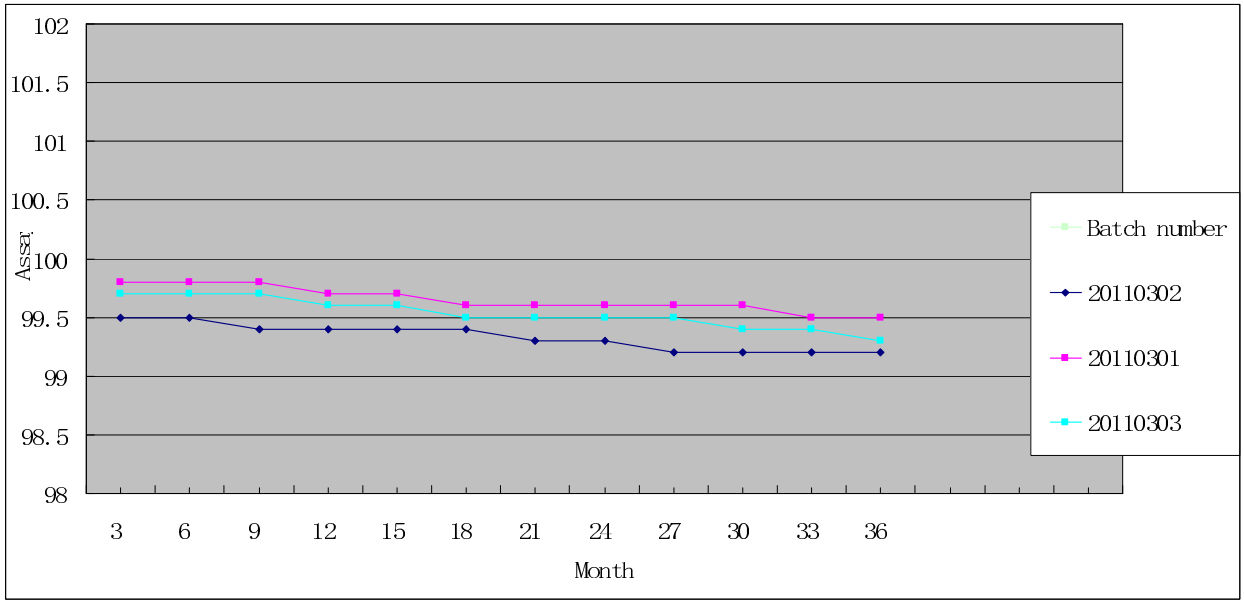
Stability Data

Results of tests

Results are given below for a series of samples from long term stability conditions up to 2 years duration. A graph of the HPLC results is also provided which shows that Glucosamine sulfate 2kcl is stable over a 2 year period.



Long term, accelerated, high-temperature, high- humidity and photostability testing

Stability data on long term accelerated , high-temperature, high-humidity and photostability, testing are provided in the following tables.

Product Code:	GLK003	**Stability Protocol Reference:**	SS-GLK003-01
Product Name:	Glucosamine sulfate 2kcl	**Date Manufactured:**	01/03/2011
Batch No:	20110301	**Date Stability Study Commenced:**	20/03/2011
Batch Type:	Production	**Storage Conditions:**	40°C/75%RH
Packaging Material:	Polyethylene bags in cardboard drums	**Testing Frequency:**	0, 3, and 6Months

Test	Specifications	Initial	3M	6M
Physical parameters				
Appearance	White or almost white crystalline powder	Complies	Complies	Complies
pH (2% Solution,25℃)	3.0-5.0	4.1	3.6	3.6
Specific Optical Rotation $[\alpha]_D^{20}$	+50° to+52°	51.3	51.2	51.1
Water (KF)	NMT1.0%	0.3	0.36	0.39
Chemical parameters				
D-Glucosamine Sulfate 2KCl	98.0-102.0 % (odb)	99.8	99.5	99.4
Total impurities	NMT 0.3%	Negative	Negative	Negative
Individual Impurities	NMT 0.1%	Negative	Negative	Negative
Sulfate	15.5-16.5%	16.1	16.3	16.3
Microbiological parameters				
Total Aerobic	NMT 1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g
E. coli	Negative in 1g	Negative	Negative	Negative
Salmonella	Negative in 10g	Negative	Negative	Negative
Staphylococcus aureus	Negative in 1g	Negative	Negative	Negative
Pseudonmonas aeruginosa	Negative in 1g	Negative	Negative	Negative

Product Name:	Glucosamine sulfate 2kcl	**Date Manufactured:**	06/03/2011
Batch No:	20110302	**Date Stability Study Commenced:**	20/03/2011
Batch Type:	Production	**Storage Conditions:**	40°C/75%RH
Packaging Material:	Polyethylene bags in cardboard drums	**Testing Frequency:**	0, 3, and 6Months

Test	Specifications	Initial	3M	6M
Physical parameters				
Appearance	White or almost white crystalline powder	Complies	Complies	Complies
pH (2% Solution,25℃)	3.0-5.0	4.5	3.6	3.6
Specific Optical Rotation $[\alpha]_D^{20}$	+50° to+52°	51.4	51.2	51.1
Water (KF)	NMT1.0%	0.2	0.26	0.29
Chemical parameters				
D-Glucosamine Sulfate 2KCl	98.0-102.0 % (odb)	99.5	99.5	99.4
Total impurities	NMT 0.3%	Negative	Negative	Negative
Individual Impurities	NMT 0.1%	Negative	Negative	Negative
Sulfate	15.5-16.5%	16.2	16.3	16.3
Microbiological parameters				
Total Aerobic	NMT 1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g
E. coli	Negative in 1g	Negative	Negative	Negative
Salmonella	Negative in 10g	Negative	Negative	Negative
Staphylococcus aureus	Negative in 1g	Negative	Negative	Negative
Pseudonmonas aeruginosa	Negative in 1g	Negative	Negative	Negative

Product Code:	GLK003	**Stability Protocol Reference:**	SS-GLK003-01
Product Name:	Glucosamine sulfate 2kcl	**Date Manufactured:**	11/03/2011
Batch No:	20110303	**Date Stability Study Commenced:**	20/03/2011
Batch Type:	Production	**Storage Conditions:**	40°C/75%RH
Packaging Material:	Polyethylene bags in cardboard drums	**Testing Frequency:**	0, 3, and 6Months

Test	Specifications	Initial	3M	6M
Physical parameters				
Appearance	White or almost white crystalline powder	Complies	Complies	Complies
pH (2% Solution,25℃)	3.0-5.0	4.4	3.6	3.6
Specific Optical Rotation $[\alpha]_D^{20}$	+50° to+52°	51.1	51.2	51.1
Water (KF)	NMT1.0%	0.2	0.23	0.23
Chemical parameters				
D-Glucosamine Sulfate 2KCl	98.0-102.0 % (odb)	99.7	99.5	99.4
Total impurities	NMT 0.3%	Negative	Negative	Negative
Individual Impurities	NMT 0.1%	Negative	Negative	Negative
Sulfate	15.5-16.5%	16.2	16.3	16.3
Microbiological parameters				
Total Aerobic	NMT 1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g
E. coli	Negative in 1g	Negative	Negative	Negative
Salmonella	Negative in 10g	Negative	Negative	Negative
Staphylococcus aureus	Negative in 1g	Negative	Negative	Negative
Pseudonmonas aeruginosa	Negative in 1g	Negative	Negative	Negative

Batch No: 20110301
Batch Type: Production
Packaging Material: Polyethylene bags in cardboard drums

Date Stability Study Commenced: 11/03/2011
Storage Conditions: 25°C/60%RH
Testing Frequency: 0, 3, 9,12,18,24 and 36 Months

Test	Specifications	Initial	3M	6M	9M	12M	18M	21M	24M	27M	30M	33M	36M
Physical parameters													
Appearance	White or almost white crystalline powder	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
pH (2% Solution,25℃)	3.0-5.0	4.1	3.6	3.6	3.6	3.5	3.6	3.5	3.5	3.4	3.5	3.6	3.5
Specific Optical Rotation $[\alpha]_D^{20}$	+50° to+52°	51.3	51.2	51.1	51	51	51.1	51	51	51.1	51.2	51.1	51
Water (KF)	NMT1.0%	0.3	0.3	0.4	0.4	0.4	0.4	0.4	0.3	0.3	0.4	0.4	0.4
Chemical parameters													
D-Glucosamine Sulfate 2KCl	98.0-102.0 % (odb)	99.8	99.8	99.8	99.7	99.7	99.6	99.6	99.6	99.6	99.6	99.5	99.5
Total impurities	NMT 0.3%	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Individual Impurities	NMT 0.1%	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Sulfate	15.5-16.5%	16.1	16.1	16.1	16.2	16.2	16.2	16.3	16.3	16.3	16.3	16.3	16.3
Microbiological parameters													
Total Aerobic	NMT 1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g
E. coli	Negative in 1g	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Salmonella	Negative in 10g	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Staphylococcus aureus	Negative in 1g	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Pseudonmonas aeruginosa	Negative in 1g	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative

Batch No: 20110302
Batch Type: Production
Packaging Material: Polyethylene bags in cardboard drums

Date Stability Study Commenced: 11/03/2011
Storage Conditions: 25°C/60%RH
Testing Frequency: 0, 3, 9,12,18,24 and 36 Months

Test	Specifications	Initial	3M	6M	9M	12M	18M	21M	24M	27M	30M	33M	36M
Physical parameters													
Appearance	White or almost white crystalline powder	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
pH (2% Solution,25℃)	3.0-5.0	4.5	4.6	4.6	4.6	4.5	4.6	4.5	4.5	4.4	4.5	4.6	4.5
Specific Optical Rotation $[\alpha]_D^{20}$	+50° to+52°	51.4	51.4	51.4	51.3	51.3	51.3	51.3	51.2	51.2	51.2	51.1	51.1
Water (KF)	NMT1.0%	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3	0.3	0.3
Chemical parameters													
D-Glucosamine Sulfate 2KCl	98.0-102.0 % (odb)	99.5	99.5	99.4	99.4	99.4	99.4	99.3	99.3	99.2	99.2	99.2	99.2
Total impurities	NMT 0.3%	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Individual Impurities	NMT 0.1%	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Sulfate	15.5-16.5%	16.2	16.2	16.2	16.3	16.3	16.3	16.3	16.3	16.3	16.3	16.4	16.4
Microbiological parameters													
Total Aerobic	NMT 1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g
E. coli	Negative in 1g	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Salmonella	Negative in 10g	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Staphylococcus aureus	Negative in 1g	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Pseudonmonas aeruginosa	Negative in 1g	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative

Batch No: 20110303
Batch Type: Production
Packaging Material: Polyethylene bags in cardboard drums

Date Stability Study Commenced: 11/03/2011
Storage Conditions: 25°C/60%RH
Testing Frequency: 0, 3, 9,12,18,24 and 36 Months

Test	Specifications	Initial	3M	6M	9M	12M	18M	21M	24M	27M	30M	33M	36M
Physical parameters													
Appearance	White or almost white crystalline powder	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
pH (2% Solution,25℃)	3.0-5.0	4.4	4.4	4.4	4.4	4.3	4.3	4.4	4.4	4.3	4.4	4.3	4.4
Specific Optical Rotation $[\alpha]_D^{20}$	+50° to+52°	51.1	51.2	51.1	51	51	51.1	51	51	51.1	51.2	51.1	51
Water (KF)	NMT1.0%	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3	0.3	0.3	0.4	0.4
Chemical parameters													
D-Glucosamine Sulfate 2KCl	98.0-102.0 % (odb)	99.7	99.7	99.7	99.6	99.6	99.5	99.5	99.5	99.5	99.4	99.4	99.3
Total impurities	NMT 0.3%	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Individual Impurities	NMT 0.1%	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Sulfate	15.5-16.5%	16.2	16.2	16.2	16.3	16.3	16.3	16.3	16.3	16.3	16.3	16.4	16.4
Microbiological parameters													
Total Aerobic	NMT 1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g	<1000 cfu/g
E. coli	Negative in 1g	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Salmonella	Negative in 10g	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Staphylococcus aureus	Negative in 1g	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Pseudonmonas aeruginosa	Negative in 1g	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative

High-temperature Stability Test (60°C),Batch No. 20110301

Characteristic/Test	Specification	Time Points (days)		
		0	5	10
Appearance	White or almost white crystalline powder	Complies	Complies	Complies
pH (2% Solution,25℃)	3.0-5.0	4.1	4.2	4.2
Specific Optical Rotation $[\alpha]_D^{20}$	+50° to+52°	51.3	51.2	51.2
Water (KF)	NMT1.0%	0.3	0.3	0.3
D-Glucosamine Sulfate 2KCl	98.0-102.0 % (odb)	99.8	99.7	99.7
Total impurities	NMT 0.3%	Negative	Negative	Negative
Individual Impurities	NMT 0.1%	Negative	Negative	Negative
Sulfate	15.5-16.5%	16.1	16.2	16.2

High- humidity Stability (25 ± 2 °C / 90% ± 5% RH), Batch No. 20110301

Characteristic/Test	Specification	Time Points (days)		
		0	5	10
Appearance	White or almost white crystalline powder	Complies	Complies	Complies
pH (2% Solution,25℃)	3.0-5.0	4.1	4.1	4.1
Specific Optical Rotation $[\alpha]_D^{20}$	+50° to+52°	51.3	51.2	51.1
Water (KF)	NMT1.0%	0.3	0.4	0.4
D-Glucosamine Sulfate 2KCl	98.0-102.0 % (odb)	99.8	99.8	99.8
Total impurities	NMT 0.3%	Negative	Negative	Negative
Individual Impurities	NMT 0.1%	Negative	Negative	Negative
Sulfate	15.5-16.5%	16.1	16.2	16.3

Photostability Stability (UV 320-400 nm, 1.2 Mio lux hours), Batch No. 20110301

Characteristic/Test	Specification	Time Points (days)		
		0	**5**	**10**
Appearance	White or almost white crystalline powder	Complies	Complies	Complies
pH (2% Solution,25℃)	3.0-5.0	4.1	4.1	4.0
Specific Optical Rotation $[\alpha]_D^{20}$	+50° to+52°	51.3	51.2	51.2
Water (KF)	NMT1.0%	0.3	0.3	0.4
D-Glucosamine Sulfate 2KCl	98.0-102.0 % (odb)	99.8	99.8	99.7
Total impurities	NMT 0.3%	Negative	Negative	Negative
Individual Impurities	NMT 0.1%	Negative	Negative	Negative
Sulfate	15.5-16.5%	16.1	16.1	16.2