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Stability, Efficacy, Absorption and Toxicity of a New Nasal Spray Formulation including Salmon Calcitonin

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Stability, efficacy, absorption and toxicity of a new nasal spray formulation including salmon calcitonin were studied in the laboratory animals. After the effects of many excipients on the stability of salmon calcitonin were evaluated using HPLC system, we selected taurine. Our experimental composition of salmon calcitonin contains taurine as a stabilizer and HPMC (hydroxypropylmethyl cellulose) as an adhesive polymer. After intranasal administration of salmon calcitonin formulations, Mia®, Men® and experimental composition, 22 IU to rats, the reduction percentages of calcium concentration in plasma (ΔD%) were 16.3%, 12.9% and 20.8%, respectively. After intranasal administration of Mia®, Men® and experimental composition to rats, C_{max} (205±161, 244±117, and 330±202 pg/ml, repectively) and AUC (41585±22070, 41191±19125, and 63357±43126 pg. min/ml, respectively) were calculated. The permeation coefficients (10^{-7},cm/sec) of salmon calcitonin in Mia®, Men® and experimental composition using Ussing chamber with rabbit nasal mucosa were 4.7±1.5, 0.75±0.4 and 5.3±1.1, respectively. The experimental composition with taurine and HPMC was proved to be excellent because it improved the stability of salmon calcitonin and enhanced the absorption of salmon calcitonin and was not irritative to the nasal mucosa.