

Happy Pharma Work Instruction

Document ID	WI-123451	Edition Number	01
Document Title	Setup, Use and Shutdown the Packing Line		
Parent SOP	SOP-123456: Completing Product Inspection		
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Purpose

The purpose of this WI is to describe how to setup, use and shutdown the packing line in area XYZ of the Happy Pharma Hong Kong facility.

Safety

The following safety requirements apply to this WI:

- Do not wear jewellery or loose clothing while operating machinery
- Spills or product contact – refer to **SOP-485787: Handling Materials in Manufacturing**
- Correct gowning within the Packing Areas – refer to **SOP-256056: Gowning in Pharmaceutical Packing Area**
- Personnel protective equipment - refer **SOP-11126: Personal Protective Equipment**

Instruction overview

Section	Description
1	General description of the packing line
2	Set up and use the inspection machine
3	Set up and use the labeller
4	Set up and use the cartoning machine
5	Set up and use the carton barcode labeller
6	Set up and use the automated cartoning unit (ACU)
7	In process checking and status lights
8	Rework rejects
9	Shutdown the packing line

Instruction

1.0 General description of the packing line

Packing Line is located within a non-graded cleanroom and consisting of the following machines.

Machine Name	Tag Number
Inspection Machine	XX
Labelling Machine (Bottle)	XX
Cartoning Machine	XX
Labelling Machine (Carton)	XX
Lift Table	XX
Accumulation Tables	XX
Automated Cartoning Unit (ACU)	XX

2.0 Set up and use the inspection machine

Refer to **SOP-XXXX: Completing Product Inspection** for an overview of the inspection process.

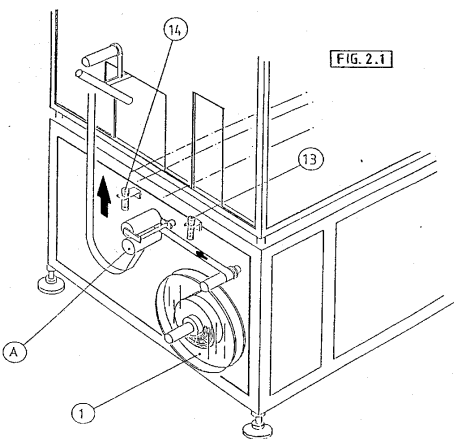
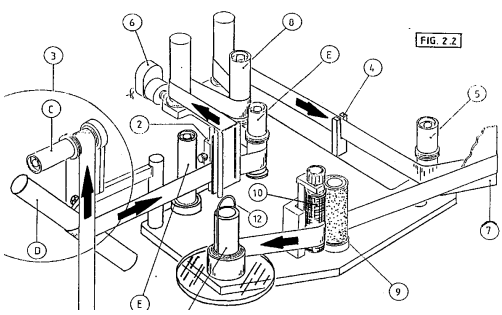
Complete the following steps to set up and use the inspection machine.

Step	Action
1	Turn on the main power switch located on machine mains cabinet.
2	Set the control panel for the appropriate inspection (product or media).
3	Reset the count display by pushing the white Scroll button. Result: The infeed and rejects should be cleared. Repeat to also reset the production hours. If the count does not reset then insert the key in the reset lock and push the key down while turning to the right. The display will indicate when the reset is complete.
4	Adjust the seat and magnifier position for the operator.
5	Position the Heavy Duty Light Meter according to the marked setting in the centre/middle of the machine. Record the Lux level reading in the batch record according to WI-XXXX: Operate the Heavy Duty Light Meter .
6	Load Inspection machine table with product and switch the eject sensor on.
7	Check the operation of the system: <ul style="list-style-type: none">• Confirm that the eject sensor is operating satisfactorily by marking a bottle at the start of the inspection process and deliberately rejecting it• Verify that the rejected bottle is ejected
8	Start the inspection by pressing the on switch.

Step	Action
9	<p>Point at each reject bottle to trigger the reject sensor (the machine will beep):</p> <ul style="list-style-type: none"> Switch the reject sensor off before marking the reject bottle Mark the reject as 'REJECT' and placed in the reject tub located in printed materials cage. <p>Complete FRM-XXXX: Operator Inspection Log Sheet Lines 1 & 2 for every inspection run.</p> <p>During the inspection process, operators may remove suspect reject product manually for further investigation.</p>

3.0 Set up and use the labeller

Complete the following steps to set up and use the labeller.

Step	Action
1	<p>Set up the Markem Smart Date Thermal Printer is set according to SOP-XXXX. Obtain the details for the overprinted on labels from the MPI and verify against SOP-XXXX.</p>
2	<ul style="list-style-type: none"> Load the label reel: Depress catch and remove outer flange from reel holder App.1 (1) Fig 2.1. Position label roll on holder. Depress catch and replace outer flange on reel holder App.1 (1) Fig 2.1. Feed the label tape through the two rollers on the unwinder, the reel will automatically be unwound App.1 (A) Fig 2.1. Feed the label through the machines dispensing system in accordance with the diagram App.2 Fig 2.2. 
3	<ul style="list-style-type: none"> Allow enough slack for the photocell to activate unwinder and automatically feed tape over the 90° bar with roller App.2 (c) Fig 2.2 and around the 60° bar App.2 (d) Fig 2.2. Loosen the pressure brushes App.2 (2) Fig 2.2 to allow for the passage of the tape between them. Feed the label tape between the buffer and the printing unit. Feed the label tape through the unit that adjusts the printing position. This consists of two guide cylinders and an adjustable moving roller in a triangular formation App.2 (8) Fig 2.2. Feed the tape in front of the code and print reading heads and thread through the slots of the photo sensor App.2 (4) Fig 2.2. Position the tape between the peeling plate and the transmission roller App.2 (7) Fig 2.2 Guide the label tape through the rewinding roller App.2 (10) Fig 2.2 feeding it through the rubberised traction roller App.2 (9) Fig 2.2. The pressure roller App.2 (10) Fig 2.2 must be loosened in order to insert the tape. Then anchor the label tape onto the take-up roller by threading it through the fork provided on the roller App.2(11) Fig 2.2. 

Step	Action
4	<p>Complete the label outlet check:</p> <ul style="list-style-type: none"> • Press the manual label button on labeller to dispense label • Check that the details are correct and the print position is suitable • Move the print by using manual controls, adjusting either vertically or horizontally. The label must have overprint details as required in SOP-XXXX: Shelf Life of Products <p>Once satisfactory verify on the batch record.</p>
5	<p>Check OCV label overprint detection system is operating correctly by placing a blue dot over the print area and ensure that OCV detects this label and that the reject label is the next label to be dispensed.</p> <p>Note: The first satisfactory label must be used as the sample for History Card. Details of this label must be transcribed onto batch record. The second satisfactory label must become the first bottle labelled. Ensure not set up labels are present online, they must all be placed on reject card before the commencement of packing.</p>

4.0 Set up and use the cartoning machine

4.1 Complete preliminary operations

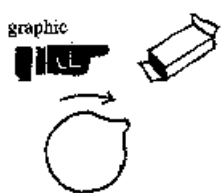

Complete the following steps to load the cartoner and set the program.

Step	Action
1	Check that the cartoning machine has been set up for both bottle and carton size according to batch record instructions.
2	Load the carton magazine with cartons so that the folding direction of the carton is facing the right way and that the cartons are resting firmly on the guides.
3	Check that the flap guide rail is set to the correct size.
4	Load the leaflet magazine, ensuring that the barcode is facing upwards and is at the top right hand corner of the leaflet.
5	<p>Program the:</p> <ul style="list-style-type: none"> • lot/batch number, • expiry and • if required Date of Manufacture (DOM) • volume (mLs).

4.2 Obtain carton samples

Warning: Take care when the machine guard is off and when manually jogging the machine. Ensure all personnel are well clear of the machine before starting. Stop the machine before attempting to reach in for samples.

Complete the following steps to obtain carton samples.

Step	Action
1	Turn the main power on ('1' position)
2	Turn the vacuum pump motor control on ('1' position).
3	Turn the machine control key to manual ('0' position).
4	Turn the manual carton switch clockwise to the open box graphic 
5	Turn the machine guard switch clockwise to the manual position. 
6	<ul style="list-style-type: none"> • Insert the manual jogger into the machine. • Switch the key from automatic to manual (if not already in manual). • Press the green button and then push the handle of the jogger.
7	When the first carton has passed the printing wheel stop the jogger and remove the carton from the machine.
8	<p>Check the:</p> <ul style="list-style-type: none"> • print quality and definition of the characters • placement on the carton • accuracy of the information printed against the MPI. <p>If satisfactory, verify the overprint details on the batch record, If not, turn off the power and reset the printer head.</p>
9	When finished with the jogger, unplug it. Turn the machine guard and manual carton switches anticlockwise and then press the green button.

5.0 Set up and use the carton barcode labeller

If the machine fails for any reason the affected product is automatically rejected.

If this occurs three consecutive times the machine will stop.

ETC...

References

External documents

Insert all external document references referred to within the text (e.g. regulations, vendor manuals etc.)

Document	Title / Clause
PIC/S	Clause XX.XX
CFR	
Eurodex	

Referenced HAPPY PHARMA documents

Insert all HAPPY PHARMA documents referenced within the text. Do not include additional references or use this table as a bibliography.

Document ID	Title

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Change History

The change history page may be removed from hardcopies if required.

Edition	Date	Change Control No.	Brief Description of Change
01	Mar 2017	CCID 987654	First issue.

TMP-XXXX:: Work Instruction Template