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4:00 PM-4:30 PM
Horiba Scientific

Rapid, Optical Technique For Sensitive Characterization and Differentiation of OTC Canine Vaccines
The pharmaceutical industry increasingly relies on spectroscopy for quality assurance and has established, and conforms to, USP (United States Pharmacopeia) regulations. While some spectroscopic approaches (NIR, FT-IR and Raman) are common, the adoption of fluorescence spectroscopy has lagged, even though it has high specificity and sensitivity in many analyses in demand, and is conveniently amenable to chemometrics analysis.

We present identification and validation of "unknown" samples with 100% certainty based on A-TEEM fluorescence analysis of Solo-Jec brand canine vaccines from Boehringer Ingelheim VetMedica: Spectra-5, Spectra-6, Spectra-9, and Spectra-10, containing 5, 6, 9 and 10 vaccine combinations, respectively of coronavirus, hepatitis, adenovirus, parainfluenze, leptospirae, parvovirus, etc. A key consideration upon an established vaccine product release is specificity. Analytical techniques need to characterize the final product, and must also differentiate between it and all others made at the facility. The 3-D fluorescence molecular fingerprints of these vaccines were subjected to chemometric analysis through PARAFAC classification as well as XGBOOST discriminant analysis. The "most probable prediction" of unknown samples with 100% certainty was substantiated by the generated *confusion matrix* supporting the A-TEEM fluorescence claim to be a powerful addition to the arsenal of validation techniques. Two lots for each vaccine were measured on one instrument and were validated with a different lot, instrument and operator. The data analysis approaches used were each able to differentiate between the vaccine products. Even Spectra-9 and Spectra-10, that differ ONLY by a coronavirus component based on publicly available SDS data, were readily distinguished.

Fluorescence EEMs (Excitation-Emission Matrix) solve the longstanding issue of imperfect quantification (a result of the Inner Filter Effect) by directly incorporating a UV spectrophotometer in the fluorometer. This allows the *simultaneous acquisition in situ* of a UV/VIS/NIR-absorbance spectrum for the real-time Inner Filter Effect (IFE) correction of the fluorescence spectrum, improving quantification accuracy and extending the usable range of concentrations over which quantification can be performed. A-TEEM (Absorbance Transmission Excitation Emission Matrix) is fully validatable using United States Pharmacopeia monograph USP <853>, given that the novel aspect of simultaneous acquisition of the UV/VIS/NIR absorbance spectrum for IFE correction is fully compatible with validation protocols. This spectroscopic approach provides a complete and traceable optical fingerprint for liquid samples that performs a similar role to chromatographic methods, and compared to other spectroscopic methodologies is faster, less expensive and can operate in production environments.

Speaker
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