

# DEVELOPMENT AND VALIDATION OF A RAPID HPLC METHOD FOR METOPROLOL SUCCINATE QUANTIFICATION IN BULK, MOUTH-DISSOLVING FILMS, AND IN DISSOLUTION SAMPLES

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## ABSTRACT

This research focuses on the development and validation of a simple RP-HPLC-PDA for the metoprolol succinate (MET) quantification in both bulk and mouth-dissolving films (MDFs). Utilizing an Inertsil ODS3 column and a 0.02 % V/V formic acid and acetonitrile (85:15 V/V) mobile phase at 1.2 mL min<sup>-1</sup>, the method demonstrated robustness and adaptability. Comprehensive estimation included specificity, accuracy, linearity, precision, assay, LOD, LOQ and dissolution analysis. Results indicated high specificity, with no interfering peaks, and excellent linearity across the 2-10 µg mL<sup>-1</sup> range. Precision analysis showed repeatability, and accuracy was confirmed with % recoveries from 98.97 % to 100.4 %. The assay consistently provided MET values of 100.93 %, confirming its reliability in bulk and dosage forms. *In vitro* dissolution studies indicated rapid and complete MET release from MDFs within 300 seconds, highlighting its pharmaceutical applicability. Thus, the current study concludes that this technique is suitable for MET quantitative analysis in both bulk and MDFs.

Keywords: HPLC, ICH Q2 (R1)