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Impact of Storage Conditions on the Temperature of Infusion Bags

Louisa Knowles, Advanced Pharmacist for Technical Services, louisa.knowles@uhb.nhs.uk

Sedika Kessani, Trainee Clinical Pharmaceutical Scientist

Introduction

For products prepared in the aseptic unit, an appropriate product shelf life is assigned to ensure the quality of the product is suitable for the patient at the time of administration (1). Storage conditions are one factor that impacts the stability of a product (2). In general, low temperatures slow down chemical degradation, however, they can result in physical instability for some products (1, 2). Following preparation, the correct temperature storage must be maintained through storage and distribution, to ensure the quality of the product is maintained (1). Refrigerated temperature is defined as 2-8°C and room temperature is defined as 15-25°C (1).

Incidents have occurred, where products have been stored at the incorrect temperature in the aseptic unit and at ward level. In these instances, an assessment must be made to determine the suitability of the product for use. This should be completed by reviewing the SmPC and stability data available, in line with “A Standard Protocol for Deriving and Assessment of Stability” (2). Where there is no stability data available to support the quality of the product being fit for use, a risk assessment must be made to determine whether the product should be used.

Aim and Objectives

Aim

To determine the effect of external temperatures on the core temperature of products prepared in the aseptic units

Objectives

• To determine how long it takes for infusion bags with a core room temperature to reach a core fridge temperature when placed in refrigerated conditions

• To determine how long it takes for infusion bags with a core fridge temperature to reach a core room temperature when placed in room temperature conditions

Method

Each Macopharma Easyflex N infusion bag was fitted with a liquid probe connected to a Testo Data Logger to continuously record the core temperature of the infusion bag. An air probe connected to a Testo Data Logger was kept alongside each infusion bag to record the air temperature surrounding the infusion bag.

All infusion bags were stored at room temperature prior to the study. They were then placed in a validated refrigerator, until they reached a core temperature <8°C. The infusion bags were then moved to room temperature storage.

Results

Time taken to reach a core fridge temperature when placed in refrigerated conditions		**Time taken to reach a core room temperature when placed in room temperature conditions**	
50ml	65 minutes	50ml	65 minutes
100ml	85 minutes	100ml	75 minutes
250ml	115 minutes	250ml	110 minutes
500ml	140 minutes	500ml	130 minutes
1000ml	150 minutes	1000ml	160 minutes

Conclusions

It takes between 65-150 minutes for infusion bags with a core room temperature to reach a core fridge temperature when placed in refrigerated conditions. Furthermore, it takes between 65-160 minutes for infusion bags with a core fridge temperature to reach a core room temperature when placed in room temperature conditions

The volume of the infusion bag and duration of the storage conditions should be taken into account when completing a risk assessment to determine if a product is fit for use when stored under inappropriate temperature conditions.

References
1.Beaney A. Quality Assurance of Aseptic Preparation Services: Standards. rps---qaaps-standards-document.pdf (rpharms.com): Royal Pharmaceutical Society and the NHS Pharmaceutical Quality Assurance Committee; 2016.
2.Committee NPQA. A Standard Protocol for Deriving and Assessment of Stability Part 1 - Aseptic Preparations (Small Molecules) 5th Edition: https://www.sps.nhs.uk/wp-content/uploads/2013/12/Stability-part-1-small-molecules-5th-Ed-Sept-19.pdf; 2019
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