



The QA and Technical Services Interest Group of the
Guild of Healthcare Pharmacists

Pharmaceutical Quality Assurance and Technical Services Symposium 2023

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International Convention Centre
Newport, Wales. NP18 1HQ



POSTER APPLICATION FORM

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Poster title	Comparative study of citrate buffered solutions on the stability of generic Piperacillin and Tazobactam

Please submit details of abstract overleaf

Please note: all poster applications must be submitted by 18th August 2023

Please return your application to:

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marking the subject as "Symposium Posters"

ABSTRACT

Introduction

A national government report by Lord Cole offering guidance called 'Transforming NHS pharmacy aseptic services', highlighted that the National Health Service (NHS) long term goals will be to focus on freeing up nurses' time for patient care and the increased automation within the NHS to reduce cost of manufacture. The report emphasised that almost 47 million vials are reconstituted throughout English hospitals over the period of 2019-2020 and that it took approximately on average 11 minutes per vial per antibiotic Intravenous infusion. Which would mean approximately 9 million hours of nursing time were unavailable for patient care. ⁽¹⁾

Reconstitution of vials is taking place at ward level by nurses operating under time pressures with little training in aseptic technique. Issues that occur due to poor aseptic technique, increases the risk of bacterial infection of patients that are normally immunocompromised which can lead to further complexation and or death of patients. ⁽²⁾

Aim

The aim of this research was to create a new 'standalone' concentrated citrate solution, with a pH 7, for the reconstitution of Piperacillin and Tazobactam 4.5g (PIPTAZ) in 100ml Sodium Chloride 0.9% non- PVC bag and investigate the effect on shelf life up to 54 days in the 5°C ±3°C.

Methods

The use of generic PIPTAZ brand Aurobindo Pharma-Mil pharma LTD was reconstituted with 3 differing solutions Sodium Chloride 0.9%, Buffered solution containing 0.9% Saline solution with 0.3% Sodium Citrate, 0.03% Citric acid (BUFNa) and Concentrated citrate solution containing 1.92% Sodium Citrate, 0.02% Citric acid and 0.9% Sodium Chloride (CONCIT). The solutions were prepared in 5 bags and stored at 5°C ±3°C and tested in duplicate at 5 time points, using a validated stability indicating HPLC method.

CONCIT solution was manufactured in a terminal sterilised unit and produced as a sterile product for use in aseptic preparation. Stability was carried out following International Conference on Harmonisation (ICH) ICH 1A (R2) guidelines.

Results

Piperacillin and Tazobactam was significantly improved with the CONCIT compared with the 0.9% Sodium Chloride solution. Using lower confidence interval CI 95%, both active substances remained within 5% regression loss for up to 54 days when stored at 5°C ±3°C.

CONCIT solution remained within pH limits and chemically stable for up to 1 year.

Conclusion

The 'standalone' product of CONCIT used in the aseptic batch manufacturing of PIPTAZ in Sodium Chloride 0.9% 100ml bags provides a significant advantage over saline as a reconstitution solution. The information unlocks up the possibility of using the sterile CONCIT product at different licensed units for the propose of batch manufacturing; giving the extended shelf life of up to 54 days.

References

(1) Department of Health and Social Care, Transforming NHS pharmacy aseptic services in England - GOV.UK, 2020. Available from Transforming NHS pharmacy aseptic services in England - GOV.UK (www.gov.uk) [Access 18/02/23]

(2) Suvikas-Peltonen, E., Hakoinen, S., Celikkayalar, E., Laaksonen, R., Airaksinen, M., 2017. Incorrect aseptic techniques in medicine preparation and recommendations for safer practices: a systematic review. *European Journal of Hospital Pharmacy* 24, 175–181.

<https://doi.org/10.1136/ejhpharm-2016-001015>

[Access 18/02/23]