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Abstract:

Piggyback infusion has been widely used in the clinic with most applications in a non-concurrent fashion for the purpose of administration convenience. In the present study, we demonstrated the application of concurrent piggyback to overcome challenges with intravenous (IV) administration of a salt-sensitive investigational protein. This setup consists of a syringe line containing drug admixture prepared in water-for-injection (WFI) which is connected to a 0.9% sodium chloride line to keep vein open ("KVO line"). Both lines are pump controlled and run concurrently at corresponding flow rate.

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The admixture compatibility study was conducted in two stages. In the first stage, admixture

(concentration range from 0.05 to 2.0 mg/mL) was demonstrated to be compatible with WFI and administration materials, such as IV bag, syringe, and syringe infusion line, for at least 24 hrs at room temperature. In the second stage, steady-state admixture concentration was demonstrated after approximately 10 min post mixing even at the slowest syringe infusion rate. No loss of protein concentration was observed after reaching steady-state infusion. Sub-visible particulates prior to and post piggybacking mixing are found well within the acceptable range.

Reference:

Shi, S., Hashemi, V., Wang, S.C., Yang, J., Yang, M.M., Semple, A., Narasimhan, C. and Antochshuk, V. (2017) Overcoming Challenges with Intravenous Administration of an Investigational Protein Therapeutic. Journal of Pharmaceutical Sciences. August 1st. .

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