



## 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

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

Product Name: Simethicone (Filix-110)	
Batch No.: RFLX	Grade:
Batch Size:	Viscosity: 2000 – 2500 cSt
Production Commenced on:	Production Completed on:
Manufacturing Date:	Retest Date:

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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Batch No. : RFLX

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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 (RMPDMS1 )					
2	Polydimethyl Siloxane (RMPDMS1 )					
3	Polydimethyl Siloxane (RMPDMS1 )					
4	Colloidal Silicon Dioxide (Fumed Silica) (RMFS100)					



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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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BMR No. : RCIPL/BMR/Fix-2300/10

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

### Equipment Status:

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

### Line Clearance Record:

Date:

S. No.	Particulars	Observation	Time (Hrs.)	Signature
1	Area Cleanliness Checked			
2	Temperature ( $^{\circ}\text{C}$ )			
3	Humidity (%RH)			





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### Process Sheet

Lot No.: 1

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

Date:

Raw Material	Batch No.	Qty (Kg.)

Process	Qty. (Kg.)	Temp. (°C)	Time (Hrs.)		Done By	Checked By
			Start	End		
Charge Polydimethylsiloxane in reactor.						
Start heating the reactor and start stirring.						
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.						
When temperature reaches 180 – 190 °C, stop heating the reactor.						
Stop stirrer and transfer the reaction mass to homogenizing tank No.- PR/BT/						



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Batch No. : RFLX

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

### Process Sheet

Lot No.: 2

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

Date:

Raw Material	Batch No.	Qty (Kg.)

Process	Qty. (Kg.)	Temp. (°C)	Time (Hrs.)		Done By	Checked By
			Start	End		
Charge Polydimethylsiloxane in reactor.						
Start heating the reactor and start stirring.						
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.						
When temperature reaches 180 – 190 °C, stop heating the reactor.						
Stop stirrer and transfer the reaction mass to homogenizing tank No.- PR/BT/						



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### Process Sheet

Lot No.: 3

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

Date:

Raw Material	Batch No.	Qty (Kg.)

Process	Qty. (Kg.)	Temp. (°C)	Time (Hrs.)		Done By	Checked By
			Start	End		
Charge Polydimethylsiloxane in reactor.						
Start heating the reactor and start stirring.						
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.						
When temperature reaches 180 – 190 °C, stop heating the reactor.						
Stop stirrer and transfer the reaction mass to homogenizing tank No.- PR/BT/						





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## Process Sheet

Lot No.: 4

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

Date:

Raw Material	Batch No.	Qty (Kg.)

Process	Qty. (Kg.)	Temp. (°C)	Time (Hrs.)		Done By	Checked By
			Start	End		
Charge Polydimethylsiloxane in reactor.						
Start heating the reactor and start stirring.						
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.						
When temperature reaches 180 – 190 °C, stop heating the reactor.						
Stop stirrer and transfer the reaction mass to homogenizing tank No.- PR/BT/						



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

Homogenizing tank No.: PR/BT/

Date	Process	Qty. (Kg.)	Time (Hrs.)		Done by	Checked by
			Start	End		
	Lot No.: 1					
	Lot No.: 2					
	Lot No.: 3					
	Lot No.: 4					
	Homogenize the product, generated from __ lots for 45 – 60 minutes.					

**In process check (After 4 lots)** : 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** : \_\_\_\_\_ 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:

Raw Material	Batch No.	Qty (Kg.)

Process	Qty. (Kg.)	Temp. (°C)	Time (Hrs.)		Done By	Checked By
			Start	End		
Charge Polydimethylsiloxane in reactor.						
Start heating the reactor and start stirring.						
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.						
When temperature reaches 180 – 190 °C, stop heating the reactor.						
Stop stirrer and transfer the reaction mass to homogenizing tank No.- PR/BT/						



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Batch No. : RFLX

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

Homogenizing tank No.: PR/BT/

Date	Process	Qty. (Kg.)	Time (Hrs.)		Done by	Checked by
			Start	End		
	Lot No.: 5					
	Homogenize the final product, generated from ___ lots for 45 – 60 minutes. Cool it to less than 80°C.					

**In process check (After 5 lots)** : 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** : \_\_\_\_\_ cSt. (Acceptable Range 2000-2500 cSt)





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Packing:

Date:

Process	Observation	Time (Hrs.)		Done By	Checked By
		Start	End		
Area cleanliness checked by Production					
Temperature ( °C) of Filling area					
Humidity (% RH) of Filling area					
Temperature ( °C) of product					
No. of drums filled.	50 Kg. -				
	200 Kg. -				

### Yield:

RM Input (Kg.) :

FG Output (Kg.) :

a. Filled in drums (Kg.) :

b. Excess filled in drums (Kg.) :

c. QC Sampling (Kg.) :

d. Stability sample (Kg.) :

e. Working standard :

f. Validation sample :

g. Filled in Jerry can / drum (Kg.) (Customer sample) :

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

Checked By :  
(Manager- Production)

Approved By :  
(Sr. Officer -QA)



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### PRODUCT LABEL

SIMETHICONE - 100%

FILIX-110

BATCH NO. : RFLX  
MFG DATE :  
RETEST DATE :

NET WT. :  
TARE WT. :

Drug Mfg. Lic. No. MH/101560  
Manufactured By:  
RioCare India Pvt. Ltd.,  
Plot No. R - 940, TTC Indl. Area,  
MIDC Rabale, Navi Mumbai - 400 701.  
Maharashtra, INDIA.