

# COMPARATIVE OF DIFFERENT INTRAVENOUS INFUSION CONTAINERS

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## OBJECTIVES

Over the course of the past 30 years, plastic has been used more and more in the manufacture of infusion bags. Compared to glass, plastic bags are lightweight, are less likely to break, and it is unnecessary for air to enter the container to replace the fluid administered.

The main disadvantage comes from a possible drug-plastic interaction. It has been reported that some active principles are incompatible with infusion bags made from PVC due the fact that the material absorbs the drug.

In these cases the use of a non-PVC material, such as polypropylene, is recommended. Laboratorios Grifols has developed Fleboflex® infusion solutions in polypropylene bags.

The objective of the study was to compare the behaviour of four PVC-incompatible drugs in polypropylene bags, PVC bags and glass as non-interactive materials. Additionally cefuroxime, a PVC-compatible drug has been studied.

## STUDY DESIGN

Four PVC-incompatible drugs were assayed: nitroglycerin, isosorbide dinitrate, propofol and diazepam. Cefuroxim was chosen as a PVC-compatible drug.

Polypropylene bags were Fleboflex® Normal Saline and Fleboflex® Dextrose 5%. PVC bags were Flebobag® Normal Saline and Flebobag® Dextrose 5%. Glass solutions were Normal Saline Grifols and Dextrose 5% Grifols. The volume of all the solutions was 100 ml

For each drug, 12 units of each material (13 with PVC) were prepared under a laminar flow hood, using the diluent and at a final concentration stated in table 1.

All the units were controlled for drug assay and pH according to the USP monographs (if available). Additional tests not included in the pharmacopoeia were color and turbidity.

Table 1 shows the diluent used and the concentration prepared for each drug.

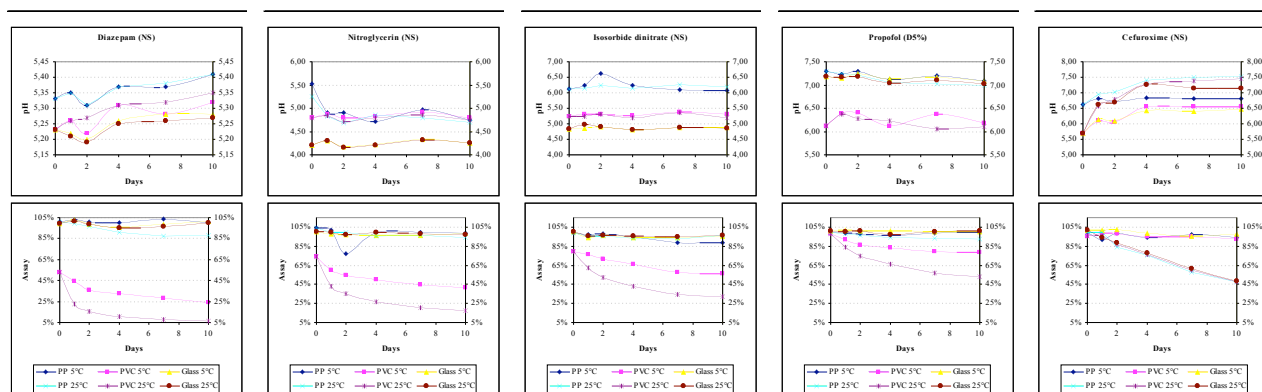
Drug	Initial concentration	Diluent	Final concentration
Diazepam	5 mg/ml	Normal Saline	50 µg/ml
Propofol	10 mg/ml	Dextrose 5%	2 mg/ml
Nitroglycerin	5 mg/ml	Normal Saline	50 µg/ml
Isosorbide dinitrate	1 mg/ml	Normal Saline	0,1 mg/ml
Cefuroxime	90 mg/ml	Normal Saline	0,5 mg/ml

All the prepared solutions were stored at 5°C and 25°C/60%HR and controlled after 0, 1, 2, 4, 7 and 10 days. DEHP content was determined in PVC units only after 10 days.

## RESULTS

The results corresponding to colour and turbidity show no differences between the materials. DEHP content at the end of the stability was below the established limit (< 5ppm) in all the PVC units.

The assay value is presented as % with respect to the theoretical value, calculated for each individually prepared unit. The graphical representation of the results corresponding to pH and assay are found below.



## DISCUSSION

All the drugs tested show the same behaviour when diluted in glass or polypropylene containers. When stored at 5°C, drug content remains over the limit of 90% for 4 days. When stored at 25°C drug content remains over the limit of 90% for 4 days, except for Cefuroxime which is stable for only 1 day.

Dilution of PVC-incompatible drugs in PVC containers leads to a decrease in drug content over time. Only Propofol has an initial content over the limit of 90%. The rest have initial values between 53% and 79%. The rate at which it diminishes is greater at 25°C, with the final values between 7% and 80%. The results corresponding to Cefuroxime show no differences between materials. The solution remains stable at 5°C but degrades rapidly at 25°C.

The pH values depend on the pH of the infusion solution, which vary depending on the material and the effect of the drug when added.

Diazepam and Isosorbide dinitrate results show three groups corresponding to the three materials assayed. Nitroglycerin shows two groups, one for PP and PVC and the other for glass. Propofol shows two groups, one for PP and glass, and the other for PVC.

Cefuroxime shows two groups, depending on the temperature. In all the cases there is an increase of almost 1 pH unit at the end of the stability study.

## REFERENCES

USP 26

Moorhatch, P., Chiou, W.L.: Interactions between drugs and plastic intravenous fluid bags, Part I, *Amer. J. Hosp. Pharm.* 31:72-78 (Jan.) 1974

## CONCLUSIONS

- Fleboflex® infusion solutions are suitable for the dilution of pvc-incompatible and compatible drugs.
- Drug solution behaviour in Fleboflex® infusion containers is similar to those prepared in glass containers.

**STATEMENT** Conflict of interest: nothing to disclose