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Raw material analysis by Fourier Transform Infrared Spectroscopy
Presentation: Quality of Manufactured Medicines – Raw material testing
"Raw Material Analysis by Fourier Transform Infrared Spectroscopy"
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FTIR was assessed to probe suitability and stability of raw materials. We found that FTIR analysis can be used to assess the suitability of various lots of a peptide-based raw material received by Sanofi Pasteur. This analytical screening using FTIR helped to manage costs since only lots determined to be suitable for the media production process were accepted for purchase. In addition, the early-stage determination of a suitable raw material lot ensures that the appropriate quality of raw material will be available to achieve the desired yield of product antigen. The FTIR method has allowed us to identify raw material lots that are associated with low yields, therefore avoiding lost time in manufacturing.

FTIR was also used for the characterization of the adjuvants based on aluminum salts; specifically their concentration, dependence on pH and buffer effect. Furthermore, FTIR was applied to probe potential structural alterations of adjuvanted antigens during stability monitoring.

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