



# STABILITY OF PEMETREXED 25 MG/ML IN GLASS VIAL AND 5 MG/ML DILUTED IN 0.9% SODIUM CHLORIDE AND STORED IN PVC CONTAINERS.



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## OBJECTIVE

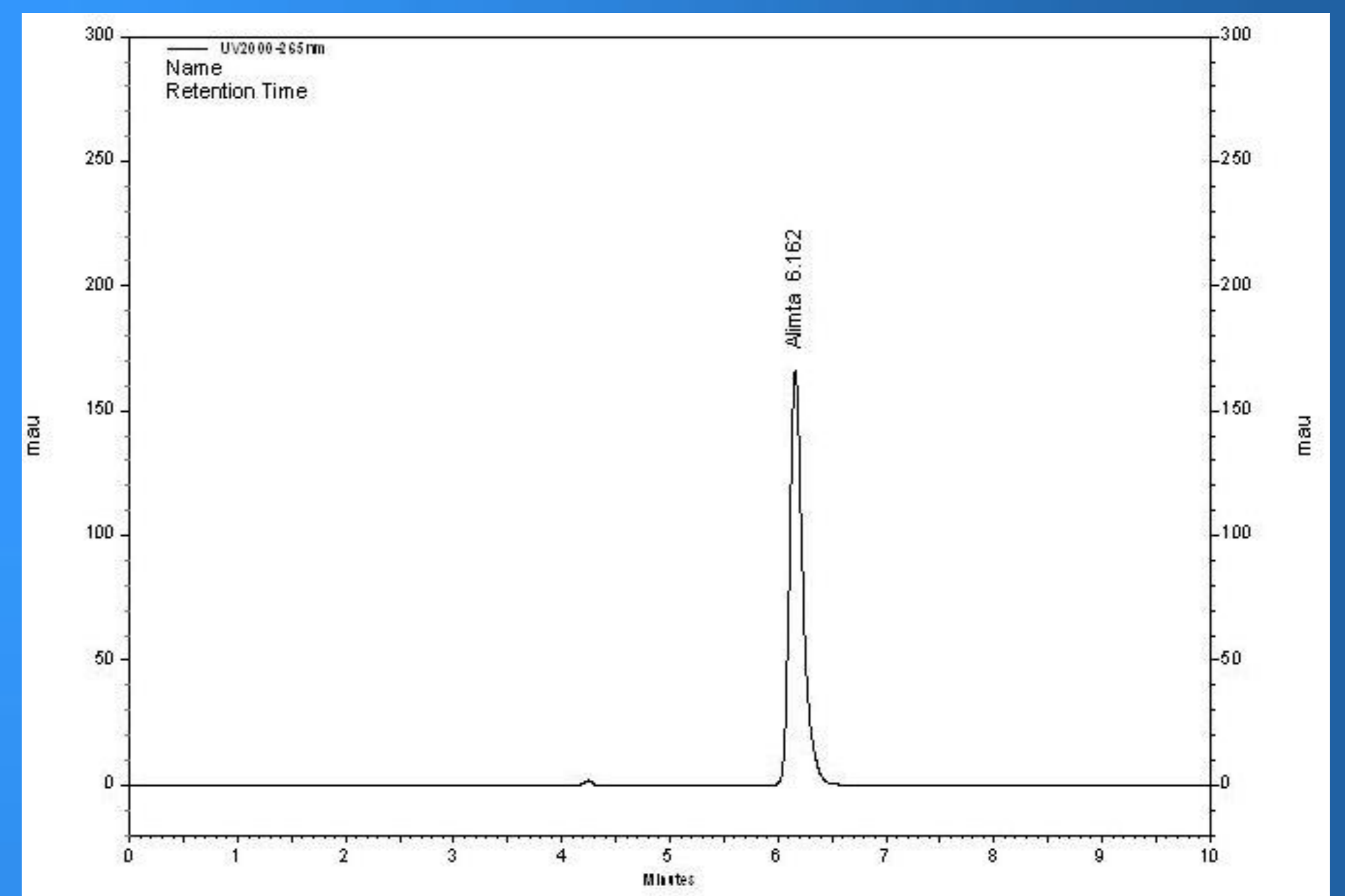
- Pemetrexed is used in the treatment of mesothelioma and non small cell lung cancer.
- The manufacturer indicate a 24 hours stability for the reconstituted solution and the infusion.
- Objectives of this study: to evaluate the stability of reconstituted pemetrexed 25 mg/ml in 0.9% sodium chloride and 5 mg/ml in PVC container after storage for one month at 2-8°C.

## STUDY DESIGN

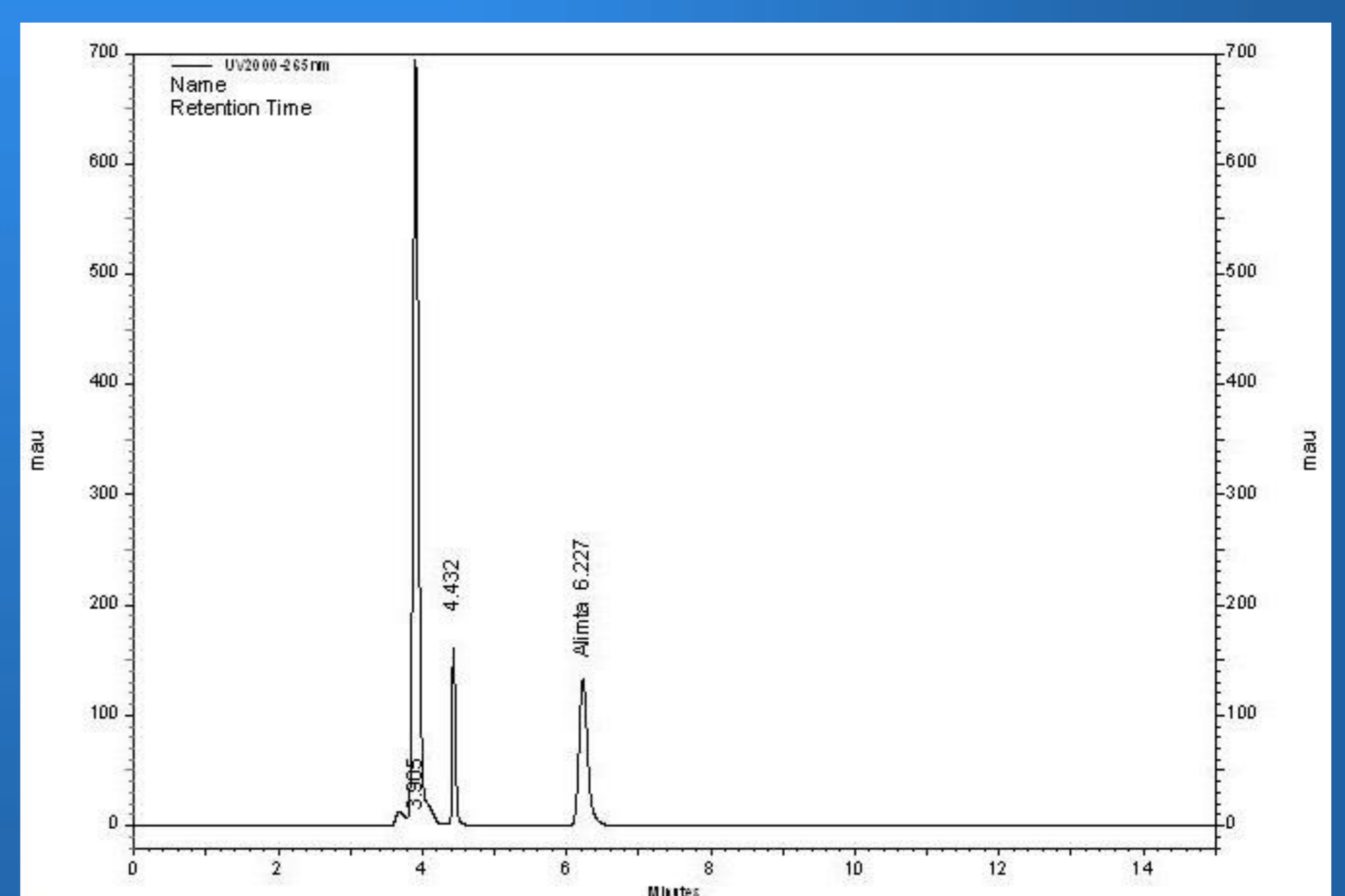
- Sample preparation under a laminar airflow hood using aseptic conditions.
- Sample concentration:
  - vial: 25 mg/ml
  - PVC container: 5 mg/ml in 0,9% sodium chloride
- Physical stability was performed by visual inspection.
- Chemical stability was performed by using a stability-indicating high-performance liquid chromatographic method (HPLC).
- Evaluations were performed at day 0, 1, 2, 7, 14, 21 and 28.

## RESULT-DISCUSSION

- After 28 days: pemetrexed concentrations remained higher than 95% of the initial concentration in reconstituted solution and in diluted solution.
- No precipitate or discoloration were observed in any sample.
- No degradation products appeared on the chromatograms.



Graph 2: Chromatogram of 25 mg/ml pemetrexed



Graph 3: Chromatogram of pemetrexed after H<sub>2</sub>O<sub>2</sub> degradation

## CONCLUSION

Reconstituted pemetrexed 25 mg/ml in glass vial and pemetrexed 5 mg/ml in PVC container were stable for 28 days at 2-8°C.

**Conflict of interest:** nothing to disclose

## REFERENCE

Pestieau SR, Stuart OA, Sugarbaker PH.  
Multi-targeted antifolate (MTA) : Pharmacokinetics of intraperitoneal administration in a rat model.  
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