



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 21/875

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

Product Name: Simethicone (Filix-110)	
Batch No.: RFLX 21/875	Grade: IP
Batch Size: 2000 Kgs	Viscosity: 2000 - 2500 cSt
Production Commenced on: 23/02/2022	Production Completed on: 24/02/2022
Manufacturing Date: 24/02/2022	Retest Date: 23/02/2026

Prepared by : _____
(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 :

Reviewed and Approved by : _____
(Sr. Officer - QA)



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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.





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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)	1731.420	2110702T	PDMs/2110702T/ 1748 - 27/01/2021	g/fwd	(2)
		—	—	—		
2	Polydimethyl Siloxane (RMPDMS1C)	191.250	2107844T	PDMs/2107844T/ 0827 - 15/09/2021	g/fwd	(2)
		—	—	—		
3	Polydimethyl Siloxane (RMPDMS1)	—	—	—	—	—
		—	—	—		
4	Colloidal Silicon Dioxide (Fumed Silica) (RMFS100)	80.000	151060514	FS/151060514/ 0708 - 01/09/2021	g/fwd	(2)
		—	—	—		



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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	✓



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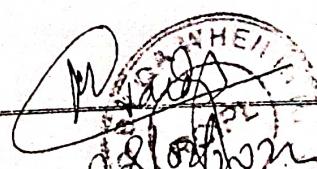
Equipment Status:

S. No.	Particulars	Batch No	Date	Signature	
				PR	QA
1	Last batch produced	RFLX 21/874	23/02/2022	(P)	
Reactor cleaned on - (Cleaning Frequency - Once in 3 months)					
2	PR/RC/001	-	15/02/2022	(P)	
	PR/RC/002	-	15/02/2022	(P)	
Homogenizing tank cleaned on- (Cleaning Frequency - Once in 3 months)					
3	PR/BT/002	-	15/02/2022	(P)	
Mesh sieve from reactor to blending tank cleaned & integrity checked on- (Cleaning Frequency - Daily)					
4	PR/BT/002	(P) 23/02/2022	23/02/2022	(P)	
Mesh sieve from blending tank to filling station cleaned & integrity checked on -(Cleaning Frequency-Daily)					
5	-	(P) 23/02/2022	23/02/2022	(P)	

Line Clearance Record:

Date: 23/02/2022

S. No.	Particulars	Observation	Time (Hrs.)	Signature
1	Area Cleanliness Checked	Clean	10:02	(P)
2	Temperature (°C)	27.9	10:02	(P)
3	Humidity (%RH)	59.8	10:02	(P)





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Ref. MFR No.: RCIPL/MFR/01/01

Process Sheet

Lot No.: 1

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

Date: 23/02/2022

Raw Material	Batch No.	Qty (Kg.)
PDMS - A	21107027	380.360
Colloidal Silicon Dioxide	151060514	16.000
-	-	-
-	-	-

Process	Qty. (Kg.)	Temp. (°C)	Time (Hrs.)		Done By	Checked By
			Start	End		
Charge Polydimethylsiloxane in reactor.	380.360	-	10:05	10:24	Shant	②
Start heating the reactor and start stirring.	-	-	10:25	-	W.C.	②
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	11:00	11:25	W.C.	②
When temperature reaches 180 - 190 °C, stop heating the reactor.	-	181	-	11:58	Shant	②
Stop stirrer and transfer the reaction mass to homogenizing tank No.- PR/BT/002	-	185	12:00	12:12	Shant	②

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Process Sheet

Lot No.: 2

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

Date: 23/02/2022

Raw Material	Batch No.	Qty (Kg.)
PDMS - A	2110702T	381.620
Colloidal Silicon Dioxide	151060514	16.000
-	-	-
-	-	-

Process	Qty. (Kg.)	Temp. (°C)	Time (Hrs.)		Done By	Checked By
			Start	End		
Charge Polydimethylsiloxane in reactor.	381.620	-	10:28	10:44	John	②
Start heating the reactor and start stirring.	-	-	10:36	-	Qb	②
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	104	11:30	11:55	Qb	②
When temperature reaches 180 - 190 °C, stop heating the reactor.	-	181	-	12:14	Wb	②
Stop stirrer and transfer the reaction mass to homogenizing tank No.- PR/BT/ 002	-	184	12:15	12:27	John	②



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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: 23/02/2022

Raw Material	Batch No.	Qty (Kg.)
PDMS - A	2110702T	381.180
Colloidal Silicon Di-oxide	2110702T	16.010

Process	Qty. (Kg.)	Temp. (°C)	Time (Hrs.)		Done By	Checked By
			Start	End		
Charge Polydimethylsiloxane in reactor.	381.180	-	12:22	12:38	✓	Q
Start heating the reactor and start stirring.	-	-	12:40	-	Q	Q
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	13:08	13:35	Q	Q
When temperature reaches 180 - 190 °C, stop heating the reactor.	-	180	-	14:02	Q	Q
Stop stirrer and transfer the reaction mass to homogenizing tank No.- PR/BT/002	-	185	14:13	14:25	✓	Q

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

Process Sheet

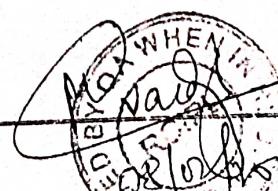
Lot No.: 4

Reactor No.: PR/RC/001 - PR/RC/002 ✓

Date: 23/02/2022

Raw Material	Batch No.	Qty (Kg.)
PDMS - A	2110702T	381.480
Colloidal Silicon Dioxide	151060514	16.010

Process	Qty. (Kg.)	Temp. (°C)	Time (Hrs.)		Done By	Checked By
			Start	End		
Charge Polydimethylsiloxane in reactor.	381.480	-	12:30	12:44	✓/man	Q
Start heating the reactor and start stirring.	-	-	12:45	-	Q	Q
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	103	13:45	14:10	Q	Q
When temperature reaches 180 - 190 °C, stop heating the reactor.	-	180	-	14:38	✓/man	Q
Stop stirrer and transfer the reaction mass to homogenizing tank No.- PR/BT/002	-	184	14:40	14:52	✓/man	Q



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Homogenizing tank No.: PR/BT/002

Date	Process	Qty. (Kg.)	Time (Hrs.)		Done by	Checked by
			Start	End		
23/02/2022	Lot No.: 1	396.360	10:05	12:12	-	②
23/02/2022	Lot No.: 2	397.620	10:28	12:27	-	②
23/02/2022	Lot No.: 3	397.190	12:22	14:25	-	②
23/02/2022	Lot No.: 4	397.490	12:30	14:52	-	②
23/02/2022	Homogenize the product, generated from <u>04</u> lots for 45 - 60 minutes.	1588.660	14:55	15:55	✓✓✓	②

In process check : Remove sample (approx. 100gm) and check for viscosity at 25 °C/ 30 RPM with LV3 (After 4 lots) spindle using Brookfield Viscometer (ID No.: PR/VM/002).

Observed value : 2905 cSt.

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 Ref. MFR No.: RCIPL/MFR/01/01

Process Sheet

Lot No.: 5

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

Date: 23/02/2022

Raw Material	Batch No.	Qty (Kg.)
PDMS - A	2110702T	209.780
PDMS - C	2107844T	191.250
Colloidal Silicon Dioxide	151060514	15.980

Process	Qty. (Kg.)	Temp. (°C)	Time (Hrs.)		Done By	Checked By
			Start	End		
Charge Polydimethylsiloxane in reactor.	298.030	—	16:05	16:22	✓	Q
Start heating the reactor and start stirring.	298.030	—	16:23	—	✓	Q
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	103	16:50	17:06	✓	Q
When temperature reaches 180 - 190 °C, stop heating the reactor.	—	180	—	17:24	✓	Q
Stop stirrer and transfer the reaction mass to homogenizing tank No.- PR/BT/002	—	183	17:25	17:35	✓	Q



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Homogenizing tank No.: PR/BT/002

Date	Process	Qty. (Kg.)	Time (Hrs.)		Done by	Checked by
			Start	End		
23/02/2022	Lot No.: 5	414.010	16:05	17:35	-	(A)
24/02/2022	Homogenize the final product, generated from 05 lots for 45 - 60 minutes. Cool it to less than 80°C.	2002.670	10:00	11:00	(B)	(A)

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 : 2296 cSt. (Acceptable Range 2000-2500 cSt)



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Packing:

Process	Observation	Time (Hrs.)		Done By	Checked By	Date:
		Start	End			
Area cleanliness checked by Production	Clean	14:40	—	—	Q	
Temperature (°C) of Filling area	24.3	14:40	—	—	Q	
Humidity (% RH) of Filling area	59.2	14:40	—	—	Q	
Temperature (°C) of product	59.0	14:40	—	—	Q	
No. of drums filled.	50 Kg. - 40	14:45	16:04	WU	D	
	200 Kg. - N/A	—	—	—	—	
	—	—	—	—	—	

Yield:

RM Input (Kg.)

: 2002.670

FG Output (Kg.)

: 2002.450

a. Filled in drums (Kg.)

: 2000.000

b. Excess filled in drums (Kg.)

: 2.250

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) : —

Actual Yield [(Output/Input)*100]

: 99.99 %

(98.00 – 102.00%)

Checked By
 (Manager- Production)

:

Approved By
 (Sr. Officer -QA)

:



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PRODUCT LABEL

SIMETHICONE IP - 100%
Activated Dimethylcova

FILIX-110

BATCH NO.	: RFLX 21/875	NET WT.	: 50 Kgs
MFG DATE	: 24 / FEB / 2022	TARE WT.	: 2.5 Kg
RETEST DATE	: 23 / FEB / 2026		

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.