

FMS-Water Activity Analyzer

SYSTEM SPECIFICATIONS

The FMS-Water Activity Analyzer is a non-destructive gas analyzer for making water activity measurements of solid dosage drug product samples. This compact analyzer utilizes a patented laser absorption technique developed with funding from the Food and Drug Administration. Light from a near-infrared laser is tuned to match an internal absorption frequency of the water vapor molecule and passed through a glass sample container in the headspace above the product. The amount of laser light absorbed is proportional to the water vapor concentration in the headspace which in turn can be directly related to the water activity of the pharmaceutical solid. The

non-destructive nature of the measurement method enables a broad range of moisture activity applications and offers significant advantages over traditional techniques.

Applications include:

- Water activity determination of solid dosage and powder product
- Real-time moisture exchange studies
- Water vapor transmission rate studies
- Replacement of Karl Fischer Titration (KFT), Loss On Drying (LOD) for lyo moisture determination
- Rubber stopper drying studies

NOMINAL SPECIFICATIONS

Moisture Measurement Linearity Range: 0 to 100% RH

Temperature Control Range 19 to 45°C

Measurement Time: 5 seconds (default)

Sample container sizes: 1ml to 50ml

PHYSICAL AND ELECTRICAL

Dimensions (HxWxD) 292 x 305 x 405 mm (11.5" x 12.0" x 15.9")

Weight 19.5 kg (43 lbs)

Power Requirements 110-240 VAC, 50/60 Hz, 180W

Controller PC





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MOISTURE PERFORMANCE DATA

Six clear glass vials were prepared with saturated salt solutions to create moisture standards at approximately 94, 75, 58, 33, 11, and 6% RH. Water and desiccant samples were used for 100% and 0% RH standards. The relative humidity in each vial was measured at an equilibration temperature of 24 degrees Celsius using the FMS-Water Activity Analyzer. The analyzer measures the absorption of laser light by water vapor molecules in the container headspace. The amplitude of the absorption signal is proportional to the relative humidity. The mean measured moisture for each

of the eight moisture standards is presented in Table 1. Figure 1 is a plot of the measured versus known relative humidity in each vial. The non-destructive nature of the measurement enables a full statistical documentation of system performance. From an application point-of-view, the non-destructive measurement enables multiple measurements on the same sample over time, 100% analysis of a batch giving insight into process variability and optimization, and real-time monitoring of moisture dynamics.

STANDARD	ACTUAL (% RH)	MEAN (% RH)	STDEV (% RH)
water	100	98.8	0.28
KNO3	93.6	93.3	0.78
NaCl	75.3	76.8	1.56
NaBr	57.6	59.9	1.20
MgCl2	32.8	33.4	0.99
LiCl	11.3	11.6	0.07
LiBr	6.4	6.8	0.14
Desiccant	0.0	0.6	0.42

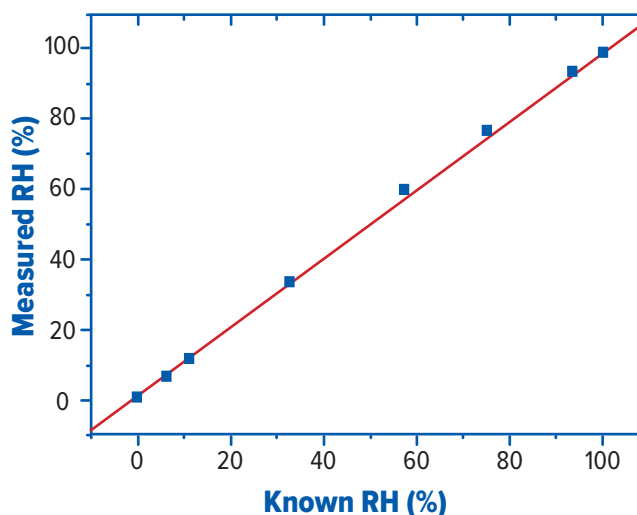


Figure 1. Linearity for moisture measurements by the FMS-Water Activity Analyzer.

Table 1.
Relative humidity measurements on known moisture standards

