

Between wet and dry

Special technology for measuring the equilibrium humidity of pharma products

Humidity and temperature measuring applications are legion in the pharmaceutical industry. Measurements in hazardous areas, at pressures up to 50 bar or in a temperature range from -50...200 °C are not at all uncommon. Suitable hardware includes ready-installed measuring transmitters with networking capability as well as independently operating digital data loggers and universal hand-held meters.

PETER MÜLLER

In hardly any other sector are the internal requirements and legal regulations both so stringent as in the pharmaceutical industry. With the wheel of globalization turning ever faster, it is becoming increasingly necessary to comply with European standards and American guidelines such as FDA CFR 21 Part 11. To satisfy these stringent requirements, household names like Boehringer Ingelheim Pharma don't leave it to chance whom they trust when it comes to hygrometry. Measuring the equilibrium humidity of pharmaceutical products demands special technology. Maximum accuracy, long term stability of the sensory mechanism as well as compatibility of the system components are all essential. HygroClip technology from Rotronic meets these demands. This modular, digital technology enables the precise determination of both moisture and temperature for all applications.

Optimizing the atmosphere

In different environments such as clean-rooms, stabilized rooms, process and production rooms, the requirements on climate regulation may vary. In some cases the supply air is controlled, in others it is the exhaust air.

Up to three humidity sensors are used to control the supply air on the basis of an average value. These sensors are constantly monitored for differences in order to ensure safe and reliable operation. If the value of one transmitter differs by more than 5%, it can be checked immediately. With exhaust air control- usually a cascade control system - an exhaust air probe supplies the actual value while an upstream supply air probe delivers the threshold value. Over-humidification is prevented by a reliable shut-off valve. Conditioning of process atmosphere is more complex. Often it is not just limited to the regulation of relative humidity and temperature but has to meet product-specific requirements. Regulation based on dew point absolute humidity or wet bulb temperature - also as a function of pressure - is not uncommon. In these cases the advantages of digital industrial measuring transmitters really pay off. Process engineers are able to optimize the relevant parameters of the freely configurable Rotronic industrial measurement transmitters in the HygroFlex series universally for whatever product they wish. Configurations such as temperature range, analogue outputs (e.g. 4...20 mA, 0...10 V etc.), on-line pressure compensation and calculated values such as dew point, mixing ratio, enthalpy, etc. can be suitably modified by jumper connection or personal computer for the requirements in question and be optimally graduated.

The responsible process engineer can thus be sure that ideal climatic conditions exist whenever the behaviour of pharmaceutical products is being researched and constant process conditions are essential.

Independent monitoring

Indication and recording of relative humidity and temperature are carried out by means of a separate independent monitoring system. The monitoring area contains in addition to the ready-installed networked measurement transmitters HygroLog dataloggers in conjunction with the HygroClip-S sensor module.

Allocation to a quality class

The compact data loggers- available with or without an LCD, are simple to program with the validated software HW3 (FDA 21 CFR Part 11) and can

be universally used. To qualify the plant in accordance with GMP, Boehringer Ingelheim uses certified HygroClip-S probes. Every measuring point is allocated to a quality class and calibrated according to work instructions. Calibrations are organized, administered and recorded on the basis of a servicing schedule. Calibration of hygrometers requires know-how, particular care and conscientiousness. Measurement of water activity is most important for all products of a hygroscopic nature, or whose handling is influenced by the presence of moisture. Where highly sensitive pharmaceutical products are concerned, this is an especially interesting area of application for the digital measuring instruments of the HygroClip series.

Essential know-how as well as the theoretical and practical fundamentals of calibration is acquired by the responsible staff through regular visits to Rotronic calibration seminars. Specific applications are also discussed here, practical suggestions examined and the necessary adjustments for products prepared. The most recent development to arise from this close cooperation is a new type of hygro / temperature sensor for measurements in nitrogen or compressed-air systems. Combining this with the HygroPalm handheld meter or the HygroLog data logger, it is simple to measure and record relative humidity, temperature and dew point or vapor concentration.

Advantages

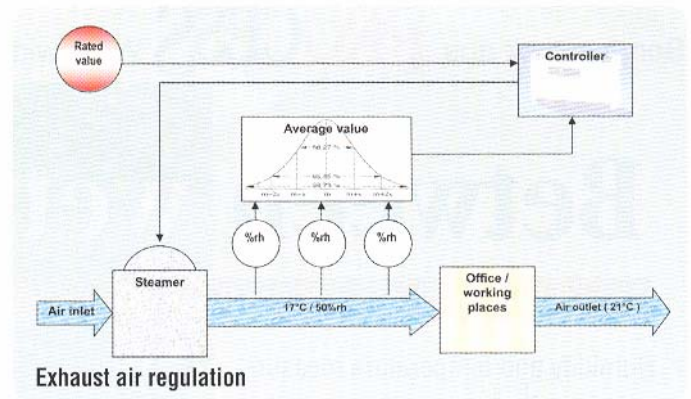
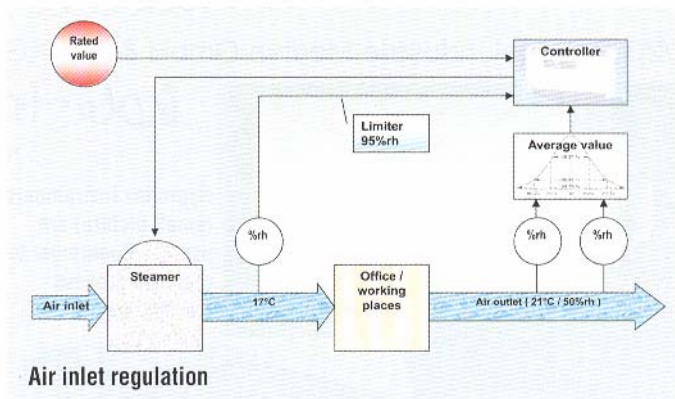
Digital signal processing offers the following decisive advantages:

- Measuring is accurate through digital linearization and temperature compensation.
- Calibration and servicing are easy with an internal memory in which the calibration data are stored.

This means that the HygroClip sensors can be exchanged in a matter of seconds and without restrictions.

- The digital circuits have greater precision and are less susceptible to alterations in temperature.
- The sensor range can be combined with measurement transmitters, laboratory table appliances or any

- other analyzing units.
- Digital technology offers the possibility of determining various psychrometric parameters such as dew point, mixing ratio or enthalpy.
 - HW3 software is qualified, validated and meets the requirements of FDA CFR 21 Part 11.



The author, Peter Müller, is product manager at Rotronic Bassersdorf/CH.

ROTRONIC AG
Grindelstrasse 6
8303 Bassersdorf

Contact:
Rainer Senn
+41 (0)44 838 13 05
senn@rotronic.ch