COMPARATIVE STUDY OF ACTIVE PHARMACEUTICAL INGREDIENT QUANTITATION THROUGH THE PACKAGING USING HANDHELD SPECTROPHOTOMETERS BASED ON CONVENTIONAL AND SPATIALLY OFFSET RAMAN SCATTERING

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Handheld Raman spectroscopy is actually booming. Recent devices aim at addressing the usual Raman spectroscopy issues: fluorescence with shifted-excitation Raman difference spectroscopy (SERDS), poor sensitivity with surface enhanced Raman scattering (SERS) and only surface information with spatially offset Raman spectroscopy (SORS). While qualitative performances of handheld devices are generally well established, the quantitative analysis of pharmaceutical samples remain challenging.

The aim of this study was to compare the quantitative performances of three commercially available handheld Raman spectroscopy devices. Two devices (ThermoFisher's Truscan and Ocean Optic's IDRaman mini) are equipped with a 785 nm laser wavelength and operate in a conventional backscattering mode. The IDRaman has the Orbital Raster Scanning (ORS) option to increase the analyzed surface. The third device (Agilent's Resolve) operates with a 830 nm laser wavelength both in a backscattering mode and in the SORS mode.

The comparative study was carried out on ibuprofen-mannitol-microcrystalline cellulose ternary mixtures. The concentration of ibuprofen ranged from 24 to 52 % (m/m) while proportions of the two excipients were varied to avoid cross-correlation as much as possible. Analyses were performed directly through a glass vial and with the glass vial in a polypropylene flask using a validated FT-NIR spectroscopy method as a reference method. Chemometric analyses were carried out with the Partial Least Squares Regression (PLS-R) algorithm. The quantitative models were validated using the total error approach and the ICH Q2R1 guidelines with +/- 15% as acceptance limits.