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Introduction

- Thiopental is a hypnotic used in the induction of general anaesthesia with or without intubation.
- In the gynaecological operating room, to ensure rapid care of a code red caesarean section, thiopental syringes at 25 mg/mL are reconstituted daily by the nurses and renewed every 24 hours.
- **Objectif** : To develop a stability-indicating assay method to control the reconstitution and physicochemical stability of thiopental syringes over 24 hours.

Materials and methods

- An HPLC-DAD method assay has been developed and validated according to ICH Q2(R1) recommendations.

Mobile phase	Flow rate	Column	λ max
Acetonitrile/Water (45/55 ; v/v)	1 mL/min	Purospher STAR RP-18 5 μ m, 150 x 4.6 mm	290 nm

- **Range** : 3.125 à 50 μ g/mL.
- **Quality control** : 3.125 (bas) – 12.5 (moyen) – 50 (haut) μ g/mL.
- **Forced degradations** : pH, temperature, oxidation, photolysis → « purity check » performed to verify the purity of the peak.
- Assessment of thiopental syringes at the time of their preparation (T0) and 24 h after (T24) under gynaecological operating room storage conditions.

Results and Discussion

- Retention time (t_R) was 4.30 min. Linearity was satisfactory with correlation coefficients > **0.999** and residual value < **8.35%**. The coefficients of variation for repeatability and intermediate fidelity studies were less than **2.48%** and **2.75%**. The average percent recovery obtained in the fidelity study remained close to **100%** of the expected value.
- Forced degradations showed degradation products at different t_R from thiopental except for the light for which the « purity check » test showed an absence of homology. A storage of the syringes away from the light is envisaged.

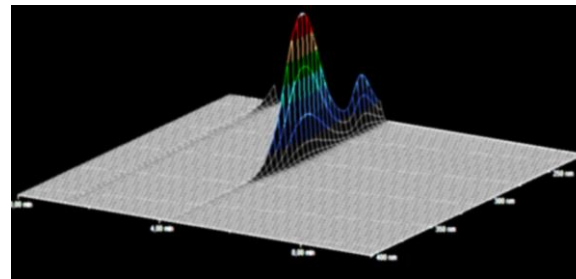


Figure n°1 : Chromatogram of thiopental by UV diode array detector

Medium	Degradation products	« Purity check »
Acid	1.75 min	Homology
Alkaline	1.60 min	Homology
Oxydative	2.00 min	Homology
Heat	6.90 min	Homology
UV	4.30 min	No homology

- The analysis of the thiopental syringes at T0 showed no significant difference with theoretical concentration ($p = 0.20$) as the comparison of the average concentrations observed at T0 and T24 ($p = 0.39$). These results show satisfactory reconstitution of thiopental syringes by the nurses and a **physico-chemical stability over 24 hours**.

Conclusion

- A **simple and rapid** analytical method was developed and validated according to international recommendations. This method has made it possible to carry out an **awareness campaign** on the reconstitution of thiopental syringes in the gynaecology unit.
- The **physicochemical stability** of thiopental at 24 hours makes it possible to envisage a longer stability study. A **microbiological stability study** of the syringes will be necessary to carry out hospital preparations.