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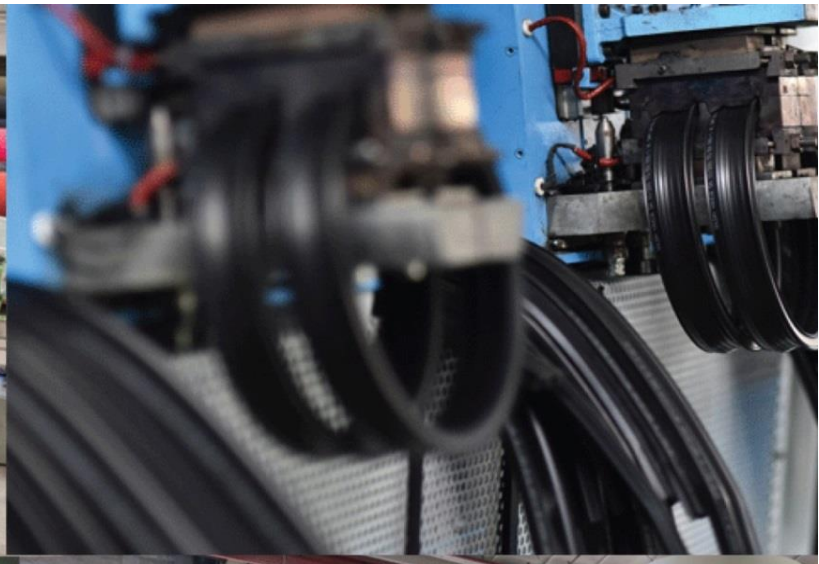
Tel- +91-251-2620542/43/44/45/46, Email-info@kerone.com, www.kerone.com

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 - 1**

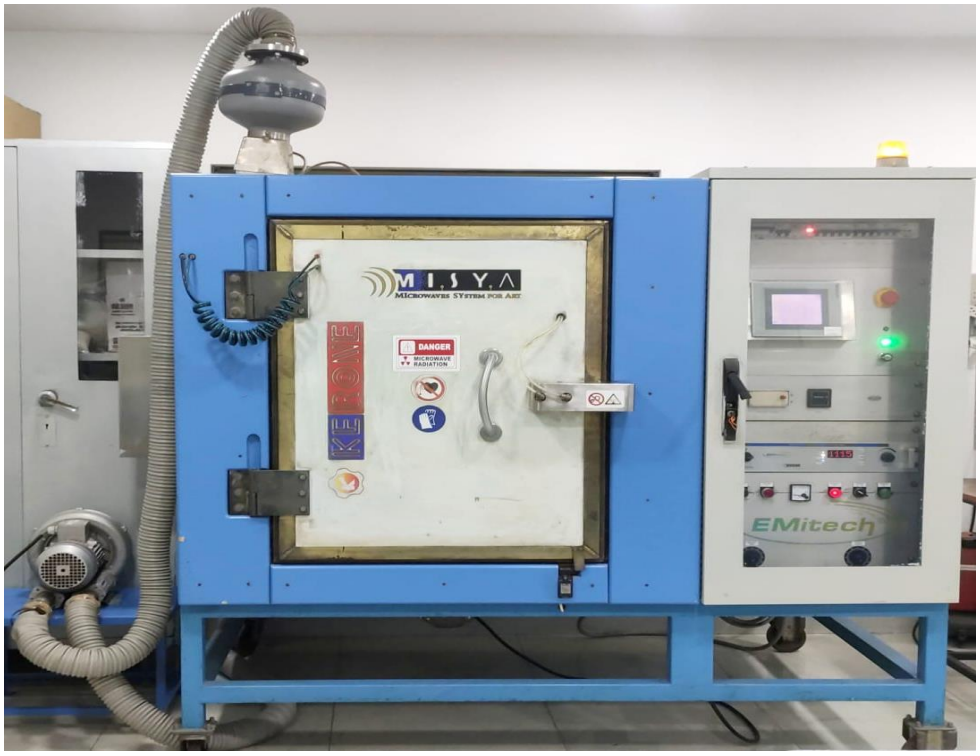
TEST REPORT No: 109/KRDC/LAB/17 Mum 13/07/2022

Date Sample reception : 11/07/2022
ID : 109/LAB/13

SAMPLE DESCRIPTION:

Sampling : As Requested
Sample Condition : Acceptable
Sampling date : 11/07/2022
Product : USV-Drug Substance-1
Start Date test : 11/07/2022
End Date test : 11/07/2022

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 ± 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 (±5°C)
Humidity (%)	≤70% RH
Pressure (kN/m2 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: ±°C (1.8°F) Temperature resolution: 0.1°C (0.2°F) Humidity range: 10%~99% RH Humidity accuracy: ±5% RH Humidity resolution: 1% RH

SAMPLE PREPARATION AND METHOD/PROCEDURE:

The experiment has been performed on Drug Substance- 1 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: Sample B1

Initial moisture: 17.7%

Cycles	Initial Weight	Specifications of Microwave	Cycle Time	Final weight	Remarks.
C1	30 g	Magnetron Power: 1.8 kW; Set temp. of MW: 80°C; Set temp. of Heater: OFF With Vacuum blower	120 min.	26 g	Moisture evaporated as desired No charring effect No Colour changed 0n product temp- (50-63)°C

Total cycle time: 2 hours.
No.of Cycle: 1
Final Moisture: 4.2%

TRIAL-2: Sample B2

Initial moisture: 17.7%

Cycles	Initial Weight	Specifications of Microwave	Cycle Time	Final weight	Remarks.
C1	30 g	Magnetron Power: 1.8 kW; Set temp. of MW: 80°C; Set temp. of Heater: 80°C; With Vacuum blower	120 min.	29 g	Moisture evaporated as desired No charring effect No Colour changed 0n product temp- (70-80)°C

Total cycle time: 2 hours.
No.of Cycle: 1
Final Moisture: 3.2%

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TRIAL-3: Sample E

Initial moisture: 17.7%

Cycles	Initial Weight	Specifications of Microwave	Cycle Time	Final weight	Remarks.
C1	20 g	MW Power: 1.4 kW; Magnetron intensity:100%; Set temp. of Heater: OFF Without Vacuum blower	120 min.	16 g	Moisture evaporated as desired No charring effect No Colour changed 0n product temp- (50-53)^{o}C

Total cycle time: 2 hours.
No.of Cycle: 1
Final Moisture: 5.6%

BEFORE AND AFTER TREATMENT PICTURES SPECIMEN SAMPLE:

Untreated Sample

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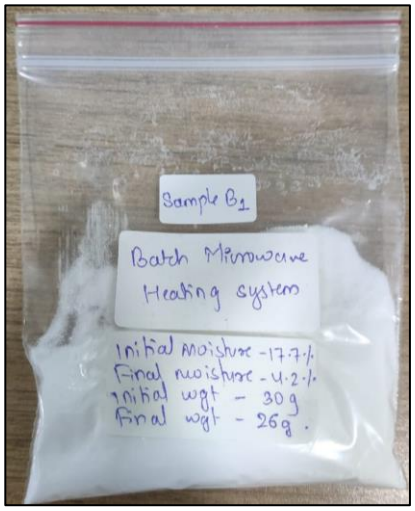
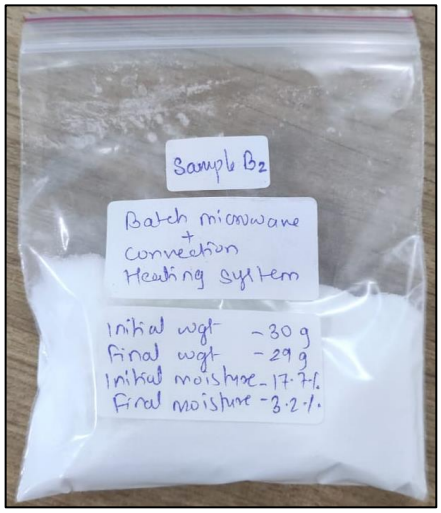
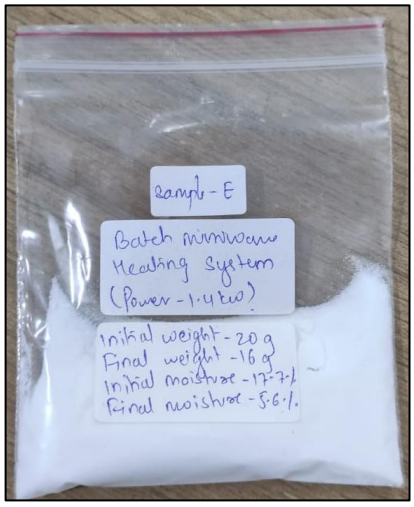






Treated Sample

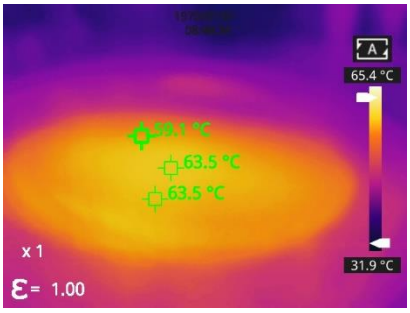
THERMAL IMAGES:

Measurements

Sp1	59.1°C
Sp2	63.5 °C
Sp3	63.5°C

Parameters

Emissivity	1.00
Temp.	65.4°C



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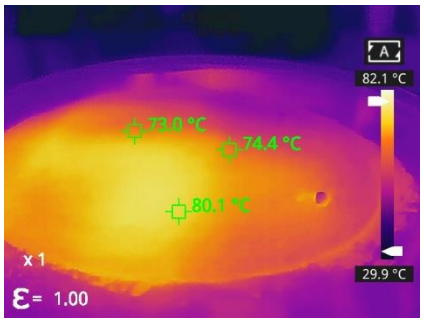
Measurements

Sp1	73.0°C
Sp2	74.4 °C
Sp3	80.1°C

Parameters

Emissivity	1.00
Temp.	82.1°C

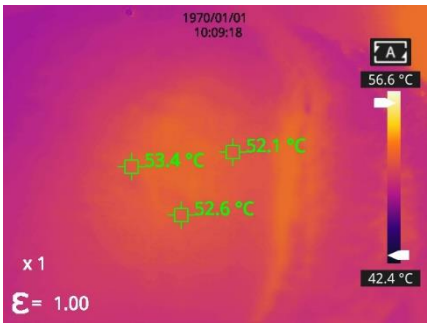


Measurements

Sp1	53.4°C
Sp2	52.1 °C
Sp3	52.6°C

Parameters

Emissivity	1.00
Temp.	56.6°C



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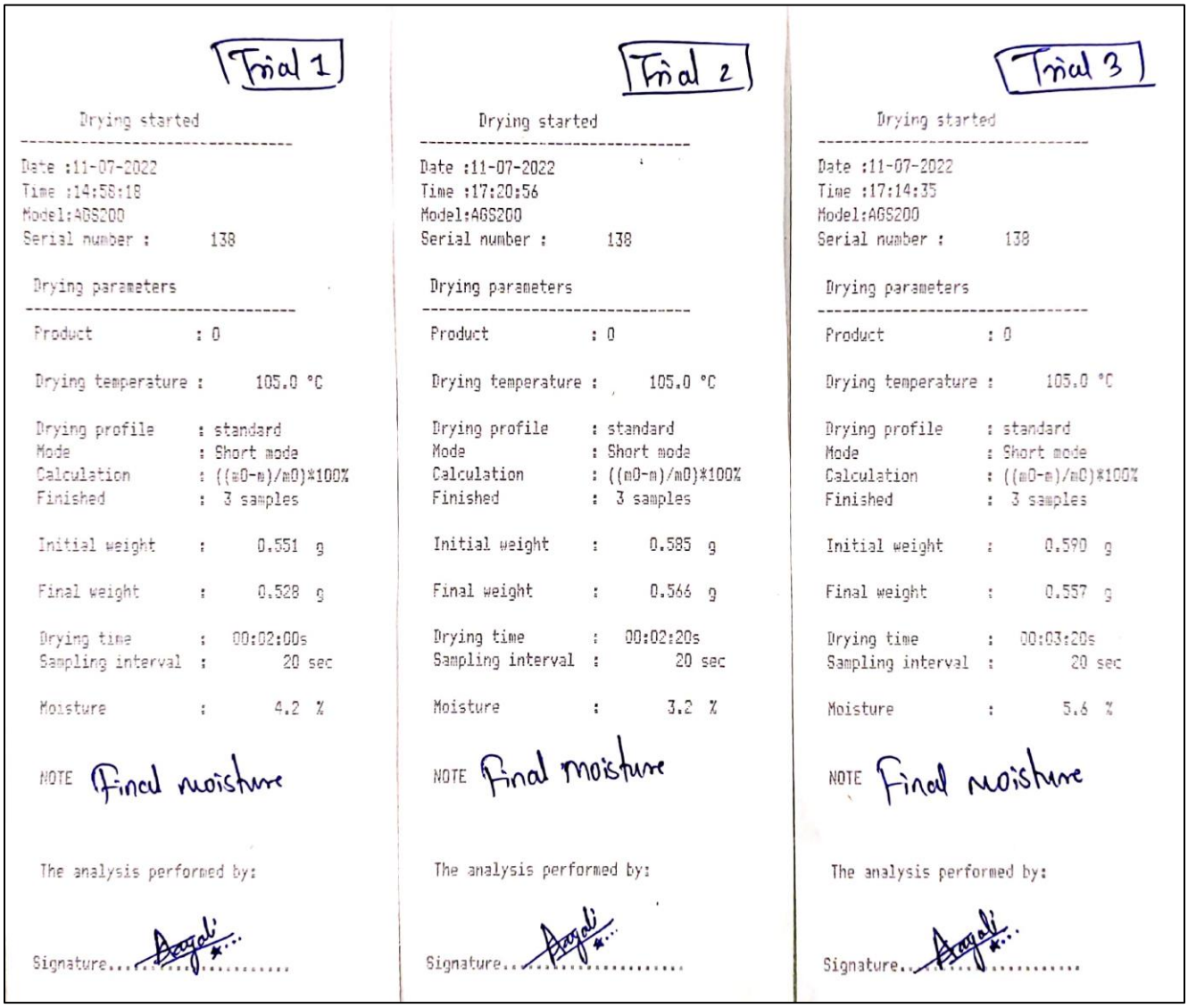
MOISTURE REPORT:



Trial 1

Drying started

Date :11-07-2022
Time :14:56:18
Model:AGS200
Serial number : 138

Drying parameters

Product : 0

Drying temperature : 105.0 °C

Drying profile : standard
Mode : Short mode
Calculation : ((m0-m)/m0)*100%
Finished : 3 samples

Initial weight : 0.551 g

Final weight : 0.528 g

Drying time : 00:02:00s
Sampling interval : 20 sec

Moisture : 4.2 %

NOTE Final moisture

The analysis performed by:

Signature.....

Trial 2

Drying started

Date :11-07-2022
Time :17:20:56
Model:AGS200
Serial number : 138

Drying parameters

Product : 0

Drying temperature : 105.0 °C

Drying profile : standard
Mode : Short mode
Calculation : ((m0-m)/m0)*100%
Finished : 3 samples

Initial weight : 0.585 g

Final weight : 0.566 g

Drying time : 00:02:20s
Sampling interval : 20 sec

Moisture : 3.2 %

NOTE Final moisture

The analysis performed by:

Signature.....

Trial 3

Drying started

Date :11-07-2022
Time :17:14:35
Model:AGS200
Serial number : 138

Drying parameters

Product : 0

Drying temperature : 105.0 °C

Drying profile : standard
Mode : Short mode
Calculation : ((m0-m)/m0)*100%
Finished : 3 samples

Initial weight : 0.590 g

Final weight : 0.557 g

Drying time : 00:03:20s
Sampling interval : 20 sec

Moisture : 5.6 %

NOTE Final moisture

The analysis performed by:

Signature.....

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OBSERVATION:

The drying behavior of Drug Substance - 1 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 the colour.

Ms. Sayali Asole
(Tested By)