DETERMINATION OF OPTIMAL DISSOLUTION TEST CONDITIONS FOR "NAVESTO" CAPSULES

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Background. The therapeutic efficacy of antihypertensive drugs is closely associated with their biopharmaceutical characteristics, particularly the solubility and dissolution behavior of the active pharmaceutical ingredients (APIs). Therefore, the evaluation of **in vitro** biopharmaceutical performance, including dissolution testing, represents a critical component of pharmaceutical quality assessment. Since the solubility of valsartan and sacubitril is highly dependent on the pH of the dissolution medium, the scientific justification of optimal dissolution test conditions for **"Navesto"** capsules containing these active ingredients is of particular importance. Establishing appropriate dissolution conditions and evaluating the **in vitro** biopharmaceutical characteristics of the formulation are essential for ensuring its quality, performance, and potential therapeutic efficacy.

Objective. The aim of this study was to evaluate the biopharmaceutical characteristics of **"Navesto"** capsules developed by researchers at the Tashkent Pharmaceutical Institute and to establish scientifically justified optimal conditions for dissolution testing. The dissolution profile of the formulation was investigated in accordance with the requirements of Section 2.9.3, *Dissolution Test for Solid Dosage Forms*, of the First Edition of the State Pharmacopoeia of the Republic of Uzbekistan. The effects of the dissolution medium, its volume, paddle rotation speed, and test duration on the dissolution profiles of sacubitril and valsartan were systematically evaluated.

Materials and Methods. The study was conducted in accordance with the requirements of Section 2.9.3, *Dissolution Test for Solid Dosage Forms*, of the First Edition of the State Pharmacopoeia of the Republic of Uzbekistan. Dissolution testing was performed using six **"Navesto"** capsules with the pharmacopoeia-recommended **basket apparatus (USP Apparatus I).** A phosphate buffer solution (pH 6.8 ± 0.05) was selected as the dissolution medium, with a total volume of 900 mL. The experiments were carried out at **37.0 ± 0.5°C.** The basket method was employed to ensure uniform exposure of the capsules to the dissolution medium and to improve the reproducibility of the test results.

Dissolution profiles of sacubitril and valsartan were determined at predefined sampling time points.

Results. The study established the optimal dissolution test conditions for **"Navesto"** 100 mg and 200 mg capsules. The optimal parameters were identified as a **900 ml phosphate buffer solution (pH 6.8 ± 0.05)** as the dissolution medium, a temperature of **37.0 ± 0.5°C, a basket apparatus (USP Apparatus I)** rotation speed of **100 rpm**, and a test duration of **45 minutes**. The developed dissolution method was validated at the Quality Control Laboratory of **Samarkand England Eco-Medical LLC**, a pharmaceutical manufacturing company. The validation results confirmed the method's accuracy, reliability, and reproducibility, demonstrating its suitability for routine quality control of **"Navesto"** 100 mg and 200 mg capsules.

Conclusions. The present study scientifically substantiated the optimal dissolution test conditions for **"Navesto"** 100 mg and 200 mg capsules containing the antihypertensive agents sacubitril and valsartan. The optimal conditions were determined to be a **900 ml phosphate buffer solution (pH 6.8 ± 0.05)**, a test temperature of **37.0 ± 0.5°C, a basket apparatus (USP Apparatus I)** rotation speed of **100 rpm**, and a dissolution time of **45 minutes**. The developed method provided reliable and reproducible evaluation of the dissolution profiles of the active pharmaceutical ingredients and was demonstrated to be suitable for assessing the biopharmaceutical characteristics and quality control of **"Navesto"** capsules