

pharmaxis

FM-304-08

Date Effective:
10-May-2023

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LINE CLEARANCE CHECKLIST FOR BLISTER PACKAGING PROCESSES AT PHARMAXIS

Lot Number: M23-045

Issued By/Date: *PS* 01Sep23

Product – Blister Description	Lot Number	Specification Number and Version
<i>Band-foil Blister Strip Australia and Europe.</i>	<i>M23-045</i>	<i>SP-623-08</i>
Line Clearance Checks		✓ each step once complete
All processing instructions, associated forms, checklist etc. are present, issued by QA and correct Lot Number identified on each.		✓
No traces of documentation/materials from previous batch in the area.		✓
No rubbish visible in surrounding area. No tools present from set-up.		✓
No alarms on EMS system (ensure alarm and strobe lighting not initiated).		✓
Room Logbook complete (LB-136).		✓
Equipment is clean and dry (visual inspection only).		✓
Cleaning records (FM-231 and FM-297) complete, removed from machine & attached to PI.		✓
Daily balance check(s) performed and recorded in associated logbook(s).		✓
Materials indicated on bill of materials present only and labelled appropriately (circle as required):	<i>WIP</i> / <i>Approved</i>	✓
All set-up materials are rejected – in clearly labelled reject containers.		✓
Ensure recipe version(s) in use for B1240 and Visio Chrom are in compliance with section 1.1 of the PI.		✓
Sample Blisters: (2 sample blisters – one from each lane):		
- Batch Number and Expiry Date are correct. Record: Batch Number <i>LOT 23045</i> Expiry Date: <i>EXP 04/2026</i>		
VERIFY FORMAT/LAYOUT AGAINST BLISTER SPECIFICATION		
- Pockets are aligned properly at sealing tool-check pockets of blister are not deformed.		✓
- Lid foil is aligned properly with format foil by checking printing on lid foil are in the correct position.		✓
- Confirmed that leak test performed and within specification (passed).		✓
- Retention samples of compliant blisters taken and included with batch record (2 sample blisters – one from each lane).		✓
I declare that the above checks have been completed and are completed to satisfaction.		
LINE CLEARANCE APPROVED BY/DATE: <i>PS</i> 08Sep23		

Authorisation signature and date:

PS 08May23

Reference: SOP-269

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