

RESIDUAL MOISTURE AND LOSS ON DRYING 420952

1 Scope

Residual Moisture and Loss on Drying testing of desiccant samples.

2 Purpose

This work instruction describes the process used to determine the moisture content of a desiccant sample.

3 Definitions

RM- Residual Moisture

LOD – Loss on Drying

IR- Infrared

4 Responsibilities

Quality personnel are responsible for testing and the release/rejection of materials.

5 Description

- 5.1 In order to determine the RM of desiccant material, the desiccant fill material must be removed from the outer packaging.
- 5.2 Primary method for Silica Gel, Clay, and 2-In-1 products: IR balance set at 200° C for 10 minutes
 - 5.2.1 Fill out the Residual Moisture (RM) Log Sheet with all the appropriate information.
 - 5.2.2 Weigh approximately 10 grams of desiccant fill material into the tarred-out aluminum weigh pan in the IR balance.
 - 5.2.3 Close the lid and press the ‘Start’ button.
 - 5.2.4 After 10 minutes read the residual moisture % on the display panel. Fill in the log sheet with the result.
- 5.3 Secondary method for Silica Gel, Clay, and 2-In1 products is to use a 150° C circulating hot air oven for 3 hours. (For USP/NF type testing, dry at 145° C in a circulation hot air oven for 4 hours)
 - 5.3.9 Fill out the Residual Moisture (RM) Log Sheet with all the appropriate information.
 - 5.3.10 Weigh approximately 10 grams of desiccant fill material into a ceramic crucible.
 - 5.3.11 Place the crucible into a 150° C circulating hot air oven for 3 hours.
 - 5.3.12 After 3 hours, remove the crucible and place into a dessicator, allowing it to reach equilibrium with room temperature. Transfer the material into a tarred-out aluminum weigh pan and record the final weigh on the log sheet.

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- 5.3.13 To calculate the % of residual moisture, use the following formula:
- $$\Delta \text{ weight (C)} = \text{Initial Sample Weight (A)} - \text{Final Sample Weight (B)}$$
- $$\% \text{RM} = [\Delta \text{ weight (C)} \div \text{Initial Sample Weight (A)}] \times 100$$
- 5.3.14 Passing RM results for finished product testing can be found in SAP.
- 5.3.15 Passing results for incoming inspection are listed in the applicable Work Instruction.
- 5.4 Method for Residual Moisture of activated Carbon samples:
- 5.4.1 After documenting the appropriate information on the log sheet, weigh approximately 10 grams of the carbon sample into a tarred-out aluminum weigh pan and record the weight. Then place the sample into the 105° C circulating hot air oven for one hour.
- 5.4.2 After 1 hour, remove the sample from the oven and place in a desiccator to cool. Record the final weight on the log sheet.
- 5.4.3 As before, calculate the % residual moisture using the formula described in 5.3.13.
- 5.4.4 Passing RM results for carbon products are located in SAP.
- 5.4.5 Passing results for incoming inspection are listed in applicable Work Instruction.
- 5.5 Loss on Drying (LOD) of Molecular sieve products:
- 5.5.1 Fill out the log sheet with all appropriate information.
- 5.5.2 Weigh out approximately 10 grams of material directly into a ceramic crucible.
- 5.5.3 Place the crucible containing the sample into the muffle furnace at 570° C. 4A and 3A molecular sieve is tested for 3 hours. 13X, tablets, and all other sieve samples are tested for 5 hours.
- 5.5.4 Remove the crucible from the furnace and place it in a desiccator to cool.
- 5.5.5 Transfer the material into a tarred-out aluminum weigh pan and record the final weight on the log sheet.
- 5.5.6 To calculate LOD, using the formula described in 5.3.13.
- 5.5.7 Passing RM results for finished product testing are in SAP.
- 5.5.8 Passing results for incoming inspection are listed in applicable Work Instruction.
- 5.6 In the event that the RM or LOD is higher than acceptable limits for the product(s), re-test the product twice to verify the results. If at least one of the retest fails, the product will be rejected.

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6 Documents/Records

GMS 991973: FORM BU MB MS US BELEN Residual Moisture Log

7 References

GMS 421006: WI BU MB MS US BELEN Dessicators Maintenance

8 Validity and Revision Cycle (including application date)

This document is valid until replacement by next review/version or it's archiving

9 Distribution

See "Distribution List" in metadata on GMS

10 Attachments

Not Applicable

11 History

Revision	Date	Change	Motive	Approval
1	10/3/2012	Original Issue	Migration to GMS	
2	10/11/2013	Update format	Update to Clariant format	
3	03/17/2016	Added reference to RM log sheet to Section 5	Update to current Clariant Process	



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