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SPECIFIC PROTEIN MEASUREMENT AND QUANTITATION USING TUNABLE LASER SPECTROSCOPY

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SUMMARY

While UV-Vis spectroscopic analysis is commonly used to measure protein concentration, it struggles to accurately quantify protein titer exceeding 100 mg/mL without dilution. However, as monoclonal antibody (mAb) formulations are trending towards significantly higher concentrations (for instance, 200-300 mg/mL), the Nirrin NXT has emerged as a simpler solution. This system utilizes a tunable laser and relies on near-infrared (NIR) spectroscopy to generate a unique and quantifiable protein signature. It offers wide dynamic range, accuracy, and precision, all without the need for dilution.

EXPERIMENTAL PROCEDURE

A sample containing 100 mg/mL of a commercial mAb in a 20mM Histidine buffer (pH adjusted with HCl) was prepared and measured using an NXT prototype following the protocol below. The sample was then analyzed using the NXT software and a validated NISTmAb spectrum from the embedded library. Next, the sample spectrum was re-analyzed using a Nirrin patented mAb characterization protocol and a unique software-generated mAb spectrum for the drug substance.

1. Pipette 15 µL of deionized water on the sample pedestal and scan (background)
2. Clean with Kimwipe
3. Pipette 15 µL of sample and scan (in seconds)
4. Select analytes for quantitation, run analysis, and obtain quantitative results

RESULTS: THE EFFECT OF MAB SPECIFICITY ON EXCIPIENT MEASUREMENTS

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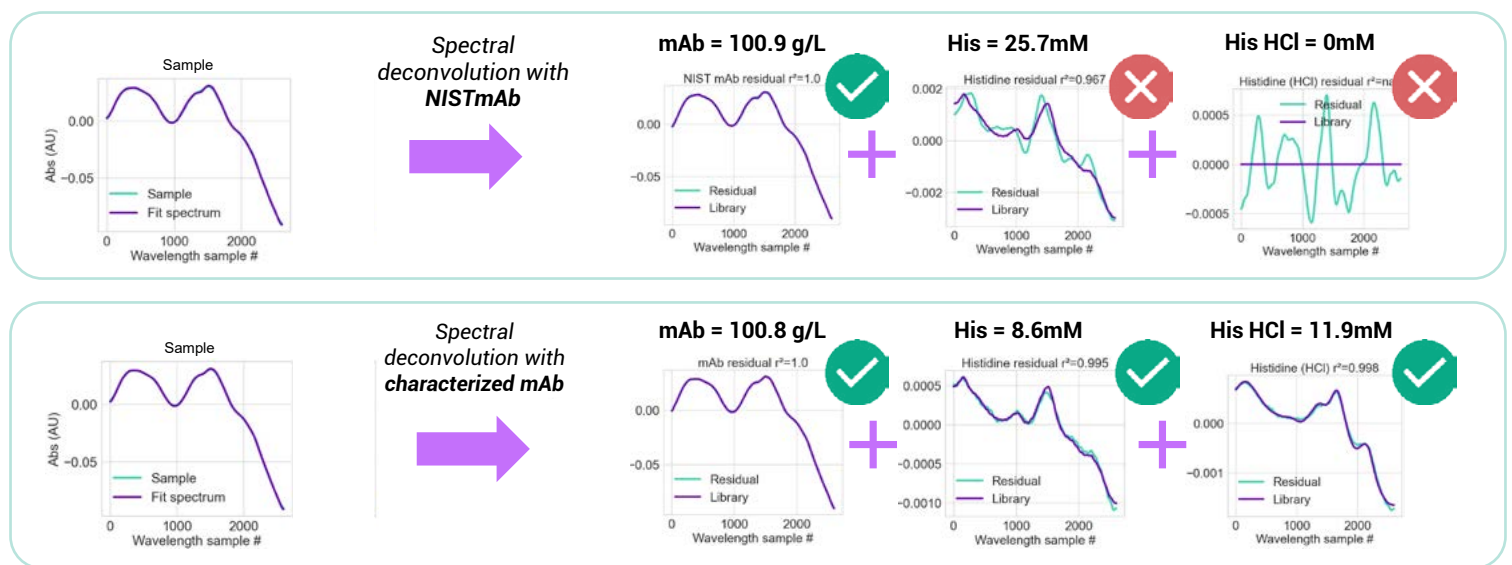
CONCLUSIONS

The Nirrin NXT tunable laser platform and patented mAb characterization protocol can generate a unique NIR spectral signature for a drug product. Using a NISTmAb library spectrum, the system accurately predicted the concentration of a proprietary mAb product, but excipient concentrations did not match the sample formulation. The Nirrin patented mAb characterization calculated a unique spectral signature of the proprietary mAb, enabling an accurate concentration determination for both protein and excipient components. NXT is the first-in-class, at-line solution for quantitative protein and excipient measurements in downstream bioprocessing.

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