



EQUIPMENT TAG-OUT FOR VALIDATION

(Ref. SOP VAL-175)

1. PURPOSE

The purpose of this operating Instruction is to outline the procedure for removing a piece of equipment from routine service for the purposes of conducting validation (also referred to as “tag-out”).

2. SCOPE

These procedures apply to all equipment and facilities located at a GMP site.

3. PROCEDURE FOR PLACING EQUIPMENT “TAG-OUT”

- 3.1. Obtain permission from the equipment owner to place the equipment (or equipment train) out of routine service for validation.
- 3.2. Complete a label containing the information required as shown in the attached templates (see section 5). The person who places the label must record the date the equipment is “tagged-out”, sign and record their contact extension. (N.B. Electronic copies of the labels may be generated from the label templates).
- 3.3. The label must be securely attached to the equipment in a position such that the label is readily visible. If necessary an additional labels may be placed at critical locations e.g. next to the equipment operation controls.

4. PROCEDURE FOR RETURNING EQUIPMENT TO PRODUCTION USE

- 4.1 Complete the label field “Returned By” and sign and date the label.
 - Complete equipment usage/log book
 - Attach the label (or a copy) to equipment usage/manufacturing records
 - Attach the label (or a copy) to validation report

5. EQUIPMENT “TAG-OUT” LABEL TEMPLATES

5.1 Large Format Label Template

[Company Name]

[Address]

**UNDERGOING
VALIDATION**

DO NOT USE WITHOUT VALIDATION
APPROVAL

Authorised by: _____
 Name Signature Date

Returned by: _____
 Name Signature Date

Contact Ext: _____

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5.2 Small Format Label Template

UNDERGOING VALIDATION DO NOT USE WITHOUT VALIDATION APPROVAL	
Contact Ext.	
Placed By	
Sign	
Date	
Returned By	
Sign	
Date	
<i>[Company Name]</i>	
<i>[Address]</i>	