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Kerone Research & Development Centre (KRDC),

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Customer:	M/s. Granules India Limited
Process :	Batch Microwave+Convection Heat Treatment for Drying of Medicine Powders

TEST REPORT No: 47/KRDC/LAB/17 Mum 24/12/2018

Date Sample reception : 24/12/2018 ID : 47/LAB/75

SAMPLE DESCRIPTION:

Sampling : As Requested Sample Condition : Acceptable

Quantity : Paracetamol-75 kg & Metformin-80 kg

Sampling date : 07/01/2019

Product : Paracetamol Powder & Metformin Powder

Requirement : Final product must have moisture content less than or equal to 0.5%

Start Date test : 07/01/2019 End Date test : 08/01/2019

LABORATORY EXPERIMENTAL SET UP:







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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 (air flow 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	1HP
Tray Size	450x950x50 mm

ENVIRONMENT-LABORATORY AMBIENT CONDITIONS:

Temperature (degree C)	28.1°C (±5°C)
Humidity (%)	≤63% 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
Infrared Thermometer		Model: FLUKE 566 Temperature Range: -40°C to 650°C Display Resolution: 0.1°
Digital Contact Thermometer		Model No: TM-902C Temperature range: -50~750°C Temperature accuracy: ±1°°C
Moisture Analyzer	A CONTRACTOR OF THE PARTY OF TH	Make: Axis Balance Description: Moisture range: 1%(sample 0.02/0.05g), 0.1% (Sample 0.5/5g), 0.01%(Sample>5g)
Thermo Hygrometer	TO BE THE STATE OF	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 Paracetamol powder and Metformin powder separately without adding any additive to speed up the drying rate. For this experimental run, particular quantity of

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sample has been taken in microwave transparent tray with uniform thickness and this powder loaded tray has been placed in heating system with different setting parameters. The observations are made on the basis of LOD and moisture content.

ANALYTICAL RESULTS:

1. Paracetamol:

Initial Moisture Content: 5.6%

	Trail	No. 1			Trial	No. 4
	Initial 15	Next 15	Trial No.2	Trial No.3	Initial 15	Next 15
	minutes	minutes			minutes	minutes
Microwave Power (kW)	1	1.5	2	2	2	2
Setting Temperature (°C)	80	80	110	140	140	140
Cake Thickness (mm)	10	10	20	15	15	15
Cycle Time (minutes)	15	(15+)15	15	20	15	(15+)15
Initial Weight (grams)	350	340	398	602	532	498
Final Weight (grams)	340	338	380	562	498	489
Temp. on Product after treatment (°C)	42-45	50-55	55-58	60-65	60-65	70-80
Final Moisture content (%)	3.6	0.47	1.1	0.5	2.1	0.2

2. Metformin:

Initial Weight: 570 grams
Initial Moisture Content: 0.8%

Microwave Power: 2 kW Setting Temperature: 140°C

Cycle Time: 5 minutes
Final Weight: 549 grams
Final Moisture Content: 0%

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MOISTURE ANALYSIS REPORTS:

1. Pracetamol:

		Drying started	Drying started
og Drying started		Date : 7-01-2019	Date : 7-01-2019
Date: 7-01-0019 Time: 15:47:20 Hodel: 486200 Serial number: 138	Pate : 7-91-2019 Time :17:99:45 Model:AGS200 Serial number : 138	Time :16:53:34 Model:x86200 Serial number : 138 Drying parameters	Time :18:29:13 Model:A69200 Serial number : 138 Drying parameters
Drying parameters	Drying parameters		
Product : Test Drying temperature : 105.0 °C	Product : Test	Product : Test Drying temperature : 105.0 °C	Product : Test Drying temperature : 105.0 °C
Drying temperature Drying profile : standard	Drying temperature : 105.0 °C Brying profile : standard : Short mode : Short mode : (m0-m)/m0/#100% : 3 samples	Drying profile : standard Node : Short mode Calculation : ((m0-m)/m0)*100% Finished : 3 samples	Drying profile : standard Hode : Short mode Calculation : ((#0-#)/#0)#180% Finished : 3 samples
Initial weight : 0.947 g	Initial weight : 0.805 g	Initial weight : 0.543 g	Initial weight : 0.506 g
Final weight : 0.894 9	Final weight : 0.801 g	Final weight : 0.537 g	Final weight : 0.505 g
	Prying time : 00:01:40s Sampling interval : 20 sec	Drying time : 00:01:40s Sampling interval : 20 sec	Drying time : 00:01:40s Sampling interval : 20 sec
Moisture : 5.6 %	Moisture 1 0.5 %	Moisture : 1.1 %	Moisture : 0.2 %
MOTE Initial	NOTE Final (Trial No.3)	MOTE Final (Trial No.2)	NOTE final (Trial No.4)
The analysis performed by:	The analysis performed by:	The analysis performed by:	The analysis performed by:
Signature	Signature. KKomaL	Signature.	Signature

2. Metformin:

		Date : 7-01-2019
Bate : 7-01-2019		Time :18:45:08
Time :18:48:20		Model:A05200
Model:AGS200		Serial number : 138
		Drying parameters
Product	- 7-st	Product : Test
		Brying temperature : 105.0 °C
Drying temperatur	e: 105.0 °C	
		Drying profile : standard
Drying profile		Brying profile : standard Mode : Short mode Calculation : ((mD-m)/mD)\$1007
Mode		Calculation : ((m0-m)/m0)*1003
Calculation	: ((#0-#)/#0)#100%	Finished : 3 samples
Finished	: 3 samples	
		Initial weight : 0.589 g
Initial weight	: 0.504 g	
		Final weight : 0.602 g
Final weight	: 0.500 g	
	01 50	Drying time : 00:01:40s
Drying time	: 00:01:405	Sampling interval : 20 sec
Sampling interval	: Zu sec	
	5 0 W	Moisture s 0.0 %
Moisture	: 0.8 %	
		6'4.1
HOTE Initial		NOTE Final
IOTE INTICO		
		The analysis performed by:
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OBSRVATIONS:

The Drying behavior of Paracetamol powder and Metformin powder has been investigated under the Microwave+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, it has been observed that there is complete drying with required moisture content without colour change.

As discussed and further suggestion received from you for more trials testing will done on your samples in large quantities and same along with reports will be submitted you in coming week for ready reference.

Based on samples submission and feedbacks from your laboratory tests and acceptance, will then proceed for submittal of techno-commercial offer for drying solutions.

> **Miss Komal Bhoite Tested By**