERSON STATEMENT

To Whom it May Concern,

Date: April 19, 2021

We, Wuxi Fortune Pharmaceutical Co., Ltd hereby confirm that the manufacturing protocol and the analysis protocol of our *Mitomycin* (AD200902A& AD201004A) are duly signed and released by responsible qualified person.

Name: Yang Chuanqi Signature: 杨传奇 Position: QA Manager

Wuxi Fortune Pharmaceutical Co., Ltd