



KERONE

A CRISIL-NSIC RATED COMPANY

ISO-9001-2008 COMPANY

Member Of



AIMCAL (USA)



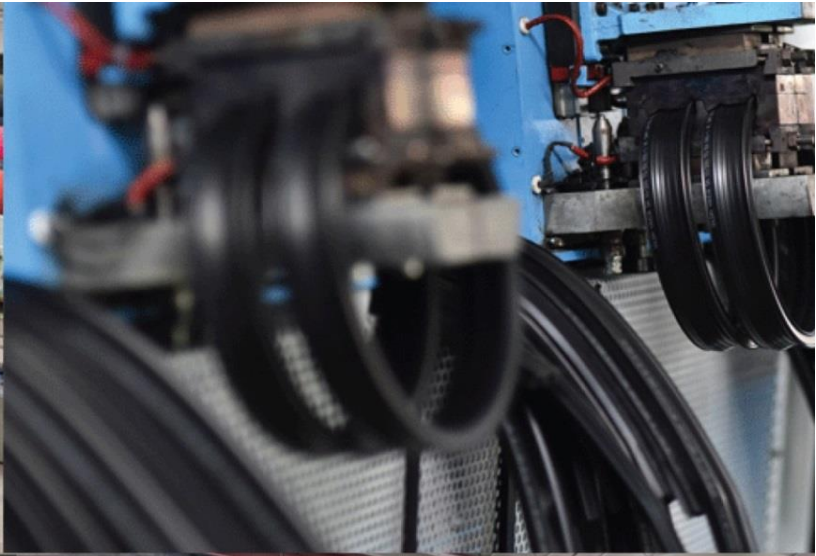
A.M.P.E.R.E (EUROPE)

In Association With



ELECTRO MAGNETIC innovative technologies

Kerone Research & Development Centre (KRDC),
B/47, Addl. MIDC. Anand Nagar, Ambernath (East), Thane- 421 506, India
Tel- +91-251-2620542/43/44/45/46, Email-info@kerone.com, www.kerone.com



**BATCH MICROWAVE+CONVECTION HEATING
SYSTEM WITH VACCUM BLOWER**



ISO 9001-2008 | ISO 9001-2015 | EMS 14001 | OHSAS 18001
In Association with SVCH-Technologii, Moscow (Russia)



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Customer:	M/s. USV Pvt. Ltd.
Process:	Batch Microwave + Convection Heat Treatment for USV-Drug Substance - 2

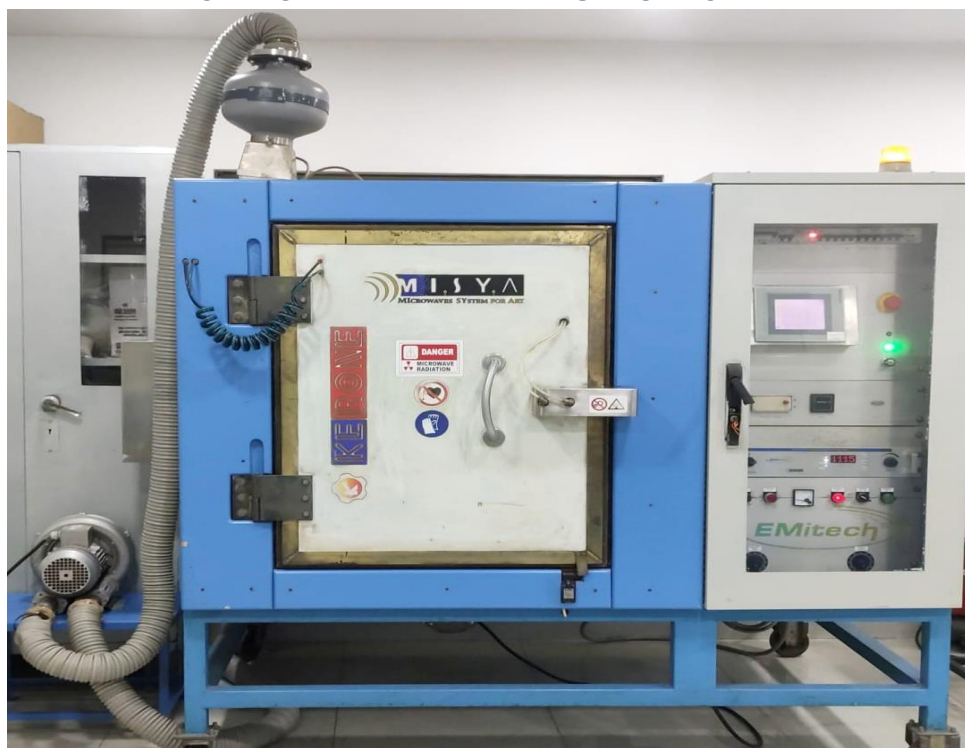
TEST REPORT No: 113/KRDC/LAB/17 Mum 14/07/2022

Date Sample reception : 12/07/2022
ID : 113/LAB/13

SAMPLE DESCRIPTION:

Sampling : As Requested
Sample Condition : Acceptable
Sampling date : 12/07/2022
Product : USV-Drug Substance-2
Start Date test : 12/07/2022
End Date test : 12/07/2022

LABORATORY EXPERIMENTAL SET UP FOR TRIAL:



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LAB BATCH MICROWAVE+CONVECTION HEATING SYSTEM SPECIFICATIONS:

Microwave Power	2 KW (CW)
Frequency	2450 MHz \pm 50
Convective Power	3.5 KW (airflow 350 l/min at 20°C)
Microwave Exposure Zone (Cavity)	1 Cubic meter
Mode Stirrer	One
Thermal Monitoring System	Single Channel Fiber Optic: Range - 40 to 250°C
Exhaust Power	1 HP
Tray size (width*height*depth)	450*950*50 mm

ENVIRONMENT-LABORATORY AMBIENT CONDITIONS:

Temperature (degree C)	27.1°C (\pm 5°C)
Humidity (%)	\leq 70% RH
Pressure (kN/m ² or kPa)	Not recorded

Note for recommendation: Environmental conditions have a direct impact on test results. Accuracy and consistency of test data are affected by the laboratory conditions.






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EQUIPMENTS USED:

Name of Equipment	Picture of Equipment	Specifications
Compact Thermal Imaging Camera		Model: FLIR E-30 Resolution: 160x 120IR Thermal sensitivity of 0.10°C
Moisture Analyzer		Make: Axis Balance Description: Moisture range: 1% (sample 0.02/0.05g), 0.1% (Sample 0.5/5g), 0.01%(Sample>5g)
Thermo Hygrometer		Model No: HTC-2 Temperature accuracy: $\pm^{\circ}\text{C}$ (1.8°F) Temperature resolution: 0.1°C (0.2°F) Humidity range: 10%~99% RH Humidity accuracy: $\pm 5\%$ RH Humidity resolution: 1% RH

SAMPLE PREPARATION AND METHOD/PROCEDURE:

The experiment has been performed on Drug Substance-2 to speed up the heating rate. For this experimental run, given sample has been taken in the crucible and placed in MW + Convection heating system with suitable parameters. Observations are made on the sample weight and appearance.

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ANALYTICAL RESULTS:

TRIAL-1:

Initial moisture: 8%

Cycles	Initial Weight	Specifications of Microwave	Cycle Time	Final weight	Remarks.
C1	15 g	Magnetron Power: 1.8 kW; Set temp. of MW: 65°C; Set temp. of Heater: 80°C With Vacuum blower	300 min.	13 g	Moisture evaporated as desired No charring effect No Colour changed On product temp- (60-63)°C

Total cycle time: 5 hours.

No. of Cycle: 1

Final Moisture: 2.9%

TRIAL-2:

Initial moisture: 8%

Cycles	Initial Weight	Specifications of Microwave	Cycle Time	Final weight	Remarks.
C1	5 g	Magnetron Power: 1.45 kW; Magnetron intensity: 100%; Set temp. of Heater: OFF Without Vacuum blower	300 min.	5 g	Moisture evaporated as desired No charring effect No Colour changed On product temp- (80-83)°C

Total cycle time: 5 hours.

No. of Cycle: 1

Final Moisture: 2.7%

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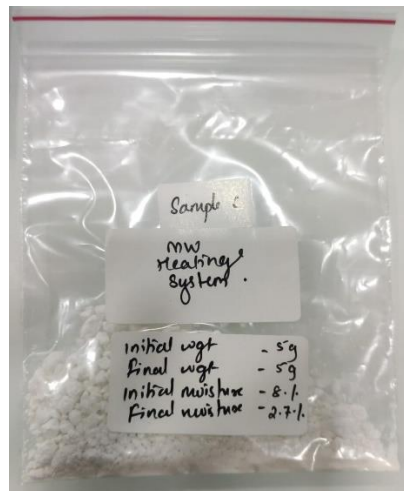
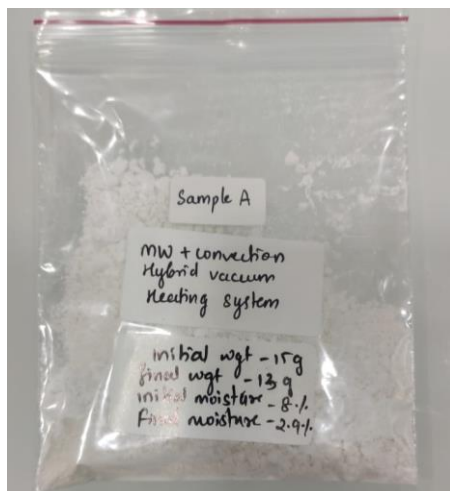
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BEFORE AND AFTER TREATMENT PICTURES SPECIMEN SAMPLE:



Untreated Sample



Treated Sample

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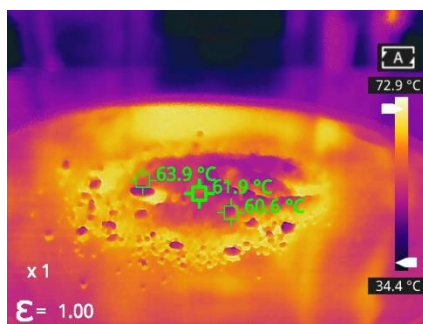
THERMAL IMAGES:

Measurements

Sp1	63.9°C
Sp2	61.9 °C
Sp3	60.6°C

Parameters

Emissivity	1.00
Temp.	72.9°C

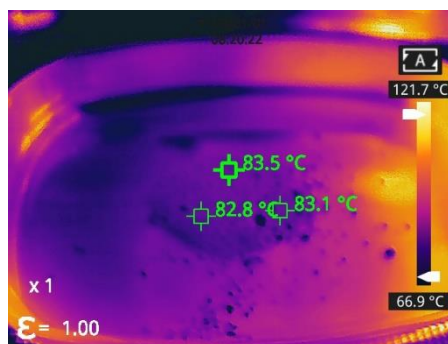


Measurements

Sp1	83.5°C
Sp2	83.1°C
Sp3	82.8°C

Parameters

Emissivity	1.00
Temp.	121.7°C



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MOISTURE REPORT:

Drying started	Drying started <u>Trial 1</u>	Drying started <u>Trial 2</u>
Date :12-07-2022	Date :12-07-2022	Date :12-07-2022
Time :11:19:52	Time :16:13:25	Time :16:21:11
Model:AGS200	Model:AGS200	Model:AGS200
Serial number : 138	Serial number : 138	Serial number : 138
Drying parameters		
Product : 0	Product : 0	Product : 0
Drying temperature : 105.0 °C	Drying temperature : 105.0 °C	Drying temperature : 105.0 °C
Drying profile : standard	Drying profile : standard	Drying profile : standard
Mode : Short mode	Mode : Short mode	Mode : Short mode
Calculation : $((m0-m)/m0)*100\%$	Calculation : $((m0-m)/m0)*100\%$	Calculation : $((m0-m)/m0)*100\%$
Finished : 3 samples	Finished : 3 samples	Finished : 3 samples
Initial weight : 0.714 g	Initial weight : 0.526 g	Initial weight : 0.524 g
Final weight : 0.657 g	Final weight : 0.511 g	Final weight : 0.510 g
Drying time : 00:02:40s	Drying time : 00:02:00s	Drying time : 00:01:40s
Sampling interval : 20 sec	Sampling interval : 20 sec	Sampling interval : 20 sec
Moisture : 8.0 %	Moisture : 2.9 %	Moisture : 2.7 %
NOTE <u>Initial moisture</u>	NOTE <u>Final moisture</u>	NOTE <u>Final moisture</u>
The analysis performed by:	The analysis performed by:	The analysis performed by:
Signature..... <u>Asadi</u>	Signature..... <u>Asadi</u>	Signature..... <u>Asadi</u>

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OBSERVATION:

The drying behavior of Drug Substance – 2 has been investigated under the Microwave + Convection heating system. The heating rate is found to be increasing with respect to an increase in time. As per the physical investigation, it has been observed that there is no charring effect. Moisture content was obtained as desired without any change in colour.

A handwritten signature in black ink, appearing to read "Sayali".

Ms. Sayali Asole
(Tested By)