Stability Summary

Product group: Biopharma

Brand name: BioHale® Sucrose

Product description: Sucrose low endotoxin grade

Dear Customer,

1. Stability Statement

DFE Pharma has defined a shelf life for all its products based on a stability testing program conforming to IPEC Excipient Stability Program Guide 2026.
DFE Pharma guarantees that its products comply with all specifications up until the end of their shelf-life period (the retest date), when stored in the original unopened packaging. For BioHale® Sucrose the established shelf life is 48 months.
There is no special controlled storage condition required. Our recommendation is to store the product in its original unopened pack at room temperature (normal warehouse conditions) and allowing temporary excursions from these conditions. This recommendation is supported by our stability studies under controlled ICH conditions covering both physical/chemical and microbiological attributes.
Our experience of many years as supplier of excipients to customers all over the world including humid and hot regions confirms that our products are stable during storage and transport.

2. Materials and Methods

DFE-Pharma conducts a stability program conforming IPEC Excipients Stability Program Guide for supporting the stability of its products. Three batches of BioHale® Sucrose, produced in The Netherlands, have been stability tested under ICH long term and accelerated conditions (Table 1). As these represent the initial three batches for DFE-Pharma an extended stability program was implemented. The batches are considered representative of all Sucrose batches manufactured at this site and packaged in drums.

Table 1: Overview of batches BioHale® Sucrose (small packs)

Batch	Prod. date	Stability start	Duration of data (months) at		
			25/60	30/65	40/75
2103008.2075	Mar 21	Mar 21	48	48	6
2103009.2075	Mar 21	Mar 21	48	48	6
2103011.2075	Mar 21	Mar 21	48	48	6

3. Packaging and storage

The stability batches were enclosed in low-density polyethylene (LDPE) bags, each containing approximately 100 g of Sucrose. The bags were subsequently packed into a 300 ml high-density

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polyethylene (HDPE) drum, which shares the same material composition and wall thickness as commercial drums (available in 50 kg, 20 kg or 1 kg size), thereby representative for these packs.

The closed drums were stored under controlled conditions at 25°C/60%RH (25/60), 30°C/65%RH (30/65) and 40°C/75%RH (40/75).

At each scheduled time point the batches were analyzed for selected tests from the product specification using the specified analytical methods. The selected tests are those deemed relevant to potential chemical, functional and microbiological product acceptability.

4. Results and Discussion

Results of the stability tests for sucrose are shown in Addendum 1 - 6.
The overall results show that all pharmacopeial parameters stay within the limits during the shelf-life of 48 months, when our recommended storage conditions are followed.

The 48 months data of the three conditions show that all Sucrose tests are within specification for all conditions, with the exception of an unexpected endotoxin failure at 48 months at 25/60.
No root cause was found, a reserve sample of 48 months at 25/60 also failed to meet the specification. All other tested timepoints and microbiological results are passing, including 48 months at 30/65 and 6 months at 40/75.
During the studies at 30/65 and 40/75, Sucrose is exposed to more stressful conditions (higher temperature and higher relative humidity) compared to the study at 25/60. The hypothesis is that the root cause is related to the worst-case scenario of small packages and/or laboratory proceedings, which increases the risk of contamination. With all other microbiological tests passing, endotoxin level will not increase. This anomaly is considered an incident, particularly as the pack at the intermediate temperature (30/65) meet the requirements for all timepoints, as well as the microbiological tests. Sucrose has a low moisture content and is stored in a highly protective drum, mitigating the risk of water uptake and microbial growth.

All tests that are stability indicating (clarity of solution, color value, loss on drying, assay and impurities) are all compliant under all conditions at all time points. There are also no trends visible in the test results of these parameters, which shows that the product is stable for a minimum of 48 months.

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5. Conclusion

The available stability data support a shelf-life of 48 months for BioHale® Sucrose.

Retest Date

The expiry date as documented on the product and the corresponding Certificate of Analysis is generated as follows:

Retest date = (Production date mm.yyyy) + (shelf life in months).

This document substitutes all previous versions issued for the brand names mentioned above.

We trust this information which is made up to the best of our knowledge will be helpful to you.

With kindest regards,

Name : MAJ Nijman
Job title : Global Quality Director
Signature :

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Stability Summary

Product group: Biopharma

Brand name: BioHale® Sucrose

Product description: Sucrose low endotoxin grade

Addendum 1: Stability Data Sucrose batch 2103008.2075 at 25/60

Product:	Biohale® Sucrose		Batch:		2103008.2075			Packaging:		Small pack (100g)		
Article Code:	1178771		Production date:		Mar-2021			Start stability study:		Mar-2021		
		months at 25°C/60%RH										
Test	Specfication	0	1	2	3	6	9	12	18	24	36	48
Identfication (IR)	complies	pass	--	--	--	--	--	--	--	--	--	pass
Identfication Cupric tartrate	complies	pass	--	--	--	--	--	--	--	--	--	pass
Clarity of solution	clear	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass
Color value	max 10	<1	4	3	3	3	3	3	4	2	4	3
Color value (ChP)	≤ Y4	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass
Conductivity	max 5 µs/cm	1	--	--	--	--	--	--	--	--	--	1
Specfiic optical rotation	66,3 - 67,0	66,6	--	--	--	--	--	--	--	--	--	66,5
Dextrins	complies	pass	--	--	--	--	--	--	--	--	--	pass
Reducing sugars	complies	pass	--	--	--	--	--	--	--	--	--	pass
Suflites	max 10 ppm	pass	--	--	--	--	--	--	--	--	--	pass
Suflate	max 60 ppm	pass	--	--	--	--	--	--	--	--	--	pass
Residue on ignition	max 0,05%	0,00	--	--	--	--	--	--	--	--	--	<0,01
Calcium	max 0,03%	pass	--	--	--	--	--	--	--	--	--	pass
Heavy metals	max 5 ppm	pass	--	--	--	--	--	--	--	--	--	pass
Loss on drying	max 0,1%	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1
Individual known impurity	max 0,2%	<0,1%	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	0,1	<0,1	<0,1
Unknown impurities	max 0,1%	<0,1%	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1
Total impurities	max 2,0%	<0,1%	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	0,1	0,1	<0,1
Residual solvents Methanol	max 300 ppm	132	--	--	--	--	--	--	--	--	--	121
Residual solvents Acetone	max 900 ppm	443	--	--	--	--	--	--	--	--	--	304
Assay	98,0-102,0%	99,8	99,8	99,7	100,1	100,1	100,1	99,9	99,4	99,3	100,0	99,4
Bacterial endotoxins	max 0,25 EU/g	pass	pass	pass	pass	--	--	--	--	--	--	pass
TAMC	max 10 CFU/g	<10	--	--	--	--	--	<10	--	<10	<10	<10
TYMC	max 10 CFU/g	<10	--	--	--	--	--	<10	--	<10	<10	<10
Staphylococcus aureus	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative
Salmonella	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative
E. coli	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative
Pseudomonas Aeruginosa	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative

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Stability Summary

Product group: Biopharma

Brand name: BioHale® Sucrose

Product description: Sucrose low endotoxin grade

Addendum 2: Stability Data Sucrose batch 2103008.2075 at 30/65 and 40/75

Product:	Biohale® Sucrose			Batch:		2103008.2075			Packaging:			Small pack (ca 100g in ldpe bag in drum 300ml)				
Article Code:	1178771			Production date:		Mar-2021			Start stability study:			Mar-2021				
		months at 30°C/65%RH											months at 40°C/75%RH			
Test	Specfiication	0	1	2	3	6	9	12	18	24	36	48	1	2	3	6
Identfiication (IR)	complies	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Identfiication Cupric tartrate	complies	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Clarity of solution	clear	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass
Color value	max 10	<1	3	3	4	3	3	4	4	3	4	4	4	4	4	3
Color value (ChP)	≤ Y4	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass
Conductivity	max 5 µs/cm	1	--	--	--	--	--	--	--	--	--	1	--	--	1	1
Specfiic optical rotation	66,3 - 67,0	66,6	--	--	--	--	--	--	--	--	--	66,4	--	--	66,4	66,3
Dextrins	complies	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Reducing sugars	complies	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Suflites	max 10 ppm	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Suflate	max 60 ppm	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Residue on ignition	max 0,05%	0,00	--	--	--	--	--	--	--	--	--	<0,01	--	--	0,01	0,00
Calcium	max 0,03%	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Heavy metals	max 5 ppm	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Loss on drying	max 0,1%	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,0	0,1	0,1	0,1	0,1
Individual known impurity	max 0,2%	<0,1%	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1
Unknown impurities	max 0,1%	<0,1%	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1
Total impurities	max 2,0%	<0,1%	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	0,2	0,1	<0,1	<0,1	<0,1	<0,1	<0,1
Residual solvents Methanol	max 300 ppm	132	--	--	--	--	--	--	--	--	--	127	--	--	117	111
Residual solvents Acetone	max 900 ppm	443	--	--	--	--	--	--	--	--	--	278	--	--	281	261
Assay	98,0-102,0%	99,8	99,4	99,8	100,1	99,3	99,1	99,9	100,2	99,2	100,2	99,8	99,9	100,3	99,9	100,7
Bacterial endotoxins	max 0,25 EU/g	pass	pass	pass	pass	--	--	--	--	--	--	pass	pass	pass	pass	pass
TAMC	max 10 CFU/g	<10	--	--	--	--	--	<10	--	<10	<10	<10	--	--	<10	<10
TYMC	max 10 CFU/g	<10	--	--	--	--	--	<10	--	<10	<10	<10	--	--	<10	<10
Staphylococcus aureus	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative	--	--	negative	negative
Salmonella	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative	--	--	negative	negative
E. coli	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative	--	--	negative	negative
Pseudomonas Aeruginosa	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative	--	--	negative	negative

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Stability Summary

Product group: Biopharma

Brand name: BioHale® Sucrose

Product description: Sucrose low endotoxin grade

Addendum 3: Stability Data Sucrose batch 2103009.2075 at 25/60

Product:	Biohale® Sucrose		Batch:		2103009.2075			Packaging:		Small pack (100g)		
Article Code:	1178771		Production date:		Mar-2021			Start stability study:		Mar-2021		
		months at 25°C/60%RH										
Test	Specfication	0	1	2	3	6	9	12	18	24	36	48
Identfication (IR)	complies	pass	--	--	--	--	--	--	--	--	--	pass
Identfication Cupric tartrate	complies	pass	--	--	--	--	--	--	--	--	--	pass
Clarity of solution	clear	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass
Color value	max 10	1	4	4	4	3	3	4	4	2	4	3
Color value (ChP)	≤ Y4	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass
Conductivity	max 5 µs/cm	1	--	--	--	--	--	--	--	--	--	1
Specfic optical rotation	66,3 - 67,0	66,7	--	--	--	--	--	--	--	--	--	66,6
Dextrins	complies	pass	--	--	--	--	--	--	--	--	--	pass
Reducing sugars	complies	pass	--	--	--	--	--	--	--	--	--	pass
Suflites	max 10 ppm	pass	--	--	--	--	--	--	--	--	--	pass
Suflate	max 60 ppm	pass	--	--	--	--	--	--	--	--	--	pass
Residue on ignition	max 0,05%	0,00	--	--	--	--	--	--	--	--	--	<0,01
Calcium	max 0,03%	pass	--	--	--	--	--	--	--	--	--	pass
Heavy metals	max 5 ppm	pass	--	--	--	--	--	--	--	--	--	pass
Loss on drying	max 0,1%	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1
Individual known impurity	max 0,2%	<0,1%	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1
Unknown impurities	max 0,1%	<0,1%	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	0,1	<0,1	<0,1
Total impurities	max 2,0%	<0,1%	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	0,2	0,1	<0,1
Residual solvents Methanol	max 300 ppm	145	--	--	--	--	--	--	--	--	--	140
Residual solvents Acetone	max 900 ppm	554	--	--	--	--	--	--	--	--	--	344
Assay	98,0-102,0%	99,6	99,8	99,5	99,8	100,4	98,5	99,9	98,2	99,2	99,5	99,8
Bacterial endotoxins	max 0,25 EU/g	pass	pass	pass	pass	--	--	--	--	--	--	pass
TAMC	max 10 CFU/g	<10	--	--	--	--	--	<10	--	<10	<10	<10
TYMC	max 10 CFU/g	<10	--	--	--	--	--	<10	--	<10	<10	<10
Staphylococcus aureus	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative
Salmonella	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative
E. coli	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative
Pseudomonas Aeruginosa	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative

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Stability Summary

Product group: Biopharma

Brand name: BioHale® Sucrose

Product description: Sucrose low endotoxin grade

Addendum 4: Stability Data Sucrose batch 2103009.2075 at 30/65 and 40/75

Product:	Biohale® Sucrose			Batch:		2103009.2075			Packaging:			Small pack (ca 100g in ldpe bag in drum 300ml)				
Article Code:	1178771			Production date:		Mar-2021			Start stability study:			Mar-2021				
		months at 30°C/65%RH											months at 40°C/75%RH			
Test	Specfiication	0	1	2	3	6	9	12	18	24	36	48	1	2	3	6
Identfiication (IR)	complies	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Identfiication Cupric tartrate	complies	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Clarity of solution	clear	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass
Color value	max 10	1	4	4	4	3	3	4	4	3	4	4	4	4	4	3
Color value (ChP)	≤ Y4	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass
Conductivity	max 5 µs/cm	1	--	--	--	--	--	--	--	--	--	1	--	--	1	1
Specfiic optical rotation	66,3 - 67,0	66,7	--	--	--	--	--	--	--	--	--	66,5	--	--	66,5	66,6
Dextrins	complies	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Reducing sugars	complies	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Suflites	max 10 ppm	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Suflate	max 60 ppm	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Residue on ignition	max 0,05%	0,00	--	--	--	--	--	--	--	--	--	<0,01	--	--	0,00	0,00
Calcium	max 0,03%	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Heavy metals	max 5 ppm	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Loss on drying	max 0,1%	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1
Individual known impurity	max 0,2%	<0,1%	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1
Unknown impurities	max 0,1%	<0,1%	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1
Total impurities	max 2,0%	<0,1%	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	0,2	0,1	<0,1	<0,1	<0,1	<0,1	<0,1
Residual solvents Methanol	max 300 ppm	145	--	--	--	--	--	--	--	--	--	152	--	--	140	123
Residual solvents Acetone	max 900 ppm	554	--	--	--	--	--	--	--	--	--	323	--	--	327	293
Assay	98,0-102,0%	99,6	99,5	99,6	99,8	99,6	99,7	99,8	99,6	99,3	100,8	99,8	99,8	100,3	99,7	100,2
Bacterial endotoxins	max 0,25 EU/g	pass	pass	pass	pass	--	--	--	--	--	--	pass	pass	pass	pass	pass
TAMC	max 10 CFU/g	<10	--	--	--	--	--	<10	--	<10	<10	<10	--	--	<10	<10
TYMC	max 10 CFU/g	<10	--	--	--	--	--	<10	--	<10	<10	<10	--	--	<10	<10
Staphylococcus aureus	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative	--	--	negative	negative
Salmonella	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative	--	--	negative	negative
E. coli	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative	--	--	negative	negative
Pseudomonas Aeruginosa	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative	--	--	negative	negative

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Stability Summary

Product group: Biopharma

Brand name: BioHale® Sucrose

Product description: Sucrose low endotoxin grade

Addendum 5: Stability Data Sucrose batch 2103011.2075 at 25/60

Product:	Biohale® Sucrose		Batch:		2103011.2075			Packaging:		Small pack (100g)		
Article Code:	1178771		Production date:		Mar-2021			Start stability study:		Mar-2021		
		months at 25°C/60%RH										
Test	Specfiication	0	1	2	3	6	9	12	18	24	36	48
Identfiication (IR)	complies	pass	--	--	--	--	--	--	--	--	--	pass
Identfiication Cupric tartrate	complies	pass	--	--	--	--	--	--	--	--	--	pass
Clarity of solution	clear	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass
Color value	max 10	1	4	4	4	3	3	4	4	3	4	4
Color value (ChP)	≤ Y4	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass
Conductivity	max 5 µs/cm	1	--	--	--	--	--	--	--	--	--	1
Specfiic optical rotation	66,3 - 67,0	66,6	--	--	--	--	--	--	--	--	--	66,6
Dextrins	complies	pass	--	--	--	--	--	--	--	--	--	pass
Reducing sugars	complies	pass	--	--	--	--	--	--	--	--	--	pass
Suflites	max 10 ppm	pass	--	--	--	--	--	--	--	--	--	pass
Suflate	max 60 ppm	pass	--	--	--	--	--	--	--	--	--	pass
Residue on ignition	max 0,05%	0,00	--	--	--	--	--	--	--	--	--	<0,01
Calcium	max 0,03%	pass	--	--	--	--	--	--	--	--	--	pass
Heavy metals	max 5 ppm	pass	--	--	--	--	--	--	--	--	--	pass
Loss on drying	max 0,1%	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1
Individual known impurity	max 0,2%	<0,1%	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	0,1	<0,1	<0,1
Unknown impurities	max 0,1%	<0,1%	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1
Total impurities	max 2,0%	<0,1%	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	0,1	0,1	<0,1
Residual solvents Methanol	max 300 ppm	151	--	--	--	--	--	--	--	--	--	137
Residual solvents Acetone	max 900 ppm	543	--	--	--	--	--	--	--	--	--	337
Assay	98,0-102,0%	99,6	99,8	100,2	100,5	98,5	100,0	99,7	99,7	101,3	99,4	99,5
Bacterial endotoxins	max 0,25 EU/g	pass	pass	pass	pass	--	--	--	--	--	--	fail
TAMC	max 10 CFU/g	<10	--	--	--	--	--	<10	--	<10	<10	<10
TYMC	max 10 CFU/g	<10	--	--	--	--	--	<10	--	<10	<10	<10
Staphylococcus aureus	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative
Salmonella	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative
E. coli	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative
Pseudomonas Aeruginosa	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative

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Stability Summary

Product group: Biopharma

Brand name: BioHale® Sucrose

Product description: Sucrose low endotoxin grade

Addendum 6: Stability Data Sucrose batch 2103011.2075 at 30/65 and 40/75

Product:	Biohale® Sucrose				Batch:	2103011.2075			Packaging:			Small pack (ca 100g in ldpe bag in drum 300ml)				
Article Code:	1178771				Production date:	Mar-2021			Start stability study:			Mar-2021				
		months at 30°C/65%RH											months at 40°C/75%RH			
Test	Specfication	0	1	2	3	6	9	12	18	24	36	48	1	2	3	6
Identfication (IR)	complies	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Identfication Cupric tartrate	complies	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Clarity of solution	clear	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass
Color value	max 10	1	4	4	4	3	4	4	4	3	4	4	4	4	4	3
Color value (ChP)	≤ Y4	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass
Conductivity	max 5 µs/cm	1	--	--	--	--	--	--	--	--	--	1	--	--	1	1
Specfic optical rotation	66,3 - 67,0	66,6	--	--	--	--	--	--	--	--	--	66,6	--	--	66,5	66,7
Dextrins	complies	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Reducing sugars	complies	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Suflites	max 10 ppm	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Suflate	max 60 ppm	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Residue on ignition	max 0,05%	0,00	--	--	--	--	--	--	--	--	--	<0,01	--	--	0,00	0,00
Calcium	max 0,03%	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Heavy metals	max 5 ppm	pass	--	--	--	--	--	--	--	--	--	pass	--	--	pass	pass
Loss on drying	max 0,1%	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1
Individual known impurity	max 0,2%	<0,1%	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1
Unknown impurities	max 0,1%	<0,1%	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1
Total impurities	max 2,0%	<0,1%	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	<0,1	0,1	0,1	<0,1	<0,1	<0,1	<0,1	<0,1
Residual solvents Methanol	max 300 ppm	151	--	--	--	--	--	--	--	--	--	148	--	--	129	130
Residual solvents Acetone	max 900 ppm	543	--	--	--	--	--	--	--	--	--	315	--	--	307	292
Assay	98,0-102,0%	99,6	99,2	99,1	99,6	99,1	98,5	100,0	98,7	99,7	100,1	99,8	99,7	100,1	99,9	99,6
Bacterial endotoxins	max 0,25 EU/g	pass	pass	pass	pass	--	--	--	--	--	--	pass	pass	pass	pass	pass
TAMC	max 10 CFU/g	<10	--	--	--	--	--	<10	--	<10	<10	<10	--	--	<10	<10
TYMC	max 10 CFU/g	<10	--	--	--	--	--	<10	--	<10	<10	<10	--	--	<10	<10
Staphylococcus aureus	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative	--	--	negative	negative
Salmonella	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative	--	--	negative	negative
E. coli	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative	--	--	negative	negative
Pseudomonas Aeruginosa	negative in 10g	negative	--	--	--	--	--	negative	--	negative	negative	negative	--	--	negative	negative

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