Extended In-Use Stability of Intravenous Actemra

This letter responds to your request for information on extended in-use stability of Actemra® (tocilizumab) diluted for intravenous (IV) infusion.

In brief

- Roche has performed an additional in-use stability study that confirms physical and chemical stability of Actemra concentrate for solution for IV infusion under specific conditions:
  - diluted with 0.9% NaCl to 0.1 mg/mL and 8.0 mg/mL
  - in PE, PVC or PP IV bags, and
  - for 24 hours at 30°C followed by up to 14 days at 2-8°C.
- Roche refers the user to the approved label for product use, including Storage and Stability information.

Abbreviations

NaCl=sodium chloride

PE=polyethylene

PP=polypropylene

PVC=polyvinyl chloride

Prescribing information

The fully diluted ACTEMRA solutions for infusion using 0.9% Sodium Chloride Injection, USP may be stored at 2° to 8°C (36° to 46°F) or room temperature for up to 24 hours and should be protected from light.

The fully diluted ACTEMRA solutions for infusion using 0.45% Sodium Chloride Injection, USP may be stored at 2° to 8°C (36° to 46°F) for up to 24 hours or room temperature for up to 4 hours and should be protected from light.

Extended in-use stability of Actemra IV

Roche evaluated the stability and product quality of Actemra concentrate for solution for IV infusion diluted to 0.1 mg/mL and 8.0 mg/mL in PE, PVC or PP IV bags containing 0.9% NaCl.[1-3]

Physical and chemical stability of Actemra IV was demonstrated for 24 hours at 30°C, followed by up to 14 days at 2-8°C.

Study objectives

The study evaluated physical and chemical stability and did not cover any microbiological aspects.[1-3]

All study samples were assessed by product quality attributes that could potentially be impacted by such study conditions. The analytical tests included analysis of[1-3]

- the general aspects, including pH, particles, color, clarity, opalescence,

- purity,
- protein content and
- potency.

Study methodology

The in-use compatability study procedures are summarised below:[1-3]

1. Two Actemra IV solutions were prepared by using Sodium Chloride 0.9% IV bags. The two concentrations tested were 0.1 mg/mL and 8.0 mg/mL, in PE, PVC and PP IV bags.

2. The IV solutions were held at 30 ºC for 24 hours under diffused light conditions, followed by storage at 2-8°C for 14 days (protected from light).

3. Simulated infusions were conducted after the described storage conditions using administration sets with standard infusion lines.

Disclaimer

Consult the approved label for product use, including Storage and Stability information. Any actions beyond the approved label information are the responsibility of the user. This assumes the product has been prepared under controlled and validated aseptic conditions.

References

1. Data on file (Accessed on July 12 2023).
2. Data on file (Accessed on July 12 2023).
3. Data on file (Accessed on July 12 2023).