

|                                                                     |                                                  |                                |
|---------------------------------------------------------------------|--------------------------------------------------|--------------------------------|
| Product: <b>Microcrystalline Cellulose</b>                          | Product Code: 4005                               | Manufacturing Date: 2021-04-12 |
| Type: <b>PH-112</b>                                                 | Packaging Specification: 20kg /each bag/each box | Sampling Date: 2021-04-17      |
| Batch No.: <b>M210405</b>                                           | Test No.: F210412                                | Re-evaluation Date: 2023-04-11 |
| Manufacturer: Jiangsu Westpoint Pharmaceutical Excipients Co., LTD. |                                                  |                                |

| Test Items                                   | Specification                                                                                                                                                                                                                  | Test Results                                        |
|----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| Appearance (USP,EP,ChP)                      | White or almost white powder                                                                                                                                                                                                   | Almost white powder                                 |
| Identification 1 (USP,EP,ChP)                | Positive                                                                                                                                                                                                                       | Positive                                            |
| Identification 2 (USP,EP,ChP)                | The degree of polymerization is not greater than 350.                                                                                                                                                                          | 255                                                 |
| Conductivity (USP,EP,ChP)                    | NMT 75 $\mu$ S/cm                                                                                                                                                                                                              | 20 $\mu$ S/cm                                       |
| pH (USP,EP,ChP)                              | pH5.0-7.5                                                                                                                                                                                                                      | 6.3                                                 |
| Water-Soluble Substances (USP,EP,ChP)        | NMT 0.2%                                                                                                                                                                                                                       | 0.12%                                               |
| Ether- Soluble Substances (USP,EP,ChP)       | NMT 0.05%                                                                                                                                                                                                                      | 0                                                   |
| Loss on Drying (USP,EP,ChP)                  | NMT 1.5%                                                                                                                                                                                                                       | 0.4%                                                |
| Residue on Ignition (USP,EP,ChP)             | NMT 0.10%                                                                                                                                                                                                                      | 0.03%                                               |
| Heavy Metals (ChP)                           | NMT 0.0010%                                                                                                                                                                                                                    | Less than 0.0010%                                   |
| Chloride (ChP)                               | NMT 0.03%                                                                                                                                                                                                                      | Less than 0.03%                                     |
| Starch (ChP)                                 | Negative                                                                                                                                                                                                                       | Negative                                            |
| Arsenic (ChP)                                | NMT 0.0002%                                                                                                                                                                                                                    | Less than 0.0002%                                   |
| Solubility (EP)                              | Dissolve completely                                                                                                                                                                                                            | Dissolve completely                                 |
| Bulk Density (USP)                           | 0.26-0.36g/ml                                                                                                                                                                                                                  | 0.31g/ml                                            |
| Particle Size Distribution (USP,EP,ChP)      | D10=14-50 $\mu$ m<br>D50=70-150 $\mu$ m ,D90=160-295 $\mu$ m                                                                                                                                                                   | D10=35 $\mu$ m,<br>D50=110 $\mu$ m ,D90=236 $\mu$ m |
| Total Aerobic Microbial (USP,EP,ChP)         | NMT1000cfu/g                                                                                                                                                                                                                   | Less than 10cfu/g                                   |
| Total Combined Molds and Yeasts (USP,EP,ChP) | NMT 100cfu/g                                                                                                                                                                                                                   | Less than 10cfu/g                                   |
| Escherichia coli (USP,EP,ChP)                | 1gNot detected                                                                                                                                                                                                                 | Not detected                                        |
| Pseudomonas aeruginosa (USP,EP)              | 1gNot detected                                                                                                                                                                                                                 | Not detected                                        |
| Staphylococcus aureus (USP,EP)               | 1gNot detected                                                                                                                                                                                                                 | Not detected                                        |
| Salmonella species (USP,EP)                  | 10gNot detected                                                                                                                                                                                                                | Not detected                                        |
| Conclusion:                                  | Tests have been conducted as per microcrystalline cellulose test method (QS4011-09). The results are consistent with the standard of China Pharmacopeia(ChP.2020) European Pharmacopoeia and the United States Pharmacopoeia . |                                                     |

Reporter/Date 报告人/日期: 王花蕊, 2021-04-22

Approver/Date 审批人/日期: 苏浩, 2021-04-22



|                                                                     |                                            |                                   |
|---------------------------------------------------------------------|--------------------------------------------|-----------------------------------|
| Product: <b>Microcrystalline Cellulose</b>                          | Product Code: 4001                         | Manufacturing Date:<br>2021-03-22 |
| Type: <b>PH-101</b>                                                 | Packaging Specification:<br>20kg /each bag | Sampling Date:<br>2021-03-24      |
| Batch No.: <b>M210309</b>                                           | Test No.: F210322                          | Re-evaluation Date:<br>2024-03-21 |
| Manufacturer: Jiangsu Westpoint Pharmaceutical Excipients Co., LTD. |                                            |                                   |

| Test Items                                   | Specification                                              | Test Results                                       |
|----------------------------------------------|------------------------------------------------------------|----------------------------------------------------|
| Appearance (USP,EP,ChP)                      | White or almost white powder                               | Almost white powder                                |
| Identification 1 (USP,EP,ChP)                | Positive                                                   | Positive                                           |
| Identification 2 (USP,EP,ChP)                | The degree of polymerization is not greater than 350.      | 264                                                |
| Conductivity (USP,EP,ChP)                    | NMT 75 $\mu$ S/cm                                          | 18 $\mu$ S/cm                                      |
| pH (USP,EP,ChP)                              | pH5.0-7.5                                                  | 6.8                                                |
| Water-Soluble Substances (USP,EP,ChP)        | NMT 0.2%                                                   | 0.13%                                              |
| Ether- Soluble Substances (USP,EP,ChP)       | NMT 0.05%                                                  | 0                                                  |
| Loss on Drying (USP,EP,ChP)                  | NMT 7.0%                                                   | 2.3%                                               |
| Residue on Ignition (USP,EP,ChP)             | NMT 0.10%                                                  | 0.01%                                              |
| Heavy Metals (ChP)                           | NMT 0.0010%                                                | Less than 0.0010%                                  |
| Chloride (ChP)                               | NMT 0.03%                                                  | Less than 0.03%                                    |
| Starch (ChP)                                 | Negative                                                   | Negative                                           |
| Arsenic (ChP)                                | NMT 0.0002%                                                | Less than 0.0002%                                  |
| Solubility (EP)                              | Dissolve completely                                        | Dissolve completely                                |
| Bulk Density (USP)                           | 0.26-0.36g/ml                                              | 0.29g/ml                                           |
| Particle Size Distribution (USP,EP,ChP)      | D10=14-30 $\mu$ m<br>D50=40-75 $\mu$ m ,D90=77-156 $\mu$ m | D10=20 $\mu$ m,<br>D50=63 $\mu$ m ,D90=148 $\mu$ m |
| Total Aerobic Microbial (USP,EP,ChP)         | NMT1000cfu/g                                               | Less than 10cfu/g                                  |
| Total Combined Molds and Yeasts (USP,EP,ChP) | NMT 100cfu/g                                               | Less than 10cfu/g                                  |
| Escherichia coli (USP,EP,ChP)                | 1gNot detected                                             | Not detected                                       |
| Pseudomonas aeruginosa (USP,EP)              | 1gNot detected                                             | Not detected                                       |
| Staphylococcus aureus (USP,EP)               | 1gNot detected                                             | Not detected                                       |
| Salmonella species (USP,EP)                  | 10gNot detected                                            | Not detected                                       |

Conclusion: Tests have been conducted as per microcrystalline cellulose test method (QS4011-08). The results are consistent with the standard of China Pharmacopoeia(ChP.2020) European Pharmacopoeia and the United States Pharmacopoeia .

Reporter/Date 报告人/日期: 王花蕊 2021-03-29

Approver/Date 审批人/日期: 张松 2021-03-29



|                                                                     |                                            |                                   |
|---------------------------------------------------------------------|--------------------------------------------|-----------------------------------|
| Product: <b>Microcrystalline Cellulose</b>                          | Product Code: 4002                         | Manufacturing Date:<br>2021-02-23 |
| Type: <b>PH-102</b>                                                 | Packaging Specification:<br>20kg /each bag | Sampling Date:<br>2021-02-24      |
| Batch No.: <b>M210209</b>                                           | Test No.: F210222                          | Re-evaluation Date:<br>2024-02-22 |
| Manufacturer: Jiangsu Westpoint Pharmaceutical Excipients Co., LTD. |                                            |                                   |

| Test Items                                   | Specification                                                                                                                                                                                                                             | Test Results                      |
|----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| Appearance (USP,EP,ChP)                      | White or almost white powder                                                                                                                                                                                                              | Almost white powder               |
| Identification 1 (USP,EP,ChP)                | Positive                                                                                                                                                                                                                                  | Positive                          |
| Identification 2 (USP,EP,ChP)                | The degree of polymerization is not greater than 350.                                                                                                                                                                                     | 263                               |
| Conductivity (USP,EP,ChP)                    | NMT 75µS/cm                                                                                                                                                                                                                               | 17µS/cm                           |
| pH (USP,EP,ChP)                              | pH5.0-7.5                                                                                                                                                                                                                                 | 6.8                               |
| Water-Soluble Substances (USP,EP,ChP)        | NMT 0.2%                                                                                                                                                                                                                                  | 0.13%                             |
| Ether- Soluble Substances (USP,EP,ChP)       | NMT 0.05%                                                                                                                                                                                                                                 | 0                                 |
| Loss on Drying (USP,EP,ChP)                  | NMT 7.0%                                                                                                                                                                                                                                  | 3.4%                              |
| Residue on Ignition (USP,EP,ChP)             | NMT 0.10%                                                                                                                                                                                                                                 | 0.01%                             |
| Heavy Metals (ChP)                           | NMT 0.0010%                                                                                                                                                                                                                               | Less than 0.0010%                 |
| Chloride (ChP)                               | NMT 0.03%                                                                                                                                                                                                                                 | Less than 0.03%                   |
| Starch (ChP)                                 | Negative                                                                                                                                                                                                                                  | Negative                          |
| Arsenic (ChP)                                | NMT 0.0002%                                                                                                                                                                                                                               | Less than 0.0002%                 |
| Solubility (EP)                              | Dissolve completely                                                                                                                                                                                                                       | Dissolve completely               |
| Bulk Density (USP)                           | 0.26-0.36g/ml                                                                                                                                                                                                                             | 0.29g/ml                          |
| Particle Size Distribution (USP,EP,ChP)      | D10=15-55µm<br>D50=80-140µm ,D90=170-283µm                                                                                                                                                                                                | D10=36µm,<br>D50=117µm ,D90=246µm |
| Total Aerobic Microbial (USP,EP,ChP)         | NMT1000cfu/g                                                                                                                                                                                                                              | Less than 10cfu/g                 |
| Total Combined Molds and Yeasts (USP,EP,ChP) | NMT 100cfu/g                                                                                                                                                                                                                              | Less than 10cfu/g                 |
| Escherichia coli (USP,EP,ChP)                | 1g Not detected                                                                                                                                                                                                                           | Not detected                      |
| Pseudomonas aeruginosa (USP,EP)              | 1g Not detected                                                                                                                                                                                                                           | Not detected                      |
| Staphylococcus aureus (USP,EP)               | 1g Not detected                                                                                                                                                                                                                           | Not detected                      |
| Salmonella species (USP,EP)                  | 10g Not detected                                                                                                                                                                                                                          | Not detected                      |
| Conclusion:                                  | Tests have been conducted as per microcrystalline cellulose quality standard (QS4011-08).<br>The results are consistent with the standard of China Pharmacopeia(ChP.2020)<br>European Pharmacopoeia and the United States Pharmacopoeia . |                                   |

Reporter/Date 报告人/日期: 2021-03-01

Approver/Date 审批人/日期: 2021-03-01



|                                                                     |                                            |                                   |
|---------------------------------------------------------------------|--------------------------------------------|-----------------------------------|
| Product: <b>Microcrystalline Cellulose</b>                          | Product Code: 4008                         | Manufacturing Date:<br>2021-01-09 |
| Type: <b>PH-200</b>                                                 | Packaging Specification:<br>20kg /each bag | Sampling Date:<br>2021-01-14      |
| Batch No.: <b>M210104T</b>                                          | Test No.: F210116                          | Re-evaluation Date:<br>2024-01-08 |
| Manufacturer: Jiangsu Westpoint Pharmaceutical Excipients Co., LTD. |                                            |                                   |

| Test Items                                   | Specification                                                                                                                                                                                                                  | Test Results                      |
|----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| Appearance (USP,EP,ChP)                      | White or almost white powder                                                                                                                                                                                                   | Almost white powder               |
| Identification 1 (USP,EP,ChP)                | Positive                                                                                                                                                                                                                       | Positive                          |
| Identification 2 (USP,EP,ChP)                | The degree of polymerization is not greater than 350.                                                                                                                                                                          | 264                               |
| Conductivity (USP,EP,ChP)                    | NMT 75µS/cm                                                                                                                                                                                                                    | 25µS/cm                           |
| pH (USP,EP,ChP)                              | pH5.0-7.5                                                                                                                                                                                                                      | 6.7                               |
| Water-Soluble Substances (USP,EP,ChP)        | NMT 0.2%                                                                                                                                                                                                                       | 0.15%                             |
| Ether- Soluble Substances (USP,EP,ChP)       | NMT 0.05%                                                                                                                                                                                                                      | 0                                 |
| Loss on Drying (USP,EP,ChP)                  | NMT 7.0%                                                                                                                                                                                                                       | 3.3%                              |
| Residue on Ignition (USP,EP,ChP)             | NMT 0.10%                                                                                                                                                                                                                      | 0.03%                             |
| Heavy Metals (ChP)                           | NMT 0.0010%                                                                                                                                                                                                                    | Less than 0.0010%                 |
| Chloride (ChP)                               | NMT 0.03%                                                                                                                                                                                                                      | Less than 0.03%                   |
| Starch (ChP)                                 | Negative                                                                                                                                                                                                                       | Negative                          |
| Arsenic (ChP)                                | NMT 0.0002%                                                                                                                                                                                                                    | Less than 0.0002%                 |
| Solubility (EP)                              | Dissolve completely                                                                                                                                                                                                            | Dissolve completely               |
| Bulk Density (USP)                           | 0.29-0.36g/ml                                                                                                                                                                                                                  | 0.36g/ml                          |
| Particle Size Distribution (USP,EP,ChP)      | D10=20-175µm<br>D50=142-280µm ,D90=275-480µm                                                                                                                                                                                   | D10=88µm,<br>D50=185µm ,D90=314µm |
| Total Aerobic Microbial (USP,EP,ChP)         | NMT1000cfu/g                                                                                                                                                                                                                   | Less than 10cfu/g                 |
| Total Combined Molds and Yeasts (USP,EP,ChP) | NMT 100cfu/g                                                                                                                                                                                                                   | Less than 10cfu/g                 |
| Escherichia coli (USP,EP,ChP)                | 1gNot detected                                                                                                                                                                                                                 | Not detected                      |
| Pseudomonas aeruginosa (USP,EP)              | 1gNot detected                                                                                                                                                                                                                 | Not detected                      |
| Staphylococcus aureus (USP,EP)               | 1gNot detected                                                                                                                                                                                                                 | Not detected                      |
| Salmonella species (USP,EP)                  | 10gNot detected                                                                                                                                                                                                                | Not detected                      |
| Conclusion:                                  | Tests have been conducted as per microcrystalline cellulose test method (QS4011-08). The results are consistent with the standard of China Pharmacopeia(ChP.2020) European Pharmacopoeia and the United States Pharmacopoeia . |                                   |

Reporter/Date 报告人/日期: 王花蕊 2021-01-19

Approver/Date 审批人/日期: 杨强 2021-01-19



|                                                                     |                                            |                                   |
|---------------------------------------------------------------------|--------------------------------------------|-----------------------------------|
| Product: <b>Microcrystalline Cellulose</b>                          | Product Code: 4011                         | Manufacturing Date:<br>2020-08-20 |
| Type: <b>PH-302</b>                                                 | Packaging Specification:<br>20kg /each bag | Sampling Date:<br>2020-08-24      |
| Batch No.: <b>M200806T</b>                                          | Test No.: F200821                          | Re-evaluation Date:<br>2023-08-19 |
| Manufacturer: Jiangsu Westpoint Pharmaceutical Excipients Co., LTD. |                                            |                                   |

| Test Items                                   | Specification                                                                                                                                                                                                                  | Test Results                                        |
|----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| Appearance (USP,EP,ChP)                      | White or almost white powder                                                                                                                                                                                                   | Almost white powder                                 |
| Identification 1 (USP,EP,ChP)                | Positive                                                                                                                                                                                                                       | Positive                                            |
| Identification 2 (USP,EP,ChP)                | The degree of polymerization is not greater than 350.                                                                                                                                                                          | 182                                                 |
| Conductivity (USP,EP,ChP)                    | NMT 75 $\mu$ S/cm                                                                                                                                                                                                              | 21 $\mu$ S/cm                                       |
| pH (USP,EP,ChP)                              | pH5.0-7.5                                                                                                                                                                                                                      | 6.8                                                 |
| Water-Soluble Substances (USP,EP,ChP)        | NMT 0.2%                                                                                                                                                                                                                       | 0.07%                                               |
| Ether- Soluble Substances (USP,EP,ChP)       | NMT 0.05%                                                                                                                                                                                                                      | 0.01%                                               |
| Loss on Drying (USP,EP,ChP)                  | NMT7.0%                                                                                                                                                                                                                        | 4.5%                                                |
| Residue on Ignition (USP,EP,ChP)             | NMT 0.10%                                                                                                                                                                                                                      | 0.06%                                               |
| Heavy Metals (ChP)                           | NMT 0.0010%                                                                                                                                                                                                                    | Less than 0.0010%                                   |
| Chloride (ChP)                               | NMT 0.03%                                                                                                                                                                                                                      | Less than 0.03%                                     |
| Starch (ChP)                                 | Negative                                                                                                                                                                                                                       | Negative                                            |
| Arsenic (ChP)                                | NMT 0.0002%                                                                                                                                                                                                                    | Less than 0.0002%                                   |
| Solubility (EP)                              | Dissolve completely                                                                                                                                                                                                            | Dissolve completely                                 |
| Bulk Density (USP)                           | 0.35-0.50g/ml                                                                                                                                                                                                                  | 0.40g/ml                                            |
| Particle Size Distribution (USP,EP,ChP)      | D10=12-58 $\mu$ m<br>D50=86-165 $\mu$ m ,D90=180-340 $\mu$ m                                                                                                                                                                   | D10=40 $\mu$ m,<br>D50=126 $\mu$ m ,D90=234 $\mu$ m |
| Total Aerobic Microbial (USP,EP,ChP)         | NMT1000cfu/g                                                                                                                                                                                                                   | Less than 10cfu/g                                   |
| Total Combined Molds and Yeasts (USP,EP,ChP) | NMT 100cfu/g                                                                                                                                                                                                                   | Less than 10cfu/g                                   |
| Escherichia coli (USP,EP,ChP)                | 1gNot detected                                                                                                                                                                                                                 | Not detected                                        |
| Pseudomonas aeruginosa (USP,EP)              | 1gNot detected                                                                                                                                                                                                                 | Not detected                                        |
| Staphylococcus aureus (USP,EP)               | 1gNot detected                                                                                                                                                                                                                 | Not detected                                        |
| Salmonella species (USP,EP)                  | 10gNot detected                                                                                                                                                                                                                | Not detected                                        |
| Conclusion:                                  | Tests have been conducted as per microcrystalline cellulose test method (QS4011-09). The results are consistent with the standard of China Pharmacopeia(ChP.2020) European Pharmacopoeia and the United States Pharmacopoeia . |                                                     |

Reporter/Date 报告人/日期: 王花蕊 2020-08-31

Approver/Date 审批人/日期: 陈书 2020-08-31



|                                                                     |                                            |                                   |
|---------------------------------------------------------------------|--------------------------------------------|-----------------------------------|
| Product: <b>Microcrystalline Cellulose</b>                          | Product Code: 4010                         | Manufacturing Date:<br>2020-06-09 |
| Type: <b>PH-301</b>                                                 | Packaging Specification:<br>20kg /each bag | Sampling Date:<br>2020-08-24      |
| Batch No.: <b>M200612T</b>                                          | Test No.: F200823                          | Re-evaluation Date:<br>2023-06-08 |
| Manufacturer: Jiangsu Westpoint Pharmaceutical Excipients Co., LTD. |                                            |                                   |

| Test Items                                   | Specification                                                                                                                                                                                                                  | Test Results                     |
|----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| Appearance (USP,EP,ChP)                      | White or almost white powder                                                                                                                                                                                                   | Almost white powder              |
| Identification 1 (USP,EP,ChP)                | Positive                                                                                                                                                                                                                       | Positive                         |
| Identification 2 (USP,EP,ChP)                | The degree of polymerization is not greater than 350.                                                                                                                                                                          | 176                              |
| Conductivity (USP,EP,ChP)                    | NMT 75μS/cm                                                                                                                                                                                                                    | 12μS/cm                          |
| pH (USP,EP,ChP)                              | pH5.0-7.5                                                                                                                                                                                                                      | 6.9                              |
| Water-Soluble Substances (USP,EP,ChP)        | NMT 0.2%                                                                                                                                                                                                                       | 0.07%                            |
| Ether- Soluble Substances (USP,EP,ChP)       | NMT 0.05%                                                                                                                                                                                                                      | 0.01%                            |
| Loss on Drying (USP,EP,ChP)                  | NMT7.0%                                                                                                                                                                                                                        | 2.1%                             |
| Residue on Ignition (USP,EP,ChP)             | NMT 0.10%                                                                                                                                                                                                                      | 0.06%                            |
| Heavy Metals (ChP)                           | NMT 0.0010%                                                                                                                                                                                                                    | Less than 0.0010%                |
| Chloride (ChP)                               | NMT 0.03%                                                                                                                                                                                                                      | Less than 0.03%                  |
| Starch (ChP)                                 | Negative                                                                                                                                                                                                                       | Negative                         |
| Arsenic (ChP)                                | NMT 0.0002%                                                                                                                                                                                                                    | Less than 0.0002%                |
| Solubility (EP)                              | Dissolve completely                                                                                                                                                                                                            | Dissolve completely              |
| Bulk Density (USP)                           | 0.35-0.50g/ml                                                                                                                                                                                                                  | 0.40g/ml                         |
| Particle Size Distribution (USP,EP,ChP)      | D10≤30μm<br>D50=40-75μm ,D90=77-156μm                                                                                                                                                                                          | D10=15μm,<br>D50=44μm ,D90=114μm |
| Total Aerobic Microbial (USP,EP,ChP)         | NMT1000cfu/g                                                                                                                                                                                                                   | Less than 10cfu/g                |
| Total Combined Molds and Yeasts (USP,EP,ChP) | NMT 100cfu/g                                                                                                                                                                                                                   | Less than 10cfu/g                |
| Escherichia coli (USP,EP,ChP)                | 1gNot detected                                                                                                                                                                                                                 | Not detected                     |
| Pseudomonas aeruginosa (USP,EP)              | 1gNot detected                                                                                                                                                                                                                 | Not detected                     |
| Staphylococcus aureus (USP,EP)               | 1gNot detected                                                                                                                                                                                                                 | Not detected                     |
| Salmonella species (USP,EP)                  | 10gNot detected                                                                                                                                                                                                                | Not detected                     |
| Conclusion:                                  | Tests have been conducted as per microcrystalline cellulose test method (QS4011-07). The results are consistent with the standard of China Pharmacopeia(ChP.2015) European Pharmacopoeia and the United States Pharmacopoeia . |                                  |

Reporter/Date 报告人/日期: 王花蕊 2020-08-31

Approver/Date 审批人/日期: 董书 2020-08-31



Product: **Microcrystalline Cellulose**

Product Code: 4017

 Manufacturing Date:  
2020-04-24

 Type: **KG-802**

 Packaging Specification:  
20kg/each bag

 Sampling Date:  
2020-08-12

 Batch No.: **200407T**

Test No.: F200809

 Re-evaluation Date:  
2023-04-23

Manufacturer: Jiangsu Westpoint Pharmaceutical Excipients Co., LTD.

| Test Items                                   | Specification                                         | Test Results        |
|----------------------------------------------|-------------------------------------------------------|---------------------|
| Appearance (USP,EP,ChP)                      | White or almost white powder                          | Almost white powder |
| Identification 1 (USP,EP,ChP)                | Positive                                              | Positive            |
| Identification 2 (USP,EP,ChP)                | The degree of polymerization is not greater than 350. | 250                 |
| Conductivity (USP,EP,ChP)                    | NMT 75 $\mu$ S/cm                                     | 16 $\mu$ S/cm       |
| pH (USP,EP,ChP)                              | pH5.0-7.5                                             | 6.4                 |
| Water-Soluble Substances (USP,EP,ChP)        | NMT 0.2%                                              | 0.07%               |
| Ether- Soluble Substances (USP,EP,ChP)       | NMT 0.05%                                             | 0                   |
| Loss on Drying (USP,EP,ChP)                  | NMT 7.0%                                              | 2.1%                |
| Residue on Ignition (USP,EP,ChP)             | NMT 0.10%                                             | 0.01%               |
| Heavy Metals (ChP)                           | NMT 0.0010%                                           | Less than 0.0010%   |
| Chloride (ChP)                               | NMT 0.03%                                             | Less than 0.03%     |
| Starch (ChP)                                 | Negative                                              | Negative            |
| Arsenic (ChP)                                | NMT 0.0002%                                           | Less than 0.0002%   |
| Solubility (EP)                              | Dissolve completely                                   | Dissolve completely |
| Bulk Density (USP)                           | 0.13-0.23g/ml                                         | 0.23g/ml            |
| Particle Size ,wt% > 250 $\mu$ m(60metsh)    | LT0.5                                                 | 0.3%,               |
| Particle Size ,wt% > 75 $\mu$ m(200metsh)    | 5-30                                                  | 23%                 |
| Total Aerobic Microbial (USP,EP,ChP)         | NMT1000cfu/g                                          | Less than 10cfu/g   |
| Total Combined Molds and Yeasts (USP,EP,ChP) | NMT 100cfu/g                                          | Less than 10cfu/g   |
| Escherichia coli (USP,EP,ChP)                | 1gNot detected                                        | Not detected        |
| Pseudomonas aeruginosa (USP,EP)              | 1gNot detected                                        | Not detected        |
| Staphylococcus aureus (USP,EP)               | 1gNot detected                                        | Not detected        |
| Salmonella species (USP,EP)                  | 10gNot detected                                       | Not detected        |

Conclusion: Tests have been conducted as per microcrystalline cellulose test method (QS4011-07). The results are consistent with the standard of China Pharmacopeia(ChP.2015) European Pharmacopoeia and the United States Pharmacopoeia .

Reporter/Date 报告人/日期: 王亚杰, 2020-08-18

Approver/Date 审批人/日期: 张松 2020-08-18





**西典医药**  
WESTPOINT PHARMA

## Certificate of Analysis

|                                                                     |                                                     |                                   |
|---------------------------------------------------------------------|-----------------------------------------------------|-----------------------------------|
| Product: <b>Microcrystalline Cellulose</b>                          | Product Code: 4003                                  | Manufacturing Date:<br>2018-09-28 |
| Type: <b>PH-103</b>                                                 | Packaging Specification:<br>20kg /each bag/each box | Sampling Date:<br>2018-10-11      |
| Batch No.: <b>181002</b>                                            | Test No.: F181002                                   | Re-evaluation Date:<br>2020-03-27 |
| Manufacturer: Jiangsu Westpoint Pharmaceutical Excipients Co., LTD. |                                                     |                                   |

| Test Items                                   | Specification                                                                                                                                                                                                                  | Test Results                                       |
|----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|
| Appearance (USP,EP,ChP)                      | White or almost white powder                                                                                                                                                                                                   | Almost white powder                                |
| Identification 1 (USP,EP,ChP)                | Positive                                                                                                                                                                                                                       | Positive                                           |
| Identification 2 (USP,EP,ChP)                | The degree of polymerization is not greater than 350.                                                                                                                                                                          | 241                                                |
| Conductivity (USP,EP,ChP)                    | NMT 75 $\mu$ S/cm                                                                                                                                                                                                              | 21 $\mu$ S/cm                                      |
| pH (USP,EP,ChP)                              | pH5.0-7.5                                                                                                                                                                                                                      | 6.0                                                |
| Water-Soluble Substances (USP,EP,ChP)        | NMT 0.2%                                                                                                                                                                                                                       | 0.2%                                               |
| Ether- Soluble Substances (USP,EP,ChP)       | NMT 0.05%                                                                                                                                                                                                                      | 0.02%                                              |
| Loss on Drying (USP,EP,ChP)                  | NMT3.0%                                                                                                                                                                                                                        | 1.0%                                               |
| Residue on Ignition (USP,EP,ChP)             | NMT 0.10%                                                                                                                                                                                                                      | 0.02%                                              |
| Heavy Metals (ChP)                           | NMT 0.0010%                                                                                                                                                                                                                    | Less than 0.0010%                                  |
| Chloride (ChP)                               | NMT 0.03%                                                                                                                                                                                                                      | Less than 0.03%                                    |
| Starch (ChP)                                 | Negative                                                                                                                                                                                                                       | Negative                                           |
| Arsenic (ChP)                                | NMT 0.0002%                                                                                                                                                                                                                    | Less than 0.0002%                                  |
| Solubility (EP)                              | Dissolve completely                                                                                                                                                                                                            | Dissolve completely                                |
| Bulk Density (USP)                           | 0.26-0.36g/ml                                                                                                                                                                                                                  | 0.34g/ml                                           |
| Particle Size Distribution (USP,EP,ChP)      | D10=14-30 $\mu$ m<br>D50=40-75 $\mu$ m ,D90=77-156 $\mu$ m                                                                                                                                                                     | D10=18 $\mu$ m,<br>D50=54 $\mu$ m ,D90=126 $\mu$ m |
| Total Aerobic Microbial (USP,EP,ChP)         | NMT1000cfu/g                                                                                                                                                                                                                   | Less than 10cfu/g                                  |
| Total Combined Molds and Yeasts (USP,EP,ChP) | NMT 100cfu/g                                                                                                                                                                                                                   | Less than 10cfu/g                                  |
| Escherichia coli (USP,EP,ChP)                | 1gNot detected                                                                                                                                                                                                                 | Not detected                                       |
| Pseudomonas aeruginosa (USP,EP)              | 1gNot detected                                                                                                                                                                                                                 | Not detected                                       |
| Staphylococcus aureus (USP,EP)               | 1gNot detected                                                                                                                                                                                                                 | Not detected                                       |
| Salmonella species (USP,EP)                  | 10gNot detected                                                                                                                                                                                                                | Not detected                                       |
| Conclusion:                                  | Tests have been conducted as per microcrystalline cellulose test method (QS4011-02). The results are consistent with the standard of China Pharmacopeia(ChP.2015) European Pharmacopoeia and the United States Pharmacopoeia . |                                                    |

Reporter/Date 报告人/日期: 王花蕊 2018-11-13

Approver/Date 审批人/日期: 董松 2018-11-13



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|                                                                     |                                                     |                                   |
|---------------------------------------------------------------------|-----------------------------------------------------|-----------------------------------|
| Product: <b>Microcrystalline Cellulose</b>                          | Product Code: 4006                                  | Manufacturing Date:<br>2018-10-12 |
| Type: <b>PH-113</b>                                                 | Packaging Specification:<br>20kg /each bag/each box | Sampling Date:<br>2018-11-06      |
| Batch No.: <b>181009</b>                                            | Test No.: F181104                                   | Re-evaluation Date:<br>2020-04-11 |
| Manufacturer: Jiangsu Westpoint Pharmaceutical Excipients Co., LTD. |                                                     |                                   |

| Test Items                                   | Specification                                                                                                                                                                                                                  | Test Results                                       |
|----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|
| Appearance (USP,EP,ChP)                      | White or almost white powder                                                                                                                                                                                                   | Almost white powder                                |
| Identification 1 (USP,EP,ChP)                | Positive                                                                                                                                                                                                                       | Positive                                           |
| Identification 2 (USP,EP,ChP)                | The degree of polymerization is not greater than 350.                                                                                                                                                                          | 243                                                |
| Conductivity (USP,EP,ChP)                    | NMT 75 $\mu$ S/cm                                                                                                                                                                                                              | 9 $\mu$ S/cm                                       |
| pH (USP,EP,ChP)                              | pH5.0-7.5                                                                                                                                                                                                                      | 6.0                                                |
| Water-Soluble Substances (USP,EP,ChP)        | NMT 0.2%                                                                                                                                                                                                                       | 0.2%                                               |
| Ether- Soluble Substances (USP,EP,ChP)       | NMT 0.05%                                                                                                                                                                                                                      | 0.01%                                              |
| Loss on Drying (USP,EP,ChP)                  | NMT2.0%                                                                                                                                                                                                                        | 0.5%                                               |
| Residue on Ignition (USP,EP,ChP)             | NMT 0.10%                                                                                                                                                                                                                      | 0.02%                                              |
| Heavy Metals (ChP)                           | NMT 0.0010%                                                                                                                                                                                                                    | Less than 0.0010%                                  |
| Chloride (ChP)                               | NMT 0.03%                                                                                                                                                                                                                      | Less than 0.03%                                    |
| Starch (ChP)                                 | Negative                                                                                                                                                                                                                       | Negative                                           |
| Arsenic (ChP)                                | NMT 0.0002%                                                                                                                                                                                                                    | Less than 0.0002%                                  |
| Solubility (EP)                              | Dissolve completely                                                                                                                                                                                                            | Dissolve completely                                |
| Bulk Density (USP)                           | 0.26-0.36g/ml                                                                                                                                                                                                                  | 0.35g/ml                                           |
| Particle Size Distribution (USP,EP,ChP)      | D10=14-30 $\mu$ m<br>D50=40-75 $\mu$ m ,D90=77-156 $\mu$ m                                                                                                                                                                     | D10=19 $\mu$ m,<br>D50=56 $\mu$ m ,D90=136 $\mu$ m |
| Total Aerobic Microbial (USP,EP,ChP)         | NMT1000cfu/g                                                                                                                                                                                                                   | Less than 10cfu/g                                  |
| Total Combined Molds and Yeasts (USP,EP,ChP) | NMT 100cfu/g                                                                                                                                                                                                                   | Less than 10cfu/g                                  |
| Escherichia coli (USP,EP,ChP)                | 1gNot detected                                                                                                                                                                                                                 | Not detected                                       |
| Pseudomonas aeruginosa (USP,EP)              | 1gNot detected                                                                                                                                                                                                                 | Not detected                                       |
| Staphylococcus aureus (USP,EP)               | 1gNot detected                                                                                                                                                                                                                 | Not detected                                       |
| Salmonella species (USP,EP)                  | 10gNot detected                                                                                                                                                                                                                | Not detected                                       |
| Conclusion:                                  | Tests have been conducted as per microcrystalline cellulose test method (QS4011-03). The results are consistent with the standard of China Pharmacopeia(ChP.2015) European Pharmacopoeia and the United States Pharmacopoeia . |                                                    |

Reporter/Date 报告人/日期: 王依蕊 2018-11-27

Approver/Date 审批人/日期: 姜伟 2018-11-27



|                                                                     |                                            |                                   |
|---------------------------------------------------------------------|--------------------------------------------|-----------------------------------|
| Product: <b>Microcrystalline Cellulose</b>                          | Product Code: 4007                         | Manufacturing Date:<br>2019-01-15 |
| Type: <b>PH 102-SCG</b>                                             | Packaging Specification:<br>20kg /each bag | Sampling Date:<br>2019-03-04      |
| Batch No.: <b>190107</b>                                            | Test No.: F190302                          | Re-evaluation Date:<br>2022-01-14 |
| Manufacturer: Jiangsu Westpoint Pharmaceutical Excipients Co., LTD. |                                            |                                   |

| Test Items                                   | Specification                                                                                                                                                                                                                  | Test Results                                        |
|----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| Appearance (USP,EP,ChP)                      | White or almost white powder                                                                                                                                                                                                   | Almost white powder                                 |
| Identification 1 (USP,EP,ChP)                | Positive                                                                                                                                                                                                                       | Positive                                            |
| Identification 2 (USP,EP,ChP)                | The degree of polymerization is not greater than 350.                                                                                                                                                                          | 240                                                 |
| Conductivity (USP,EP,ChP)                    | NMT 75 $\mu$ S/cm                                                                                                                                                                                                              | 17 $\mu$ S/cm                                       |
| pH (USP,EP,ChP)                              | pH5.0-7.5                                                                                                                                                                                                                      | 6.5                                                 |
| Water-Soluble Substances (USP,EP,ChP)        | NMT 0.2%                                                                                                                                                                                                                       | 0.2%                                                |
| Ether- Soluble Substances (USP,EP,ChP)       | NMT 0.05%                                                                                                                                                                                                                      | 0.04%                                               |
| Loss on Drying (USP,EP,ChP)                  | NMT7.0%                                                                                                                                                                                                                        | 2.5%                                                |
| Residue on Ignition (USP,EP,ChP)             | NMT 0.10%                                                                                                                                                                                                                      | 0.03%                                               |
| Heavy Metals (ChP)                           | NMT 0.0010%                                                                                                                                                                                                                    | Less than 0.0010%                                   |
| Chloride (ChP)                               | NMT 0.03%                                                                                                                                                                                                                      | Less than 0.03%                                     |
| Starch (ChP)                                 | Negative                                                                                                                                                                                                                       | Negative                                            |
| Arsenic (ChP)                                | NMT 0.0002%                                                                                                                                                                                                                    | Less than 0.0002%                                   |
| Solubility (EP)                              | Dissolve completely                                                                                                                                                                                                            | Dissolve completely                                 |
| Bulk Density (USP)                           | 0.26-0.36g/ml                                                                                                                                                                                                                  | 0.32g/ml                                            |
| Particle Size Distribution (USP,EP,ChP)      | D10=20-90 $\mu$ m<br>D50=100-205 $\mu$ m ,D90=220-400 $\mu$ m                                                                                                                                                                  | D10=57 $\mu$ m,<br>D50=158 $\mu$ m ,D90=296 $\mu$ m |
| Total Aerobic Microbial (USP,EP,ChP)         | NMT1000cfu/g                                                                                                                                                                                                                   | Less than 10cfu/g                                   |
| Total Combined Molds and Yeasts (USP,EP,ChP) | NMT 100cfu/g                                                                                                                                                                                                                   | Less than 10cfu/g                                   |
| Escherichia coli (USP,EP,ChP)                | 1gNot detected                                                                                                                                                                                                                 | Not detected                                        |
| Pseudomonas aeruginosa (USP,EP)              | 1gNot detected                                                                                                                                                                                                                 | Not detected                                        |
| Staphylococcus aureus (USP,EP)               | 1gNot detected                                                                                                                                                                                                                 | Not detected                                        |
| Salmonella species (USP,EP)                  | 10gNot detected                                                                                                                                                                                                                | Not detected                                        |
| Conclusion:                                  | Tests have been conducted as per microcrystalline cellulose test method (QS4011-04). The results are consistent with the standard of China Pharmacopeia(ChP.2015) European Pharmacopoeia and the United States Pharmacopoeia . |                                                     |

Reporter/Date 报告人/日期: 王秋燕 2019-03-14

Approver/Date 审批人/日期: 陈伟 2019-03-14