QUALITY ASSESSMENT – UNLICENSED "SPECIAL" MEDICINE

Product: **Flucloxacillin in Intermate device**
250mg – 2000mg in sodium chloride 0.9% variable volume

Company: **Baxter Healthcare**
Caxton Way
Thetford
Norfolk, IP24 3SE

Basis of assessment: **Information provided by Baxter in support of the Yorkshire and Humber Homecare antimicrobials tender.**

Date of report: **3/7/2013**

Summary of Quality Assessment Outcome:

There is sufficient evidence provided to give assurance that this medicine is consistently manufactured, labelled and packaged to an acceptable quality, and the shelf life assigned supported by acceptable data.

1. Product Specification

The product is prepared under the Manufacturer's Specials Licence.

A sample label was received for an example concentration of 870 mg / 50ml in 0.9% sodium chloride (page 3).

The product is:-

- prepared from licensed components
- filled into Intermate devices, which are individually heat sealed in UV protective clear plastic single overwrap
- assigned a 10 day shelf life when stored at 2-8°C.

Photographs and samples of the product type were submitted.

Intermate infusion devices are latex-free. Latex-free gloves are used within the compounding unit. No information is available on the latex status of the vials or other components/disposables used in preparation with the exception of syringes which are latex free.

An approved list of suppliers was received (see Company Dossier).

2. Quality Statements/Certificates

A certificate of conformity is supplied with every batch (see sample on page 4).

This states that product is compounded under the provisions of the Manufacturer's (Specials) Licence (MS 116) and that the product meets Baxter's release criteria.

The cold chain is validated but no cold chain certificate is provided with each delivery. However, there is a mechanism in place for customers to be contacted if the cold chain is breached. This is acceptable.

3. Manufacturing Method

The product is aseptically compounded in Grade A isolators. The Grade A zone, and all items transferred into it, are sanitised with vaporised hydrogen peroxide.

The manufacturing process is stated to be carried out under the Manufacturer's (Specials) Licence and in compliance with EU GMP. Compounding is done according to the product specification.

Production involves the reconstitution of vials as per SmPC, withdrawal from the vials into syringes, and direct addition to the Intermate devices.

Batch documentation and products are checked in accordance with SOPs. This includes in-process checks.

4. Quality Control

A detailed release procedure has been provided.

Satisfactory data has been provided regarding the microbiological integrity of the final container for the shelf life given.

A study provided shows that hydrogen peroxide gas penetration into the containers is negligible and is assessed to have no effect on product stability.

The stability data pro forma has been completed and refers to two Baxter in-house studies using a BP method (HPLC). These assign a 10 day expiry at 2-8°C for concentrations of 10-50 mg/ml based on 95% remaining.

5. QCNW labelling and packaging assessment

The label on the specification is clear and complies with the principles of packaging and labelling for safety.

The dose is expressed as total mg/total mls.

Recommendations to purchaser:

- Check product received matches the product specification/sample labels
- Check the C of C matches the product received and has been signed by an authorised person
- Check no notification received of any breach in the cold chain
- Complete unlicensed medicines documentation as per local policy

Assessment prepared by: Sharon Hart-Davies
QA Specialist

Approved by: Alison Darbyshire
QA Pharmacist

Baxter
[REPRINT]

CERTIFICATE OF CONFORMITY

Baxter Healthcare Ltd
Caxton Way, Thetford IP24 3SE

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The following batch has been aseptically compounded under (Specials Manufacturing) Licence no MS 116

PRODUCT CODE	
DESCRIPTION	
DEVICE	
BATCH NUMBER	
USE BEFORE	
STORAGE	

In accordance with relevant Baxter Healthcare Standard Operating Procedures the above batch is considered to meet the release criteria.

Pharmacist/QA Authorised Signatory: _____

Date: _____