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Development and Validation of an UV-spectrophotometric Method for the Dissolution Studies of Sitagliptin Tablets

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SUMMARY. A simple UV-spectrophotometric method was developed and validated for the analysis and dissolution studies of sitagliptin phosphate in tablets. Specificity test indicated an adequate UV detection at 267 nm. The method was validated regarding Specificity/accuracy/precision (RSD < 2 %), linearity (r^2 = 0.9999), and partial robustness. Tablets uniformity was 102.52 % (RSD = 2.54 %). The method was applied for the determination of the drug in commercial tablet preparations and proved to be reliable for quantification It was also used for the comparison of dissolution profiles of sitagliptin tablets. After dissolution tests comparing eight different conditions through dissolution efficiency (DE), the chosen condition for posterior tests was USP apparatus 1 (basket) in 0.01M HCl pH 3.0, at a stirring rate of 50 rpm. The methodology was applied to two batches of sitagliptin phosphate tablets, giving similar dissolution profiles compared by the difference and similarity factor, obtaining values within the specified limits.

KEY WORDS: Dissolution, Sitagliptin, UV-spectrophotometry, Validation.

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