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The stability of cefaclor monohydrate syrup was studied under various temperature and time differences. Refrigerated condition(4℃), room temperature and accelerated condition(40℃) were investigated for temperature differences and 4h., 8h., 12h., 24h., 2 days to 20 days(every day) were investigated for time differences.
The contents of cefaclor monohydrate was determined for 9 commercial dried cefaclor-syrup by High Performance Liquid Chromatography with Hypersil ODS column and triethylamine/glacial acetic acid/acetonitrile/D.W = 5/20/25/875 mobile phase. The detection was performed at 254nm.
The calibration curves showed a good linearities having r value of 0.99935 and detection limit was 0.953ppm.
At 40℃, the rate of degradation was significantly higher than that of the others. By the time passed, the pH of the syrup was decreased.
At room temperature, the rate of degradation was slightly decreased. The result showed that cefaclor monohydrate content to be stable for at least 5 days at room temperature and at least 14 days at refrigerated condition.

[PD4-15] [10/19/2001 (Fri) 09:00 - 12:00 / Hall D]

A Collaborative Study to Establish a Korean Reference Standard for Factor VIII:C Concentrate

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A collaborative study was carried out to evaluate the suitability of the candidate preparation to serve as a Korean Reference Standard for Factor VIII:C concentrate. Five laboratories including three manufacturers and two national control laboratories participated in this study, and the potency of this candidate was determined using two different methods. The one is the one-stage clotting method, described in the Minimum Requirements for Biological Products, and the other is the chromogenic assay, described in the European Pharmacopoeia. To minimize possible substantial discrepancies among laboratories and between assay methods, the following recommendations by the International Society on Thrombosis and Haemostasis were adopted for the assays , e.g., pre-dilution of samples in FVIII-deficient plasma, inclusion of 1% albumin in the dilution buffer and calibration against the 6th International Standard for blood coagulation Factor VIII:C, coded 97/616. The results of this study were in good agreements among laboratories with the inter-laboratory coefficient of variations of 10.51%. The mean value for estimates obtained by the one-stage clotting method was 8.27 IU/vial, and that by the chromogenic assay was 6.88 IU/vial. Based on the results of the collaborative study, the candidate reference standard is judged to be suitable to serve as the National Reference Standard for Factor VIII:C Concentrate.

[PD4-16] [10/19/2001 (Fri) 09:00 - 12:00 / Hall D]

Comparison of the Chromogenic Assay and Clotting Assay Methods for the Potency Test of the Intermediate and High Purity Factor VIII:C Concentrates in Korea

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The clotting assay was replaced by the chromogenic substrate assay which is recommended by the