

ウリナスタチンの安定性について

—トリプシン阻害活性とエラスターゼ阻害活性—

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Stability of Ulinastatin

—Trypsin and Erastase Inhibitory Activities—

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Summary

The stability of UTI in the hospital formulation was investigated by determining the inhibitory activities of UTI against trypsin and erastase in phosphate buffer (pH 7.4), isotonic sodium chloride solution, water and acetate buffer (pH 5.0) containing 0.8% sodium chloride after 0, 1, 3, 5, 8 and 14 days at room temperature or at 37°C.

Trypsin inhibitory activity was found to be stable in all solutions for 2 weeks, while erastase inhibitory activity was decreased in water both at room temperature and at 37°C, and in isotonic sodium chloride solution at 37°C. Both inhibitory activities were found to be most stable in acetate buffer among the solutions tested, i.e., virtually no decrease in the activities was observed even after 14-day incubation in the acetate buffer at 37°C.

SDS PAGE analysis after treatment of UTI with chondroitinase ABC and N-glycosidase F indicated that chondroitin bound to Ser¹⁰ on UTI was eliminated first, and then oligosaccharide bound to Asn⁴⁵.

In conclusion, in order to avoid decrease in the activities of UTI during storage, acetate buffer (pH 5) containing 0.8% sodium chloride is recommended as the diluent to be used for the hospital formulation of UTI.

Key words

Ulinastatin, Trypsin inhibitory activity, Erastase inhibitory activity, Stability in storage, Vaginal suppository