

BACKGROUND

We demonstrated that the physicochemical stability of Durvalumab in diluted solution at 1 and 6 mg/ml or concentrated (50 mg/ml vials after opening) was maintained for **at least 4 weeks at 4°C**.

We also demonstrated that these diluted solutions could be stored **7 days at 25°C (protected from light)** without physicochemical alterations.

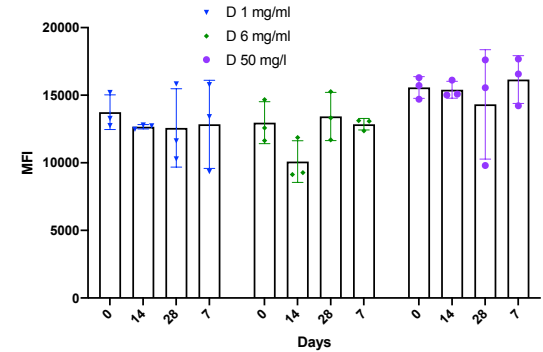
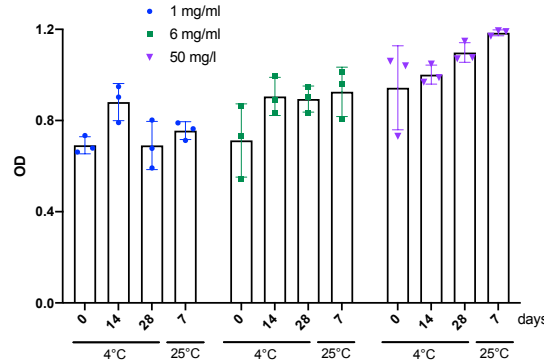
OBJECTIVES

The purpose of this work is to assess the biological stability of Durvalumab solutions diluted at 1 and 6 mg/ml and vials at 50 mg/ml after opening.

METHODS

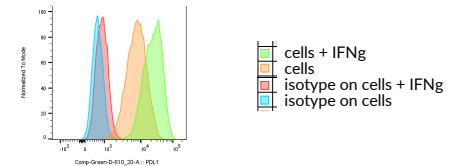
1. Durvalumab in 0.9% NaCl at 1 and 6 mg/ml prepared sequentially and stored at 4°C or 25°C.
2. Physicochemical analyzes to ensure the compliance of these solutions.
3. **Commercial ELISA test anti-Durvalumab** (in triplicate)
4. **Flow cytometry test** (in triplicate): PDL1-expressing MDA-MB231 cell line / polyclonal secondary antibody specific for human IgG.
5. The samples stored at 4°C were studied on D0, D14 and D28. The samples stored at 25°C on D0 and D7.

RESULTS



The amount of Durvalumab was measured in aliquots of each bag by ELISA or Flow cytometry methods. Individual data are representing optical density (OD) or fluorescence intensity (MFI) with the mean \pm SD.

PDL1 detection on MDA-MB231 cells



DISCUSSION-CONCLUSION

Durvalumab's ability to bind to its target is stable at 4°C for 28 days and 7 days at room temperature. The biological stability of Durvalumab indicates that the binding of Durvalumab to PDL1-expressing cells is not altered. The mechanisms involved in the clinical effect are therefore conserved.