

Pyrogen Test For Large Volume Parenteral Pharmaceuticals

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Abstract

Large Volume Parenteral (LVP) refers to injection of large volume of intravenous solution including electrolytes, substitute plasma, amino acids, and vitamins, etc. into patients recovering from surgery. Contamination with pyrogen would cause threat to the health of patients. The purpose of this study was to investigate the quality of LVP Pharmaceuticals in vitamin product and existing drug monitoring pyrogenic contamination, in order to ensue safety of the patients in Taiwan. A total of 256 samples were collected by the local health authorities from hospitals, clinics, pharmacies and manufacturers in 21 different counties. 243 samples (94.9%) were produced by local manufacturers (10 factories) and 13 (5.1%) were imported (5 factories). The volume of the samples was 100 mL, 200 mL, 300 mL, 400 mL, 500 mL and 1000 mL, respectively. Glass bottles (72 samples), plastic bottles (127 samples) and soft bags (57 samples) were used as containers. The pyrogen test was adopted from the US Pharmacopoeia XXVII and the Chinese Pharmacopoeia V, using rabbits as the laboratory recipients. The result showed that all samples met pyrogenic contamination guidelines. However one imported sample did not have Chinese labeling, and so was sent to the local health authority for penalty according to Pharmaceutical Affairs Act.

Key Words: large volume parenteral, pyrogenic contamination, pyrogen test