STABILITY OF COMPOUNDED NIVOLUMAB SOLUTION AFTER PNEUMATIC SYSTEM TRANSPORTATION

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Background and importance

In our hospital, all compounded monoclonal antibodies are delivered via pneumatic system to the Oncologic Day Hospital unit from the Pharmacy compounding department. Pneumatic delivery is not recommended for medicinal products that could undergo physical alteration of the active ingredient, like protein denaturation (Peak, 2003). The review of the literature reveals that solution air-liquid interface and number of travel cycles can be risk determinig factors for compounded monoclonal antibodies stability after pneumatic delivery (Vieillard, et al., 2012) (Vieillard, et al., 2013) (Vieillard, et al., 2014).

Aim and objectives

To investigate the stability of nivolumab compounded solution after pneumatic delivery, and the effect of residual air inside the infusion bag.

Materials and methods

The following nivolumab samples, diluted at 2.4 mg/mL in a pre-filled 0.9% sodium chloride polyolefin infusion bag, were prepared: **sample NIVO, not undergoing pneumatic delivery**, **sample PNA, with residual air**, and **sample PN, without residual air**, **both undergoing single travel inside the pneumatic delivery system**. During the same day of preparation, all samples were analyzed in terms of pH, osmolality, turbidimetry, DLS, SEC-HPLC and NMR.

Results

All samples were clear, without particulate or precipitates and turbidity-free at 350 nm. Obtained pH shifted from 5.77 and 5.92. Osmolality values ranged from 286 and 296 mOsm/kg. DLS revealed a monodisperse peak at about 11 nm, with similar shape and intensitiy. SEC-HPLC did not reveal any peak retention time variations, and NMR didn't reveal any modifications regarding peaks shape and intensity.

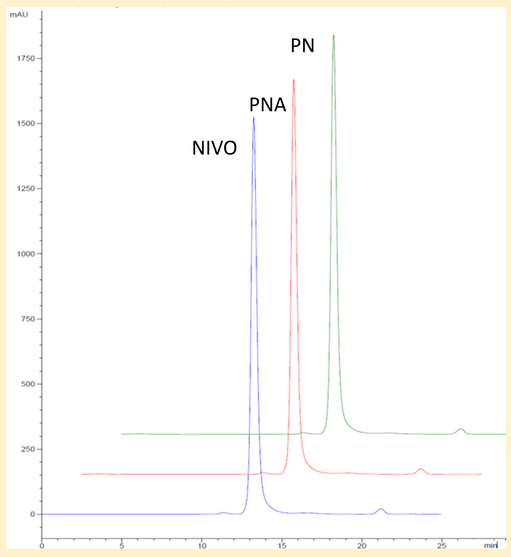
pH

NIVO	PNA	PN
5.83 ± 0.09	5.77 ± 0.02	5.92 ± 0.05

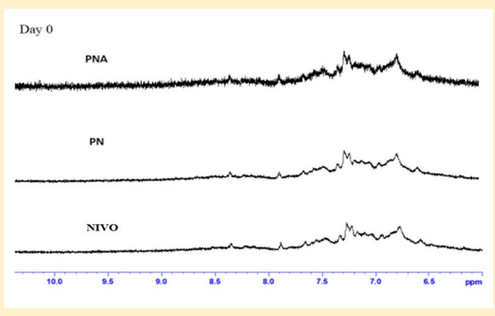
Osmolality (mOsm/kg)

NIVO	PNA	PN
296 ± 17	287 ± 14	286 ± 16

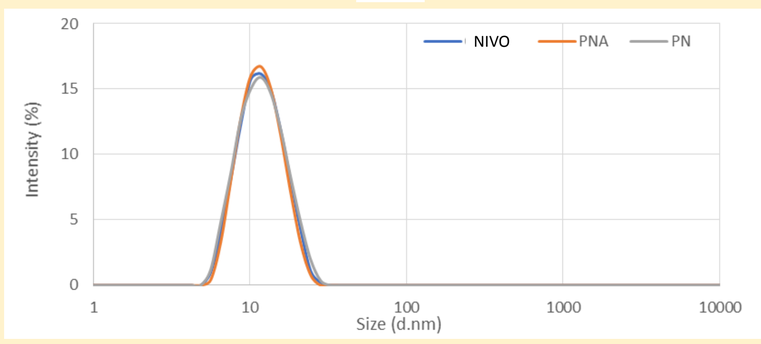
SEC-HPLC



NMR



DLS



Conclusion and relevance

No difference on physical and chemical stability was found between compounded nivolumab solutions not undergoing and undergoing single travel inside the pneumatic system. Presence of air-liquid interface inside the solution bag was not risk determining for solution stability. The pneumatic delivery system at our hospital can be used for compounded nivolumab solution delivery to the Oncologic Day Hospital.

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