Work Instruction

RESIDUAL MOISTURE AND LOSS ON DRYING

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-In1 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:

\[ \Delta \text{weight (C)} = \text{Initial Sample Weight (A)} - \text{Final Sample Weight (B)} \]

\[ \%\text{RM} = \left( \frac{\Delta \text{weight (C)}}{\text{Initial Sample Weight (A)}} \right) \times 100 \]

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

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