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Analytical Method Development and Validation of Anti-Psychotic drug Clozapine

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Abstract: Antipsychotic medications are used to treat psychiatric diseases and have a primary influence on psycho (mental processes). An accurate, precise, reproducible, easy, and speedy Reverse-Phase High-Performance Liquid Chromatography (RP-HPLC) method for quantifying the antipsychotic medication Clozapine was developed and validated in this study. The liquid chromatography was performed on an epic C12 analytical column with diameters of 250, 4.6 mm, and 5 mm, with a mobile phase of 70:30:0.1 v/v and a combination of methanol, water, and Trifluoro acetic acid. The sample was injected in a volume of 20 ml and measured at a flow rate of 1 ml/min at 245 nm (Methanol: water: TFA). The reference and sample medication had 3.43 minute retention times, respectively. Clozapine was shown to be linear in the calibration curve in the concentration range of 30-90g/mL, with a regression coefficient (R2) of 0.9998. The percentage recovery of clozapine was in the range of 98.10–103.65 percent, indicating that the current approach is extremely accurate. Reproducibility and recovery investigations revealed that the percent relative standard deviation with intra and inter-day precision was less than 2%, demonstrating that the devised approach was repeatable. The method was verified according to the (ICH) requirements, and it is the most reliable and quick approach for routine clozapine analysis. statistical validation of the data revealed that the suggested method can be used to estimate clozapine.

Keywords : antipsychotic, RP-HPLC, Clozapine, validation.

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