

(Officer-Production)

Prepared by : *Sumanth Laddom*
Checked by : *Karthick P. Duleek*Prepared by : *Sumanth Laddom*
Checked by : *Karthick P. Duleek*

Lot No.	Drum No.	Batch No	Time		Gross Wt.	Qty of PDMs charged into reactor	Drum after charging	Drum after PDMs	Actual Trace PDMs	Wt. of PDMs charged	Wt. of PDMs charged into reactor	(A.)	(B) = (C)	(D)	(E)	(D-E)	PDMs Loss	Drained PDMs (C-D)
			Start	End														
A-05 814	2105636T	11:46	-	221.170	198.786	22.390	21.380	21.170	0.210	0.210	1.016							
A-06 814	2105636T		-	221.810	182.520	22.970	22.020	21.810	0.260	0.260	0.960							
A-07 814	2106643T	12:20	-	221.710	198.760	22.950	22.140	21.710	0.430	0.430	0.810							
A-08 814	2106643T		-	221.360	182.520	22.940	21.920	21.920	-	-	-							
A-09 814	2105636T, 2106643T	15:31	-	85.950	63.980	22.020	-	21.52	0.320	0.320	0.500							
A-10 814	2105636T		-	72.370	50.380	22.390	21.58	21.190	0.390	0.390	0.810							
C-11 814	2105812T		-	131.660	110.010	21.650	21.300	21.230	0.090	0.090	0.350							
C-12 814	2105812T		-	221.130	190.660	-	-	-	-	-	-							
A-13 814	2106643T		-	15:47	221.320	135.690	86.030	86.030	9.440	9.440	-							
																	Total Oil	





RioCare India Private Limited
Plot No. R-940, TTC Industrial Area, MIDC Rabale, Navi Mumbai – 400 701, Maharashtra, INDIA

No. :

RAW DATA SHEET OF BATCH MANUFACTURING RECORD FOR SIMETHICONE-100%

Batch No. : RFLX21/814

Grade : IP

Viscosity : 2000 cps

Commenced on : 29/10/2021

Manufacturing Date : 30/10/2021

Retest date : 29/10/2021

Process to be followed for each lot :

1. Charge Polydimethylsiloxane in reactor. Start heating the reactor and start stirring.
2. Once the temp is between 100 – 120°C, start the inline mixer and charge 16 kg Colloidal Silicon dioxide in reactor for each lot simultaneously and increase stirring speed.
3. When temperature reaches 180 – 190°C, stop heating the reactor. Stop stirrer and transfer the reaction mass to homogenizing tank no. – PR/BT/003
4. Homogenize the product, generated from 4 lots for 45- 60 minutes and check for the viscosity.
5. Homogenize the final product, generated from 5 lots for 45- 60 minutes. Cool it to less than 80°C.

Lot No.	Drum No	Batch No	Time		Gross Wt. (A.)	Qty of PDMS charged into reactor (A-C) = (B)	Wt. of Drum after charging (C)	Wt. of Empty Drum after draining PDMS (D)	Actual Tare Wt. of Drum. (E)	PDMS Loss (D-E)	Drained PDMS (C-D)
			Start	End							
1	A-01/814	2105636T	09:35	—	221.870	198.770	23.100	22.160	21.870	0.290	0.940
	A-02/814	2105636T	—	221.150	Removed 16kg	initial - 21.470 final - 37.670	—	—	—	—	—
			—	09:51	204.700	182.270	22.430	21.500	21.150	0.350	0.930
						381.040					
2	A-03/814	2105636T	09:52	—	221.880	198.680	23.200	22.050	21.880	0.170	1.150
	A-04/814	2105636T	—	221.200	Removed 16kg	initial - 37.670 final - 53.620	—	—	—	—	—
			—	10:07	205.470	183.080	22.390	21.370	21.200	0.170	1.020
						381.760					

ANNEXURE-V

No. : 485

DETAILS OF SAMPLING QUANTITY OF FINISHED PRODUCT

From	: Quality Control	To	: Production
Sampling date	: 30/10/2021		
Product Name	: Sime Hiccon e		
Batch No.	: RFLX 21 819		
		Viscosity	: 2000 - 2500 cSt

Details of Sample quantity taken by QC Department:

S.No.	Details of sampling quantity	Quantity(Kg)
1	Regular analysis sample	0.200 Kg
2	Validation sample	-
3	Stability sample	-
4	Working standard sample	-
5	Total quantity	0.200 Kg

Signature/ Date : 30/10/2021 (Vaishali B.) Praveen (30/10/2021)
 (Officer- Quality Control) (Officer- Production)

RioCare India Private Limited
Plot No. 10, Sector 15, MIDC, Rabale, Navi Mumbai – 400070, Maharashtra, INDIA

No. : 484

ANNEXURE-II

PACKING MATERIAL ISSUAL SLIP

Stores

BatchNo. : RFDX21 / 814

To : Production

S. No.	Packing Material Name	Capacity (Kg)	Quantity (No.)	AR No./Date
1	HDPE drum (100) Win White Inner and Black Outer side.	50	40	HOPE Win/81 038 - 20 10 2021.
2.	Sample bottle	0.050	01	—

Signature/ Date

(Manager- Stores)

ANNEXURE-I

RAW MATERIAL ISSUAL SLIP

From : Stores

To: Production

Batch No. : RF24 21/814

Date : 28/10/2021.

Signature/ Date

Marvin G
2811 Oldham
(Manager - Stores)

Somorjai János

Somorjai, János

RioCare India Private Limited
R-940, TTC Industrial Area, MIDC Rabale, Navi Mumbai

Mumbai - 400070, Maharashtra, INDIA

No. : 484

ANNEXURE-II

PACKING MATERIAL REQUISITION SHEET

Production From : **From**

BatchNo. : RFLX21 / 814

To : Stores

Date : 23/10/2021

S. No.	Packing Material Name	Capacity (Kg.)	Quantity (No)
1.	HDPE drum (nm) with inner white cap and Outer Black lids	50	50
2.	Sample bottle	0.050	01

Signature/ Date :

(Officer-Production)

(Manager- Stores)

Franklin 28/10/1941

28/01/2011
Samurkaf

RioCare India Private Limited

RioCare India Private Limited
240, TTC Industrial Area, MIDC Rabale, Navi Mumbai - 400701, Maharashtra, INDIA

No. :482

ANNEXURE-I

RAW MATERIAL REQUISITION SLIP

From : Production

To : Stores

BatchNo. : RFLX21/814

Date : 28/10/2021

Signature/ Date :

(Officer-Production)

Somarlfodam.

(Manager- Stores)

Part No : PR/FS/001
Act Name : Simeethicone IP-100%
Batch No. : RFLX21/814
Date : 30/Oct/2021
JTE

Drum No.	Time	Gross WT.	Net WT.
1	14:53:12	68.90 kg	50.05 kg
2	14:55:37	68.90 kg	50.05 kg
3	14:57:54	68.90 kg	50.05 kg
4	15:00:08	68.90 kg	50.05 kg
5	15:02:24	68.90 kg	50.05 kg
6	15:04:40	68.90 kg	50.05 kg
7	15:06:56	68.90 kg	50.05 kg
8	15:09:15	68.90 kg	50.05 kg
9	15:11:33	68.90 kg	50.05 kg
10	15:13:50	68.90 kg	50.05 kg
11	15:16:07	68.90 kg	50.05 kg
12	15:18:26	68.90 kg	50.05 kg
13	15:20:44	68.90 kg	50.05 kg
14	15:23:01	68.90 kg	50.05 kg
15	15:25:26	68.90 kg	50.05 kg
16	15:27:47	68.90 kg	50.05 kg
17	15:30:11	68.90 kg	50.05 kg
18	15:32:33	68.90 kg	50.05 kg
19	15:34:53	68.90 kg	50.05 kg
20	15:36:09	68.90 kg	50.05 kg
21	15:38:26	68.90 kg	50.05 kg
22	15:40:44	68.90 kg	50.05 kg
23	15:43:04	68.90 kg	50.05 kg
24	15:45:25	68.90 kg	50.05 kg
25	15:47:42	68.90 kg	50.05 kg
26	15:49:59	68.90 kg	50.05 kg
27	15:51:18	68.90 kg	50.05 kg
28	15:53:36	68.90 kg	50.05 kg
29	15:55:53	68.90 kg	50.05 kg
30	15:58:11	68.90 kg	50.05 kg
31	16:00:34	68.90 kg	50.05 kg
32	16:02:55	68.90 kg	50.05 kg
33	16:04:12	68.90 kg	50.05 kg
34	16:06:29	68.90 kg	50.05 kg
35	16:08:46	68.90 kg	50.05 kg
36	16:11:00	68.90 kg	50.05 kg
37	16:12:17	68.90 kg	50.05 kg
38	16:15:31	68.90 kg	50.05 kg
39	16:17:46	68.90 kg	50.05 kg
40	16:20:04	68.90 kg	50.05 kg

Total Net weight : 2002.00kg

Remark : Filling done successfully

Done By : *Pratik Rathod*

Date : *30/10/2021* / *30/10/2021*

Checked By : *Suraj*
Date : *30/10/2021*

RioCare India Private Limited

Plot R-940, TTC Industrial Area, MIDC Rabale, Navi Mumbai - 400 701, Maharashtra, INDIA.

Batch Manufacturing Record

Product Name: Simethicone (Flix-110)
Batch No. : RFLX 21/814

BMR No. : RCIPL/BMR/Flx-2300/10
Ref. MFR No.: RCIPL/MFR/01/01

PRODUCT LABEL

SIMETHICONE IP - 100%
(Activated Dimethylcone)
FILIX-110

BATCH NO. : RFLX 21/814
MFG DATE : 30/OCT/2021
RETEST DATE : 29/OCT/2025

NET WT. : 50 Kg
TARE WT. : 2.5 Kg

Drug Mfg. Lic. No. 25-MH/101560

Manufactured By:
RioCare India Pvt. Ltd.,
Plot No. R - 940, TTC Indl. Area,
MIDC Rabale, Navi Mumbai - 400 701.
District: Thane, Maharashtra, INDIA.



RioCare India Private Limited
 Plot R-940, TTC Industrial Area, MIDC Rabale, Navi Mumbai - 400 701, Maharashtra, INDIA.

Batch Manufacturing Record

Product Name: Simethicone (Filix-110)
 Batch No. : RFLX 21/814

BMR No. : RCIPL/BMR/Flx-2300/10
 Ref. MFR No.: RCIPL/MFR/01/01

Packing:

Date: 30/10/2021

Process	Observation	Time (Hrs.)		Done By	Checked By
		Start	End		
Area cleanliness checked by Production	Clean	14:47	-	-	as.
Temperature (°C) of Filling area	25.7	14:47	-	-	as.
Humidity (% RH) of Filling area	56.1	14:47	-	-	as.
Temperature (°C) of product	63.0	14:47	-	-	as.
No. of drums filled.	50 Kg. - 40	14:53	16:20	Pete	as.
	200 Kg. - N.A	-	-	-	-
	0.050 Kg - 01	16:22	16:24	Pete	as.

Yield:

RM Input (Kg.)	: 2005.400
FG Output (Kg.)	: 2002.250
a. Filled in drums (Kg.)	: 2000.000
b. Excess filled in drums (Kg.)	: 2.000
c. QC Sampling (Kg.)	: 0.200
d. Stability sample (Kg.)	: -
e. Working standard	: -
f. Validation sample	: -
g. Filled in Jerry can / drum (Kg.) (Customer sample)	: 0.050

Actual Yield [(Output/Input)*100] : 99.84% (98.00 – 102.00%)

Checked By
 (Manager- Production)

Approved By
 (Sr. Officer -QA)

: M. Vaishali 12/11/2021



RioCare India Private Limited

Plot R-940, TTC Industrial Area, MIDC Rabale, Navi Mumbai – 400 701, Maharashtra, INDIA.

Batch Manufacturing Record

*product Name: Simethicone (Filix-110)
Batch No. : RFLX 21/814*

BMR No. : RCIPL/BMR/Flx-2300/10
Ref. MFR No.: RCIPL/MFR/01/01

Homogenizing tank No.: PR/BT/003

Date	Process	Qty. (Kg.)	Time (Hrs.)		Done by	Checked by
			Start	End		
29/10/2021	Lot No.: 5 Homogenize the final product, generated from <u>5</u> lots for 45 – 60 minutes. Cool it to less than 80°C.	415.900 2005.400	15:31	17:11	-	cos.
30/10/2021			09:50	10:50	sharmat	cos.

In process check : Remove sample (approx. 100gm) and check for viscosity at 25 °C/ 30 RPM with LV3 spindle using Brookfield Viscometer (ID No.: PR/VM/002).
(After 5 lots)

Observed value : 2324 cSt. (Acceptable Range 2000-2500 cSt)

RioCare India Private Limited

Plot R-940, TTC Industrial Area, MIDC Rabale, Navi Mumbai - 400 701, Maharashtra, INDIA.

Batch Manufacturing Record

Product Name: Simethicone (Felix-110)
Batch No. : RFLX 21|814

BMR No. : RCIPLBMR/Flix-2300/10
Ref. MFR No.: RCIPLMFR/01/01

Lot No.: 5

Reactor No.: PR/RC/001 - PR/RC/002

Date: 29/10/2021

Process Sheet

Raw Material	Batch No.	Qty (Kg.)
PDMS-A	2105636T	105.570
PDMS-A	2106643T	153.520
PDMs-C	2105812T	140.830
Colloidal Silicon Dioxide	150082714	15.980

Process	Qty. (Kg.)	Temp. (°C)	Time (Hrs.)		Done By	Checked By
			Start	End		
Charge Polydimethylsiloxane in reactor.	399.92	-	15:31	15:47	Shubh	s.
Start heating the reactor and start stirring:	-	-	15:48	-	S. K. Patel	s.
Once the temperature is between 100-120°C start the Inline mixer and charge Colloidal Silicon Dioxide (Fumed Silica) in reactor simultaneously and increase stirring speed.	15.980	102	16:06	16:25	W.	s.
When temperature reaches 180 - 190 °C, stop heating the reactor.	-	180	-	16:51	Shubh	s.
Stop stirrer and transfer the reaction mass to homogenizing tank No.- PR/BT/003	-	184	16:57	17:11	Shubh	s.

Batch Manufacturing Record

Product Name: Simethicone (Filix-110)
 Batch No. : RFLX 21/814

BMR No. : RCIPL/BMR/Flx-2300/10
 Ref. MFR No.: RCIPL/MFR/01/01

Homogenizing tank No.: PR/BT/003

Date	Process	Qty. (Kg.)	Time (Hrs.)		Done by	Checked by
			Start	End		
29/10/2021	Lot No.: 1	397.050	09:35	11:45	-	✓
29/10/2021	Lot No.: 2	397.760	09:52	12:19	-	✓
29/10/2021	Lot No.: 3	397.410	11:46	13:37	-	✓
29/10/2021	Lot No.: 4	397.280	12:20	14:01	-	✓
29/10/2021	Homogenize the product, generated from <u>4</u> lots for 45 – 60 minutes.	1589.500	14:05	15:05	<i>[Signature]</i>	✓

In process check : Remove sample (approx. 100gm) and check for viscosity at 25 °C/ 30 RPM with LV3 spindle using Brookfield Viscometer (ID No.: PR/VM/002).

Observed value : 2906 cSt.



RioCare India Private Limited

Plot R-940, TTC Industrial Area, MIDC Rabale, Navi Mumbai - 400 701, Maharashtra, INDIA.

Batch Manufacturing Record

Product Name: Simethicone (Filix-110)
Batch No. : RFLX 21 | 814

BMR No. : RCIPL/BMR/Flx-2300/10
Ref. MFR No.: RCIPL/MFR/01/01

Process Sheet

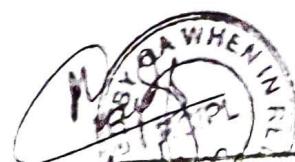
Lot No.: 4

Reactor No.: PR/RC/001 - PR/RC/002

Date: 29/10/2021

Raw Material	Batch No.	Qty (Kg)
PDMS-A	2106643T	381.280
Colloidal Silicon Dioxide	150082714	16.000
-	-	-
-	-	-

Process	Qty. (Kg.)	Temp. (°C)	Time (Hrs.)		Done By	Checked By
			Start	End		
Charge Polydimethylsiloxane in reactor.	381.280	-	12:20	12:40	<i>Amit</i>	<i>...</i>
Start heating the reactor and start stirring.	-	-	12:41	-	<i>Amit</i>	<i>...</i>
Once the temperature is between 100-120°C start the Inline mixer and charge Colloidal Silicon Dioxide (Fumed Silica) in reactor simultaneously and increase stirring speed.	16.000	105	13:07	13:22	<i>...</i>	<i>...</i>
When temperature reaches 180 - 190 °C, stop heating the reactor.	-	180	-	13:44	<i>...</i>	<i>...</i>
Stop stirrer and transfer the reaction mass to homogenizing tank No.- PR/BT/003	-	184	13:48	14:01	<i>Amit</i>	<i>...</i>



Batch Manufacturing Record

Product Name: Simethicone (Flix-110)
 Batch No. : RFLX 21/814

BMR No. : RCIPL/BMR/Flx-2300/10
 Ref. MFR No.: RCIPL/MFR/01/01

Process Sheet

Lot No.: 3

Reactor No.: PR/RC/001 - PR/RC/002

Date: 29/10/2021

Raw Material	Batch No.	Qty (Kg.)
PDMS-A	2105636T	381.400
Colloidal Silicon Dioxide	150082714	16.010
-	-	-
-	-	-

Process	Qty. (Kg.)	Temp. (°C)	Time (Hrs.)		Done By	Checked By
			Start	End		
Charge Polydimethylsiloxane in reactor.	381.400	-	11:46	12:01	✓	✓
Start heating the reactor and start stirring.	-	-	12:02	-	✓	✓
Once the temperature is between 100-120°C start the Inline mixer and charge Colloidal Silicon Dioxide (Fumed Silica) in reactor simultaneously and increase stirring speed.	16.010	104	12:25	12:44	✓	✓
When temperature reaches 180 - 190 °C, stop heating the reactor.	-	180	-	13:20	✓	✓
Stop stirrer and transfer the reaction mass to homogenizing tank No.- PR/BT/003	-	184	13:25	13:37	✓	✓



RioCare India Private Limited
 Plot R-940, TTC Industrial Area, MIDC Rabale, Navi Mumbai - 400 701, Maharashtra, INDIA.

Batch Manufacturing Record

Product Name: Simethicone (Flix-110)
 Batch No. : RFLX 21/814

BMR No. : RCIPPL/BMR/Flx-2300/10
 Ref. MFR No.: RCIPPL/MFR/01/01

Process Sheet

Lot No.: 2

Reactor No.: PR/RC/001 - PR/RC/002 ✓

Date: 29/10/2021

Raw Material	Batch No.	Qty (Kg.)
PDMS-A	210563GT	381.760
Colloidal Silicon Dioxide	150082714	16.000
-	-	-
-	-	-

Process	Qty. (Kg.)	Temp. (°C)	Time (Hrs.)		Done By	Checked By
			Start	End		
Charge Polydimethylsiloxane in reactor.	381.760	-	09:52	10:07	<i>Patel</i>	<i>su</i>
Start heating the reactor and start stirring.	-	-	10:20	-	<i>Patel</i>	
Once the temperature is between 100-120°C start the Inline mixer and charge Colloidal Silicon Dioxide (Fumed Silica) in reactor simultaneously and increase stirring speed.	16.000	105	10:58	11:24	<i>Patel</i>	<i>su</i>
When temperature reaches 180 - 190 °C, stop heating the reactor.	-	180	-	12:05	<i>Patel</i>	<i>su</i>
Stop stirrer and transfer the reaction mass to homogenizing tank No.- PR/BT/003	-	185	12:09	12:19	<i>Patel</i>	<i>su</i>



RioCare India Private Limited

Plot R-940, TTC Industrial Area, MIDC Rabale, Navi Mumbai - 400 701, Maharashtra, INDIA.

Batch Manufacturing Record

Product Name: Simethicone (Filix-110)
Batch No. : RFLX 21/814

BMR No. : RCIPL/BMR/Flx-2300/10
Ref. MFR No.: RCIPL/MFR/01/01

Process Sheet

Lot No.: 1

Reactor No.: PR/RC/001 - PR/RC/002

Date: 29/10/2021

Raw Material	Batch No.	Qty (Kg.)
PDMS-A	2105636T	381.040
Colloidal Silicon Dioxide	150082714	16.010
-	-	-
-	-	-

Process	Qty. (Kg.)	Temp. (°C)	Time (Hrs.)		Done By	Checked By
			Start	End		
Charge Polydimethylsiloxane in reactor.	381.040	-	09:35	09:51	<i>Akash</i>	<i>~~</i>
Start heating the reactor and start stirring.	-	-	09:52	-	<i>Akash</i>	<i>~~</i>
Once the temperature is between 100-120°C start the Inline mixer and charge Colloidal Silicon Dioxide (Fumed Silica) in reactor simultaneously and increase stirring speed.	16.010	102	10:24	10:54	<i>AK</i>	<i>~~</i>
When temperature reaches 180 - 190 °C, stop heating the reactor.	-	180	-	11:30	<i>AK</i>	<i>AK</i>
Stop stirrer and transfer the reaction mass to homogenizing tank No.- PR/BT/003	-	184	11:35	11:45	<i>AK</i>	<i>AK</i>

RioCare India Private Limited

Plot R-940, TTC Industrial Area, MIDC Rabale, Navi Mumbai – 400 701, Maharashtra, INDIA.

Batch Manufacturing Record

Product Name: Simethicone (Filix-110)
Batch No. : RFLX 21 | 814

BMR No. : RCIPL/BMR/Flx-2300/10
Ref. MFR No.: RCIPL/MFR/01/01

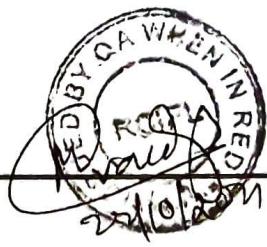
Equipment Status:

S. No.	Particulars	Batch No	Date	Signature	
				PR	QA
1	Last batch produced	RFLX 21 813	29/10/2021	~~	MV
Reactor cleaned on - (Cleaning Frequency - Once in 3 months)					
2	PR/RC/001	-	09/09/2021	~~	MV
	PR/RC/002	-	09/09/2021	~~	MV
Homogenizing tank cleaned on- (Cleaning Frequency - Once in 3 months)					
3	PR/BT/003	-	09/09/2021	~~	MV
	Mesh sieve from reactor to blending tank cleaned & integrity checked on- (Cleaning Frequency - Daily)				
4	PR/BT/003	-	29/10/2021	~~	MV
	Mesh sieve from blending tank to filling station cleaned & integrity checked on -(Cleaning Frequency-Daily)				
5	-	-	29/10/2021	~~	MV

Line Clearance Record:

Date: 29/10/2021

S. No.	Particulars	Observation	Time (Hrs.)	Signature
1	Area Cleanliness Checked	Clean	09:33	~~
2	Temperature (°C)	28.2	09:33	~~
3	Humidity (%RH)	42.1	09:33	~~



RioCare India Private Limited

Plot R-940, TTC Industrial Area, MIDC Rabale, Navi Mumbai - 400 701, Maharashtra, INDIA.

Batch Manufacturing Record

Product Name: Simethicone (Filix-110)
Batch No. : RFLX 21 | 814

BMR No. : RCIPL/BMR/Flx-2300/10
Ref. MFR No.: RCIPL/MFR/01/01

List of Equipment in Manufacturing Process:

S. No.	Equipment Name	Equipment Code	Equipment to be used
1	SS Reactor	PR/RC/001	✓
2	SS Reactor	PR/RC/002	✓
3	SS Homogenising tank	PR/BT/001	—
4	SS Homogenising tank	PR/BT/002	—
5	SS Homogenising tank	PR/BT/003	✓
6	Filling Station	PR/FS/001	✓

RioCare India Private Limited

Plot R-940, TTC Industrial Area, MIDC Rabale, Navi Mumbai – 400 701, Maharashtra, INDIA.

Batch Manufacturing Record

Product Name: Simethicone (Filix-110)
Batch No. : RFLX 21/814

BMR No. : RCIPL/BMR/Flx-2300/10
Ref. MFR No.: RCIPL/MFR/01/01

Bill of Raw Material Details and Weighing Record:

S. No	Raw Material	Quantity (Kg.)	Batch No.	AR No. / Date	Weighed By	Checked By
1	Polydimethyl siloxane (RMPDMS1A)	1249.770	2105636T	PDMS 2105636T	gaurav	cm
		-	-	0468 - 09/08/2021		
2	Polydimethyl Siloxane (RMPDMS1A)	534.800	2106643T	PDMS 2106643T	gaurav	cm
		-	-	0634 - 26/08/2021		
3	Polydimethyl Siloxane (RMPDMS1C)	140.830	2105812T	PDMS 2105812T	gaurav	cm
		-	-	0522 - 09/08/2021		
4	Colloidal Silicon Dioxide (Fumed Silica) (RMFS100)	80.000	150082714	FS 150082714	gaurav	cm
		-	-	9714 - 30/12/2026		



RioCare India Private Limited
Plot R-940, TTC Industrial Area, MIDC Rabale, Navi Mumbai – 400 701, Maharashtra, INDIA.

Batch Manufacturing Record

Product Name: Simethicone (Filix-110)
Batch No. : RFLX 21/814

BMR No. : RCIPL/BMR/Flx-2300/10
Ref. MFR No.: RCIPL/MFR/01/01

General Instruction for Manufacturing.

Precaution for Safety:

- 1) Use Hand gloves, Nose mask and safety goggles while handling raw materials.
- 2) Use Hand gloves, Nose mask while handling finished product.
- 3) Follow personal hygiene requirements.

Notes:

- a) Manufacturing has to be carried as per requirements of current GMP.
- b) Use clean and dry S.S equipments at all stages of manufacturing.
- c) Before weighing operation check cleanliness of balance.
- d) All ingredients must have been approved by QC and within expiry/retest date.
- e) Batch size may vary, depending upon requirement. Prior permission should be obtained from QA.



RioCare India Private Limited
Plot R-940, TTC Industrial Area, MIDC Rabale, Navi Mumbai – 400 701, Maharashtra, INDIA.

Batch Manufacturing Record

Product Name: Simethicone (Filix-110)
Batch No. : RFLX 211814

BMR No. : RCIPL/BMR/Flx-2300/10
Ref. MFR No.: RCIPL/MFR/01/01

Product Name: Simethicone (Filix-110)

Batch No.: RFLX 211814	Grade: IP
Batch Size: 2000 kg	Viscosity: 2000 – 2500 cSt
Production Commenced on: 29/10/2021	Production Completed on: 30/10/2021
Manufacturing Date: 30/10/2021	Retest Date: 29/10/2025

Prepared by :

 30/10/2021
Somarth Kadamb

(Officer-Production)

Checked by :

(Manager-Production)

This batch has / has not been produced according to instruction given in MFR No. RCIPL/MFR/01/01

Deviation sheet attached

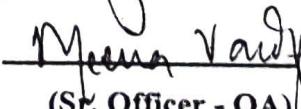
: Yes / No 

The batch is approved / not approved on

: 12/11/2021

 12/11/2021

Reviewed and Approved by

: 
(Sr. Officer - QA)

