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Background



Lugol's solution 5% (iodine / iodide) is used to saturate the thyroid before MIBG scintigraphy.



Random shelf-life quality controls revealed out-of-specification iodine levels, raising concerns about iodine loss.

Hypothesis

- High volatility
- Photosensitivity

Objectives :

- Evaluate iodine loss over time from 5% Lugol's solution depending on the type of packaging, before opening
- Propose improvements ensuring better stability

Material et methods

Production of 3 batches of 10 units packaged differently:



Dropper without box (initial)



Dropper with box



Cap with box

Stability before opening: weekly or bi-weekly dosage for 10 weeks, then monthly for up to 6 months

Automatic titrator
Na₂S₂O₃ 0.1M

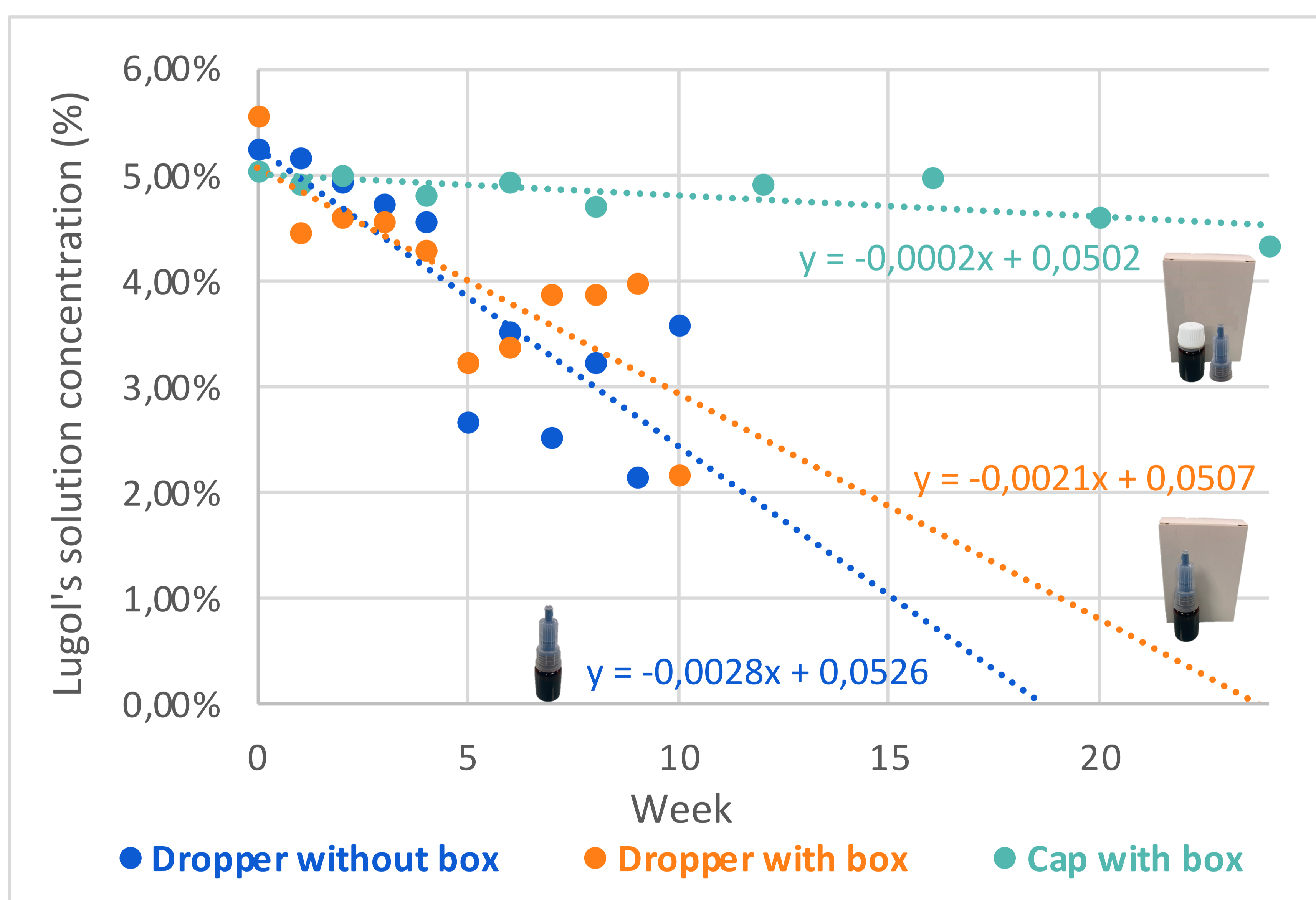
Electrode DMi
140-SC



Mettler Toledo T5

- 1.2g of Lugol 5%
- 10 mL HCl 1M
- 30 mL osmosis water

Results



Time after which the Lugol's solution concentration falls below the specification (< 4.5%):

- ✗ Dropper without box = 2,7 weeks
- ✗ Dropper with box = 2,7 weeks
- ✓ Cap with box = 25,9 weeks

Conclusion

Packaging has a critical impact on the stability of 5% Lugol's solution.

Improvements ensuring greater stability :



- The shelf-life before opening was reduced from 1 year to 6 month
- The shelf-life was limited to 1 week after opening
- Bakelite caps, with droppers supplied separately in cardboard secondary packaging