

Bikhazi AB, Shiatis JA, Haddad AF.

Quantitative estimation of particulate matter in pharmaceutical preparations intended for intravenous administration.

J Pharm Sci. 1977; 66: 181-6.

A fast, reproducible, economical, and dependable automated counter method is recommended for the quality control of pharmaceutical preparations intended for intravenous administration. The USP gives no specifications on the limitations of particulate matter in intravenous products, while the BP specifies limitations on intravenous solutions of more than 500-ml volume. Out of 15 different marketed products, few passed the BP specifications. The microscopically identifiable particles included starch, cellulose fibers, glass, rubber, lacquer flakes, carbon black, and metal shavings. The proposed quality control method introduces a modification to the BP specifications. The method includes a standard log-log plot obtainable from a least-squares line fit to the data of the marketed products showing minimal particle contamination. The standard plot is compared to the experimental data obtained from any other product and, accordingly, it is decided whether the product is acceptable or not