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Simultaneous UV Spectrophotometric Method for Estimation of Nirmatrelvir and Ritonavir in Bulk and Tablet Dosage Form

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Abstract: A simple, specific, precise, and accurate UV spectrophotometric method has been created for the simultaneous measurement of Nirmatrelvir and Ritonavir in pharmaceutical dosage forms. The absorption maxima of the drugs were found to be at 240 nm and 258 nm for Nirmatrelvir and Ritonavir respectively. Nirmatrelvir and Ritonavir obeyed Beer's law in the concentration range of 12-18 µg/ml and 8-12 µg/ml respectively. Different analytical parameters such as linearity, precision, accuracy, limit of detection (LOD) and limit of quantification (LOQ) were determined as per ICH guidelines. Limit of detection and quantification values for Nirmatrelvir 1.25 and 3.85 µg/ml and for Ritonavir 0.34 and 1.12 µg/ml respectively. The accuracy of the methods was assessed by recovery studies and recovery values between prescribed limit of 99-101 % shows that method is free from interference of excipients present in formulation. The developed method was free from interferences due to excipients present in formulation and it can be used for routine quality control analysis. The results were validated statistically as per ICH Q2 R1 guideline and were found to be satisfactory. The proposed methods were successfully applied for the determination of for Nirmatrelvir and Ritonavir in commercial pharmaceutical dosage form.

Keywords: Ritonavir, Nirmatrelvir, Simultaneous estimation, Absorbance maxima method, AreaICH.

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