SUBVISIBLE PARTICULATE MATTER IN INTRAVENOUS PREPARATIONS - A COMPARISON OF INNOVATOR AND GENERIC DICLOFENAC SODIUM

E. Lehner¹, D. Haider¹

¹ Sozialmedizinisches Zentrum Süd - Kaiser-Franz-Josef-Spital mit Gottfried von Preyer'schem Kinderspital, Pharmacy Department, Vienna, Austria

BACKGROUND

Hazardous effects of contamination of intravenous preparations evolve by submerging smallest subvisible particulate matter into the bloodstream. Possible pathological consequences ultimately lead to severe disease patterns.

PURPOSE

The aim was to compare often used drugs in their innovator and generic form and to optimize workflow in busy work environments to improve patient safety. Mixtures of 0.9% sodium chloride solution and two diclofenac sodium preparations (Voltaren® and Diclobene®) and the influence of a buffer were investigated regarding their particulate count and size.

MATERIAL AND METHODS

250 millilitres (mL) of sodium chloride 0.9% solution was mixed with either Diclobene® 75 milligram (mg) or Voltaren® 75 mg/3 mL injectable solution and the required buffer containing sodium bicarbonate solution additive. The number of particles greater than or equal 10 micrometers (Figure 1) and 25 µm (Figure 2) were counted shortly after mixing the components and after 30, 60, 90, 120 and 150 minutes.

RESULTS

The mixture of Diclobene® had a consistently low particulate count which was way below the threshold value for subvisible particulate matter contamination regulated by the European Pharmacopoeia whereas Voltaren® bicarbonate solutions had a high range of fluctuation exceeding the threshold value. Surprisingly the mixture of Voltaren® without the required buffer had an average particulate count below the compulsory threshold.

CONCLUSIONS

The conducted measurements neither resulted in substantial changes of particulate count and size in the Diclobene® and the Voltaren® preparation. Mixtures of Diclobene® with sodium chloride 0.9% solution resulted in considerably less particulate count than the Voltaren® mixture. Taken into account that adding the buffer to the preparation of Voltaren® is an additional step, Diclobene® might be of facilitated use in a busy ward environment thus enhancing patient safety.