

COCREATE GLOBAL TECHNOLOGIES PRIVATE LIMITED

CIN: U21009KA2023PTC179006

Registered address: FFK Towers, #445, 2nd & 3rd Floor, 17th Cross Road, Sector 4, HSR Layout, Bangalore, Bangalore South, Karnataka - 560102, India.

Email: info@scimplify.com **Website:** www.scimplify.com



LONG TERM STABILITY STUDY						
Temperature: 25±2°C		Relative Humidity: 60 ± 5%		Duration: 5 Years		
Product: Piroctone Olamine						
Packing Condition: Packed double white polythene bags, kept in HDPE containers and stored in long stability chamber.						
Test	Specification	Batch No.: SCPCO24001		Mfg. Date: March-2024		
		Initial Day: 05-05-2024	3rd Month: 02-09-2024	6th Month	9th Month	12th Month
Appearance	White or slightly yellow crystalline powder	White crystalline powder	White crystalline powder			
Solubility	Soluble in Ethanol and Chloroform	Complies	Complies			
20%w/v solution in Methanol	Clearly soluble, without particle.	Complies	Complies			
Melting range	130 – 136°C	133.4 - 134.5°C	133.5 - 134.6°C			
pH of 1% suspension in pH 7 water	8.5 - 10.0	9.52	9.50			
Loss on drying	Not more than 0.30% w/w	0.14 %	0.13 %			
Sulphated ash	Not more than 0.20% w/w	0.10 %	0.11 %			
Monoethanolamine content (on dried basis)	20.05% - 20.9%	20.58 %	20.66%			
Bulk Density (Tapped Density)	Report the value (g/mL)	0.50 g/mL	0.50 g/mL			
Purity by HPLC	Not less than 99.0%	99.94 %	99.97 %			

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LONG TERM STABILITY STUDY						
Temperature: 25±2°C		Relative Humidity: 60 ± 5%		Duration: 5 Years		
Product: Piroctone Olamine						
Packing Condition: Packed double white polythene bags, kept in HDPE containers and stored in long stability chamber.						
Test	Specification	Batch No.: SCPCO24002		Mfg. Date: March-2024		
		Initial Day: 05-05-2024	3rd Month: 02-09-2024	6th Month	9th Month	12th Month
Appearance	White or slightly yellow crystalline powder	White crystalline powder	White crystalline powder			
Solubility	Soluble in Ethanol and Chloroform	Complies	Complies			
20%w/v solution in Methanol	Clearly soluble, without particle.	Complies	Complies			
Melting range	130 – 136°C	134.1 – 135.2°C	134.3- 135.4°C			
pH of 1% suspension in pH 7 water	8.5 - 10.0	9.57	9.56			
Loss on drying	Not more than 0.30% w/w	0.16 %	0.15 %			
Sulphated ash	Not more than 0.20% w/w	0.11 %	0.12 %			
Monoethanolamine content (on dried basis)	20.05% - 20.9%	20.60 %	20.63 %			
Bulk Density (Tapped Density)	Report the value (g/mL)	0.50 g/mL	0.50 g/mL			
Purity by HPLC	Not less than 99.0%	99.97 %	99.96 %			

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LONG TERM STABILITY STUDY						
Temperature: 25±2°C		Relative Humidity: 60 ± 5%		Duration: 5 Years		
Product: Piroctone Olamine						
Packing Condition: Packed double white polythene bags, kept in HDPE containers and stored in long stability chamber.						
Test	Specification	Batch No.: SCPCO24001		Mfg. Date: March-2024		
		Initial Day: 05-05-2024	3rd Month: 02-09-2024	6th Month	9th Month	12th Month
Appearance	White or slightly yellow crystalline powder	White crystalline powder	White crystalline powder			
Solubility	Soluble in Ethanol and Chloroform	Complies	Complies			
20%w/v solution in Methanol	Clearly soluble, without particle.	Complies	Complies			
Melting range	130 – 136°C	132.9-134.0°C	133.1 – 134.2°C			
pH of 1% suspension in pH 7 water	8.5 - 10.0	9.38	9.37			
Loss on drying	Not more than 0.30% w/w	0.15 %	0.15 %			
Sulphated ash	Not more than 0.20% w/w	0.11 %	0.10 %			
Monoethanolamine content (on dried basis)	20.05% - 20.9%	20.40 %	20.45 %			
Bulk Density (Tapped Density)	Report the value (g/mL)	0.51 g/mL	0.50 g/mL			

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Purity by HPLC	Not less than 99.0%	99.97 %	99.83 %			
ACCELERATED STABILITY STUDY						
Temperature: 40±2°C		Relative Humidity: 60 ± 5%		Duration: 6 Months		
Product: Piroctone Olamine						
Packing Condition: Packed double white polythene bags, kept in HDPE containers and stored in long stability chamber.						
Test	Specification	Batch No.: SCPCO24001		Mfg. Date: March-2024		
		Initial Day: 05-05-2024	3rd Month: 02-09-2024	6th Month	9th Month	12th Month
Appearance	White or slightly yellow crystalline powder	White crystalline powder	White crystalline powder			
Solubility	Soluble in Ethanol and Chloroform	Complies	Complies			
20%w/v solution in Methanol	Clearly soluble, without particle.	Complies	Complies			
Melting range	130 – 136°C	133.4 - 134.5°C	133.4 - 134.5°C			
pH of 1% suspension in pH 7 water	8.5 - 10.0	9.52	9.51			
Loss on drying	Not more than 0.30% w/w	0.14 %	0.15 %			
Sulphated ash	Not more than 0.20% w/w	0.10 %	0.11 %			
Monoethanolamine content (on dried basis)	20.05% - 20.9%	20.58 %	20.68%			
Bulk Density (Tapped Density)	Report the value (g/mL)	0.50 g/mL	0.50 g/mL			

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Purity by HPLC	Not less than 99.0%	99.94 %	99.97 %			
ACCELERATED STABILITY STUDY						
Temperature: 40±2°C		Relative Humidity: 60 ± 5%		Duration: 6 Months		
Product: Piroctone Olamine						
Packing Condition: Packed double white polythene bags, kept in HDPE containers and stored in long stability chamber.						
Test	Specification	Batch No.: SCPCO24002		Mfg. Date: March-2024		
		Initial Day: 05-05-2024	3rd Month: 02-09-2024	6th Month	9th Month	12th Month
Appearance	White or slightly yellow crystalline powder	White crystalline powder	White crystalline powder			
Solubility	Soluble in Ethanol and Chloroform	Complies	Complies			
20%w/v solution in Methanol	Clearly soluble, without particle.	Complies	Complies			
Melting range	130 – 136°C	134.1 – 135.2°C	134.3-135.4°C			
pH of 1% suspension in pH 7 water	8.5 - 10.0	9.57	9.58			
Loss on drying	Not more than 0.30% w/w	0.16 %	0.10 %			
Sulphated ash	Not more than 0.20% w/w	0.11 %	0.12 %			
Monoethanolamine content (on dried basis)	20.05% - 20.9%	20.60 %	20.44%			

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Bulk Density (Tapped Density)	Report the value (g/mL)	0.50 g/mL	0.50 g/mL			
Purity by HPLC	Not less than 99.0%	99.97 %	99.95 %			
ACCELERATED STABILITY STUDY						
Temperature: 40±2°C		Relative Humidity: 60 ± 5%		Duration: 6 Months		
Product: Piroctone Olamine						
Packing Condition: Packed double white polythene bags, kept in HDPE containers and stored in long stability chamber.						
Test	Specification	Batch No.: SCPCO24003		Mfg. Date: March-2024		
		Initial Day: 05-05-2024	3rd Month: 02-09-2024	6th Month	9th Month	12th Month
Appearance	White or slightly yellow crystalline powder	White crystalline powder	White crystalline powder			
Solubility	Soluble in Ethanol and Chloroform	Complies	Complies			
20%w/v solution in Methanol	Clearly soluble, without particle.	Complies	Complies			
Melting range	130 – 136°C	132.9-134.0°C	133.2- 134.3°C			
pH of 1% suspension in pH 7 water	8.5 - 10.0	9.38	9.39			
Loss on drying	Not more than 0.30% w/w	0.15 %	0.12 %			
Sulphated ash	Not more than 0.20% w/w	0.11 %	0.10 %			

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Monoethanolamine content (on dried basis)	20.05% - 20.9%	20.40 %	20.31 %			
Bulk Density (Tapped Density)	Report the value (g/mL)	0.50 g/mL	0.50 g/mL			
Purity by HPLC	Not less than 99.0%	99.97 %	99.92 %			