



# Certificate of Analysis

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 D50=70-150 $\mu$ m ,D90=160-295 $\mu$ m	D10=35 $\mu$ m, 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 Pharmacopoeia(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: 蒋培, 2021-04-22



# Certificate of Analysis

Product: <b>Microcrystalline Cellulose</b>	Product Code: 4001	Manufacturing Date: 2021-03-22
Type: <b>PH-101</b>	Packaging Specification: 20kg /each bag	Sampling Date: 2021-03-24
Batch No.: <b>M210309</b>	Test No.: F210322	Re-evaluation Date: 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 75µS/cm	18µS/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=14-30µm D50=40-75µm ,D90=77-156µm	D10=20µm, D50=63µm ,D90=148µm
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: 王花蓉 2021-03-29

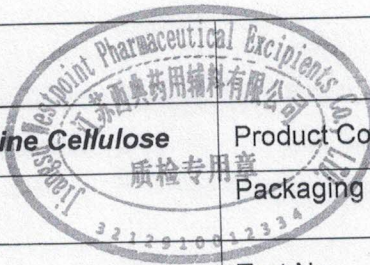
Approver/Date 审批人/日期: 蔡培 2021-03-29

Product: <b>Microcrystalline Cellulose</b>	Product Code: 4002	Manufacturing Date: 2021-02-23
Type: <b>PH-102</b>	Packaging Specification: 20kg /each bag	Sampling Date: 2021-02-24
Batch No.: <b>M210209</b>	Test No.: F210222	Re-evaluation Date: 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 D50=80-140µm ,D90=170-283µm	D10=36µm, 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). 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: 蔡磊 2021-03-01

Approver/Date 审批人/日期: 平勇 2021-03-01



## Certificate of Analysis

Product: <b>Microcrystalline Cellulose</b>	Product Code: 4008	Manufacturing Date: 2021-01-09
Type: <b>PH-200</b>	Packaging Specification: 20kg /each bag	Sampling Date: 2021-01-14
Batch No.: <b>M210104T</b>	Test No.: F210116	Re-evaluation Date: 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 D50=142-280µm ,D90=275-480µm	D10=88µm, 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 Pharmacopoeia(ChP.2020) European Pharmacopoeia and the United States Pharmacopoeia .

Reporter/Date 报告人/日期: 王夜蕊 2021-01-19      Approver/Date 审批人/日期: 张松 2021-01-19



Product: <b>Microcrystalline Cellulose</b>	Product Code: 4011	Manufacturing Date: 2020-08-20
Type: <b>PH-302</b>	Packaging Specification: 20kg /each bag	Sampling Date: 2020-08-24
Batch No.: <b>M200806T</b>	Test No.: F200821	Re-evaluation Date: 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 D50=86-165 $\mu$ m ,D90=180-340 $\mu$ m	D10=40 $\mu$ m, 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: 王花蓉 2020-08-31

Approver/Date 审批人/日期: 张军 2020-08-31



## Certificate of Analysis

Product: <b>Microcrystalline Cellulose</b>	Product Code: 4010	Manufacturing Date: 2020-06-09
Type: <b>PH-301</b>	Packaging Specification: 20kg /each bag	Sampling Date: 2020-08-24
Batch No.: <b>M200612T</b>	Test No.: F200823	Re-evaluation Date: 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 75 $\mu$ S/cm	12 $\mu$ S/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 $\leq$ 30 $\mu$ m D50=40-75 $\mu$ m ,D90=77-156 $\mu$ m	D10=15 $\mu$ m, D50=44 $\mu$ m ,D90=114 $\mu$ 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 (QS4011-07). 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: 董其 2020-08-31



# Certificate of Analysis

Product: <b>Microcrystalline Cellulose</b>	Product Code: 4017	Manufacturing Date: 2020-04-24
Type: <b>KG-802</b>	Packaging Specification: 20kg/each bag	Sampling Date: 2020-08-12
Batch No.: <b>200407T</b>	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: 王莉, 2020-08-18      Approver/Date 审批人/日期: [Signature], 2020-08-18

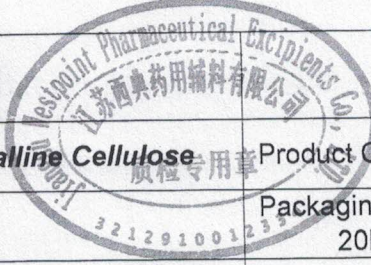
Product: <b>Microcrystalline Cellulose</b>	Product Code: 4003	Manufacturing Date: 2018-09-28
Type: <b>PH-103</b>	Packaging Specification: 20kg /each bag/each box	Sampling Date: 2018-10-11
Batch No.: <b>181002</b>	Test No.: F181002	Re-evaluation Date: 2020-03-27
Manufacturer: Jiangsu Westpoint Pharmaceutical 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 D50=40-75 $\mu$ m ,D90=77-156 $\mu$ m	D10=18 $\mu$ m, 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: 蔡松 2018-11-13





Product: <b>Microcrystalline Cellulose</b>	Product Code: 4006	Manufacturing Date: 2018-10-12
Type: <b>PH-113</b>	Packaging Specification: 20kg /each bag/each box	Sampling Date: 2018-11-06
Batch No.: <b>181009</b>	Test No.: F181104	Re-evaluation Date: 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 D50=40-75 $\mu$ m ,D90=77-156 $\mu$ m	D10=19 $\mu$ m, 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 Pharmacopoeia(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: 蔡书 2018-11-27

Product: <b>Microcrystalline Cellulose</b>	Product Code: 4007	Manufacturing Date: 2019-01-15
Type: <b>PH 102-SCG</b>	Packaging Specification: 20kg /each bag	Sampling Date: 2019-03-04
Batch No.: <b>190107</b>	Test No.: F190302	Re-evaluation Date: 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 D50=100-205 $\mu$ m ,D90=220-400 $\mu$ m	D10=57 $\mu$ m, 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 .

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