PC9020

TEMPERATURE AND RELATIVE HUMIDITY CONTROL IN THE PACKAGING ENCLOSURE OF SOLID ORAL DOSAGE FORMS.

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What was done?

A temperature (t) and Relative Humidity (RH) control system has been established in the enclosure where the solid oral dosage forms (SODFs) are packaged in unit doses.

How was it done?

Among the diversity of hygrometric sensors commercialized, a device equipped with a condenser was chosen.

The operation is based on modifying the capacity when varying the dielectric constant of the medium, in this case, due to varying the amount of water contained in the air between the plates.

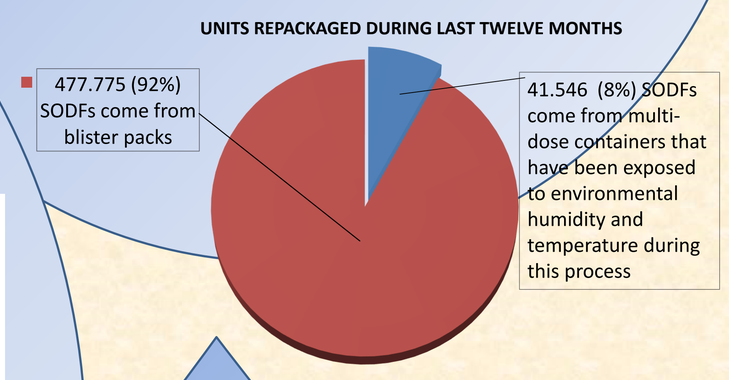
$C = \varepsilon A / D$

- C: capacity value.
- ε: dielectric constant.
- A: area of the condenser plates.
- D: distance between the condenser plates.

The device also incorporates a temperature sensor.
The t (ºC) and RH of each moment, are shown, for visual inspection, on the device screen.
The data obtained with certain time frequency can be stored on a Secure Digital memory card and be downloaded on a computer that has that program installed (on spreadsheet format) helping to obtain graphics as well.

Why was it done?

The purpose is to control two environmental conditions to guarantee the comfort of the workforce and the quality of the finished product.
519.321 SODFs have been repackaged in unit doses last year. Employees have been exposed to identical conditions.



What has been achieved?

The range of t (ºC) has remained stable between 26 and 24 ºC for 6 months, with minimal variations from maximum 28,5 ºC to minimum 23,4 ºC
The UNE 100713: 2005 is met.
RH has been below 45% during 68% of the days worked, which has favored the repackaging of the units affected by humidity but not the worker.
The range of RH has varied between 56,3% and 23,6%, not complying with the UNE 100713: 2005 standard.

What next?

Metabolic rate, clothing insulation, air temperature, radiant temperature, air speed and humidity shall be addressed when defining conditions for acceptable thermal comfort. It would be helpful to regulate the commercialization of multidose pharmaceutical specialties susceptible to deterioration when opening the package.

https://www.eahp.eu/gpis/temperature-and-relative-humidity-control-packaging-enclosure-solid-oral-dosage-forms