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Quality by Design (QBD) Approach Prior to The Validation for Simultaneous Estimation of Related Substances in Lopinavir- Ritonavir Soft Gelatin Capsules by High Performance Liquid Chromatography

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ABSTRACT

The present study focuses to determine the design space for a stability-indicating HPLC method prior to validation by systematic design of experiments (DoE) approach with the principle of quality by design (QbD). A simultaneous multivariate approach was carried out for mobile phase pH, flow rate, percentage of organic content and column temperature by employing DoE. Statistical analysis of the experimental data is not sufficient enough to cover all the significant chromatographic factors by performing one factor at a time instead of multi variant fractional factorial design. By analyzing the statistical experimental data for resolution to screen the chromatographic factors, flow and temperature displayed the most effective chromatographic factors. The inferences evaluated includes summary of fit, lack of fit, analysis of variance and parameter estimates. The chromatographic factors within the acceptable limits were displayed as a Contour plot defining the 'design space' of the method. A satisfactory QbD was deduced to finalize the method prior to validation from the range of operating conditions. The stability-indicating method is simple, rapid and robust for the related substances determination of lopinavir and ritonavir in lopi-rito soft gelatin capsules. The method was validated according to ICH guidelines for accuracy, precision, linearity, range, specificity, ruggedness and robustness (one factor varied at a time).The method has been successfully transferred to the quality control department for product analysis of manufactured batches and stability samples.

Keywords: Quality of design (QbD), Design of experiments (DoE), Stability indicating HPLC, lopi-rito soft gelatin capsules.