



Equivalence of Diluents for Cleaning the IntelliFill® i.v.

INTRODUCTION

Cross-contamination studies are performed using sterile water for injection as a diluent because the presence of other substrates (e.g., sodium chloride or dextrose) interferes with the analysis method used to detect low amounts of the drug.

Health systems, however, use 0.45% sodium chloride or 0.9% sodium chloride as their diluent. This is due to safety issues that arise from the use of sterile water for injection, which can cause hemolysis if injected directly into the blood stream without contents that increase its osmotic load.

We, therefore, need to establish the rationale for applying data from sterile water for injection cleansings to data from 0.45% sodium chloride or 0.9% sodium chloride cleansings.

0.45% sodium chloride represents an intermediate case between sterile water for injection and 0.9% sodium chloride for injection, so its effects can be inferred from a review of the characteristics of 0.9% sodium chloride.

Potential differences would arise in the use of these solutions if: (a) drugs are more or less soluble in one solution vs. the other, or (b) the dissolution of sodium chloride in water significantly changes the surface tension or viscosity of the diluent at these concentrations.

SOLUBILITY

A review of the solubility of drugs used on IntelliFill i.v. was performed using *Trissel's Handbook of Injectable Drugs, 13th Edition*.¹ Drugs reviewed were those known to have significant issues related to cleansing – notably cephalosporin antibiotics, vancomycin and penicillin antibiotics – in sterile water for injection, 0.9% sodium chloride and dextrose 5% in water.

Of the drugs reviewed, all but cefotaxime indicated equivalence of the use of sterile water for injection, 0.9% sodium chloride and dextrose 5% in water as diluents for reconstitution and injection. Cefotaxime specifies sterile water for injection, but describes 0.9% sodium chloride and dextrose 5% in water as “compatible solutions.”

Articles related to drugs where solubility is diluent-specific call out the use specific diluents; the lack of such information for cephalosporins indicates equivalence.

For practical purposes, the three solutions are interchangeable in their ability to dissolve drugs.

SURFACE TENSION/VISCOSITY

There are no discrete measures of viscosity or surface tension among dextrose, saline and sterile water. However, there is an observed correlation between viscosity and specific gravity, where solutions with specific gravities of 1.2 g/mL tend to show visible differences in viscosity.

The specific gravity of 0.9% sodium chloride is 1.01; a 1% difference from sterile water for injection (0.998 g/mL).

When IntelliFill i.v. is used in Reservoir Mode, no adjustments to the reservoir apparatus are required when switching from sterile water for injection as a diluent to 0.9% sodium chloride or 5% dextrose in water. The three solutions appear to flow in similar fashion through the tubing.

When IntelliFill i.v. is used in Vial Mode, no adjustments are required in the pumps' calibration or in the device operation to achieve comparable flow through the tube sets.

It, therefore, appears that there are no visible differences in viscosity or flow of these solutions when used in IntelliFill i.v.

SUMMARY

Given that there is no documented difference in drug solubility in these solutions, no observed differences in flow characteristics on IntelliFill i.v. between these solutions and that specific gravities are so close, it is reasonable to conclude that sterile water for injection, 0.45% sodium chloride, 0.9% sodium chloride and dextrose 5% in water are functionally equivalent for cleaning purposes.

IntelliFill i.v. is manufactured for Baxa Corporation by FHT, Inc.