parallel testing was performed using Chemfort VA from which the filter system had been removed.

Results No drug was found in any of the test samples with the intact air filter system in Chemfort VAs, either fresh, following aging for 3 years or after 7 days of exposure to drug vapours. Recovered vapour was consistently found in the positive control samples which had Chemfor VAs without a filter system. Mean±SD (n=5) levels were 69±34 and 35±20 ng for cyclophosphamide and 5-FU, respectively.

Conclusion and relevance The results confirm the efficacy of the Chemfort air filtration system, even after 7 days of exposure to drug vapour or a shelf life of 3 years.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest Corporate sponsored research or other substantive relationships:

   The author is an employee of Simplivia Healthcare.

3PC-013 COMPARATIVE BIOPHYSICAL STABILITY STUDY OF ZIV-AFLIBERCEPT (ZALTRAP, OPENED VIALS) STORED AT 4°C AND ROOM TEMPERATURE FOR 2 WEEKS

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Background and importance Ziv-aflibercept (Zaltrap) is an Fc-fusion protein used in the treatment of colorectal cancer. Changes in the structure or aggregation, which may arise from handling and storage, may affect the efficacy of the treatment and it could cause severe immune reactions in patients. The shelf life indicated by the manufacturer for the unopened vial is 3 years; there is no information on the sur- plus of opened vials.

Aim and objectives To compare the biophysical stability of ziv-aflibercept (Zaltrap) stored refrigerated at 4°C and at room temperature protected from light for 2 weeks.

Material and methods Three independent samples of fresh ziv-aflibercept were collected from hospital and stored in amber glass vials protected from light at 4°C and at room temperature.

- Particulate: dynamic light scattering (DLS) readings were carried out in a protein solution DynaPro-99 system dynamic light scattering module equipped with a temperature control micro sampler (Wyatt, Santa Bárbara, California, USA) for obtaining the hydrodynamic radius and polydispersity.
- Tertiary structure: intrinsic tryptophan fluorescence measurements were carried out on a Cary eclipse spectrofluorimeter (Agilent, Santa Clara, California, USA). Each spectrum was reduced to a single a dimensional number (centroid):

\[ C = \frac{\sum_{i=1}^{n} f_i \lambda_i}{\sum_{i=1}^{n} f_i} \]

LMW aggregates: size exclusion chromatography (SEC) was used. The analysis was performed by liquid chromatography using an Agilent 1100 chromatograph equipped with a quaternary pump, degasser, autosampler, column oven and photodiode array detector (Agilent).

Results No significant changes were detected in the samples stored refrigerated by any of the techniques used: aggregation did not occur, supported by the results from DLS and SEC. No changes in conformation were detected: fluorescence centroid was maintained.

Significant changes were detected in the samples stored at room temperature: the start of aggregation was detected by SEC but larger aggregates were not detected by DLS. Centroid value increased significantly, indicating conformational modifications.