pharmaxis	FM-361-04	Date Effective: 22-Nov-18	Page 1 of 1

BLISTER RELEASE

Specification Number:	SP-623 - 08	Blister Lot Number:	M23-045
Description:	Bronchitol Blister Strip Australia and Europe.		

Checklist		Initial and Date
Production records have been reviewed and comply with requirements. (PIs, forms and associated records other than LBs)		JW 05 Oct 23
Room/Equipment Logbook reviewed, entries and cleaning comply with requirements.	LB-136 Primary Packaging Room – B1.022 - Logbook	JW 05 Oct 23.
Test results conform to specification		JW 05 Oct 23.
Packaging materials released and within expiry at time of consumption		JW 05 Oct 23
Micro results have been entered in QC APQR Log		JW 05 Oct 23.

		Record details	Initial and Date
Incident reports appropriately resolved (DR/NCPR/OOS/MTIR/CR/CAR/EMS OOL/EBM)		N/A.	JW 05 Oct 23.
Retention sample number		223-208, 209, 210	JW 05 Oct 23
Capsule lots packed	0mg		
	5mg		
	10mg	N/A. J Walsh 05 Oct 23	
	20mg		
	40mg	M23-039.	JW 05 Oct 23.
Expiry date of capsules		23 Oct 23.	JW 05 Oct 23
Date of blister packing		8, 11 and 12-Sep-23	JW 05 Oct 23
Capsules have been released and were within expiry at time of consumption			JW 05 Oct 23
Batch number of blisters		LOT23045	JW 05 Oct 23
Expiry date of blisters		EXP 07/2026	JW 05 Oct 23
No restrictions/conditions for release • All tests required for all markets as per SP performed and comply • No restrictions/conditions arising from incident reports • No restrictions/conditions arising from restrictions/conditions on use of starting, packaging materials or intermediates.		NO restrictions	JW 05 Oct 23

Details of conditional release/Comments

N/A. J Walsh 05 Oct 23

Quantity on paperwork (units)	27880	Quantity entered in Navision (units)	27880.
Document quantity was derived from	PI-122-12 section 13.1.		

Batch meets requirements for (tick box)	Full release	✓	Conditional release	
QA released by (sign and date):	J Walsh 05 Oct 23			
Production record scanned, ELB-091 completed	J Walsh 10 Oct 23			

Authorisation signature and date: 05Nov18 Reference: SOP-295

Not entered on day of action J Walsh 10 Oct 23

PROCESSING INSTRUCTIONS: UHLMANN B1240 BRONCHITOL BLISTER STRIP AU/EU (SP-623)

Issued By/Date	01Sep23	Lot Number:	M23-045

	Name	Position	Signature	Date
Author:	G.Velagala	Production Supervisor	V.G	6 Dec 21
Checked by	Michael Lay	Production Operator		10 Dec 21
Checked by (QA)	A. Dooley	QA Team Leader		10 Dec 21
Authorised by:	S. Duffy	Production Manager		10 Dec 21

1 PRODUCT DESCRIPTION - completed by Production Supervisor/Packaging Leader

1.1		
	Blister Description	Bronchitol Blister Strip Australia and Europe
	Specification Number (incl. version number)	SP-623-09
	Blister Lot Size (approx.)	* ~~40,000~~ 30,000 Blisters
	Sample Plan (dependant on lot size).	Total blisters required (from spec): 155 **Start (qty):** 51 blisters **Middle (qty):** 53 blisters at each of following blister points: * ~~20,000~~ 15,000 **End (qty):** 51 blisters
	Batch Number to be Debossed on Blister	LOT 23045
	Expiry Date to be Debossed on Blister	EXP 07/2026
	B1240 Control System recipe: (include version number)	4 Format 10 - 02
	VisioChrom Control System recipe: (include version number)	VC_Bronchitol 10'S - 09
	Filled Capsules Lot Number	M23-039
	Lid Foil Description & Specification Number	Bronchitol Foil Australia & Europe 20RR (SP-603)
	Clean required for the major equipment after batch (circle appropriate clean) as per SOP-271	(Major) Minor
	COMPLETED BY/DATE: 05-SEP-23	

* The blister lot size is an estimate based on the output of the encapsulation process. The batch size is being changed to 30,000 and multiple samples to 15 per as the output from the B1240 is only 40,000 blisters.

- **ENSURE SAFETY PRECAUTIONS ARE TAKEN AT ALL THE TIMES.**
- **FOLLOW THE STEPS IN ORDER AS SET OUT IN THE PI.**
- **REPORT ANY INCIDENTS TO THE SUPERVISOR IMMEDIATELY.**

PROCESSING INSTRUCTIONS: UHLMANN B1240 BRONCHITOL BLISTER STRIP AU/EU (SP-623)

Issued By/Date [illegible] 01Sep23 | **Lot Number:** M23-045

2 BILL OF MATERIALS

Material Name	Specification Number	Quantity per unit/Batch	Theoretical estimation of qty required	Lot Number	Expiry date
40mg Filled Printed Clear Capsules	SP-501	0.9g /Blister	27,000 g 30,000 +	M23-039	23 OCT 23
Blister Form Foil 160mm	SP-627	3g/Blister	90,000 g Increased *	Tq122-080 N/A N/A	18 OCT 23
Bronchitol Foil Australia and Europe – 20RR	SP-603	0.8 g/Blister	24,000 g Increased *	Tq22-041 N/A N/A	14 MAY 25
COMPLETED BY/DATE: [illegible] 01 Sep 23					

* Lot size had been adjusted - 04 Sept 23

PROCESSING INSTRUCTIONS: UHLMANN B1240 BRONCHITOL BLISTER STRIP AU/EU (SP-623)

Issued By/Date	01Sep23	Lot Number:	M23-045

3 ROOM & PRINCIPAL EQUIPMENT

3.1	• Primary Packaging – 20RR (B1.022) • Uhlmann B1240 Blister Thermoformer (Tag 00407) • Calibrated Balances

4 CLEANING CHECKS

4.1	Is this the first lot to be manufactured after a major clean? ☑YES ☐NO If **Yes**, Check If more than 5 days have elapsed since the equipment was last sanitised, then: • Re-sanitise all product contact surfaces with 70% IPA. • Record re-sanitisation on the Equipment Cleaning Tag (FM-231) & in the primary packaging Log book (LB-136). • Ensure all surfaces are dry. If **No**, this section is not applicable. Sign below when it is confirmed that the equipment is within the sanitisation expiry time. ***COMPLETED BY/DATE:*** 07 Sep 23
4.2	If it is the first lot since a major clean, then attach FM-297 to the processing instructions. Refer SOP-269. ***COMPLETED BY/DATE:*** 07 Sep 23
4.3	Attach FM-231 to the processing instructions. Refer SOP-269. ***COMPLETED BY/DATE:*** 07 Sep 23

5 ROOM CLEARANCE & EQUIPMENT SET-UP

5.1	Log in to the Primary Packaging Room (B1.022) - Logbook (LB-136). ***COMPLETED BY/DATE:*** 07 Sep 23
5.2	Ensure the room is clear of all unnecessary material – refer to SOP-142. Room clearance to be performed as per FM-391 by the second trained person (not involved in completing the above steps). ***COMPLETED BY/DATE:*** 07 Sep 23 ***ROOM CLEARANCE CHECKED BY/DATE:*** 07 Sep 23
5.3	Issue the foil. Check foils specification against Bill of Materials (Section 2). Ensure correct foils are issued and checked by a second trained person. Record foil details (directly from foil label – 1 label per roll of foil) and gross weight on FM-302. ***COMPLETED BY/DATE:*** 07 Sep 23
5.4	Set-up the Uhlmann B1240 Blister Thermoformer (Tag 00407) according to SOP-270. Record set-up on FM-301 (Uhlmann B1240 Format 10 Setup Checklist - 20RR). Whilst set-up is occurring, the process may continue.

6 FILLED CAPSULES

6.1 If the blister packaging lot is a continuation of a campaign using the same filled capsules as the previous lot, then record the previous blister packaging lot details:

Previous Blister Lot Number:	N/A
Previous Blister Description:	N/A

COMPLETED BY/DATE: 07 Sep 23

6.2 Complete the following table:

Capsule Description	40mg Filled Printed Clear Capsules
SP Number	SP-501
Lot Number	M23-039
Expiry Date (ensure capsules are within expiry)	23 OCT 23
Bag Numbers Issued	1 – 10

COMPLETED BY/DATE: 07 Sep 23

6.3 Label the following sterile plastic bags. Refer SOP-037:
Reject Capsules (Label "Reject" & with filled capsule lot details). Record the tare weight on label.
Waste Foil (Label "Reject" with blister lot details).
Filled Blisters to be Stripped (Label "WIP" with blister lot details).

COMPLETED BY/DATE: 08 Sep 23

6.4 **Set-up of Uhlmann Blisterpacker is complete** once the blister integrity test is complete and a 'Pass' result was achieved & recorded.

- Attach the completed Format Setup Checklist (FM-301) to the PI.

COMPLETED BY/DATE: 08SEP 23

PROCESSING INSTRUCTIONS: UHLMANN B1240 BRONCHITOL BLISTER STRIP AU/EU (SP-623)

Issued By/Date	01Sep23	Lot Number:	M23-045

7 RECIPE & MACHINE DETAILS

7.1 Switch on the B1240 as described in SOP-269 & login to the B1240 Control System & VisioChrom Control System.

Record recipes selected and ensure in compliance with Section 1.1

B1240 Control System recipe (incl. version number):	4 FORMAT 10-02
VisioChrom Control System recipe (incl. version number):	VC_Bronchitol 10s_09

Allow sealing plate temperature to increase and settle within range. If it does not settle within range, contact Supervisor/Packaging Leader.

Record the sealing plate temperature & machine speed:

Sealing Plate Temperature:	179 °C	179-181°C
Machine Speed:	40 **Cycles/min**	SET

COMPLETED BY/DATE: 08 Sep 23

8 ROOM CONDITIONS

8.1 Check for EMS alarms. If no alarms are occurring on the EMS regarding the pressure differentials, temperatures and relative humidity in Room B1.022, then it is accepted that all values are within their acceptable ranges for production to occur.
If an alarm is present, do not proceed with the batch until the conditions are restored to within acceptable limits (no alarms) or a Deviation report (FM-016) has been raised and approved.

COMPLETED BY/DATE: 08 Sep 23

9 PREPARATION FOR START UP

9.1
- Re-position the Compensation Pendulum to the running position.
- Place the "Waste Foil" bag under the machine reject outlet.

COMPLETED BY/DATE: 08 Sep ~~26~~ 23 08 Sep 23

9.2 Start the machine and perform batch challenge testing for 'Reject Mechanism" as detailed in SOP-269 and record the results below when performed:

Test	Challenge Test	Expected Results	Lane 1 (Passed=Yes/No)	Lane 2 (Passed=Yes/No)
1	Blister with Empty pockets	Reject	Yes	Yes

Do not proceed if the test does not comply, report minor incident and inform production supervisor immediately. Sign/date below when it is confirmed that test(s) complies.

COMPLETED BY/DATE: 08 Sep 23

9.3	Label each hopper (in pouches provided) with a WIP label showing filled capsule details. Pour the capsules directly from the bag(s) into the hoppers. A small amount of capsules should be poured from the filled capsule bag into a sanitised 'Hand Filling Capsules' container. Label the container with a WIP label referencing 'Hand Filling Capsules' & filled capsule details. Record the addition time/date, balance details, capsule details & bag weights on FM-302 as capsules are introduced into the hoppers. All weights must be checked by a 2nd operator. **Filled Capsule Description** / **Fill Pockets By**: 40mg Filled Printed Clear Capsules / SIMTAP Feeder Hoppers ***COMPLETED BY/DATE:*** [illegible] 08 Sep 23
9.4	Train the Visio Chrom camera as per SOP-269. ***COMPLETED BY/DATE:*** [illegible] 08 Sep 23
9.5	• Set the SIMTAP Feeder switch to position 1 (manual) & fill the Sorting Plate until capsules stop feeding. • Switch the SIMTAP Feeder switch to position 2 (automatic). Ref CM-23-003 [illegible] 08 Sep 23 • Press reset & then start the machine. ***COMPLETED BY/DATE:*** [illegible] 08 Sep 23
9.6	Perform start of the batch challenge testing for Visio Chrom Camera as detailed in SOP-269 and record the results below when performed: Test / Challenge Test / Expected Results / Lane 1 (Passed=Yes/No) / Lane 2 (Passed=Yes/No): 1 / Empty Pocket / Reject / Yes / Yes 2 / Good Capsules in all pockets / Accept / Yes / Yes Do not proceed if the test (s) does not comply record minor incident and inform production supervisor immediately. Sign/date below when it is confirmed that test(s) complies. Place capsules used for camera verification and blisters produced in the corresponding reject bag. ***COMPLETED BY/DATE:*** [illegible] 08 Sep 23
9.7	Run the machine until filled blisters reach the punching station and stop immediately. ***COMPLETED BY/DATE:*** [illegible] 08 Sep 23
9.8	Reset statistical data as detailed in SOP-269. ***COMPLETED BY/DATE:*** [illegible] 08 Sep 23
9.9	Line clearance must be performed as per SOP-142 and recorded on FM-304 (Line Clearance Checklist for Blister Packaging Processes at Pharmaxis). ***LINE CLEARANCE PERFORMED BY/DATE:*** [illegible] 08Sep23

10 BATCH MANAFACTURE

10.1 Commence batch blister packing.
Record training of the camera, in-process checks, leak test sampling, weights of raw / WIP materials & machine adjustments in FM-302. Refer to the table below & SOP-269.

Check-point	Train Camera	In-Process Check	Leak Test (6 blisters – 3 from each lane)	Sealing Plate temperature
Start of Production / Day	Yes	Yes	Yes	Yes
Hourly Check	No	Yes	Yes	No
Lid Foil - end of roll	No	Yes	Yes	No
Lid Foil - start of roll	No	Yes	Yes	No
Form Foil Change	No	Yes	Yes	No
After break	No	Yes	No	No
End of Production / Day	No	Yes	Yes	No
QC samples	As described in section 1. Samples must be taken equally from each lane. Label and handle QC samples as described in SOP-269.			

COMPLETED BY/DATE: JJ 12 Sep 23

10.2 When the requisite number of blisters has been prepared and the amount obtained in secondary is ensured:
Switch the SIMTAP feeder to position zero Ref. CM-23-009-01 JJ 12 Sep 23
Run off the good blisters to secondary until the SIMTAP feeder is empty
Stop the machine as per SOP-269

COMPLETED BY/DATE: JJ 12 Sep 23

11 ACTIONS AT COMPLETION OF LOT BLISTER PACKING

11.1 Start the machine and perform end of the batch challenge test for 'Reject Mechanism" as detailed in SOP-269 and record the results below when performed:

Test	Challenge Test	Expected Results	Lane 1 (Passed=Yes/No)	Lane 2 (Passed=Yes/No)
1	Blister with Empty pockets	Reject	Yes	Yes

Do not proceed if the test does not comply record minor incident and inform production supervisor immediately. Sign/date below when it is confirmed that test(s) complies.

COMPLETED BY/DATE: JJ 12 Sep 23

11.2 Perform end of the batch challenge testing for Visio Chrom Camera as detailed in SOP-269 and record the results below when performed:

Test	Challenge Test	Expected Results	Lane 1 (Passed=Yes/No)	Lane 2 (Passed=Yes/No)
1	Empty Pocket	Reject	Yes	Yes
2	Good Capsules in all pockets	Accept	Yes	Yes

Do not proceed if the test (s) does not comply record minor incident and inform production supervisor immediately. Sign/date below when it is confirmed that test(s) complies.

Place capsules used for camera verification and blisters produced in the corresponding reject bag.

COMPLETED BY/DATE: JJ 12 Sep 23

11.3 Place all remaining capsules in the SIMTAP Distributor Plate, capsules remaining in the 'Hand Filling' container and blisters produced from end of batch challenge testing in the corresponding "Reject" labelled bag, if applicable.

COMPLETED BY/DATE: JJ 12 Sep 23

11.4 Save the lot Statistical Data to a removable storage device.
The '.pdf' file should have the following format: LOT NUMBER – DATE.
Log out of the B1240 and VisioChrom control system – refer to SOP-269.

COMPLETED BY/DATE: JJ 12 Sep 23

11.5 Remove unused lid foil & form foil from the machine. Unused foil is to be weighed & checked by trained operators. Record tare weights on FM-302.
Return unused foil to the Warehouse.

COMPLETED BY/DATE: JJ 12 Sep 23

11.6 At the end of the batch, unused capsules (if any) remaining in the hoppers may be recovered. Label each recovered capsule bag with a WIP label, weigh empty and record tare weight & the description on WIP label as "Recovered 40mg Filled Printed Clear Capsules – 20RR".
Weigh the recovered (i.e. Unused) capsule bag and record the Gross Weight below. Calculate the Net Weight.
Weights and calculations must be checked by a 2nd Operator. JJ 12 Sep 23
Balance Used (Tag): _____

Description	Gross Weight	Tare Weight	Net Weight
Recovered Unused Capsules	g	g	g

COMPLETED BY/DATE: _____

CHECKED BY/DATE: _____

11.7	Strip the capsules from the "Filled Blisters to be Stripped" blisters and place in the 'Reject Capsules' bag. ***COMPLETED BY/DATE:*** 12 SEP 23
11.8	Weigh the Reject Capsule bag. All weights must be checked by a 2nd Operator. **Balance Used (Tag):** 0011

Description	Gross Weight	Tare Weight	Net Weight
Reject Capsules	2304.7 g	42.3 g	2262.4 g

COMPLETED BY/DATE: 13 Sep 23
CHECKED BY/DATE: 13 Sep 23

11.9	Enter consumption of materials into all associated inventory forms. Tick (✓) when the values for each material type have been entered.

Capsules	✓
Lid Foil	✓
Blister Form Foil	✓

Also ensure the correct values have been entered on all forms.

COMPLETED BY/DATE: 13 SEP 23
CHECKED BY/DATE: 13 Sep 23

12 MACHINE SHUTDOWN & CLEANING

12.1	Logout of the VisioChrom and Blister Thermoformer HMIs as described in SOP-269. Turn off main switch at the rear of the machine. The air supply automatically cuts off. Perform cleaning described in Sect 1.1 of PI. Type of cleaning performed: Major **<u>Note</u>: Ensure that a major clean is done for the used format parts if the batch is the final lot of the campaign. Otherwise minor clean is to be completed. Contact Production Supervisor to confirm, as required.** ***COMPLETED BY/DATE:*** 14 Sep 23

13 CONSUMPTION & RECONCILIATION

13.1 Calculate the total consumption of the following materials from FM-302.

Material	Spec. Number	Lot Number(s)	Total Quantity Used per Lot
40mg Filled Printed Clear Capsules	SP-501	M23-036	Total issued on FM-302 – Recovered Capsules 27493.1 g
Blister Form Foil 160mm (Record different lot numbers separately)	SP-627	Ign22-08	77753.2 g
		N/A	N/A g
		N/A	N/A g
Bronchitol Foil Australia and Europe – 20RR (Record different lot numbers separately)	SP-603	Ign22-041	23206.5 g
		N/A	N/A g
		N/A	N/A g

COMPLETED BY/DATE: 13 Sep 23

CHECKED BY/DATE: 13 Sep 23

13.2 Print a copy of the Statistical data file.
Write Lot number and sign/date the printout. Attach to PI.

COMPLETED BY/DATE: 13 Sep 23

13.3 At the end of each lot, complete the capsule reconciliation for the capsules used on MES-034. If reconciliation limit is exceeded, initiate a Deviation Report (as per SOP-030). Also record output (Blisters Transferred to Secondary Packaging).

Output:	Quantity Blisters (EA) 27886

COMPLETED BY/DATE: 13 Sep 23

14 MINOR INCIDENT REPORT

Record any observation made during the batch manufacture – refer to SOP-142 for minor incident definition, identification and subsequent action. Alert the Production Supervisor immediately. **Action!**

Date/Time	Operator Initials	Incident/Observation – brief description/actions	Supervisor Evaluation - root cause, product impact, immediate action	Product Quality Impact – If N - provide brief justification If Y - reference deviation report.	Supervisor Approval – Sign/Date
08 Sep 23	[illegible]	Start of the Batch still the same issued of the VC-Camera ring at my packet the Lane one and same with I machine error to produce unit meras	Both issues are known to production and engineering the current reject rate is same as previous runs which is acceptable for the current run.	No Quality impact on Final Product only performance issue and production will all defects will be detected and reject during the run	13SEP23
N/A	N/A	reject rate Engr, Manager was informed.	N/A	N/A	N/A
				N/A 13 Sep 23	

PROCESSING INSTRUCTIONS: UHLMANN B1240 BRONCHITOL BLISTER STRIP AU/EU (SP-623)

Issued By/Date	01Sep23	Lot Number:	M23-045

15 NAVISION & TRENDING UPDATE

15.1	Perform Navision Production Journal transactions as per SOP-165 and enter Trending as per SOP-241 ***COMPLETED BY/DATE:*** 14 Sep 23

16 BATCH REVIEW

16.1	Verify Navision Production Journal transactions as per SOP-165. ***COMPLETED BY/DATE:*** 15SEP23
16.2	Ensure production journal is posted & trending is completed accurately. ***COMPLETED BY/DATE:*** 19 Sep 23
16.3	Record any Associated Deviation, CR or CAR – to be completed by Production staff **Reports** N/A ***COMPLETED BY/DATE:*** 22SEP23
16.4	The Process Instructions & the associated documents have been reviewed as detailed in SOP-291 ***COMPLETED BY/DATE:*** 22SEP23

17 APPROVAL BY PRODUCTION MANAGER/PRODUCTION SUPERVISOR

These Processing Instructions & associated documents have been reviewed & the lot produced in compliance with GMP.

Print Name: [illegible] ***Sign/Date:*** 05 Oct 23

18 ASSOCIATED DOCUMENTS AND QA REVIEW

Include details of any associated documents

Associated Document	Document Number	Initial/Date
EMS OOL	N/A	05 Oct 23
CAR Number(s)	N/A	05 Oct 23
DR Number(s)	N/A	05 Oct 23
NCPR Number(s)	N/A	05 Oct 23
CR Number(s)	N/A	05 Oct 23
OOS Number(s)	N/A	05 Oct 23

BATCH DOCUMENT QA REVIEWED BY

Print Name: [illegible] ***Sign/Date:*** 05 Oct 23

PROCESS CONTROL RECORD FOR BLISTER-PACKING PROCESS AT PHARMAXIS

Issued By/Date: [illegible] 08Sep23 **Lot Number:** M23-045

PRINT ON A3 CLEANROOM PAPER ONLY

CONTROL RECORD TO BE COMPLETED REGULARLY – REFER TO PROCESS DETAILS BELOW

PROCESS DETAILS
1. Lid Foil Change (End of Roll)
2. Lid Foil Change (Start of Roll)
3. Adjustment-Raise Minor Incident Report
4. Start – start of day/ production
5. End – end of day/production
6. In-process check – hourly check (and leak test)
7. Before/after break
8. Form Foil Change (start of roll)

Date	Time	Process Record – choose code from above & enter detailed description for any adjustments.	Sealing Plate temp. (°C) (at start of each day only)	TRAIN CAMERA? (Y/N) (at start of production or when the camera has been powered off)	LEAK TEST SAMPLE DETAILS: Leak Test? (Y/N)	Blister qty. for leak test (6blisters)	Blister Sample # (A, B, C...)	IN-PROCESS CHECKS ONLY *Place 'Y/N' in appropriate box after checking – if not satisfactory (i.e. Y), stop process immediately, contact Production Supervisor and raise Minor Incident Report.*: Blister– Any visual defects (Y/N)	Foil is aligned, Any visual defects (Y/N)	Embossing is correct and clear? (Y/N)	NUMBER OF BLISTER – FROM COUNTER: Good Blisters	Rejects	QC SAMPLES: Qty. of blisters	Initials	LEAK TEST RESULT – *(to be completed by Production after test complete)*: Pass (P) /Fail (F)	Initials
08 Sep 23	12:20	4, QC sample	179	Y	Y	6	A	N	N	Y	64	116	52	~~SS~~	P	~~SS~~
08 Sep 23	13:20	6	N/A	N	Y	6	B	N	N	Y	3284	556	N/A	~~SS~~	P	~~SS~~
08 Sep 23	13:35	5	N/A	N	Y	6	C	N	N	Y	4104	636	N/A	~~SS~~	P	~~SS~~
11 Sep 23	06:46	4	179	N	Y	6	D	N	N	Y	4116	994	N/A	~~SS~~	P	~~SS~~
11 Sep 23	07:45	6	N/A	N	Y	6	E	N	N	Y	7538	1374	N/A	~~SS~~	P	~~SS~~
11 Sep 23	09:15	7, 6, 8	N/A	N	Y	6	F	N	N	Y	10452	1720	N/A	~~SS~~	P	~~SS~~
11 Sep 23	10:08	1	N/A	N	Y	6	G	N	N	Y	14108	2636 *11Sep23	N/A	~~SS~~	P	~~SS~~
11 Sep 23	10:19	2, 6	N/A	N	Y	6	H	N	N	Y	14124	2248	N/A	~~SS~~	P	~~SS~~
11 Sep 23	10:56	Mod Pro QC sample	N/A	N	N	N/A	N/A	N	N	Y	15012	2362	54	~~SS~~	N/A	~~SS~~
11 Sep 23	11:20	6	N/A	N	Y	6	I	N	N	Y	18285	2560	N/A	~~SS~~	P	~~SS~~
11 Sep 23	12:10	7	N/A	N	Y	6	J	N	N	Y	18678	2576	N/A	~~SS~~	P	~~SS~~
11 Sep 23	13:01	8	N/A	N	Y	6	K	N	N	Y	21402	3026	N/A	~~SS~~	P	~~SS~~
11 Sep 23	13:10	6	N/A	N	Y	6	L	N	N	Y	22122	3048	N/A	~~SS~~	P	~~SS~~
11 Sep 23	13:46	5	N/A	N	Y	6	M	N	N	Y	24480	3198	N/A	~~SS~~	P	~~SS~~
12 Sep 23	06:40	4	179	N	Y	6	N	N	N	Y	24492	3398	N/A	~~SS~~	P	~~SS~~
12 Sep 23	07:40	6	N/A	N	Y	6	O	N	N	Y	27936	3968	N/A	~~SS~~	P	~~SS~~
12 Sep 23	07~~08~~:53 *08:12 Sep 23*	5	N/A	N	Y	6	P	N	N	Y	28114 ©	© ~~4066~~ 4124	52	~~SS~~	P	~~SS~~
							N/A	~~SS~~ 13 Sep 23								

© 2x SS 12 Sep 23

PROCESS CONTROL RECORD FOR BLISTER-PACKING PROCESS AT PHARMAXIS

Issued By/Date: [illegible] 01Sep23 **Lot Number:** M23-045

PROCESS DETAILS 1. Lid Foil Change (End of Roll) 2. Lid Foil Change (Start of Roll) 3. Adjustment-Raise Minor Incident Report 4. Start – start of day/ production 5. End – end of day/production 6. In-process check – hourly check (and leak test) 7. Before/after break 8. Form Foil Change (start of roll)			Sealing Plate temp. (°C) (at start of each day only)	TRAIN CAMERA? (Y/N) (at start of production or when the camera has been powered off)	LEAK TEST SAMPLE DETAILS			IN-PROCESS CHECKS ONLY *Place 'Y/N' in appropriate box after checking – if not satisfactory (i.e. Y), stop process immediately, contact Production Supervisor and raise Minor Incident Report.*			NUMBER OF BLISTER – FROM COUNTER		QC SAMPLES	Initials	LEAK TEST RESULT – *(to be completed by Production after test complete)*	
Date	Time	Process Record – choose code from above & enter detailed description for any adjustments.			Leak Test? (Y/N)	Blister qty. for leak test (6blisters)	Blister Sample # (A, B, C...)	Blister– Any visual defects (Y/N)	Foil is aligned, Any visual defects (Y/N)	Embossing is correct and clear? (Y/N)	Good Blisters	Rejects	Qty. of blisters		Pass (P) /Fail (F)	Initials
									N/A	gg 13 Sep 23						

PROCESS CONTROL RECORD FOR BLISTER-PACKING PROCESS AT PHARMAXIS

Issued By/Date: JY 01Sep23 | **Lot Number:** M23-045

PROCESS DETAILS 1. Lid Foil Change (End of Roll) 2. Lid Foil Change (Start of Roll) 3. Adjustment-Raise Minor Incident Report 4. Start – start of day/ production 5. End – end of day/production 6. In-process check – hourly check (and leak test) 7. Before/after break 8. Form Foil Change (start of roll)			Sealing Plate temp. (°C) (at start of each day only)	TRAIN CAMERA? (Y/N) (at start of production or when the camera has been powered off)	LEAK TEST SAMPLE DETAILS			IN-PROCESS CHECKS ONLY *Place 'Y/N' in appropriate box after checking – if not satisfactory (i.e. Y), stop process immediately, contact Production Supervisor and raise Minor Incident Report.*			NUMBER OF BLISTER – FROM COUNTER		QC SAMPLES	Initials	LEAK TEST RESULT – *(to be completed by Production after test complete)*	
Date	Time	Process Record – choose code from above & enter detailed description for any adjustments.			Leak Test? (Y/N)	Blister qty. for leak test (6blisters)	Blister Sample # (A, B, C...)	Blister– Any visual defects (Y/N)	Foil is aligned, Any visual defects (Y/N)	Embossing is correct and clear? (Y/N)	Good Blisters	Rejects	Qty. of blisters		Pass (P) /Fail (F)	Initials
					N/A	10	13 Sep 23									

PROCESS CONTROL RECORD FOR BLISTER-PACKING PROCESS AT PHARMAXIS

Issued By/Date: [illegible] 01Sep23 **Lot Number:** M23-045

CAPSULE - record capsule lot number and weights used in table below.

Balance Tag #: 00011 **Completed by/date** [illegible] 08 Sep 23

Capsule Type (mg): 40mg ; **Capsule Lot No.** M23-039 ; **Expiry Date:** 23 OCT 23

Date	Bag No.	Gross Weight (g)	Tare Weight (g)	Net Weight (g)	Completed by (Initials)	Checked by (Initials)	Date/Time (immediately prior to addition to hopper)
08Sep23	1	3405.1	56.2	3348.9	[illegible]	[illegible]	08Sep23 10:33
08Sep23	2	3407.3	56.4	3350.9	[illegible]	[illegible]	08Sep23 13:11
08Sep23	3	2504.7	56.4	2448.3	[illegible]	[illegible]	11Sep23 07:16
08Sep23	4	1347.9	56.5	1291.4	[illegible]	[illegible]	11Sep23 07:17
08Sep23	5	3399.4	56.3	3343.1	[illegible]	[illegible]	11Sep23 08:06
08Sep23	6	3210.0	56.0	3154.0	[illegible]	[illegible]	11Sep23 09:38
08Sep23	7	2410.7	56.1	3354.6	[illegible]	[illegible]	11Sep23 10:32
08Sep23	8	3401.7	56.1	3345.6	[illegible]	[illegible]	11Sep23 11:17

Capsule Type (mg): _____ ; **Capsule Lot No.** _____ ; **Expiry Date:** _____

Date	Bag No.	Gross Weight (g)	Tare Weight (g)	Net Weight(g)	Completed by (Initials)	Checked by (Initials)	Date/Time (immediately prior to addition to hopper)
					N/A [illegible]	13 Sep 23	
					N/A [illegible]		

Capsule Type (mg): 40mg ; **Capsule Lot No.** M23-037 ; **Expiry Date:** 23OCT23

Date	Bag No.	Gross Weight (g)	Tare Weight (g)	Net Weight (g)	Completed by (Initials)	Checked by (Initials)	Date/Time (immediately prior to addition to hopper)
11Sep23	9	2439.0	56.0	2383.0	[illegible]	[illegible]	11Sep23 13:31
11Sep23	10	1128.6	55.3	1073.3	[illegible]	[illegible]	11Sep23 13:33
				N/A	[illegible] 13	Sep 23	

Capsule Type (mg): _____ ; **Capsule Lot No.** _____ ; **Expiry Date:** _____

Date	Bag No.	Gross Weight (g)	Tare Weight (g)	Net Weight(g)	Completed by (Initials)	Checked by (Initials)	Date/Time (immediately prior to addition to hopper)

Authorisation signature and date: [illegible] 16Mar 23 Reference: SOP-269

PROCESS CONTROL RECORD FOR BLISTER-PACKING PROCESS AT PHARMAXIS

Issued By/Date: 01Sep23 | Lot Number: M23-045

LID FOIL - record details and weights used in table below.

Balance Tag #:	00011	Completed by/date	07 Sep 23

Date	Lot No.	Artwork Number/ Version	Expiry Date	Container No. __ of __ (foil)	Gross Weight (g)	Completed by (Initials)	Checked by (Initials)	Date/Time (Immediately prior to load onto the machine)	Tare Weight (g)	Net Weight (g)	Completed by (Initials)	Checked by (Initials)
07Sep23	IGn22-041	SP603/02	19 MAY 25	10 OF 13	12410.			07 Sep 23 10:53	178.2	12231.8		
07Sep23	IGn22-041	SP603/02	19 MAY 25	4 OF 13	13285.			11 Sep 23 10:07	2310.3	10974.7		
N/A 13 Sep 23												
									Total (g)	23206.5		

PROCESS CONTROL RECORD FOR BLISTER-PACKING PROCESS AT PHARMAXIS

Issued By/Date: JV 01Sep23 | **Lot Number:** M23-045

FORM FOIL - record details and weights used in table below.

Balance Tag #: C0011 | **Completed by/date** gg 07 Sep 23

Date	Lot No.	Artwork Number/ Version	Expiry Date	Container No. __ of __ (foil)	Gross Weight (g)	Completed by (Initials)	Checked by (Initials)	Date/Time (Immediately prior to load onto the machine)	Tare Weight (g)	Net Weight (g)	Completed by (Initials)	Checked by (Initials)
07 Sep 23	Ign22-080	N/A	08 OCT 23	~~4~~ 12 OF 28 gg 07 Sep 23	4536.1	gg	[signature]	07 Sep 23 10:56	516.0	4020.1	gg	[signature]
07 Sep 23	Ign22-080	N/A	08 OCT 23	4 OF 28	28407.	gg	[signature]	08 Sep 23 10:24	516.0	27891.	gg	[signature]
08 Sep 23	Ign22-080	N/A	08 OCT 23	15 OF 28	28258.	gg	[signature]	11 Sep 23 09:03	515.9	27742.1	gg	[signature]
11 Sep 23	Ign22-080	N/A	08 OCT 23	1 OF 28	28471.	gg	[signature]	11 Sep 23 12:51	10371.	18100.	gg	[signature]

N/A gg 13 Sep 23

Total (g) 77753.2

MES-034-05
Reconciliation of Filled Capsules After Blisterpacking on the Uhlmann B1240

Modified 10-Jul-15
Excel 2016
Reference: SOP-269

Capsule Lot Number: M23-039
Capsule Description: 40mg Filled printed Clear Capsuls
Capsule Specification Number: SP-501
Average Gross Capsule Weight (g): 0.08815 (from Encapsulation MES-031)

Blister Lot Number: M23-045
Number of Capsules per Blister: 10 (from PI)
Weight of Capsules Issued (g): 27,093.1 (from FM-302)

	Blisters (Count)	Capsule Weight (g)	
Capsules Issued:		**27,093.1**	
Reject Capsules:		2,262.4	(from PI)
Recovered Capsules:		0.0	(from PI)
Leak Test Sample Blisters:	96	84.6	(only leak test sample blisters which contain capsules, from FM-302)
QA Sample Blisters:	158	139.3	(from FM-302)
Good Blisters:	28,134	24,800.1	(from Uhlmann .pdf)
Total Capsules Accounted for:		**27,062.5**	

Blister Lot Number: Fill-in
Number of Capsules per Blister: Fill-in (from PI)
Weight of Capsules Issued (g): Fill-in (from FM-302)

	Blisters (Count)	Capsule Weight (g)	
Capsules Issued:		**0.0**	
Reject Capsules:		Fill-in	(from PI)
Recovered Capsules:		Fill-in	(from PI)
Leak Test Sample Blisters:	Fill-in	0.0	(only leak test sample blisters which contain capsules, from FM-302)
QA Sample Blisters:	Fill-in	0.0	(from FM-302)
Good Blisters:	Fill-in	0.0	(from Uhlmann .pdf)
Total Capsules Accounted for:		**0.0**	

Blister Lot Number: Fill-in
Number of Capsules per Blister: Fill-in (from PI)
Weight of Capsules Issued (g): Fill-in (from FM-302)

	Blisters (Count)	Capsule Weight (g)	
Capsules Issued:		**0.0**	
Reject Capsules:		Fill-in	(from PI)
Recovered Capsules:		Fill-in	(from PI)
Leak Test Sample Blisters:	Fill-in	0.0	(only leak test sample blisters which contain capsules, from FM-302)
QA Sample Blisters:	Fill-in	0.0	(from FM-302)
Good Blisters:	Fill-in	0.0	(from Uhlmann .pdf)
Total Capsules Accounted for:		**0.0**	

Blister Lot Number: Fill-in
Number of Capsules per Blister: Fill-in (from PI)
Weight of Capsules Issued (g): Fill-in (from FM-302)

	Blisters (Count)	Capsule Weight (g)	
Capsules Issued:		**0.0**	
Reject Capsules:		Fill-in	(from PI)
Recovered Capsules:		Fill-in	(from PI)
Leak Test Sample Blisters:	Fill-in	0.0	(only leak test sample blisters which contain capsules, from FM-302)
QA Sample Blisters:	Fill-in	0.0	(from FM-302)
Good Blisters:	Fill-in	0.0	(from Uhlmann .pdf)
Total Capsules Accounted for:		**0.0**	

RECONCILIATION OF CAPSULES - UHLMANN

Total Weight of Capsules Issued (g):	27,093.1	
Total Weight of Capsules Accounted for (g):	27,062.5	
% Reconcilliation:	**99.9**	(Limits: 98.0-102.0%)
Result:	**Pass**	(Pass / Fail)

BLISTERS TO SECONDARY PACKAGING ROOM

Blister Lot Number:	**M23-045**	N/A	N/A	N/A
Blisters Transferred to Secondary Packaging Room:	**27,880**	N/A	N/A	N/A

Completed by/date: 13 Sep 23

Checked by/date: 13 Sep 23

Refer to any DR/CAR/CR/NCPR etc.

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ROOM CLEARANCE CHECKLIST

Lot Number: M23-045	Issued By/Date: [signature] 01Sep23

ROOM CLEARANCE CHECKS	✓ each step once complete
Correct area, is in use (as specified in the process instructions).	✓
The outer door of the room is status labelled.	✓
All the documentation, products and materials from the previous production operation have been removed from the room.	✓
Ensure the following: • Equipment is appropriate to use - cleaning completed as required. Yes☑ No ☐ • Equipment is clean & dry (visible inspection only). Yes☑ No ☐ • Sanitisation is within the time frame as specified in the PI. Yes☐ N/A ☑	✓
Cleaning tags are attached to the PI and ensure that the major clean has been approved (if applicable).	✓
All the steps up to the room clearance section are completed in the corresponding PI.	✓
All the logbooks involved are checked for completeness (e.g., Login, batch details, minor clean/daily clean performed).	✓
The Balances involved are calibrated and the daily check(s) performed.	✓
No alarms on EMS system (ensure alarm and strobe lighting not initiated).	✓
Only the Bill of Materials listed in the PI are present in the room and are within expiry date.	✓
Ensure that the details recorded in PI for the bill of materials are accurate.	✓
Comments: B1-022	
If any of the checks above does not comply, do not proceed with Room Clearance. ***ROOM CLEARANCE COMPLETED BY/DATE:*** [signature] 01 Sep 23	

Sign & Date in the PI & in the corresponding logbook upon successful completion of the Room Clearance.

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LINE CLEARANCE CHECKLIST FOR BLISTER PACKAGING PROCESSES AT PHARMAXIS

Lot Number: M23-045 | **Issued By/Date:** 01Sep23

Product – Blister Description	Lot Number	Specification Number and Version
Brandlitol Blister Strip Australia and Europe	M23-045	SP-625-08

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): *WIP* / *Approved*	✓
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** LOT 23045 **Expiry Date:** EXP 04/2026 **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: 08Sep23

Authorisation signature and date: 08May 23	Reference: SOP-269

UHLMANN B1240 FORMAT 10 SETUP CHECKLIST

Issued By / Date (QA):	01Sep23	Lot Number:	M23-645

PRODUCT DESCRIPTION – to be completed by Production Supervisor/Packaging Leader

Blister Description:	Bronchitol Blister Strip Australia and Europe		
Blister Specification Number:	SP-623-08		
Batch Number to be Embossed on Blister:	LOT 23045		
Expiry Date to be Embossed on Blister: (N/A if no expiry on blister)	EXP 07/2026		
VisioChrom Recipe to be used (circle):	VC_Bronchitol 10s	VC_RedOpaque 10s	VC_Demo 10s
Lid Foil Description:	Bronchitol Foil Australia and Europe 2022		
Lid Foil Specification Number:	SP-603		
COMPLETED BY/DATE: *Prod. Supervisor/Pack. Leader*	05 SEP 23		

	Task Description	Completed(✓)
1.	Trained **Operators** must issue and weigh lid & form foils (gross weights only required) & record the balance tag- as detailed in SOP-269.	✓
2.	Login to B1240 control system.	✓
3.	Set B1240 to "Format Change-Over" mode.	✓
4.	Load 'Format 10' format recipe into B1240 control system. Record the Version No. and confirm it to be the same as PI Sect 1.1; **Version Number loaded:** 02	✓
5.	Check condition of following tooling and install.	

Part Name	Part Number	Completed(✓)
Forming Tool	59/1646-1A	✓
Sealing Tool	59/1646-1A02	✓
Presealing Plate	Pharmaxis drg no 097-030 rev2	✓
Punching Tool	59/1646-1A	✓
Punching Tool Guide	59/1646-1A	✓
SIMTAP Feed Tubes	1A (40 off)	✓
SIMTAP Sorting Plate	59/1646-1A	✓
SIMTAP Feed Manifold	59/1646-1A	✓
Lid Foil Rollers	(Various)	✓
Lid Foil Stretching Station	(Various)	✓
Form Foil Bush	N/A	✓

6.	Ensure vibrating cylinders are mounted approximately 20° from vertical.	✓
7.	Set SIMTAP switch to '1'.	✓
8.	Wipe lid foil rollers with a sterile wipe dampened with 70% IPA.	✓
9.	Thoroughly wipe foil stretching station clamping tape with a sterile wipe dampened with 70% IPA to remove burrs and/or build-up.	✓

UHLMANN B1240 FORMAT 10 SETUP CHECKLIST

Issued By / Date (QA): [illegible] 01Sep23 | Lot Number: M23-045

	Task Description	Completed (✓)
10.	Set positions of equipment to the following settings.	

Equipment	Machine Setting	Actual Setting
Form Foil Reel Stop	65 mm	65 mm
Lid Foil Reel Stop	67 mm	67 mm
Reversing Station	145 mm	145mm
Compensation Pendulum	10 mm (adjustable)	10 mm
Print Registration	33 mm	33mm
Registration Sensor Traverse	29 mm	29 mm
Lid Foil Splice Sensor	107 mm (adjustable)	107 mm
Punching Tool	926.5 mm (adjustable)	926.5mm
Camera Position	40 mm (adjustable)	40 mm
SIMTAP Sorting Plate Stroke Speed	480	480
SIMTAP Base Position	18.3 cm	18.3 cm
SIMTAP Traverse Position	54.5 mm	54.5 mm
SIMTAP Longitudinal Position	40.0±3.0 mm	40.0mm
SIMTAP Hopper Outlet	15 mm	15 mm
SIMTAP Level Sensor	50 mm (left and right)	52 mm left / 52 mm right
SIMTAP Sorting Plate Vibration Pressure	2.4 bar (machine stationary)	2.4 bar
SIMTAP Filling Tube Vibration Pressure	3.2 bar (machine stationary)	3.2 bar

Shaded cells indicate critical parameters.

11.	Set embossing type, lot number & expiry date **VERIFY FORMAT/LAYOUT AGAINST BLISTER SPECIFICATION**	✓
12.	Feed form foil and lid foil.	✓
13.	Set B1240 to "Test Run" mode.	✓
14.	Install SIMTAP feed manifold.	✓
15.	Start B1240 and check sealing station aligned with blister pockets. Adjust form foil position and compensation pendulum as necessary. Check depth of seal knurling. Adjust if required – refer SOP-270	✓
16.	Position guide before pinhole detector.	✓
17.	Login to VisioChrom control system. Load VisoChrom Camera control system recipe as per the product description. Record the Recipe Name & Version No loaded and confirm it to be the same as PI Sect 1.1: **VisioChrom Control System Recipe:** VC_Brenwintol_10's **Version Number:** 09	✓
18.	Check alignment of seal and pockets by inspecting blisters. Adjust alignment by releasing indexing clamps after sealing station.	✓

UHLMANN B1240 FORMAT 10 SETUP CHECKLIST

Issued By / Date (QA):	08Sep23	Lot Number:	M23-045

	Task Description	Completed (✓)
19.	Run machine & check lid foil print registration mark at the blister seam. If the registration mark is immediately left & to the side of the seam, the machine will automatically align. Otherwise see SOP-269 for foil adjustment.	✓
20.	Ensure that control block 2/3 pneumatic regulator is set to 4 bar.	✓
21.	Check VisioChrom camera image is aligned with pockets and adjust camera position as necessary.	✓
22.	Check chiller water level is good, pump operating and controlling to setpoint temperature.	✓
23.	Set B1240 to "Production" mode to activate the detection system.	✓
24.	Run B1240 for approximately 100 cycles and check blisters for: • No visual defects • Sealing aligned to pockets • Embossing is correct and clear • Lid foil printing aligned • Sufficient sealing border around perimeter	✓
25.	Sample preliminary leak test blisters as detailed in SOP-270. Manually sample 6 blisters (3 from each lane) & stop the machine. Send blister samples to QC for seal integrity testing.	✓
26.	Remove two blisters for retention. Label as R1 and R2 appropriately (where 1 and 2 correspond to lane 1 and 2).	✓
27.	Perform pinhole challenge test as per SOP-270.	✓
28.	Raise compensation pendulum (to prevent foil slippage on loss of compressed air).	✓
29.	Logout of B1240 control system and VisioChrom camera if not starting batch immediately after setup.	✓ / NA
30.	Additional Comments: N/A	
31.	Assembly and set-up completed according to SOP-270 by: **Print Name:** German G. **Sign/Date:** 99 07 Sep 23	
32.	**Blister Seal Integrity Testing** Integrity of sealing tested as per TM-046. If blisters fail leak test, refer to SOP-270 to rectify leak. Repeat preliminary leak test sampling. Once a 'PASS' result is achieved, continue batch processing as per PI. **Print Name:** German G. **Sign/Date:** 99 08 Sep 23 Operator/Maintenance Engineer	

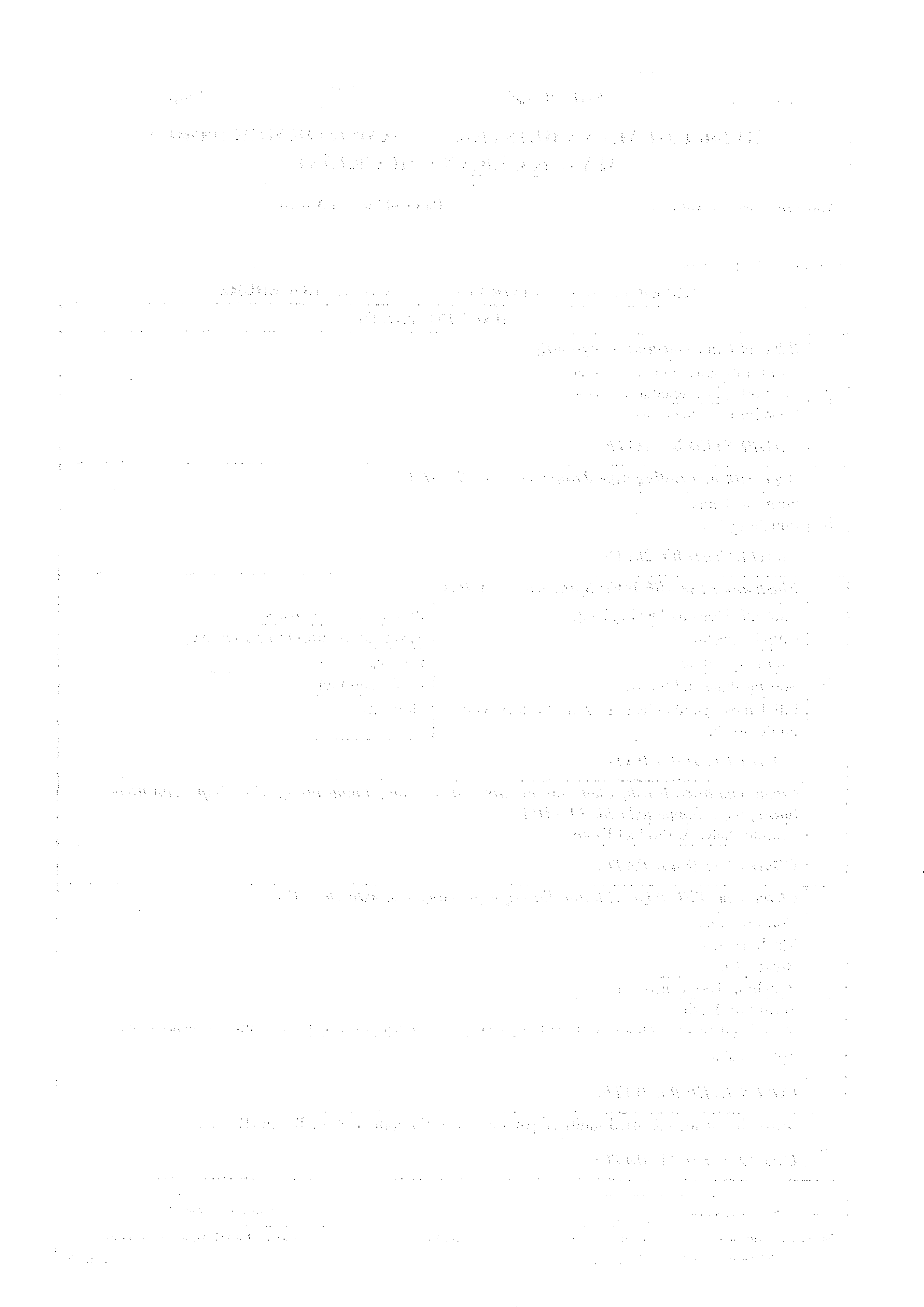
B1240 UHLMANN BLISTER THERMOFORMER (00407) MAJOR CLEAN CHECKLIST

Machine Cleaned After Lot: M23-024 **Batch of 70% IPA used:** IPA-0496

Completed By / Date: JJ 06 Sep 23

REFER TO SOP-271 FOR FULL CLEANING PROCEDURE

	MACHINE PARTS	
1.	***Wipe with dry non-linting wipe only***	
	Form film splice detection sensor	
	Lid Foil splice detection sensor	
	VisioChrom camera lens	
	COMPLETED BY/ DATE: JJ 06 Sep 23	
2.	***Wipe with non-linting wipe dampened with 70% IPA***	
	Forming Tools	
	Punching Tool	
	COMPLETED BY/ DATE: JJ 06 Sep 23	
3.	***Flush and rinse with WFI; Spray with 70% IPA***	
	Shut-Off Housing Dosing Rings	Product Chute Covers
	Chip Collectors	SIMTAP Manifold (disassemble)
	Vibratory Chute	Feeding Hoses
	Sorting Plate and Frame	Perforated Plates
	Fill Tubes - gently clean internal surfaces with bottle brush.	Hoppers
	COMPLETED BY/ DATE: JJ 06 Sep 23	
4.	***Clean with brass brush; Clear out the film residue using a non-linting wipe; Wipe with non-linting wipe dampened with 70% IPA***	
	Sealing Plates & Product Haloes	
	COMPLETED BY/ DATE: JJ 06 Sep 23	
5.	***Clean with WFI/ Wipe with non-linting wipe dampened with 70% IPA***	
	Control Panel	
	Machine Base	
	Blister Slide	
	Punching Tool Conveyor	
	Form Foil Bush (Note: Check for any wear/tear on the bush, any issues should be notified to production supervisor immediately.)	
	Splice Table	
	COMPLETED BY/ DATE: JJ 06 Sep 23	
6.	Move the cleaned & dried sanitised parts to Clean Equipment Store Room (B1.026).	
	COMPLETED BY/ DATE: JJ 06 Sep 23 JJ 06 Sep 23	



B1240 UHLMANN BLISTER THERMOFORMER (00407) MAJOR CLEAN CHECKLIST

	EQUIPMENT INSPECTION & APPROVAL
7.	**A second person (trained in TD-038: Responsibility of a Checker) must inspect and approve (if satisfactory) the cleaning of B1240 Blister machine (tag no. 00407) and all the parts.** **The Checker is to inspect / check the following:**
	The equipment is visually clean, dry and fit for use.
	Equipment parts are visually clean and dry.
	Thoroughly check equipment for visual signs of any foreign particles (i.e. dust, rust on any part, etc.) or any visible equipment or gasket damage.
	External surfaces of the equipment are clean and dry.
	Area surrounding the equipment is clean, dry and free of rubbish.
	Ensure that cleaning tags are attached to the major equipment and its cleaned detachable parts as per SOP-191.
	Sign below only if the checker is fully satisfied that the equipment is clean and fit for use. Report any non-conformities to the Production Supervisor: **Checked By/ Date:** 06 Sep 23

CLEANING TAG/EQUIPMENT STATUS

EQUIPMENT

Equipment Name	Conveyor Belt
Equipment Tag Number	00910

Cleaning Status:

Type of clean	Completed By	Date
Minor Clean	[illegible]	07 Sep 23
Minor Clean Awaiting Major Clean		
Major Clean		N/A [illegible] 07 Sep 23
Major Clean Approved		[illegible]
Resanitisation? (Include sign and date)		

CLEANING TAG/EQUIPMENT STATUS

EQUIPMENT

Equipment Name	UHLMANN BIZHD (Bronchitol 10's)
Equipment Tag Number	CC407

Cleaning Status:

Type of clean	Completed By	Date
Minor Clean	N/A	N/A
Minor Clean Awaiting Major Clean	N/A	N/A
Major Clean	[illegible]	06 Sep 23
Major Clean Approved	[signature]	06 Sep 23
Resanitisation? (Include sign and date)	N/A	N/A

CLEANING EQUIPMENT CHECKLIST

Equipment Name:

Equipment Tag Number:

Cleaning Reason:

Type of Clean	Completed By	Date
Minor Clean		
Major Clean Opening		
Major Clean		
Major Clean Approval		
Reassembly		
Inspection		

CLEANING TAG/EQUIPMENT STATUS

EQUIPMENT

Equipment Name	UHLMANN B1240 (Parts)
Equipment Tag Number	00407

Cleaning Status:

Type of clean	Completed By	Date
Minor Clean	N/A	N/A
Minor Clean Awaiting Major Clean	N/A	N/A
Major Clean	[illegible]	06 SEP 23
Major Clean Approved	[signature]	06 Sep 23
Resanitisation? (Include sign and date)	N/A	*N/A

* DUMPED ON DRY [illegible] 05 OCT 23

CLEANING TAG/EQUIPMENT STATUS

EQUIPMENT

Equipment Name	UHLMANN B124D
Equipment Tag Number	00407

Cleaning Status:

Type of clean	Completed By	Date
Minor Clean	N/A	N/A
Minor Clean Awaiting Major Clean	N/A	N/A
Major Clean	JJ	06 Sep 23
Major Clean Approved		06 Sep 23
Resanitisation? (Include sign and date)	N/A	N/A

OUTPUT BLISTERS FROM UHLMANN B1240

Lot Number: M23-045	Issued By/Date: [signature] 01Sep23

SECTION 1 - to be completed by Production Supervisor/Packaging Leader/Delegate

Lot Number	M23-045	Expiry Date	EXP 07/2026
Blister Description	Branched Blister Strip AU EU	Specification Number(include version)	SP-623-05
Completed By/Date:	[signature] / 05SEP23		

SECTION 2 – Perform room clearance.

Room clearance must be performed by an appropriately trained person.	✓ each step once complete
Correct area (Secondary Packaging – B1.034) is in use.	✓
The outer door of the Secondary Packaging room is status labelled.	✓
All the documentation, products and materials from the previous production operation have been removed from the Secondary Packaging room.	✓
Ensure that the appropriate cleaning has been performed/approved for the Conveyor Belt (00910).	✓
Cleaning tag (FM-231) for Conveyor Belt (00910) has been attached to this FM-305.	✓
LB-180 (Secondary Packaging) and LB-207 (Conveyor Belt) are checked for completeness (eg., Login, batch details, minor clean/ daily clean performed).	✓
No alarms on EMS system (ensure alarm and strobe lighting not active).	✓
Comments: B1.034	
I declare that the above checks have been completed to my satisfaction. *ROOM CLEARANCE APPROVED BY/DATE:* 5208SEP23	

Sign & Date in the Secondary Packaging Area (LB-180) logbook upon successful completion of the Room Clearance.

OUTPUT BLISTERS FROM UHLMANN B1240

Lot Number: M23-045	Issued By/Date: 01Sep23

SECTION 3- PROCEDURE

1. Use shippers 52 x 36 x 47cm for collecting blisters.
2. Pack blisters in configuration described on page 4 of this form.
3. Collect the blisters from conveyor belt, count and pack the blisters in to the shipper as detailed in SOP-297. Separate each layer of blister with blank paper sheet (A3)/inserts.
4. Once shipper is full, complete WIP label (CL-008). The shippers are numbered sequentially. Complete the table below after each shipper is filled/complete.

Shipper No.	Date	Shipper End Time	Blister Quantity Packed per shipper	Initial
1	08 Sep 23	12:58	1700	
2	08 Sep 23	13:24	1700	
3	11 Sep 23	07:08	1700	
4	11 Sep 23	07:36	1700	
5	11 Sep 23	07:58	1700	
6	11 Sep 23	08:22	1700	
7	11 Sep 23	09:35	1700	
8	11 Sep 23	10:00	1700	
9	11 Sep 23	10:35	1700	
10	11 Sep 23	11:05	1700	
11	11 Sep 23	12:13	1700	
12	11 Sep 23	12:39	1700	
13	11 Sep 23	13:13	1700	
14	11 Sep 23	13:36	1700	
15	12 Sep 23	06:59	1700	
16	12 Sep 23	07:35	1700	
17	12 Sep 23	07:51	656	
18				
19				
20			N/A	
21			12 Sep 23	
22				
23				
24				

OUTPUT BLISTERS FROM UHLMANN B1240

Lot Number: M23-045 **Issued By/Date:** 01Sep23

Shipper No.	Date	Shipper End Time	Blister Quantity Packed per shipper	Initial
25				
26				
27				
28				
29			N/A	
30			2 Sep 23	
31				
32				
33				
34				
35				

SECTION 3. RECONCILIATION

Total number of blisters rejected during the collection: 1

Completed By/Date: 2 Sep 23

Ensure that the data recorded on all the shipper labels is accurate.

Checked By/Date: DG 12 SEP 23

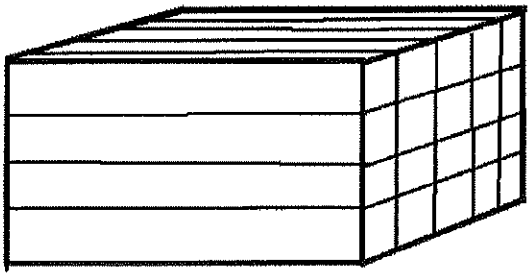
PRODUCTION DOCUMENT REVIEW: To be completed by production delegate

Checked By/Date: 13 SEP 23

OUTPUT BLISTERS FROM UHLMANN B1240

Lot Number: M23-045	Issued By/Date: [signature] 01Sep23

Aridol /Osmohale Blister Strip 1

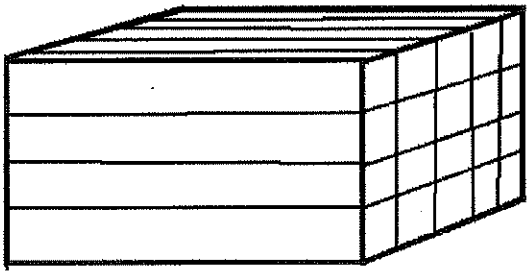


130 Blisters per row

5 rows = 5 x 130 blisters = 650 blisters

4 Layers = 4 x 650 blisters = **2600 blisters**

Aridol/Osmohale Blister Strip 2 and 3

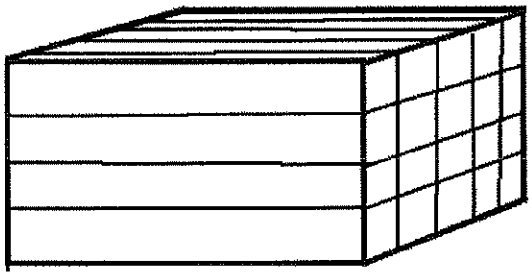


85 Blisters per row

5 rows = 5 x 85 blisters = 425 blisters

4 Layers = 4 x 425 blisters = **1700 blisters**

Bronchitol Blisters (applies to any Format 10 blister)



85 Blisters per row

5 rows = 5 x 85 blisters = 425 blisters

4 Layers = 4 x 425 blisters = **1700 blisters**

Statistic - Thermoformer

Uhlmann

Format 4 Format 10-02

M23-045 Bronchitol Blister Strip AU/EU

Good blister	28134
Misfilled blisters	4120
MSR init	232
Total rejection	843
Missing product	855
Empty blisters	1264
Test run	0
Splice forming film	42
Overheated web heating station	0
Forming fault cause emergency stop	28
Pinhole detection	12
Fill control not ready	0
Error Data-Valid fill control	0
Splice lid foil	6
Code error	0
Overheated web sealing station	838
Overload sealing station	0

GG 12 Sep 23

pharmaxis

Production Order - Job Card

Pharmaxis Master Data

Production Order

Prod. Order No.	23/109
Status	Released

Item	Bronchitol Blister AU EU
Item No.	200045
SP No.	SP-623-08
Lot No.	M23-045

Starting Date	24/12/18
Starting Time	12:00:00 PM
Ending Date	31/12/18
Ending Time	2:00:00 PM

Expected Quantity	40,000	Each
Output Bin Code	20-F1K PACK. STAGGIN	

Routing

Routing No.	SP-623

Operation No.	10
Type	Work Center
No.	B1.022
Description	Primary Packaging Room #20
Time Needed	42 HR

Material Requirements

Item No.	SP No.	Item	Expected Quantity	Unit of Measure Code	Consumed Quantity	Lot No.	Bin Code
200042	SP-501-10	40mg Print Clear capsule #20RR	36,452	G			
300144	SP-603-06	Bronchitol Foil AU/EU - #20RR	29	KG			
300153	SP-627-04	Blister Form Foil 160mm -20RR	96	KG			

Output

Gross Output		Each
Samples		Each
Net Output		Each