

Baxa Oral/Enteral Dispensers Cleaning & Re-Use Validation (Product Codes: 1101-1120; 1601-1650; 1701-1790)

1. Validation of Cleaning Method

An independent, UKAS registered, testing laboratory validated the cleaning guidelines described in the Instructions For Use (1061-1189) using procedures in accordance with GLP (Good Laboratory Practice).

The work was repeated three times, filling dispensers with either Paracetamol Suspension, proprietary feed or Protein (in the form of Bovine Serum Albumin). Cleaning was performed using warm water and domestic washing-up liquid.

2. Multiple Use Validation

Dispensers should always be cleaned using the methods described above and in the Instructions For Use. Other methods may subsequently be used to provide additional cleaning. These are summarised:

Standard Cleaning -

- a. Warm water and washing up liquid (2 minutes)

Followed by one of -

- b. Processing in a dishwasher (50 mL size only – tip uppermost)
- c. Immersion in boiling water (3 minutes)
- d. Immersion in cold sterilising solution (see solution manufacturer's instructions. N.B. Immersion should NOT be permanent between uses)
- e. Processing in a steam steriliser (see manufacturer's instructions)

To validate each of these methods, ten dispensers were cleaned using each method. The physical performance throughout 30 cleaning cycles was tested. After each cleaning cycle the following actions were carried out:

- Visual inspection for cracks, damage and graduation marking clarity
- Leak test

After 30 cycles every dispenser was tested for:

- Volume accuracy of +/- 5% @ 15 mL, 30 mL, 45 mL & 60 mL markings

3. Results of Validation

The testing concluded that the “the cleaning procedure is valid and adequately cleans the syringe”. There was no loss of performance or loss of accuracy with any of the dispensers using cleaning methods (2a-2e). However, using method 2b (dishwasher test) resulted in the graduated markings becoming eroded and the plunger became stiff to operate after ten washes. (N.B. Dishwasher used was not a short-cycle commercial washer but a domestic appliance with a two hour operating cycle)

Certified By:

Date: 20th June 2006



C. Price
Director of Quality

