The central role of NIR spectroscopy in the oral solid dosage Real Time Release testing

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Over the past few years, the role of the NIR spectroscopy into drug product release testing has become crucial. The NIRs analysis performed on core and coated tablets to evaluate assay and API content uniformity substituted the classical chromatographic technique. Furthermore, NIR spectroscopy outcomes are used also as input for the development of surrogate models predicting tablet dissolution profile.

These applications in addition with the “sunsetting” of some specific tests lead into a significant testing time reduction allowing faster and in quality product release on the market.

This presentation will elucidate the main steps of the first Janssen Real Time Release testing application on batch manufacturing production. Starting from the multivariate evaluations behind the eligibility of the application of this alternative release strategy, a specific focus on the use of the NIR spectroscopy will be provided including model maintenance strategy.

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