Stability of cefuroxime solution in polypropylene syringes : a review

M.Carbonne, S.Henn-Ménétré, I.May
Pharmacy, Brabois Hospital, Nancy University Hospital, France
e-mail : m.carbonne@chu-nancy.fr

Introduction

Endophtalmitis is a rare but serious postoperative infectious complication following cataract surgery. According to the **Agence française de sécurité sanitaire des produits de santé recommendations 2011** there is a preventive treatment to minimize it, consisting in the administration of an **intracameral injection of 0.1 ml of cefuroxime 1mg/0.1mL**, after a not complicated surgery. This treatment is not marketed and must be prepared within a Hospital Pharmacy.

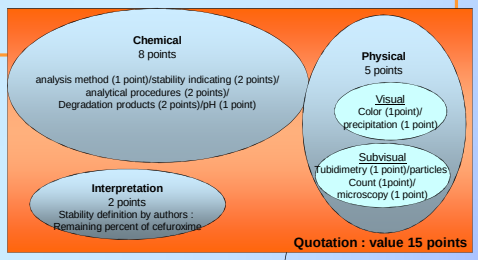
Objective

This work aims to list and to analyse studies concerning the stability of cefuroxime eyed solutions to improve efficiency of manufacturing.

Material and Method

A review of the literature was made according to 14 references, stemming *Trissel's stability of compounded formulations*, *Handbook on injectable drugs*, or databases such as Scopus. Keys words for research were : "stability, cefuroxime, intracameral, ophtalmic preparation, storage".

On one hand various criteria were listed depending on the study: the concentration of the solution, the solvent, the conditions of storage and the stability data, on the other hand **a value** (**quotation** of 15 points) is attributed for each of study according to **analytical criteria**. Those are **chemical criteria** (pH, analysis method, stability indicating, respect for the analytical practices of laboratories, quality and quantity of the degradation products), **physical criteria** (visual such as color change, precipitation and subvisual such as turbidimetry, counting of particles) and **interpretation criteria** (definition of stability by authors). Studies are classified in a summary table.



Results

Hospital Pharmacy of Nancy University Hospital makes batches of syringes of 0.2 mL of cefuroxime 10 mg/mL of 0.9 % sodium chloride in 1 mL graduated polypropylene syringes. These hospital preparations are produced once a week and then stored at +4℃.

Defrosting performed at room temperature

Cefuroxime solutions are stored away from light to limit degradation of the antibiotic.

Concentration (mg/mL)	Dilution solvent	Container	Condition of storage	Stability	References	Quotation
10	0.9% NaCl	PP	-18℃	**120 days**	Poster HUG, EAHP Nice 2010, http://pharmacie.hug-ge.ch/infposters.htm/	13
7.5	0.9% NaCl	PP	+4℃ 25℃	7 days 1 day	Eur Hosp Pharm 2000; 6:17-23	11
15	5% G	PE	+4℃	30 days	Eur Hosp Pharm 2006;12:32-34	10
50	WFI	PP	-30℃ +2℃ +25℃	**360 days** 21 days 1 day	Int J Pharm Prac 1991; 1:19-22	10
150	5% G	PE	-20℃	21 days	Ann Pharmacother 2005;39:1244-8	9
10	0.9% NaCl or 5% G	PVC	+4℃ -10°C	**30 days** **30 days**	J Clin Hosp Pharm 1986;11:47-54	8
150	5% G	PVC	+4℃	13 days	J Clin Pharm Ther 1996;21:185-9	7
50	0.9% NaCl	G	+4℃	**30 days**	Inter J of Pharm Prac	7
7.5	0.9% NaCl or 5% G	PP	+25℃	1 day	Drug Intell Clin Pharm 1988;22:54-7	5
10	BSS	PP	-21℃	**28 days**	Poster HCL, SFPC St Malo 2008	5
60	WFI	PVC	-20℃	**30 days**	Am J Hosp Pharm 1992;49:2761-4	4
150	0.9% NaCl or 5%G	PVC	+4℃	4 days	Pharmazie 1994;49:425-7	4
10	0.9% NaCl	PP	+4℃	7 days	Poster, Hopipharm Vittel 2010	3
10	-	G	-10 ℃	**30 days**	Atencion Farmaceutica 2008;10:44-7	NQ

0.9 % NaCl : 0.9% sodium chloride
5% G : 5% glucose
WFI : water for injections
BSS : balanced salt solution

PP : polypropylene
PVC : polyvinyl chloride
PE : polyethylene
G : glass

Arsene M et al. (J.Pharm.Clin,2002; 27:205-209) state that cephalosporin at 40 mg/mL in 20℃ is more s table in the glass container than PP container, and this stability is better in PP container than PVC container. We base one's argument on that broaden researches on stability cefuroxime solutions in other containers. Solutions in PE container seem to have the same stability as PVC container. So cefuroxime solution which is stable in PVC or PE will stable in PP.

Discussion & Conlusion

The review of the literature has enabled to point out that **freezing** is essential to a shelf life beyond 7 days. Furthermore, this mode of preservation assures a **stability until 4 months**. At -21℃, a 10 mg/mL cefuroxim solution in BSS wa s stable for 28 days and in 0.9 % NaCl for 4 months. The way of storage in the Nancy University Hospital should evolve to increase the duration of stability of its preparations, indeed the best way to preserve for a long time is freezing.

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