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ISO-9001-2008 COMPANY

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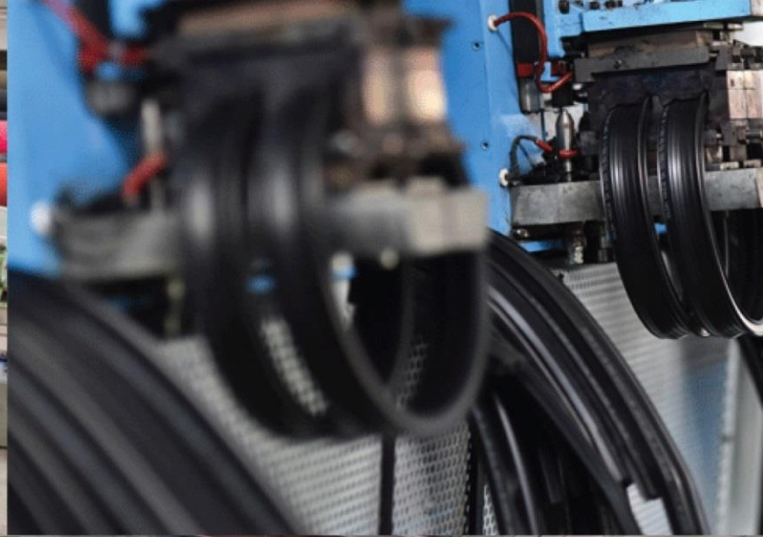
A.M.P.E.R.E (EUROPE)

In Association With



ELECTRO MAGNETIC innovative technologies

Kerone Research & Development Centre (KRDC),
B/47, Addl. MIDC. Anand Nagar, Ambarnath (East), Thane- 421 506, India
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**Spray Drying Heat Treatment for
Drying of USV Drug Substance-1**

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



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Customer :	M/s. USV Pvt. Ltd.
Process :	Spray Drying Heat Treatment for Drying of USV Drug Substance-1

TEST REPORT No: 110/KRDC/LAB/59 Mum 13/07/2022

Date Sample reception : 11/07/2022
ID : 110/LAB/13

SAMPLE DESCRIPTION:

Sampling : As Requested
Sample Condition : Acceptable
Quantity : 75 gms
Sampling date : 11/07/2022
Product : USV Drug Substance-1
Requirement : Dried upto powder formation
Start Date test : 11/07/2022
End Date test : 11/07/2022

LABORATORY EXPERIMENTAL SET UP:



Format: F/R&D/01



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LAB ELECTRIC SPRAY DRYING SYSTEM SPECIFICATIONS:

Drying chamber Installed Power	4.5 KW
Drying chamber Heat Load	250°C maximum
Pneumatic Air Pressure	6 bar
Dossing pump	6-7 rpm min.




ENVIRONMENT-LABORATORY AMBIENT CONDITIONS:

Temperature (degree C)	33°C (±5°C)
Humidity (%)	≤65% RH
Dehumidifier Set Parameters	Temp. 50°C & RH- 10.0%
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 plant surrounding conditions.



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: $\pm 1^{\circ}\text{C}$ (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 given sample of Drug Substance to speed up the drying rate. For this experimental run, given sample has been mixed in water and prepared as liquid solution 1:5 ratio (product: water) and then treated in spray drying system under different setting parameters. The observations are made on the basis final moisture content and physical appearance of final powder.



ANALYTICAL RESULTS:

Initial Substance: 75 gms in 375 ml water (Solution 450 ml)

Input Temperature(Heater): 220 °C

Process Temperature (chamber) (°C)	Cycle Mode	Dossing Pump (rpm)	Remark, if any
220	Continuous	5.0	Liquid converted to powder with desired particle size

Time req. to reach 230°C: 20min.

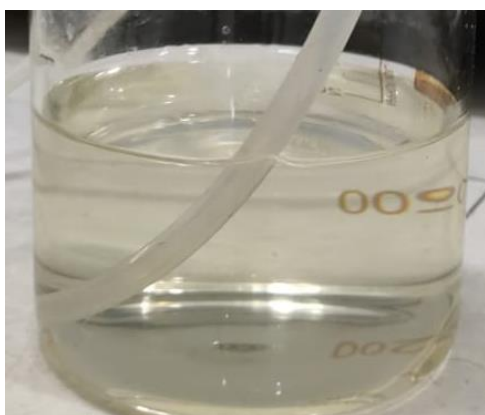
Total cycle time: 45 min.

Flow rate: 10 ml/min

Final Moisture Content: 7.2%

Final sample recovered: 10g

BEFORE AND AFTER TREATMENT PICTURES OF SPECIMEN SAMPLE:



Untreated



Treated



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MOISTURE ANALYSIS REPORT:

Drying started

Date :11-07-2022
Time :16:07:32
Model:AGS200
Serial number : 138

Drying parameters

Product : D

Drying temperature : 105.0 °C

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

Initial weight : 0.570 g
Final weight : 0.529 g

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

Moisture : 7.2 %

NOTE *Fined moisture.*

The analysis performed by:

Signature *Aayali*

OBSERVATION:

The drying behavior of USV-Drug Substance has been investigated under the Spray drying system. It has been found that the moisture content on the dry basis (%) decreases with respect to increase in input heating & dwell time. As per physical investigation, the solution become soft powder with desired particle size on drying. And the desired moisture content is obtained.

Tested By,
Ms. Sayali Asole