

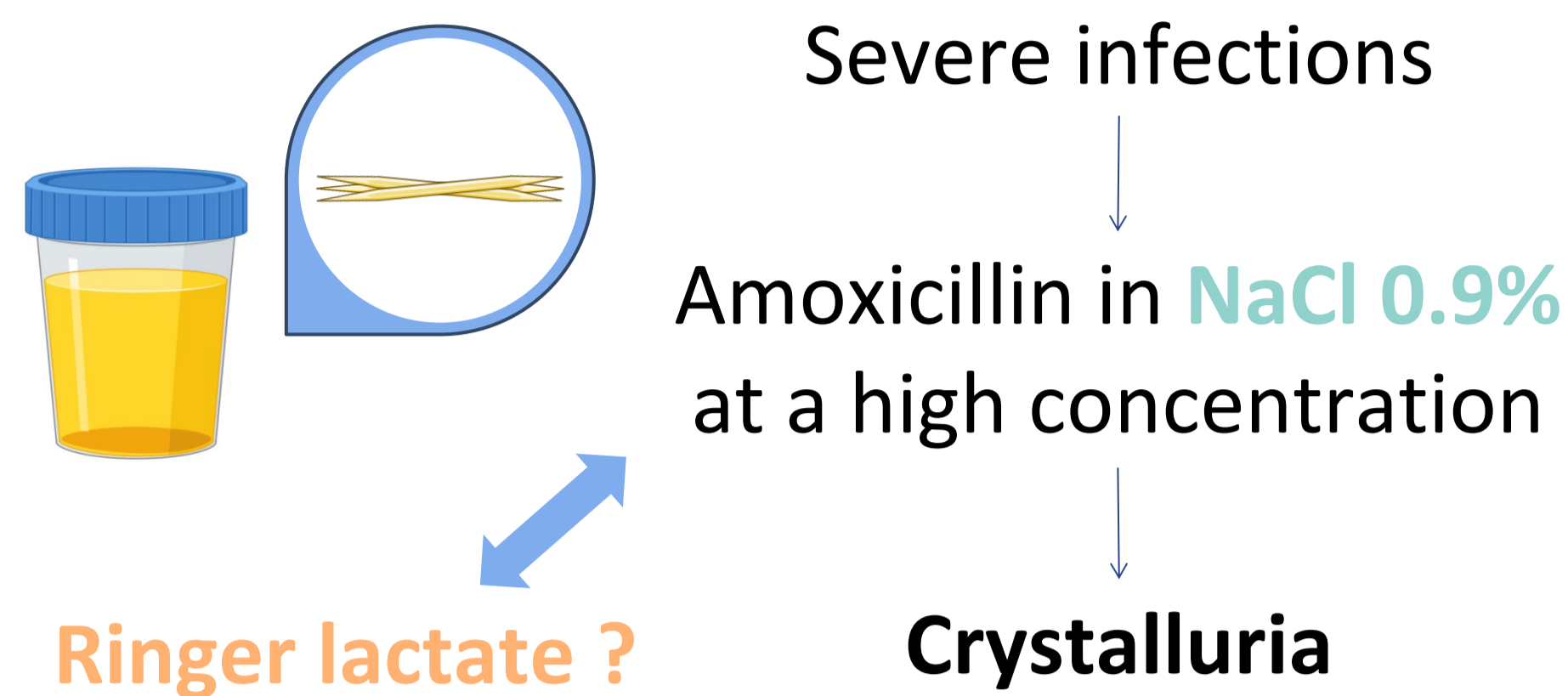


PC61892

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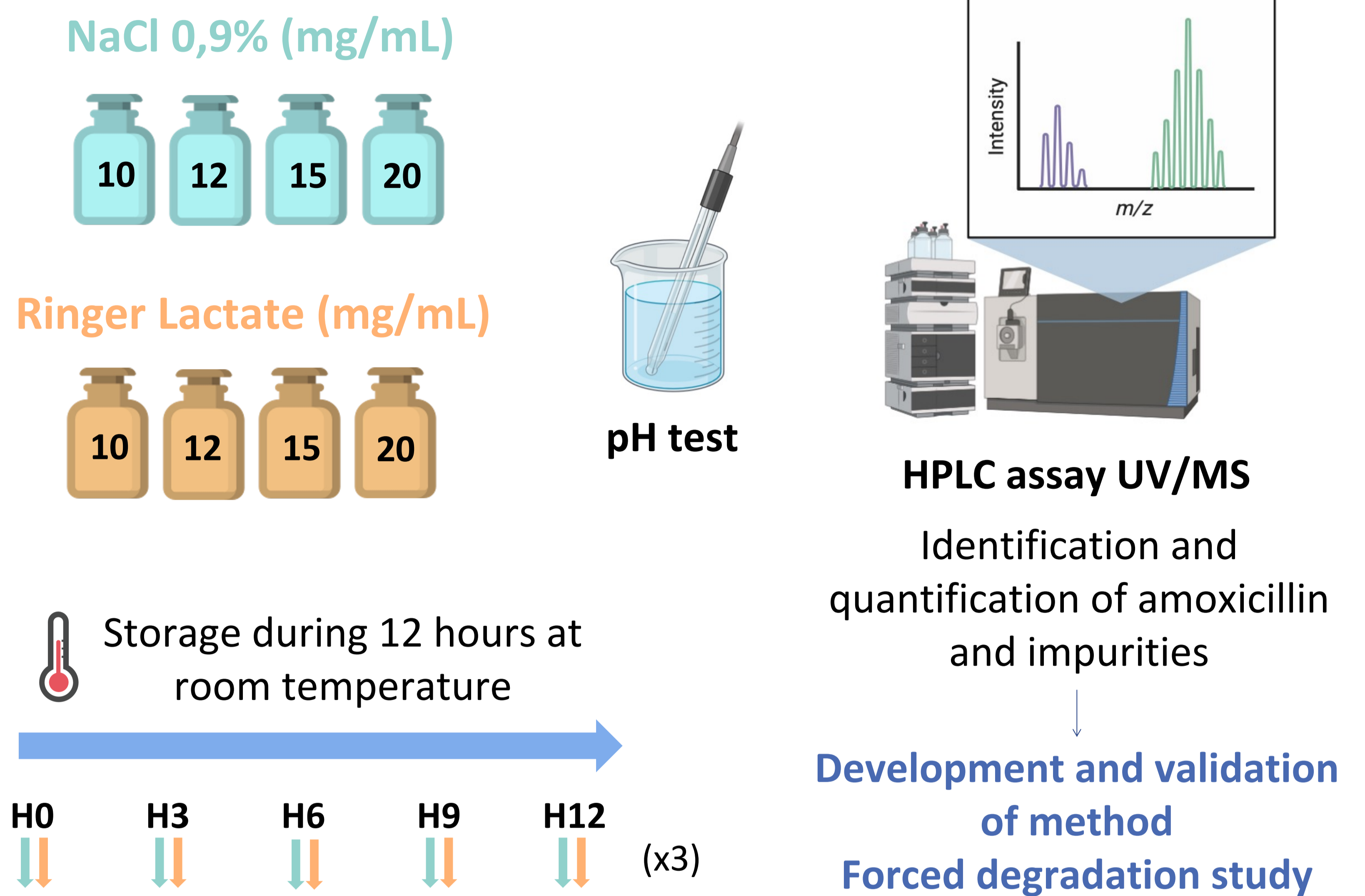
## Background



### Objectives:

- Evaluate the stability of amoxicillin (at 10–20 mg/mL) in 0.9% NaCl and Ringer's lactate solvents over a 12-hour period at room temperature
- Monitor the degradation products in each solvent over time

## Material et methods



## Results

$\lambda_{\text{detection}} = 250 \text{ nm}$   
Column C18 (2.6 $\mu\text{m}$  ; 10cm)

Gradient: ammonium formate buffer (100% → 60%) + ACN (0% → 40%)

Accurate to 100  $\mu\text{g/mL}$  (CV<0.5%)

Exactly at 25, 50, 500  $\mu\text{g/mL}$  (CV<4,3%)

LOD = 1.4 $\mu\text{g/mL}$   
LOQ = 2.2 $\mu\text{g/mL}$

Linear from 25 to 500  $\mu\text{g/mL}$  ( $R^2=0.999$ )

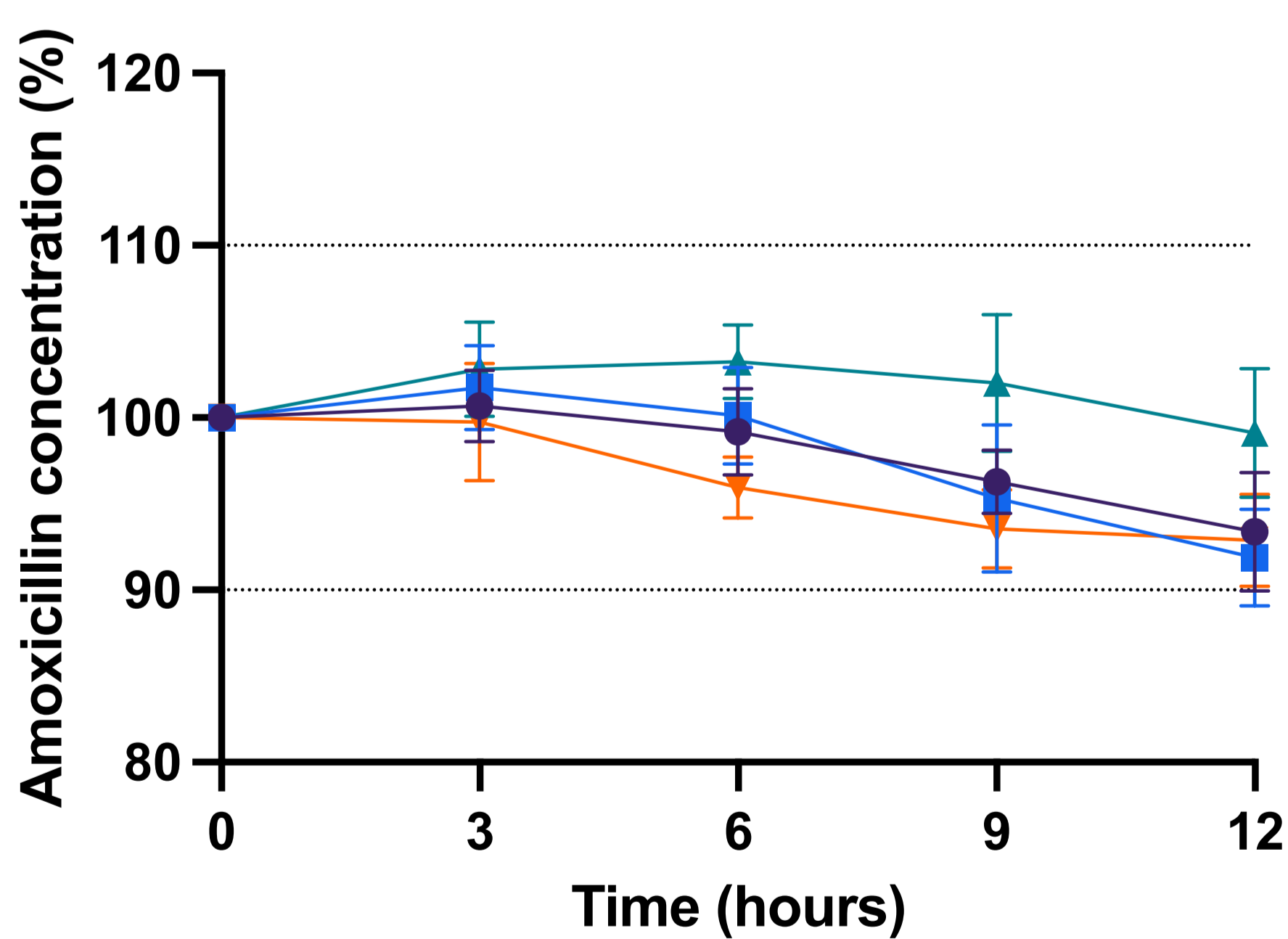
**Validated method**

**Amoxicillin:** Tr = 7.9 min

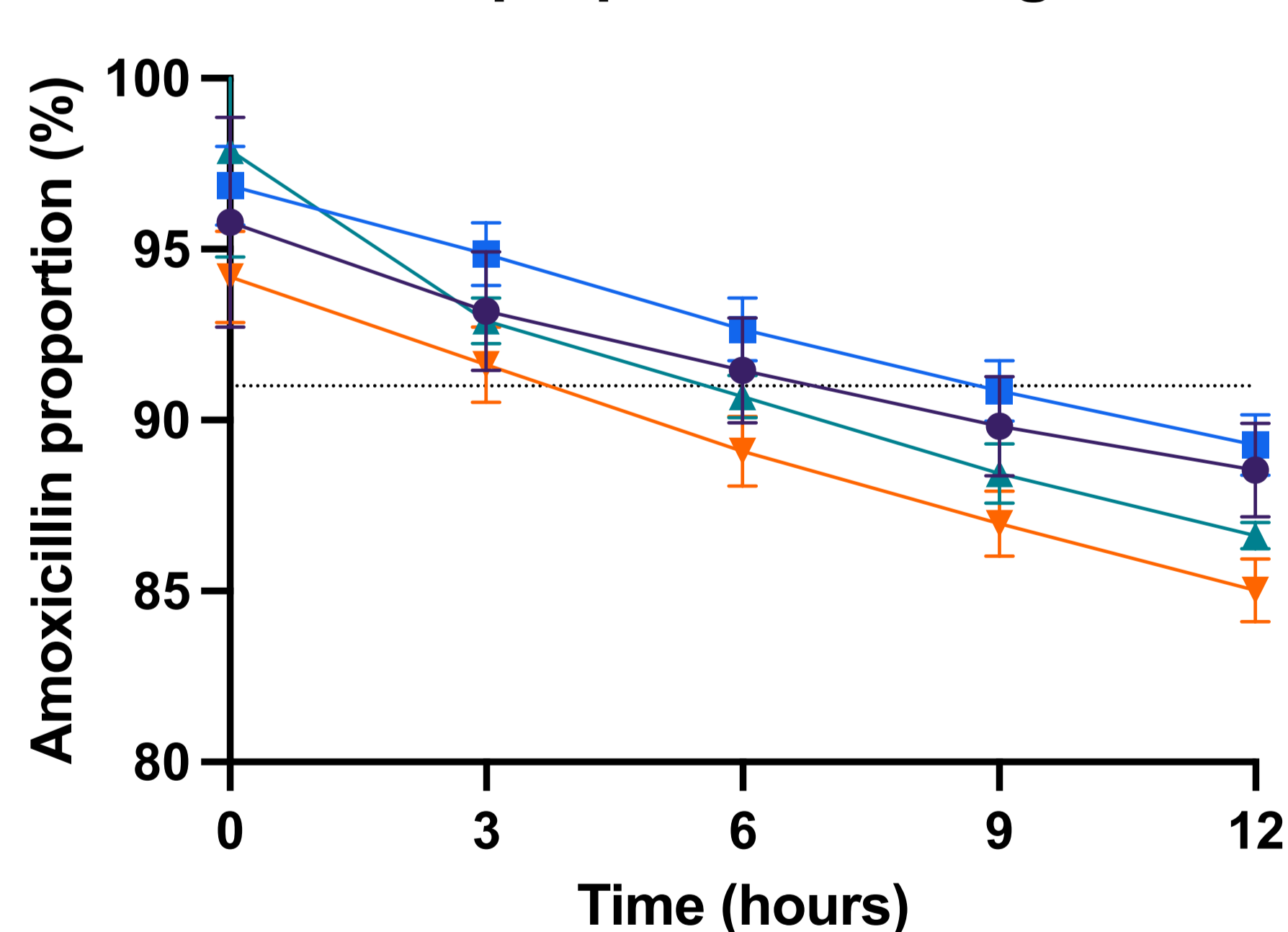
### Degradation products:

- Penicilloic acid (impurity D): Tr = 6.1 min
- Phenylpyrazin (impurity F): Tr = 13.4 min
- Diketopiperazine (impurity C): Tr = 14.3 min
- Co-oligomers (impurity J): Tr = 15.7 min
- Adduct: Tr = 15.1 min

### Relative stability in Ringer Lactate



### Amoxicillin proportion in Ringer Lactate



- No significant difference with NaCl in terms of relative stability (t test)
- Significant difference with NaCl at 20mg/mL and from H6 at 15 mg/mL in terms of amoxicillin proportion (t test)
- Relative stability compliant (10%)
- Proportion of degradation products appearing non-compliant with European Pharmacopoeia (>9%) after 6 and 9 hours depending concentration

No modification of the **visual aspect**

**pH decreased** from 8.8 to 8.6 during the 12 hours of study

## Conclusion

- ✓ Relative stability of amoxicillin after 12 hours at room temperature at high concentration
  - ✗ Appearance of degradation products whose toxicology must be verified
- ➔ If the impurities are deemed acceptable, Ringer's lactate could be a clinically viable alternative to NaCl, due to its lower sodium content and buffering effect, which helps reduce the risk of metabolic acidosis.