IMPACT OF LIGHT STRESS ON THE ISOFORM PROFILE OF NIVOLUMAB (OPDIVO®) IN OPENED VIALS ESTIMATED BY (RP)UHPLC-UV-(HESI/Orbitrap)-MS

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Background and importance

Nivolumab (Opdivo®) is a human IgG4 monoclonal antibody (mAb) from the group of immunomodulators, which binds to programmed death receptor 1 (PD-1). As a complex protein, physical aggregation and chemical degradation can occur throughout its life, and even modest environmental stresses could cause extensive damage [1]. As indicated in its technical report [2], the unopened vials can be stored at controlled room temperature up to 25 °C, with room light for up to 48 hours.

Aim and objectives

To assess the impact on the isoforms profile of nivolumab 10 mg/mL (Opdivo®) promoted by exposure to light in its own opened vial at controlled temperature of 25 °C to evaluate likely risks from unintentional mishandling in real hospital conditions.

Materials and methods

Nivolumab (Opdivo®, 10 mg/mL) was placed in an accelerated stress test chamber to simulate sunlight.

Results

- A decrease in the area of the chromatographic peaks corresponding to the light-stressed sample was observed.
- A new peak was detected right before the main nivolumab chromatographic peak in the TIC corresponding to the light-stressed sample.

Conclusion and relevance

The exposure to light may cause modifications in the nivolumab isoform profile which suggests protein degradation. This has been confirmed by the results obtained. The current work shows the importance of protecting from light the opened vials of the medicine Opdivo® (and for extension, the bags for infusion), when they are placed at room temperature (up to 25 °C).