

Headspace Moisture Analysis in Medical Device Packages

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Moisture levels in medical device packages influence a variety of crucial device properties, e.g. mechanical properties, corrosion and leach rates, drug potency, and ultimately shelf life. This is especially true for drug releasing and biodegradable device materials. It is therefore important to establish a high degree of control and accuracy of the humidity levels at all relevant stages in the production process as well as in the final package. In the current study we demonstrate a newly developed method for accurate headspace moisture trace level analysis in medical device packages using extractive gas phase Fourier transform infrared (FTIR)

spectroscopy. Volumetric aliquots were extracted, using a specially designed extraction assembly, from the headspace of medical device relevant packages. The headspace water concentration was analyzed using a validated gas phase FTIR system¹. Water bands in the spectral region 1600–2200 cm⁻¹ were chosen for the quantitative analysis. Sample spectra were compared, with a least square fit procedure, to water reference spectra at known concentration. Accurate quantification was demonstrated for headspace water vapor concentrations less than 100 ppm. This is considerably lower than feasible with conventional package headspace moisture analysis techniques. The results of this study demonstrate the benefits of using extractive gas phase FTIR for low level moisture analysis of small headspace volumes.