

Studies on pharmaceutical assay method using Near Infrared Spectroscopy (NIRS) (II)

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This study developed effective assay method of pharmaceutical quality control was developed by near-infrared spectroscopy (NIRS).

The calibration equation model of assay was developed by 2nd derivative PLS(Partial Least Squares) regression method with NIRS over the wavelength range from 1100 to 1400nm using diazepam tablets (2mg, 5mg). Although diazepam tablets are made by 5-different manufacture, they have similar formulation.

When the correlation was compared with values by NIRS and HPLC, the R-2s and standard error of calibration (SEC) for 2mg were 0.9300 and 0.98%, the R-2s and SEC for 5mg were 0.9165 and 0.63%.

The validation of the calibration equation model yielded that the R-2s and standard error of prediction (SEP) for 2mg were 0.9611 and 0.995%, the R-2s and SEP for 5mg were 0.9114 and 0.842%.

The method was validated on assay method for diazepam tablets by the calibration equation.