

CONTEXT

Ceftazidime 20mg/mL syringes for intravitreal injection are currently prepared extemporaneously in the operating room by a physician for the emergency treatment of endophthalmitis. In order to secure the preparation, the syringes will be prepared, controlled and stored at the pharmacy to provide the dispensing upon request.

OBJECTIVE

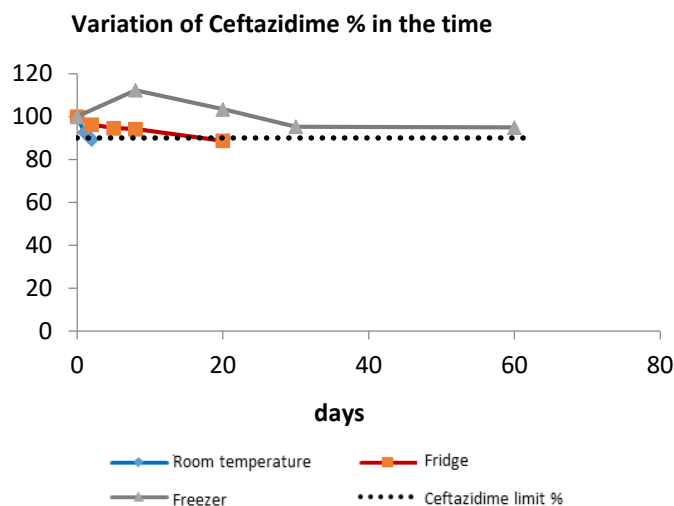
The objective is to conduct a preliminary study of the stability of the ceftazidime solution at 20mg/mL in polypropylene syringes at 3 different storage conditions.

METHOD

Eighty-four syringes were prepared under isolator by reconstitution and dilution with 0.9% sodium chloride (NaCl 0.9%), of one vial of ceftazidime 2g.

- 12 syringes were stored at room temperature
- 24 syringes were stored between +2°C and +8°C
- 48 syringes were stored at -20°C

Ceftazidime concentration was monitored by high performance liquid chromatography (HPLC) with a 255 nm UV detector. Degradation products, including pyridine, have also been quantified. The following criteria were also studied: pH, osmolarity, sterility.



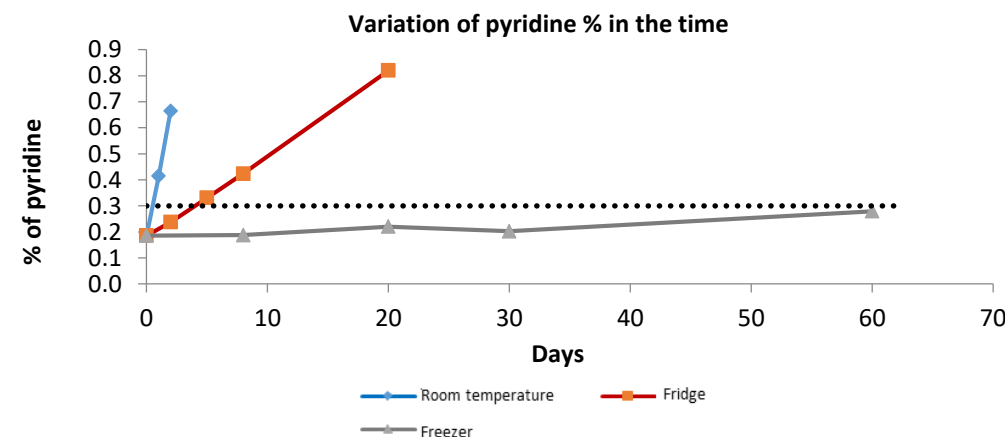
Others : Whatever the conditions of conservation:

- pH : constant – 7,5
- Osmolarity: constant – [350-450] mOsmol/L
- Microbiological controls: negative

RESULTS

	Room temperature	+2°C et +8°C	-20°C
Ceftazidime	D2: Concentration less than 90% of the initial concentration	Measured concentration greater than 90% of initial concentration until D10	Concentration in the tolerance range up to D60
Pyridine	D1: Content > Maximum permitted value (MPV) *	D5: Pyridine content > MPV	Pyridine content < MPV until D60

*Maximum permitted value by the European Pharmacopeia: 0.3%



DISCUSSION/CONCLUSION

Ceftazidime 20mg/mL solution in polypropylene syringes appears to be chemically stable for 60 days in the freezer.

The pyridine content is the limiting factor for setting storage conditions and shelf life. A stability study will be conducted on syringes stored in the freezer to confirm the results.