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Assay of endogenous drugs

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The quantitative determination of endogenous compounds in biological samples by chromatographic techniques presents a number of complications, because of the typical lack of analyte-free matrix. Traditionally xenobiotics quantitative determination is assumed to be straight forward and endobiotics assay is complicated and indirect.

The small molecule validation guidance documents which also include endogenous analytes are specifically written for xenobiotics. The validation parameters such as selectivity, recovery, limit of quantification and matrix effect evaluation are challenging and not straight forward. There are different approaches followed in constructing calibration curves, and this is the key for success of the type of assay followed.

Biography

Dr. D.Vijaya Bharathi has completed her MSc from Osmania University and MPhil, Ph.D from Jawahar Lal Nehru University, school of Chemistry. She is working as Head- Bioanalytical in Dr.Reddys Laboratories, an emerging global pharmaceutical company.

She has about 16 years for industrial experience. She has brought around 13 years of expertise in mass spectrometry in terms of analytical and bioanalytical research including identification, characterization of unknown impurities, metabolites and quantitative bioanalysis. She has published more than 35 papers in reputed journals. She has guided thesis of PhD, M Pharm, MSc, BTech students. She is the recipient of excellence award in the area of Bioanalysis.

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