Stability Summary

Product group: Co-Processed MCC

Brand name: Pharmacel® sMCC 90 / sMCC 50

Product description: Silicified Microcrystalline Cellulose

Dear Customer,

1. Stability Statement

DFE Pharma has defined a retest date 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 pharmacopeial specifications up until the end of their retest date period, when stored in the original unopened packaging. For product group Pharmacel® sMCC the established retest date is four years.
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 and normal warehouse conditions covering physical/chemical and microbiological attributes.

Our experience of many years as supplier of Microcrystalline cellulose 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 to the IPEC Excipients Stability Program Guide for supporting the stability of its products. Batches of Pharmacel® sMCC 90 have been tested on stability and reviewed in this report (Table 2). DFE Pharma uses a bracketing and matrixing approach for supporting the stability of its products. Pharmacel® sMCC90 and sMCC50 differ only in particle size and bulk density. Therefore, stability data generated for one grade are considered representative and supportive of the stability of the other grade. The batches were manufactured at Chemfield Cellulosics PVt. Ltd.(CCPL) and produced exclusively for DFE Pharma in Nagpur, India and are representative for Pharmacel® sMCC made in this factory. The article codes are given in Table 1.

Table 1: Overview article codes in SAP and Navision of product group Pharmacel® sMCC

Pharmacel grade	Sap article code	Navision article code
sMCC 90	1177333	13127-5355
sMCC 50	1277998	13106-5355

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Table 2: Overview of batches Pharmacel® sMCC 90 (small pack)

Pharmacel grade	Batch	Prod. date	Stability start	Duration of data (months) at	
				25°C/60%RH	40°C/75%RH
sMCC 90	CB20L1149	Dec-20	Dec-20	48	6
sMCC 90	CB20L1150	Dec-20	Dec-20	48	6
sMCC 90	CB20L1151	Dec-20	Dec-20	48	6

3. Packaging and storage

The batches were stored in downscaled commercial bags at 25°C/60% RH (25/60) during shelf life or for 6 months at 40°C/75% RH (40/75).

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

4. Results and discussion

Results of the stability tests for Pharmacel® sMCC 90 are shown in Addendum 1-3.

The results show that all pharmacopeial parameters stay within the limits during shelf-life, when our recommended storage conditions are followed.
The expected stability indicating parameter is Loss on Drying (LOD) as Silicified Microcrystalline Cellulose is hygroscopic and may gain or lose moisture over time. Consequently, gradual increases or decreases in moisture content can be anticipated, depending on storage conditions and packaging. LOD remained within specification for all batches at all time points and conditions, as did all other parameters.
Overall, the results demonstrated stable product quality throughout the study period.

5. Conclusion

The data are supportive of the retest date of 4 years assigned to Pharmacel® sMCC 90 and 50.

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

Retest date = (Production date) + (shelf life in months) – (one month)
Pharmacel® sMCC = (Production date) + 47 months

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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 : Peter Ebben
Job title : Global Quality Control Manager
Signature :

This document is controlled by a validated, electronic system and is valid without signature.
The above facsimile signature is only for display.

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Stability Summary

Product group: Co-Processed MCC

Brand name: Pharmacel® sMCC 90 / sMCC 50

Product description: Silicified Microcrystalline Cellulose

Addendum 1: Stability data Pharmacel® sMCC 90

Pharmacel sMCC90		**Batch:**		**CB20L1149**		**Production dat**		**Dec/2020**	
Packaging: Small scale packaging		**Article code:**		**1177333**		**Start study:**		**Dec/2020**	
		months at 25/60						**at 40/75**	
Test	**Specfiication**	**0**	**6**	**12**	**24**	**36**	**48**	**3**	**6**
Identfiication (A,B,C,C)	pass	pass	pass	pass	pass	pass	pass	pass	pass
Degree of polymerization	max 350	201	203	204	205	206	206	201	201
Solubility	pass	pass	pass	pass	pass	pass	pass	pass	pass
pH	5,0 - 7,0	6,2	6,2	6,3	6,3	6,2	6,2	6,2	6,2
Conductivity	max 75 µS/cm	28	29	29	31	31	30	29	29
Ether soluble substances	max 0,05%	0,02	0,02	0,02	0,02	0,02	0,02	0,02	0,02
Water soluble substance	max 0,24%	0,15	0,15	0,15	0,15	0,15	0,16	0,15	0,15
Heavy metals	max 10 ppm	pass	pass	pass	pass	pass	pass	pass	pass
Loss on drying	max 6,0%	3,4	3,7	3,9	4,1	4,1	3,6	3,5	3,6
Residue on ignition	max 1,8 - 2,2%	2,0	2,0	2,0	2,0	2,0	2,0	2,0	2,0
Particle size >75 µm	45,0 - 80,0 %	54	54	54	54	53	52	54	54
Particle size >250 µm	max 8%	0	0	0	0	0	0	0	0
Particle size d10 (Malvern)	20-50 µm	33	33	35	33	33	33	37	33
Particle size d50 (Malvern)	90-150 µm	110	111	111	110	108	109	119	111
Particle size d90 (Malvern)	190-300 µm	269	239	225	234	229	230	245	228
Bulk density	0,25 - 0,37 g/ml	0,32	0,32	0,32	0,32	0,32	0,31	0,32	0,32
Tapped density	0,37 - 0,50 g/ml	0,47	0,47	0,47	0,47	0,47	0,47	0,47	0,47
TAMC	max 100 cfu/g	<100	--	--	--	<100	<100	--	--
TYMC	max 20 cfu/g	<20	--	--	--	<20	<20	--	--
Escherichia coli	Negative in 10 g	neg	--	--	--	neg	neg	--	--
Staphylococcus aureus	Negative in 10 g	neg	--	--	--	neg	neg	--	--
Pseudomonas aeruginosa	Negative in 10 g	neg	--	--	--	neg	neg	--	--
Salmonella	Negative in 10 g	neg	--	--	--	neg	neg	--	--

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Stability Summary

Product group: Co-Processed MCC

Brand name: Pharmacel® sMCC 90 / sMCC 50

Product description: Silicified Microcrystalline Cellulose

Addendum 2: Stability data Pharmacel® sMCC 90

Pharmacel sMCC90		**Batch:**		**CB20L1150**		**Production dat**		**Dec/2020**	
Packaging: Small scale packaging		**Article code:**		**1177333**		**Start study:**		**Dec/2020**	
		months at 25/60						**at 40/75**	
Test	**Specfiication**	**0**	**6**	**12**	**24**	**36**	**48**	**3**	**6**
Identfiication (A,B,C,C)	pass	pass	pass	pass	pass	pass	pass	pass	pass
Degree of polymerization	max 350	200	201	202	204	205	205	201	201
Solubility	pass	pass	pass	pass	pass	pass	pass	pass	pass
pH	5,0 - 7,0	6,2	6,2	6,2	6,2	6,3	6,2	6,2	6,2
Conductivity	max 75 µS/cm	29	30	30	31	32	30	30	30
Ether soluble substances	max 0,05%	0,01	0,01	0,01	0,01	0,01	0,02	0,01	0,01
Water soluble substance	max 0,24%	0,16	0,16	0,16	0,16	0,15	0,18	0,16	0,16
Heavy metals	max 10 ppm	pass	pass	pass	pass	pass	pass	pass	pass
Loss on drying	max 6,0%	3,0	3,3	3,5	3,6	3,7	3,8	3,3	3,3
Residue on ignition	max 1,8 - 2,2%	2,1	2,1	2,1	2,1	2,1	2,0	2,1	2,1
Particle size >75 µm	45,0 - 80,0 %	55	55	55	55	54	56	55	55
Particle size >250 µm	max 8%	0	0	0	0	0	0	0	0
Particle size d10 (Malvern)	20-50 µm	32	30	33	34	31	33	34	31
Particle size d50 (Malvern)	90-150 µm	110	108	111	110	115	109	118	108
Particle size d90 (Malvern)	190-300 µm	271	226	228	235	232	230	245	231
Bulk density	0,25 - 0,37 g/ml	0,31	0,31	0,30	0,30	0,30	0,31	0,31	0,31
Tapped density	0,37 - 0,50 g/ml	0,45	0,45	0,45	0,45	0,45	0,44	0,45	0,45
TAMC	max 100 cfu/g	<100	--	--	--	<100	<100	--	--
TYMC	max 20 cfu/g	<20	--	--	--	<20	<20	--	--
Escherichia coli	Negative in 10 g	neg	--	--	--	neg	neg	--	--
Staphylococcus aureus	Negative in 10 g	neg	--	--	--	neg	neg	--	--
Pseudomonas aeruginosa	Negative in 10 g	neg	--	--	--	neg	neg	--	--
Salmonella	Negative in 10 g	neg	--	--	--	neg	neg	--	--

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Stability Summary

Product group: Co-Processed MCC

Brand name: Pharmacel® sMCC 90 / sMCC 50

Product description: Silicified Microcrystalline Cellulose

Addendum 3: Stability data Pharmacel® sMCC 90

Pharmacel sMCC90		**Batch:**		**CB20L1151**		**Production dat**		**Dec/2020**	
Packaging: Small scale packaging		**Article code:**		**1177333**		**Start study:**		**Dec/2020**	
		months at 25/60						**at 40/75**	
Test	**Specfiication**	**0**	**6**	**12**	**24**	**36**	**48**	**3**	**6**
Identfiication (A,B,C,C)	pass	pass	pass	pass	pass	pass	pass	pass	pass
Degree of polymerization	max 350	199	200	201	202	204	204	199	200
Solubility	pass	pass	pass	pass	pass	pass	pass	pass	pass
pH	5,0 - 7,0	6,2	6,3	6,2	6,2	6,2	6,3	6,3	6,3
Conductivity	max 75 µS/cm	28	29	30	31	31	32	29	30
Ether soluble substances	max 0,05%	0,01	0,01	0,01	0,01	0,01	0,02	0,01	0,01
Water soluble substance	max 0,24%	0,16	0,16	0,16	0,16	0,16	0,17	0,16	0,16
Heavy metals	max 10 ppm	pass	pass	pass	pass	pass	pass	pass	pass
Loss on drying	max 6,0%	2,9	3,0	3,1	3,4	3,4	3,6	3,0	3,1
Residue on ignition	max 1,8 - 2,2%	2,0	2,0	2,0	2,0	2,0	2,1	2,0	2,0
Particle size >75 µm	45,0 - 80,0 %	54	54	54	54	53	53	54	54
Particle size >250 µm	max 8%	0	0	0	0	0	0	0	0
Particle size d10 (Malvern)	20-50 µm	32	34	36	33	37	36	38	35
Particle size d50 (Malvern)	90-150 µm	109	112	118	109	112	113	122	117
Particle size d90 (Malvern)	190-300 µm	266	234	238	236	237	236	248	244
Bulk density	0,25 - 0,37 g/ml	0,30	0,30	0,30	0,30	0,30	0,30	0,30	0,30
Tapped density	0,37 - 0,50 g/ml	0,45	0,45	0,45	0,45	0,45	0,47	0,45	0,45
TAMC	max 100 cfu/g	<100	--	--	--	<100	<100	--	--
TYMC	max 20 cfu/g	<20	--	--	--	<20	<20	--	--
Escherichia coli	Negative in 10 g	neg	--	--	--	neg	neg	--	--
Staphylococcus aureus	Negative in 10 g	neg	--	--	--	neg	neg	--	--
Pseudomonas aeruginosa	Negative in 10 g	neg	--	--	--	neg	neg	--	--
Salmonella	Negative in 10 g	neg	--	--	--	neg	neg	--	--

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