

Stability Data Sheet (SDS)

According to the expression of related data about HPMC, this material is one kind of cellulose ethers with stable chemical property. It doesn't occur chemical reaction with air and water; besides, it also doesn't encourage multiplying of microbion due to its metabolizing inertia. So under formal condition, it won't occur decomposition or deteriorate even if place it for a long time. Therefore, we have made the following experiment in order to verify its stability.

1. Influencing factor experiment

1.1. High-temperature test

1.1.1. Testing procedure

1.1.1.1. Take one lot of HPMC (lot number: 20010702) and sampling. Make testing according to 'Chinese Pharmacopoeia' edition 2000, 2nd segment "Hydroxypropyl Methyl Cellulose" part, then issuing testing report.

1.1.1.2. Put the sample into Petri dish and spread out into folium less than 5mm, then place it into thermostat opening for 10 days.

1.1.1.3. Sampling separately on the 5th day and the 10th day, make testing according to 'Chinese Pharmacopoeia' edition 2000, 2nd segment "Hydroxypropyl Methyl Cellulose", then issuing testing report.

1.1.2. Make vertical contrast among 3 testing results, we can see from attached list 1 that there is no distinct change of each index about HPMC after placing under 60°C for 10 days. So we can conclude that the property of HPMC keeping stable under high temperature.

1.2. High humidity test

1.2.1. Testing procedure

1.2.1.1. Take one lot of HPMC (lot number: 20010702) and sampling. Make testing according to 'Chinese Pharmacopoeia' edition 2000, 2nd segment "Hydroxypropyl Methyl Cellulose" part, then issuing testing report.

1.2.1.2. Put the sample into Petri dish and spread out into folium less than 5mm, then place it into the environmental chamber with relative humidity of 90%±5% opening for 10 days.

1.2.1.3. Sampling separately on the 5th day and the 10th day, make testing according to 'Chinese Pharmacopoeia' edition 2000, 2nd segment "Hydroxypropyl Methyl Cellulose", then issuing testing report.

1.2.1.4. Make vertical contrast among 3 testing results, we can see from attached list 2 that moisture absorption loaded is more than 5%, so it needs to make another testing under the relative humidity of 75%±5%.

1.2.1.5. Sampling the product (lot number: 20010702), Put the sample into Petri dish and spread out into folium less than 5mm, then place it into the

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Tel: +86-533-6281218

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environmental chamber with relative humidity of $75\% \pm 5\%$ opening for 10 days.

1.2.1.6. Still sampling separately on the 5th day and the 10th day, make testing according to 'Chinese Pharmacopoeia' edition 2000, 2nd segment "Hydroxypropyl Methyl Cellulose", then issuing testing report.

1.1.1. Make vertical contrast among 3 testing results under the relative humidity of $75\% \pm 5\%$ (see attached list 3), we can conclude that:

HPMC can be seriously effected by the factor of humidity, it can easily absorb moisture. Although it doesn't decompose or deteriorate and in general its component content is not be influenced after absorbing moisture, it occurs agglomeration and affect using. So this product should be paid attention to pressuring, dampproofing and flashing.

2. Accelerated test:

2.1. Testing procedure

2.1.1. Take 3 lots of HPMC (lot number: 20010702, 20010703, 20010704) and sampling separately. Make testing according to 'Chinese Pharmacopoeia' edition 2000, 2nd segment "Hydroxypropyl Methyl Cellulose" part, then issuing testing report.

2.1.2. Put this 3 lots of products with marketing package in the finished goods warehouse for 6 months. Keeping the temperature at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and relative humidity $75\% \pm 5\%$. Sampling at the end of 1st month, 2nd month, 3rd month and 6th month during the period of testing, make testing according to 'Chinese Pharmacopoeia' edition 2000, 2nd segment "Hydroxypropyl Methyl Cellulose" part, then issuing testing report respectively.

2.1.3. Make vertical contrast among 5 testing results of this 3 lots, we can see from the check list of testing results (attached list 4, 5 and 6) that each index as well as physical and chemical speciality just like properties, content, etc. are stable and changing a little during the accelerated test of 6 month long.

3. Long-term test

3.1. Testing procedure

3.1.1. Prepare 3 lots of HPMC (lot number: 20010101, 20010102, 20010103) and sampling separately. Sampling and make testing according to 'Chinese Pharmacopoeia' edition 2000, 2nd segment "Hydroxypropyl Methyl Cellulose" part, then issuing testing report.

3.1.2. Put this 3 lots of products with marketing package in the finished goods warehouse for 12 months. Keeping the temperature at $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and relative humidity $60\% \pm 10\%$. Sampling every 3 month, that is sampling in the 3rd month, 6th month, 9th month and 12th month. Make testing according to 'Chinese Pharmacopoeia' edition 2000, 2nd segment "Hydroxypropyl Methyl Cellulose" part, then issuing testing report respectively.

3.1.3. Preserving this 3 lots samples, it still requires sampling for test in the 18th month, 24th month and 36th month during the period of experiment. And

then make comparative analysis against the previous testing data.

3.1.4. Make vertical contrast among 5 testing results of 3 lots samples, we can see from the attached list 7,8 and 9 that each index and character just like properties,content,etc. are stable and changing a little during the long-term test.

Conclusion

It proves that the property of this product is stable enough and not easily occur decomposing and deteriorating through the above experiment. When stored normally with marketing package,it can be preserved for long time and doesn't effect its using,so we temporarily make the validity period of this product 3 years.

Test Report

Product No.: 20010702

No.: 20010702

Product	HPMC	From	Chemical Plant
Lot No.	20010702	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-07-04
Expiry Date		Report Date	2001-07-05
Purpose	Stability Analysis	Remark	Original

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	5.08
Viscosity (Pa·S)	0.005-0.075	0.053
Insoluble Impurity (%)	≤0.5	0.09
Loss on Drying (%)	≤5.0	2.20

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Residue on Ignition (%)	≤1.5	0.32
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.58
Hydroxypropoxy (%)	4.0-12.0	7.98
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010707

No.: 20010707

Product	HPMC	From	Chemical Plant
Lot No.	20010702	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-07-09
Expiry Date		Report Date	2001-07-10
Purpose	Stability Analysis	Remark	High tem.test—5 days

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	5.11

Viscosity (Pa·S)	0.005-0.075	0.051
Insoluble Impurity (%)	≤0.5	0.09
Loss on Drying (%)	≤5.0	2.26
Residue on Ignition (%)	≤1.5	0.32
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.49
Hydroxypropoxy (%)	4.0-12.0	8.02
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010715

No.: 20010715

Product	HPMC	From	Chemical Plant
Lot No.	20010702	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-07-14
Expiry Date		Report Date	2001-07-15
Purpose	Stability Analysis	Remark	High tem.test—10 days

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction

(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	5.10
Viscosity (Pa·S)	0.005-0.075	0.051
Insoluble Impurity (%)	≤0.5	0.10
Loss on Drying (%)	≤5.0	2.28
Residue on Ignition (%)	≤1.5	0.32
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.51
Hydroxypropoxy (%)	4.0-12.0	8.01
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010724

No.: 20010724

Product	HPMC	From	Chemical Plant
Lot No.	20010702	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-07-20
Expiry Date		Report Date	2001-07-21
Purpose	Stability Analysis	Remark	High tem. test ⁽¹⁾ — 5 days

Test Item	Criterion	Test Result
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[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	5.10
Viscosity (Pa·S)	0.005-0.075	0.052
Insoluble Impurity (%)	≤0.5	0.10
Loss on Drying (%)	≤5.0	6.41
Residue on Ignition (%)	≤1.5	0.32
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.61
Hydroxypropoxy (%)	4.0-12.0	7.93
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010730

No.: 20010730

Product	HPMC	From	Chemical Plant
Lot No.	20010702	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-07-25
Expiry Date		Report Date	2001-07-26

Purpose	Stability Analysis	Remark	High tem. test ⁽¹⁾ – 10 days
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Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	5.11
Viscosity (Pa·S)	0.005-0.075	0.053
Insoluble Impurity (%)	≤0.5	0.10
Loss on Drying (%)	≤5.0	8.05
Residue on Ignition (%)	≤1.5	0.32
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.54
Hydroxypropoxy (%)	4.0-12.0	7.99
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010801

No.: 20010801

Product	HPMC	From	Chemical Plant
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Email:sales@kimachemical.com

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Lot No.	20010702	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-07-31
Expiry Date		Report Date	2001-08-01
Purpose	Stability Analysis	Remark	High tem. test ⁽²⁾ – 5 days

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	5.08
Viscosity (Pa·S)	0.005-0.075	0.051
Insoluble Impurity (%)	≤0.5	0.10
Loss on Drying (%)	≤5.0	4.33
Residue on Ignition (%)	≤1.5	0.31
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.53
Hydroxypropoxy (%)	4.0-12.0	8.01
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010807

No.: 20010807

Product	HPMC	From	Chemical Plant
Lot No.	20010702	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-08-05
Expiry Date		Report Date	2001-08-06
Purpose	Stability Analysis	Remark	High hum.test(2) — 10 days

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	5.10
Viscosity (Pa·S)	0.005-0.075	0.051
Insoluble Impurity (%)	≤0.5	0.09
Loss on Drying (%)	≤5.0	5.86
Residue on Ignition (%)	≤1.5	0.32
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.54
Hydroxypropoxy (%)	4.0-12.0	7.99
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000

Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010803

No.: 20010803

Product	HPMC	From	Chemical Plant
Lot No.	20010702	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-08-04
Expiry Date		Report Date	2001-08-05
Purpose	Stability Analysis	Remark	Accelerate test — end Jan.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	5.08
Viscosity (Pa·S)	0.005-0.075	0.052
Insoluble Impurity (%)	≤0.5	0.11
Loss on Drying (%)	≤5.0	2.21
Residue on Ignition (%)	≤1.5	0.32
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.58

Hydroxypropoxy (%)	4.0-12.0	7.98
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010902

No.: 20010902

Product	HPMC	From	Chemical Plant
Lot No.	20010702	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-09-04
Expiry Date		Report Date	2001-09-05
Purpose	Stability Analysis	Remark	Accelerate test — end Feb.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	5.10
Viscosity (Pa·S)	0.005-0.075	0.052
Insoluble Impurity (%)	≤0.5	0.10
Loss on Drying (%)	≤5.0	2.21
Residue on Ignition (%)	≤1.5	0.30
Heavy Metal (PPM)	≤20	<20

Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.65
Hydroxypropoxy (%)	4.0-12.0	7.91
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20011003

No.: 20011003

Product	HPMC	From	Chemical Plant
Lot No.	20010702	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-10-04
Expiry Date		Report Date	2001-10-05
Purpose	Stability Analysis	Remark	Accelerate test — end Mar.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	5.10
Viscosity (Pa·S)	0.005-0.075	0.050
Insoluble Impurity (%)	≤0.5	0.09

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Loss on Drying (%)	≤5.0	2.25
Residue on Ignition (%)	≤1.5	0.32
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.51
Hydroxypropoxy (%)	4.0-12.0	8.01
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20020104

No.: 20020104

Product	HPMC	From	Chemical Plant
Lot No.	20010702	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2002-01-04
Expiry Date		Report Date	2002-01-05
Purpose	Stability Analysis	Remark	Accelerate test — end Jun.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		

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PH Value	4.0-8.0	5.12
Viscosity (Pa·S)	0.005-0.075	0.051
Insoluble Impurity (%)	≤0.5	0.10
Loss on Drying (%)	≤5.0	2.26
Residue on Ignition (%)	≤1.5	0.32
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.56
Hydroxypropoxy (%)	4.0-12.0	7.97
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010704

No.: 20010704

Product	HPMC	From	Chemical Plant
Lot No.	20010703	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-07-04
Expiry Date		Report Date	2001-07-05
Purpose	Stability Analysis	Remark	Accelerate test — Original

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		

(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	6.19
Viscosity (Pa·S)	0.005-0.075	0.048
Insoluble Impurity (%)	≤0.5	0.10
Loss on Drying (%)	≤5.0	2.95
Residue on Ignition (%)	≤1.5	0.41
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.30
Hydroxypropoxy (%)	4.0-12.0	8.03
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010804

No.: 20010804

Product	HPMC	From	Chemical Plant
Lot No.	20010703	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-08-04
Expiry Date		Report Date	2001-08-05
Purpose	Stability Analysis	Remark	Accelerate test — end Jan.

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Tel: +86-533-6281218

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Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	6.15
Viscosity (Pa·S)	0.005-0.075	0.046
Insoluble Impurity (%)	≤0.5	0.11
Loss on Drying (%)	≤5.0	2.97
Residue on Ignition (%)	≤1.5	0.41
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.33
Hydroxypropoxy (%)	4.0-12.0	8.01
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010903

No.: 20010903

Product	HPMC	From	Chemical Plant
Lot No.	20010703	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-09-04

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Tel: +86-533-6281218

Email:sales@kimachemical.com

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Expiry Date		Report Date	2001-09-05
Purpose	Stability Analysis	Remark	Accelerate test — end Feb.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspect]		
PH Value	4.0-8.0	6.16
Viscosity (Pa·S)	0.005-0.075	0.048
Insoluble Impurity (%)	≤0.5	0.11
Loss on Drying (%)	≤5.0	2.97
Residue on Ignition (%)	≤1.5	0.40
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.37
Hydroxypropoxy (%)	4.0-12.0	7.99
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20011004

No.: 20011004

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Add:Zhangdian,Zibo, Shandong, P.R.China

Tel: +86-533-6281218

Email:sales@kimachemical.com

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Product	HPMC	From	Chemical Plant
Lot No.	20010703	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-10-04
Expiry Date		Report Date	2001-10-05
Purpose	Stability Analysis	Remark	Accelerate test — end Mar.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	6.20
Viscosity (Pa·S)	0.005-0.075	0.045
Insoluble Impurity (%)	≤0.5	0.10
Loss on Drying (%)	≤5.0	2.96
Residue on Ignition (%)	≤1.5	0.41
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.41
Hydroxypropoxy (%)	4.0-12.0	7.99
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20020105

No.: 20020105

Product	HPMC	From	Chemical Plant
Lot No.	20010703	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2002-01-04
Expiry Date		Report Date	2002-01-05
Purpose	Stability Analysis	Remark	Accelerate test — end Jun.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	6.20
Viscosity (Pa·S)	0.005-0.075	0.045
Insoluble Impurity (%)	≤0.5	0.10
Loss on Drying (%)	≤5.0	3.01
Residue on Ignition (%)	≤1.5	0.40
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.35
Hydroxypropoxy (%)	4.0-12.0	8.00
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000

Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010705

No.: 20010705

Product	HPMC	From	Chemical Plant
Lot No.	20010704	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-07-04
Expiry Date		Report Date	2002-07-06
Purpose	Stability Analysis	Remark	Accelerate test — Original

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	5.90
Viscosity (Pa·S)	0.005-0.075	0.054
Insoluble Impurity (%)	≤0.5	0.12
Loss on Drying (%)	≤5.0	2.65
Residue on Ignition (%)	≤1.5	0.51
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.57

Hydroxypropoxy (%)	4.0-12.0	7.84
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010805

No.: 20010805

Product	HPMC	From	Chemical Plant
Lot No.	20010704	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-08-04
Expiry Date		Report Date	2001-08-06
Purpose	Stability Analysis	Remark	Accelerate test — end Jan.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	5.87
Viscosity (Pa·S)	0.005-0.075	0.052
Insoluble Impurity (%)	≤0.5	0.11
Loss on Drying (%)	≤5.0	2.68
Residue on Ignition (%)	≤1.5	0.50
Heavy Metal (PPM)	≤20	<20

Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.62
Hydroxypropoxy (%)	4.0-12.0	7.80
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010904

No.: 20010904

Product	HPMC	From	Chemical Plant
Lot No.	20010704	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-09-04
Expiry Date		Report Date	2001-09-06
Purpose	Stability Analysis	Remark	Accelerate test — end Feb.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	5.92
Viscosity (Pa·S)	0.005-0.075	0.054
Insoluble Impurity (%)	≤0.5	0.12

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Loss on Drying (%)	≤5.0	2.69
Residue on Ignition (%)	≤1.5	0.50
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.56
Hydroxypropoxy (%)	4.0-12.0	7.83
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20011005

No.: 20011005

Product	HPMC	From	Chemical Plant
Lot No.	20010704	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-10-04
Expiry Date		Report Date	2001-10-06
Purpose	Stability Analysis	Remark	Accelerate test — end Mar.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		

PH Value	4.0-8.0	5.92
Viscosity (Pa·S)	0.005-0.075	0.054
Insoluble Impurity (%)	≤0.5	0.12
Loss on Drying (%)	≤5.0	2.68
Residue on Ignition (%)	≤1.5	0.51
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.65
Hydroxypropoxy (%)	4.0-12.0	7.78
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20020106

No.: 20020106

Product	HPMC	From	Chemical Plant
Lot No.	20010704	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2002-01-04
Expiry Date		Report Date	2002-01-06
Purpose	Stability Analysis	Remark	Accelerate test — end Jun.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		

(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	5.92
Viscosity (Pa·S)	0.005-0.075	0.051
Insoluble Impurity (%)	≤0.5	0.11
Loss on Drying (%)	≤5.0	2.70
Residue on Ignition (%)	≤1.5	0.50
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.60
Hydroxypropoxy (%)	4.0-12.0	7.80
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010103

No.: 20010103

Product	HPMC	From	Chemical Plant
Lot No.	20010101	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-01-05
Expiry Date		Report Date	2001-01-07
Purpose	Stability Analysis	Remark	Long-term test — Original

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Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	6.45
Viscosity (Pa·S)	0.005-0.075	0.048
Insoluble Impurity (%)	≤0.5	0.09
Loss on Drying (%)	≤5.0	3.54
Residue on Ignition (%)	≤1.5	0.46
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	27.63
Hydroxypropoxy (%)	4.0-12.0	7.84
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010402

No.: 20010402

Product	HPMC	From	Chemical Plant
Lot No.	20010101	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-04-05

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Expiry Date		Report Date	2001-04-07
Purpose	Stability Analysis	Remark	Long-term test—Mar.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	6.47
Viscosity (Pa·S)	0.005-0.075	0.045
Insoluble Impurity (%)	≤0.5	0.10
Loss on Drying (%)	≤5.0	3.58
Residue on Ignition (%)	≤1.5	0.46
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	27.70
Hydroxypropoxy (%)	4.0-12.0	7.80
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010704

No.: 20010704

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Product	HPMC	From	Chemical Plant
Lot No.	20010101	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-07-05
Expiry Date		Report Date	2001-07-06
Purpose	Stability Analysis	Remark	Long-term test – Jun.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	6.46
Viscosity (Pa·S)	0.005-0.075	0.046
Insoluble Impurity (%)	≤0.5	0.10
Loss on Drying (%)	≤5.0	3.59
Residue on Ignition (%)	≤1.5	0.45
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	27.61
Hydroxypropoxy (%)	4.0-12.0	7.86
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20011006

No.: 20011006

Product	HPMC	From	Chemical Plant
Lot No.	20010101	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-10-05
Expiry Date		Report Date	2001-10-06
Purpose	Stability Analysis	Remark	Long-term test — Sep.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	6.48
Viscosity (Pa·S)	0.005-0.075	0.045
Insoluble Impurity (%)	≤0.5	0.09
Loss on Drying (%)	≤5.0	3.58
Residue on Ignition (%)	≤1.5	0.45
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	27.72
Hydroxypropoxy (%)	4.0-12.0	7.77
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000

Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20020106

No.: 20020106

Product	HPMC	From	Chemical Plant
Lot No.	20010101	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2002-01-05
Expiry Date		Report Date	2002-01-06
Purpose	Stability Analysis	Remark	Long-term test—Dec.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	6.48
Viscosity (Pa·S)	0.005-0.075	0.046
Insoluble Impurity (%)	≤0.5	0.10
Loss on Drying (%)	≤5.0	3.58
Residue on Ignition (%)	≤1.5	0.45
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	27.67

Hydroxypropoxy (%)	4.0-12.0	7.76
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010104

No.: 20010104

Product	HPMC	From	Chemical Plant
Lot No.	20010102	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-01-05
Expiry Date		Report Date	2001-01-07
Purpose	Stability Analysis	Remark	Long-term test—Origin

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	5.80
Viscosity (Pa·S)	0.005-0.075	0.033
Insoluble Impurity (%)	≤0.5	0.10
Loss on Drying (%)	≤5.0	3.67
Residue on Ignition (%)	≤1.5	0.47
Heavy Metal (PPM)	≤20	<20

Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	27.63
Hydroxypropoxy (%)	4.0-12.0	8.09
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010403

No.: 20010403

Product	HPMC	From	Chemical Plant
Lot No.	20010102	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-04-05
Expiry Date		Report Date	2001-04-07
Purpose	Stability Analysis	Remark	Long-term test—Mar.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	5.83
Viscosity (Pa·S)	0.005-0.075	0.032
Insoluble Impurity (%)	≤0.5	0.09

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Loss on Drying (%)	≤5.0	3.71
Residue on Ignition (%)	≤1.5	0.45
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	27.68
Hydroxypropoxy (%)	4.0-12.0	8.03
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010705

No.: 20010705

Product	HPMC	From	Chemical Plant
Lot No.	20010102	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-07-05
Expiry Date		Report Date	2001-07-06
Purpose	Stability Analysis	Remark	Long-term test—Jun.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		

PH Value	4.0-8.0	5.81
Viscosity (Pa·S)	0.005-0.075	0.032
Insoluble Impurity (%)	≤0.5	0.11
Loss on Drying (%)	≤5.0	3.69
Residue on Ignition (%)	≤1.5	0.45
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	27.65
Hydroxypropoxy (%)	4.0-12.0	8.12
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20011007

No.: 20011007

Product	HPMC	From	Chemical Plant
Lot No.	20010102	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-10-05
Expiry Date		Report Date	2001-10-06
Purpose	Stability Analysis	Remark	Long-term test—Sep.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		

(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	5.83
Viscosity (Pa·S)	0.005-0.075	0.031
Insoluble Impurity (%)	≤0.5	0.11
Loss on Drying (%)	≤5.0	3.70
Residue on Ignition (%)	≤1.5	0.45
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	27.59
Hydroxypropoxy (%)	4.0-12.0	8.08
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20020107

No.: 20020107

Product	HPMC	From	Chemical Plant
Lot No.	20010102	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2002-01-05
Expiry Date		Report Date	2002-01-06
Purpose	Stability Analysis	Remark	Long-term test—Dec.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	5.84
Viscosity (Pa·S)	0.005-0.075	0.032
Insoluble Impurity (%)	≤0.5	0.10
Loss on Drying (%)	≤5.0	3.68
Residue on Ignition (%)	≤1.5	0.46
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	27.65
Hydroxypropoxy (%)	4.0-12.0	8.06
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010105

No.: 20010105

Product	HPMC	From	Chemical Plant
Lot No.	20010103	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-01-05

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Expiry Date		Report Date	2001-01-08
Purpose	Stability Analysis	Remark	Long-term test — Original

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	6.28
Viscosity (Pa·S)	0.005-0.075	0.041
Insoluble Impurity (%)	≤0.5	0.10
Loss on Drying (%)	≤5.0	2.35
Residue on Ignition (%)	≤1.5	0.39
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	27.93
Hydroxypropoxy (%)	4.0-12.0	7.68
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010404

No.: 20010404

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Product	HPMC	From	Chemical Plant
Lot No.	20010103	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-04-05
Expiry Date		Report Date	2001-04-08
Purpose	Stability Analysis	Remark	Long-term test—Mar.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	6.28
Viscosity (Pa·S)	0.005-0.075	0.040
Insoluble Impurity (%)	≤0.5	0.10
Loss on Drying (%)	≤5.0	2.38
Residue on Ignition (%)	≤1.5	0.38
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	27.96
Hydroxypropoxy (%)	4.0-12.0	7.66
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20010706

No.: 20010706

Product	HPMC	From	Chemical Plant
Lot No.	20010103	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-07-05
Expiry Date		Report Date	2001-07-07
Purpose	Stability Analysis	Remark	Long-term test – Jun.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	6.26
Viscosity (Pa·S)	0.005-0.075	0.042
Insoluble Impurity (%)	≤0.5	0.09
Loss on Drying (%)	≤5.0	2.39
Residue on Ignition (%)	≤1.5	0.38
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	27.89
Hydroxypropoxy (%)	4.0-12.0	7.71
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000

Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20011008

No.: 20011008

Product	HPMC	From	Chemical Plant
Lot No.	20010103	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2001-10-05
Expiry Date		Report Date	2001-10-07
Purpose	Stability Analysis	Remark	Long-term test—Sep.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	6.25
Viscosity (Pa·S)	0.005-0.075	0.042
Insoluble Impurity (%)	≤0.5	0.10
Loss on Drying (%)	≤5.0	2.38
Residue on Ignition (%)	≤1.5	0.39
Heavy Metal (PPM)	≤20	<20
Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	27.96

Hydroxypropoxy (%)	4.0-12.0	7.68
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	

Test Report

Product No.: 20020108

No.: 20020108

Product	HPMC	From	Chemical Plant
Lot No.	20010103	Package	Plastic sample bag
Specification	20kg/bag	Test Date	2002-01-05
Expiry Date		Report Date	2002-01-07
Purpose	Stability Analysis	Remark	Long-term test—Dec.

Test Item	Criterion	Test Result
[Appearance]	White to slightly off-white powder	White Powder
[Identification]		
(1) Physical Reaction		Positive Reaction
(2) Physical Reaction		Positive Reaction
[Inspection]		
PH Value	4.0-8.0	6.29
Viscosity (Pa·S)	0.005-0.075	0.040
Insoluble Impurity (%)	≤0.5	0.10
Loss on Drying (%)	≤5.0	2.40
Residue on Ignition (%)	≤1.5	0.36
Heavy Metal (PPM)	≤20	<20

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Arsenic (PPM)	≤2	<2
[Content]		
Methoxy (%)	19.0-30.0	28.93
Hydroxypropoxy (%)	4.0-12.0	7.69
[Sanitary Inspection]		
Bacteria (/g)	<1000	<1000
Mold (/g)	<100	<100
Bacterium Coli	Absent	Absent
Conclusion:	Conform	