[PD1-52] [04/18/2003 (Fri) 13:30 - 16:30 / Hall P]

Synthesis of N,N',N''-Trisubstituted Thiourea Derivatives and their Antagonistic Effect on the Vanilloid Receptor

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Twenty-seven N,N',N''-trisubstituted thiourea derivatives were prepared. Among them, 1-[3-(4'-hydroxy-3'-methoxy-phenyl)-propyl]-1,3-diphenethyl-thiourea (8l, IC_{50} = 0.32 μM), showed 2-fold higher antagonistic activity than that of capsazepine (3, IC_{50} = 0.65 μM) against the vanilloid receptor in a Ca^{2+}-influx assay.

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Collaborative Study for the Establishment of a National Reference Preparation for Erythropoietin

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National regulatory authority have the duty to ensure that available pharmaceutical products are of the required quality. This is particularly difficult for biotechnological products, the quality of which cannot be established entirely by test on the material in the final container. In general biotechnological products are distinguished from other drugs by being derived from genetically modified microorganism to humans, and frequently have a complex molecular structure. They require special quality considerations because of the biological nature of (a) starting material and /or (b) the manufacturing process and/or (c) the test methods needed to characterize batches of the product. In doing test, biotechnological products require biological methods to characteries batches of the product to ensure the level of purity and potency. Thus data from physicochemical analysis alone are not sufficient to permit prediction of potency, so some form of assay measuring an action in a biological system -a bioassay- is required to assess potency.

Bioassays are complex system, and are inherently variable between assays, laboratories and over time. Comparison of the response obtained with a sample and with common reference standards, that is , a relative potency, permits valid inter-assay and inter-laboratory comparison. In view of the above, there is a critical requirement for stable, universally accepted, reference standards to ensure comparability between assays, laboratories and manufacturer world wide. The World Health Organization(WHO) international laboratory responsible for the preparation and distribution. But it is desirable for appropriate national (secondary) reference materials, calibrated against international reference materials, to be established by the national control authority and made available to manufacturers.
Biotechnological products are increased in Korea but any effort to standardize this products have not been made so manufacturer have used their own in-house standards. To prepare and establish national reference standards, the project should be carried out by the collaborative study with WHO international laboratory, NIBSC.