Stability Summary

Product group: Co-Processed MCC

Brand name: Pharmacel® sMCC 90

Article code: SAP: 1177333, Navision: 13127-5355

Product descriptions: Silicified Microcrystalline Cellulose

Dear Customer,

1. Stability Statement

DFE Pharma has defined a shelf life for all of its products based on a stability testing program conforming to IPEC Excipient Stability Program Guide 2022.
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 Pharmacel® sMCC 90 the established shelf life is 48 months, based on ongoing stability studies.
There is no special controlled storage condition required. Our recommendation is to store the product in its original unopened pack at normal warehouse conditions. This recommendation is supported by our stability studies covering both 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 IPEC Excipients Stability Program Guide 2022 for supporting the stability of its products. Pharmacel® sMCC 90 batches were produced at Chemfield Cellulosics PVt. Ltd.(CCPL) and produced exclusively for DFE Pharma in Nagpur, India. The batches have been stability tested under ICH long term and accelerated conditions (Table 1) and are representative of Pharmacel® sMCC 90 batches made in this factory.

Table 1: Overview of batches Pharmacel® sMCC 90

Batch	Prod. date	Pack on stability	Stability start	Duration of data (months) at	
				25°C/60%RH	40°C/75%RH
CB20L1149	Dec-20	small	Dec-20	36	6
CB20L1150	Dec-20	small	Dec-20	36	6
CB20L1151	Dec-20	small	Dec-20	36	6

3. Packaging and storage

The batches were stored in downscaled commercial bags, consisting of 400g sample in single PE inner liner (80 micron) and outer bag (200µm). The packaged material was stored at 25°C/60%RH or 40°C/75%RH.
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

The data show that all tested parameters are within specification. The moisture content is the stability indicating parameter and remains well within specification for all tested batches.

Extrapolation of the moisture content show no risk for out of specifications up to at least 48 months. This approach is in compliance with IPEC stability guide and in line with the product knowledge and experience we have regarding the stability of other grades of Microcrystalline. This supports an extension of the retest data for Pharmacel® sMCC 90 to 48 months.

To exemplify the results the data of the batches Pharmacel® sMCC 90 are shown in the tables in the appendix.

5. Conclusion

For Pharmacel® sMCC 90, based on 36 months stability data and our knowledge of other grades of Microcrystalline Cellulose, the product shelf life is extended to 48 months.

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

Retest date = (Production date) + (retest date in months) – (one month)
Pharmacel® sMCC 90 = (Production date) + 47 months

The retest date in the ERP system and CoA has been adapted with the extended shelf life and will be printed on newly produced batches. It is not possible to adapt the retest/ expiry date printed on the CoA and packaging label of batches produced before this shelf life extension. Batches produced before the shelf life extension fulfill the product specification parameters till the revised shelf life and DFE Pharma confirms with this document that the customer can use batches produced prior to the shelf life extension until the extended shelf life of 48 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 : 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.

Stability Summary

Product group: Co-Processed MCC

Brand name: Pharmacel® sMCC 90

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Product descriptions: Silicified Microcrystalline Cellulose

Appendix: Stability data Pharmacel® sMCC 90

Product	Batch		Prod date		Start stab		Packaging				
sMCC 90	CB20L1149		Dec-20		Dec-20		small				
Article code: 1177333	1081HDB		months at 25°C/60%							40°C/75%rH	
Test	Specification	0	3	6	9	12	18	24	36	3	6
Identification (A,B,C,C)	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass
Degree of polymerization	max 350	201	202	203	203	204	204	205	206	201	201
Solubility	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass
pH	5,0 - 7,0	6,2	6,2	6,2	6,3	6,3	6,3	6,3	6,2	6,2	6,2
Conductivity	max 75 µS/cm	28	28	29	29	29	30	31	31	29	29
Ether soluble substances	max 0,05%	0,02	0,02	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	0,15	0,15	0,15	0,15	0,15
Heavy metals	max 10 ppm	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass
Loss on drying	max 6,0%	3,4	3,6	3,7	3,8	3,9	4,0	4,1	4,1	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	2,0	2,0
Particle size >75 µm	45,0 - 80,0 %	54	54	54	54	54	54	54	53	54	54
Particle size >250 µm	max 8%	0	0	0	0	0	0	0	0	0	0
Particle size d10 (Malvern)	20-50 µm	33	38	33	34	35	32	33	33	37	33
Particle size d50 (Malvern)	90-150 µm	110	121	111	110	111	106	110	108	119	111
Particle size d90 (Malvern)	190-300 µm	269	247	239	224	225	233	234	229	245	228
Bulk density	0,25 - 0,37 g/ml	0,32	0,32	0,32	0,32	0,32	0,32	0,32	0,32	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	0,47	0,47
TAMC	max 100 cfu/g	<100	--	--	--	--	--	--	<100	--	--
TYMC	max 20 cfu/g	<20	--	--	--	--	--	--	<20	--	--
Escherichia coli	Negative in 10 g	neg	--	--	--	--	--	--	neg	--	--
Staphylococcus aureus	Negative in 10 g	neg	--	--	--	--	--	--	neg	--	--
Pseudomonas aeruginosa	Negative in 10 g	neg	--	--	--	--	--	--	neg	--	--
Salmonella	Negative in 10 g	neg	--	--	--	--	--	--	neg	--	--

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Release date: 20-01-2025

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Product descriptions: Silicified Microcrystalline Cellulose

Appendix: Stability data Pharmacel® sMCC 90

Product	Batch		Prod date		Start stab		Packaging				
sMCC 90	CB20L1150		Dec-20		Dec-20		small				
Article code: 1177333	1081HB9		months at 25°C/60%							40°C/75%rH	
Test	Specification	0	3	6	9	12	18	24	36	3	6
Identification (A,B,C,C)	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass
Degree of polymerization	max 350	200	200	201	201	202	203	204	205	201	201
Solubility	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass
pH	5,0 - 7,0	6,2	6,2	6,2	6,3	6,2	6,3	6,2	6,3	6,2	6,2
Conductivity	max 75 µS/cm	29	30	30	30	30	31	31	32	30	30
Ether soluble substances	max 0,05%	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01
Water soluble substance	max 0,24%	0,16	0,16	0,16	0,16	0,16	0,16	0,16	0,15	0,16	0,16
Heavy metals	max 10 ppm	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass
Loss on drying	max 6,0%	3,0	3,2	3,3	3,4	3,5	3,6	3,6	3,7	3,3	3,3
Residue on ignition	max 1,8 - 2,2%	2,1	2,1	2,1	2,1	2,1	2,1	2,1	2,1	2,1	2,1
Particle size >75 µm	45,0 - 80,0 %	55	55	55	55	55	55	55	54	55	55
Particle size >250 µm	max 8%	0	0	0	0	0	0	0	0	0	0
Particle size d10 (Malvern)	20-50 µm	32	36	30	33	33	32	34	31	34	31
Particle size d50 (Malvern)	90-150 µm	110	119	108	112	111	109	110	115	118	108
Particle size d90 (Malvern)	190-300 µm	271	246	226	229	228	236	235	232	245	231
Bulk density	0,25 - 0,37 g/ml	0,31	0,31	0,31	0,31	0,30	0,30	0,30	0,30	0,31	0,31
Tapped density	0,37 - 0,50 g/ml	0,45	0,45	0,45	0,45	0,45	0,45	0,45	0,45	0,45	0,45
TAMC	max 100 cfu/g	<100	--	--	--	--	--	--	<100	--	--
TYMC	max 20 cfu/g	<20	--	--	--	--	--	--	<20	--	--
Escherichia coli	Negative in 10 g	neg	--	--	--	--	--	--	neg	--	--
Staphylococcus aureus	Negative in 10 g	neg	--	--	--	--	--	--	neg	--	--
Pseudomonas aeruginosa	Negative in 10 g	neg	--	--	--	--	--	--	neg	--	--
Salmonella	Negative in 10 g	neg	--	--	--	--	--	--	neg	--	--

Stability Summary

Appendix: Stability data Pharmacel® sMCC 90

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Product descriptions: Silicified Microcrystalline Cellulose

Product	Batch		Prod date		Start stab		Packaging				
sMCC 90	CB20L1151		Dec-20		Dec-20		small				
Article code: 1177333	1081HCR		months at 25°C/60%							40°C/75%rH	
Test	Specification	0	3	6	9	12	18	24	36	3	6
Identification (A,B,C,C)	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass
Degree of polymerization	max 350	199	199	200	200	201	202	202	204	199	200
Solubility	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass
pH	5,0 - 7,0	6,2	6,3	6,3	6,3	6,2	6,2	6,2	6,2	6,3	6,3
Conductivity	max 75 µS/cm	28	29	29	29	30	31	31	31	29	30
Ether soluble substances	max 0,05%	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01
Water soluble substance	max 0,24%	0,16	0,16	0,16	0,16	0,16	0,16	0,16	0,16	0,16	0,16
Heavy metals	max 10 ppm	pass	pass	pass	pass	pass	pass	pass	pass	pass	pass
Loss on drying	max 6,0%	2,9	3,0	3,0	3,0	3,1	3,3	3,4	3,4	3,0	3,1
Residue on ignition	max 1,8 - 2,2%	2,0	2,0	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	54	54	54	53	54	54
Particle size >250 µm	max 8%	0	0	0	0	0	0	0	0	0	0
Particle size d10 (Malvern)	20-50 µm	32	38	34	37	36	32	33	37	38	35
Particle size d50 (Malvern)	90-150 µm	109	121	112	117	118	108	109	112	122	117
Particle size d90 (Malvern)	190-300 µm	266	246	234	237	238	237	236	237	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	0,30	0,30
Tapped density	0,37 - 0,50 g/ml	0,45	0,45	0,45	0,45	0,45	0,45	0,45	0,45	0,45	0,45
TAMC	max 100 cfu/g	<100	--	--	--	--	--	--	<100	--	--
TYMC	max 20 cfu/g	<20	--	--	--	--	--	--	<20	--	--
Escherichia coli	Negative in 10 g	neg	--	--	--	--	--	--	neg	--	--
Staphylococcus aureus	Negative in 10 g	neg	--	--	--	--	--	--	neg	--	--
Pseudomonas aeruginosa	Negative in 10 g	neg	--	--	--	--	--	--	neg	--	--
Salmonella	Negative in 10 g	neg	--	--	--	--	--	--	neg	--	--