

CFGT SOP

OUTLINE OF PROCEDURE

PRINCIPLE

The multidose trial (MDT) will be placebo controlled; therefore all aspects of the trial where a patient or staff member could be un-blinded to the product or placebo must be monitored and controlled, including delivery of the pots to and from pharmacy. This protocol also reduces infection risk for the patient.

OBJECTIVE

- 1) To correctly and appropriately tape the nebuliser pots so that a patient or staff member cannot be un-blinded to product or placebo inside.
- 2) To ensure the nebulisers and nasal spray pots are infection free.
- 3) To ensure that the nasal pot does not leak.

SECTION 1 Summary of health and safety

GENERAL The main risks involved in this protocol are:

N/A

PROTECTIVE EQUIPMENT

N/A

EQUIPMENT

- Nebuliser packing (nebuliser pot + nebuliser tubing)
- White electrical tape
- Gloves
- Lab Coat
- Extractor Hood
- Scissors
- Filter paper
- Falcon pot – Blue max 17 x 120mm style
- Antibacterial wipes

SPILLAGE PROCEDURES

N/A

WASTE DISPOSAL

General waste

SECTION 2 Protocol

1. Put on all personal protective equipment.
2. Switch on the extractor hood.
3. Ensure all of the equipment required is at hand.
4. Wipe the surface with an antibacterial wipe and cover with a sterile utility drape/clean surface cover.
5. Open the nebuliser packaging and remove the nebuliser.
6. Dispose of the mouthpiece and retain the packing with nebuliser tubing in a box (the Pari Filter/Ventil set will be used to dose the patients – not this mouthpiece).
7. Wipe the nebuliser with antibacterial wipes and leave to dry.
8. Fold a piece of opaque circular filter paper into 4 'pie' segments and cut the end off to reveal a hole in the middle (see figure 2).
9. Place the filter paper into the end of the nebuliser.
10. Tape the bottom of the nebuliser with 4 strips of tape ensuring that a hole is left in the middle (see figure 3).
11. Prepare strips of tape or wind the tape around the nebuliser pot starting at the bottom and working up the pot until the pot is fully covered (see figure 1). **Ensure that the tape strips always overlap, that the end of the nebuliser pot is neat and that there are no gaps.**
12. Clean the sterile tube lid (see figure 4) with the antibacterial wipe; place the tube lid into the hole of the nebuliser.
13. Complete the quality control sheet (see appendix 1) with another person and amend the nebuliser pot if necessary.
14. Place into a sealable bag and send to pharmacy.

Figure 1.



Figure 3.



Figure 2.



Figure 4.



Training Log

BLINDING PROCEDURE – TAPING THE NEBULISER POTS CFGT/SOP/638/MDT

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| Date | Version | Competent | Name of Investigator | Signature of investigator | Next review | Name of Reviewer | Signature of reviewer |
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