



PHARMACY CHECKLIST

Does your temperature monitoring comply with current regulations?



The safe and secure handling of medicines

Rotronic offers solutions and support for pharmacy owners to help them meet the latest requirements for temperature monitoring at all stages of pharmaceutical distribution. Contact us to discuss your requirements. Email: instruments@rotronic.co.uk or call: 01293 571000.

TEMPERATURE MONITORING

Do you monitor temperature critical areas, how do you know if conditions are out of specification?

Requirements			Monitoring?		Current equipment?
Area	Minimum	Maximum	Yes	No	
Shop Floor	15 °C	25 °C	<input type="radio"/>	<input type="radio"/>
Fridges / cold rooms	2 °C	8 °C	<input type="radio"/>	<input type="radio"/>
Freezers		-15 °C	<input type="radio"/>	<input type="radio"/>
Goods in area	15 °C	25 °C	<input type="radio"/>	<input type="radio"/>
Warehouse	15 °C	25 °C	<input type="radio"/>	<input type="radio"/>
Dispensing area	15 °C	25 °C	<input type="radio"/>	<input type="radio"/>
During transport	15 °C	25 °C	<input type="radio"/>	<input type="radio"/>

MONITORING APPROACH

Is your monitoring approach compliant and effective?

Specification		Adherence		Current methodology
Activity	Interval	Yes	No	
Temperature monitoring	Continuous	<input type="radio"/>	<input type="radio"/>
Control and recording keeping	Daily	<input type="radio"/>	<input type="radio"/>
Deviation records	As they occur	<input type="radio"/>	<input type="radio"/>
Instrument calibration	As per regulations (typically annually)	<input type="radio"/>	<input type="radio"/>

DOCUMENTATION

How and what do you document?

Requirements	Adherence		Current methodology
	Yes	No	
Is monitoring data and records immutable with full audit trail?	<input type="radio"/>	<input type="radio"/>
Are procedures defined and acted on to ensure product quality?	<input type="radio"/>	<input type="radio"/>
Is evidence of non-compliance to temperature recorded and retained?	<input type="radio"/>	<input type="radio"/>
Are procedures defined for when temperature limits are exceeded. Eg standard operating procedures (SOP)	<input type="radio"/>	<input type="radio"/>

OTHER IMPORTANT PARAMETERS

In addition to the legal requirements of temperature compliance, other measurement parameters may also be important for individual applications.

Application area	Parameter	Required		Details
		Yes	No	
Drug processing areas	Relative humidity	<input type="radio"/>	<input type="radio"/>
Laboratories	Differential pressure	<input type="radio"/>	<input type="radio"/>
Packing areas / cleanrooms	Differential pressure	<input type="radio"/>	<input type="radio"/>
Work areas	CO ₂ and Lux	<input type="radio"/>	<input type="radio"/>

IMPORTANT CONSIDERATIONS!

- For optimum placement of the temperature monitoring devices it is recommended that a thermal mapping be undertaken beforehand to define monitoring locations.
- Humidity and temperature measurement devices should be calibrated annually.
- Always consider the life cost of a system or process including user time, maintainence, flexiblty and expandability... and of course compliance to current and potential future standards.