Background and importance Rituximab (RTX) is a therapeutic monoclonal antibody used for the treatment of certain types of cancer. As a complex protein, routine handling or unintentional mishandling of its solutions may cause degradation that could remain unnoticed but could potentially compromise the clinical safety and efficacy of the drug product.

Aim and objectives To assess the impact on the aggregation of RTX (Mabthera) aggregation process promoted by slight modification in the concentration of the compound (NaCl 0.9% and glucose 5%) used to prepare the clinical diluted solution of RTX 1.0 mg/mL. Also, to assess the impact on the aggregation of RTX clinical diluted solutions (1.0 mg/mL in NaCl 0.9% and glucose 5%) promoted by manual shaking.

Material and methods RTX (Mabthera 10 mg/mL) was diluted to 1 mg/mL using different NaCl (from 0.5% to 1.5%) and glucose (from 1% to 10%) concentrations. Manual gentle shaking was performed for 10 minutes. Particulate was tracked by dynamic light scattering (DLS) and readings were carried out in a protein solution DynaPro-99 system dynamic light scattering module equipped with a temperature control micro sampler (Wyatt, Santa Barbara, California, USA) for obtaining the hydrodynamic radius (HR) and polydispersity.

Results Reference 1.0 mg/mL RTX samples diluted in NaCl 0.9% and glucose 5% showed a single particulate population with a HR of 10.51±2.210 nm and 10.72±2.694 nm, respectively, attributed to monomers of RTX. No significant changes were obtained for HR when the concentration of the diluents was changed. Also, no significant changes were observed when the samples were shaken, with the HR values always within the interval of the size of the monomers. Polydispersity remained unchanged in all of the samples analysed.

Conclusion and relevance Variation in NaCl and glucose concentrations around clinical concentrations of 0.9% and 5% did not promote aggregation in a 1 mg/mL RTX solution detected by DLS. Also, shaking did not have any impact on aggregation in this clinical RTX solution.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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