KERONE

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ELECTRO MAGNETIC Innovative Technologies

Kerone Research & Development Centre (KRDC),
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Batch Convection + Dehumidifier Heat Treatment on USV Drug Substance-2

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 Convection + Dehumidifier Heat Treatment on USV Drug Substance - 2**

TEST REPORT No: 112/KRDC/LAB/66 Mum 14/07/2022

Date Sample reception : 12/07/2022
ID : 112/LAB/13

SAMPLE DESCRIPTION:

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

LAB BATCH CONVECTION + DEHUMIDIFIER HEATING SYSTEM

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LAB BATCH CONVECTION + DEHUMIDIFIER HEATING SYSTEM SPECIFICATIONS:

Heating Zone (width*height*depth)	550*650*550 mm
No. of Heaters	4
Total Heater Power	3 kW
Motor	0.5 HP
No. of trays	7
Tray size (width*height*depth)	600500 X 35
Nominal Capacity of Dehumidifier	1 tr each
Humidity Range of Dehumidifier	20-90%
Max. Ambient Temperature of Dehumidifier	40°C
Water Removal Rate of Dehumidifier	80 lt per day at NTP

ENVIRONMENT-LABORATORY AMBIENT CONDITIONS:

Temperature (°C)	26°C (±5°C)
Humidity (%)	≤74% 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 120 IR 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 to speed up the drying rate. For this experimental run, given sample has been placed on a SS tray and then placed in Horizontal Batch Convection Oven at certain decided temperature and time cycle. Observations are made on the final moisture content of sample weight and appearance of product.

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ANALYTICAL RESULTS:

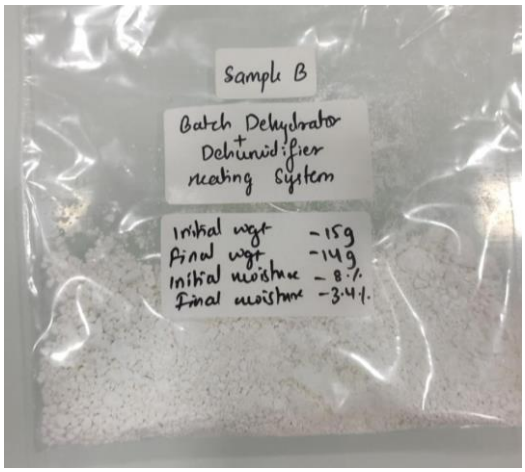
Trail 1:
Initial weight: 15g
Initial moisture: 8%

Sr. No.	Cycle time (mints.)	Heater temp. (˚C)	DEHUMIDIFIER		Remark, if any
			Relative Humidity (%)	Set temp (˚C)	
1	After 300 mints.	55	65	55	**Dried as desired On product temp- (57-59) ˚C**

Total cycle time: 5 hours
Final weight:13g
Final moisture: 3.4%

BEFORE AND AFTER PICTURES OF TREATED SPECIMEN SAMPLE:

Untreated



Treated

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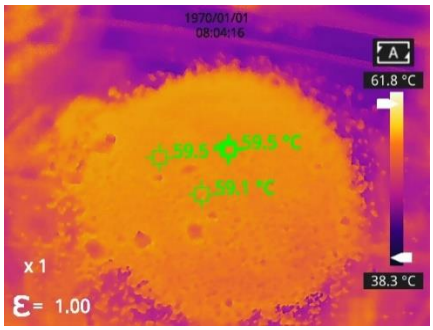
THERMAL ANALYSIS REPORTS:

Measurements

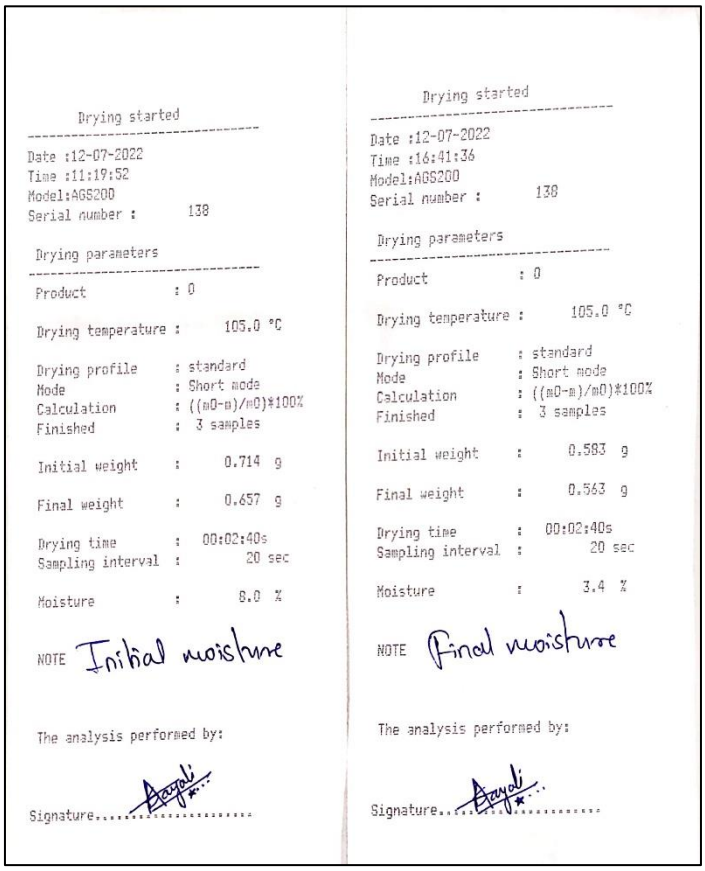
Sp1	59.5°C
Sp2	59.5°C
Sp3	59.1°C

Parameters

Emissivity	1.00
temp.	61.8°C



MOISTURE ANALYSIS REPORT:



Drying started

Date :12-07-2022
Time :11:19:52
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 : 0.714 g
Final weight : 0.657 g
Drying time : 00:02:40s
Sampling interval : 20 sec
Moisture : 8.0 %

NOTE Initial moisture

The analysis performed by:

Signature.....

Drying started

Date :12-07-2022
Time :16:41:36
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 : 0.583 g
Final weight : 0.563 g
Drying time : 00:02:40s
Sampling interval : 20 sec
Moisture : 3.4 %

NOTE Final moisture

The analysis performed by:

Signature.....

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OBSERVATIONS:

The Drying behavior of USV-Drug Substance-2 has been investigated under the convection heating system. The Drying rate is found to be increasing with respect to increasing drying time. It has been found that the moisture content on the dry basis (%) decreases with respect to increase drying time. As per physical investigation the product is allowed to dry steadily at different temperatures with Relative humidity around 65%, the desired moisture content was obtained.

Ms. Sayali Asole
Tested By