HPLC IN THE CLINICAL LABORATORY

There has been a recent trend towards an increased use of high performance liquid chromatography in the clinical laboratory for the purpose of therapeutic drug monitoring. The versatility and selectivity of LC has allowed it to surplant gas chromatography in this clinical specialty area. However, just because a technique has gained rapid popularity within a discipline, it does not necessarily follow that all methods employed with this technique have met the proper degree of analytical scrutiny. This statement is especially true with regard to clinical medicine as the end result of improper method evaluation could result in jeopardizing patient health care.

With this last fact in mind, we feel that before an assay will be accepted for a Waters Clinical Reference Method, a distinct series of analytical criteria must be met prior to its release to clinical laboratories. These criteria include accuracy, precision, reproducibility, linearity, sensitivity, possible drug interference and correlation with existing reference methods. To date, there are several drug analyses which have met some of these criteria which has facilitated their release as an Application Note. One method, tricyclic antidepressants, has recently undergone full clinical documentation and is currently under review for upgrading from an Application Note to a Reference Method.

The following is a list of applications currently available:

J35   Procainamide in Serum – Steel – μBONDAPAK™ C_{18} Column

N84   Procainamide and N-acetylprocainamide from Serum – Radial-PAK™ C_{18} Column

J45   Antiarrhythmics in Serum – Radial-PAK™ μBONDAPAK™ C_{18} Column

J34   Theophylline in Serum – Steel – μBONDAPAK™ C_{18} Column

N85   Theophylline from Serum – Radial-PAK™ C_{18} Column

J29   Anticonvulsants in Serum – Steel – μBONDAPAK™ C_{18} Column

N83   Antiepileptic Drugs from Serum – Radial-PAK™ C_{18} Column

J30   Gentamicin Components in Serum – Steel – μBONDAPAK™ C_{18} Column

J42   Acetaminophen in Serum – Steel – μBONDAPAK™ C_{18} Column

N82   Tricyclic Antidepressants from Serum – Radial PAK™ Si Column

We hope you appreciate the needs of this particular market and will understand the reference methods are the end product of a time-intensive evaluation, both in-house and with collaborating laboratories, and as such, will not appear rapidly, but when available, can be used with confidence.

John Nagle