A study of the stability of Ceftriaxone preparations in two vehicles for epicutaneous allergy tests

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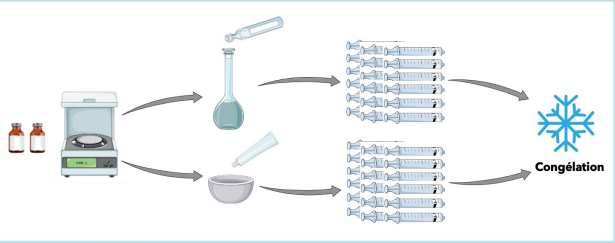
Introduction

Patch tests play an important role in determining the origin of drug hypersensitivity as well as in exploring the risk of cross-reactions with related molecules.
Among the patch tests performed, Ceftriaxone is the most frequently prescribed by our allergology department. Furthermore, the literature on the stability of this type of preparation is limited.

Objectives

we studied the physicochemical stability of Ceftriaxone compound preparations in the form of patch tests. This approach will allow us to produce them in advance in series and to store them in appropriate conditions, allowing their good conservation, subject to registration with the ANSM as hospital preparations.



Method

Tests preparation

Patch tests are made from Ceftriaxone powder dispersed or diluted in two types of vehicles (white petrolum or sterile water) with a concentration of 10% .

Sampling time

The stability study is carried out in seven stages on three different batches per type of vehicle (T0 , D2, D7, D14, D30, D60 and D90 .

Storage conditions

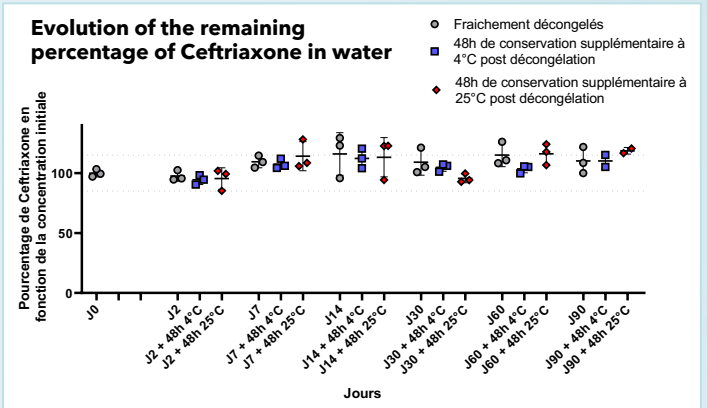
Freezing at -20°C, then, store at +4°C or +25°C for an additional 48 hours

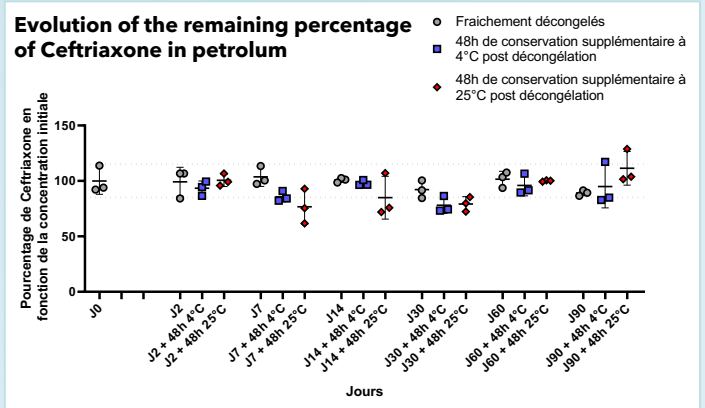
Method of analysis

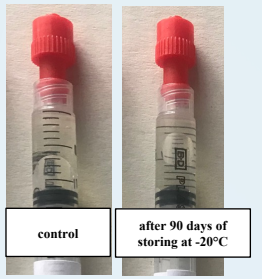
High performance chromatography coupled to a tandem mass spectrometer

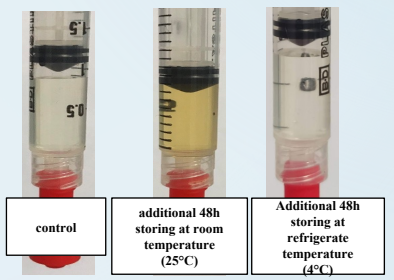
Results

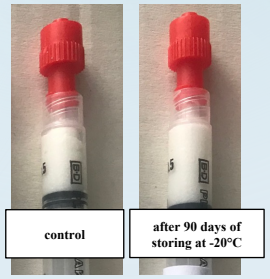
After three months of storage at -20 ° ± 5 ° C, no physicochemical instability was demonstrated in the 2 vehicles. The content observed during the study was within ± 15% around the value at T0. There was also no evidence of instability in preparations thawed and then stored for two days in the refrigerator. However, there was a change in coloration of the "Water" samples thawed and stored at 25 ° C ± 2 ° C protected from light

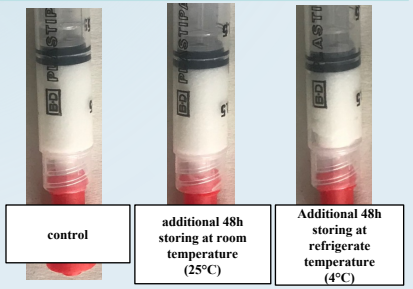












Conclusion

These results demonstrate the stability of the patch tests of Ceftriaxone at 10% in the two types of vehicles studied for 3 months at -20 ° C ± 5 ° C, which allows us to prepare these tests in advance. After thawing, the tests can be stored for 48 hours at 5 ° C ± 3 ° C.