FM-361-04

Date Effective: 22-Nov-18

Page 1 of 1

BLISTER RELEASE

Specification Number:	SP- <u>623</u>	<u></u>	<u> </u>	Blist	er Lot N	umbe	r:	M23-045
Description:	Bromekite	d 84	ater x	llup	Rusti	olia		Europe.
Checklist Production records have been reviewed and comply with requirements. (PIs, forms and								Initial and Date
		nd com	ply with i	requirer	nents. (Pl	Is, form	ns and	111/ 000 100
associated records other than I			TD 100	n.:				1-400 05 Oct 23
Room/Equipment Logbook re and cleaning comply with requ		ries	B1.022		ry Packag	ging Ko	oom 🔻	W 05 Oct 23.
Test results conform to specifi			DIOLL	- Llogot				-/W 05 Oct 23.
Packaging materials released a		evnim e	t time of	congun	ntion			1 /
Micro results have been entere				COHSUII	ipuon			M 05 Oct 23
TVITOTO TOSUMS MAYO DOOM CHILORO			75	Recor	d details			{/// 05 Oct 23 . Initial and Date
Incident reports appropriately	resolved	MERCHANIC					PERSONAL SERVICES	A West State of the Control of the C
(DR/NEPR/OOS/MTTR/ER/GAR/EMS C		N	/A					Al 05 Oct 23.
Retention sample number		223	-208	, 200	7 210	0		11 05 Oct 23
	0mg			7	<i>y</i>			and the second s
	5mg			. À	ā 7.7	05 Q	ct 23	and and a second
Capsule lots packed	10mg		.140. 2	4111				
	20mg		CH C					
	40mg	M á	3-03	э.	· · · · · · · · · · · · · · · · · · ·			-N 05 Oct 23.
Expiry date of capsules		23	4	ટેડ .				-/N 25 Oct 23
Date of blister packing 8, 11 and 12-defr - 23			AV 05 Oct 23					
Capsules have been released and were within expiry at time of consumption			-10 05 Oct 23					
Batch number of blisters $\angle OT \mathcal{A}$			· · ·	*				4W 05 Oct 23
T			EXP 07/2026			1W 05 Oct 23.		
No restrictions/conditions for	release		<u> </u>		.,,.			 7/** × × × × * * * * · · · ·
All tests required for all markets	as per SP							
performed and complyNo restrictions/conditions arising	r from	1	0 16	n Adi	ctio.	MA		1/4
incident reports	, x. v. v. v.	1 9	o joo	Owe 1 ***		· , U V		M 05 Oct 23
No restrictions/conditions arising								
restrictions/conditions on use of packaging materials or intermedi								
Details of conditional release	/Commen	3	0 <u>5 0</u>	at 29	2,		and an advantage and an add a	The force of the final street is a final street of the first of the fi
NH in	+ Wak	V-	<u> </u>		and the second s			
	225		1876		entered	isana		
Quantity on paperwork (uni	Contractive Contra	<u>880</u>	- Sept.	PROFESSIONS		SECULO PAREZAMEN	Y181011 (1	inits) 27880 4
Document quantity was der	ved from	P	1-122-1	2 , X	ect con	<u>r 13.</u>	<u>(,</u>	
Batch meets requirements for	r (tick bo	c) Fi	ill releas	ð			Conditi	onal release
QA released by (sign and date)	•		4/11	100 (6)	1 n	·	£ 23	
Production record scanned,	ELB-091 c	omple	ted				1 4 (1	hlah 10 Oct 23 1
Authorisation signature and date:		7 05	Nov18	,		(Ref	erence: SOP-295
Confidential, Staff must comply with the			•		s of this doc	ument are	uncontrolle	ed and may not be the current
version. Not for unauthorised distribution).		Nort	242 1 040	d and	000	s actio	TE-002-03
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PI-122-12

Date Effective: 23-Dec-21

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

Issued By/Date

OISepa3

Lot Number:

M23-045

	Name	Position	Signature	Date
Author:	G.Velagala	Production Supervisor	V.978-	b Dec 21
Checked by	Michael Lay	Production Operator	WA	10 DEC 31
Checked by (QA)	A. Dooley	QA Team Leader		10Dec 21
Authorised by:	S. Duffy	Production Manager	Steel Buller	10 Ou 21

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
	Blister Lot Size (approx.)	* 40,000 Blisters
		Total blisters required (from spec):
	Sample Plan (dependant on lot size).	of following blister points:
		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
	VisioChrom Control System recipe: (include version number)	VC_Bronchitol 10'S
	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: A CK-S	EP-23.

- ► 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.

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TE-011-07

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Phormaxis
PI-122-12
Date Effective:
23-Dec-21
Page 2 of 12
Page 2 of 12
PROCESSING INSTRUCTIONS: UHLMANN B1240
BRONCHITOL BLISTER STRIP AU/EU (SP-623)

Issued By/Date

O(Sep 3)
Lot Number: Max - 045

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 8 3-60664 x	M. A. C. S. S.	23 007 23.
Blister Form Foil 160mm	SP-627	3g/Blister	9(CC. 8	191122-080 1018 1018	08 ect 23
Bronchitol Foil Australía and Europe – 20RR	SP-603	0.8 g/Blister	8 22 Let. 8	Ton 97 - CUP) 5/4	10 MAY 25
COMPLETED BYDATE:	99 CYSCP 23	6			

7

BILL OF MATERIALS

pharmaxis	PI-122-12	Date Effective: 23-Dec-21	Page 3 of 12
PROCES	SSING INSTRU	CTIONS: UHLMAN	N B1240
BRONG	CHITOL BLIST	ER STRIP AU/EU (SP-623)
Issued By/Date	Olsepa 3	Lot Number: M23 - Ø	45

ROOM & PRINCIPAL EQUIPMENT

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

4 C	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: 34 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: 37 57 56 23
4.3	Attach FM-231 to the processing instructions. Refer SOP-269.
	COMPLETED BY/DATE: 3007 Sep 22
T D	DOM CLEADANCE & FOUIPMENT SETTIP

5.1	Log in to the Primary Packaging Room (B1.022) - Logbook (LB-136).
	COMPLETED BY/DATE: 36 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: 199 U / 3 CF 2 S
	COMPLETED BY/DATE: 1901 SEP 23 ROOM CLEARANCE CHECKED BY/DATE: 100 000 Sec 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: 49 07 S 49 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.

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

BRONCINTOL BLISTER STRIT AC/EC (SI -023)
Issued By/Date // O(Sep 23 Lot Number: MQ3-045

6	TITI	TTT) CA	DCTI	TEC
v	$\mathbf{F}\mathbf{H}$	بالناليان		-	LLO

6.1		the blister packaging lot is a contevious lot, then record the previous	inuation of a campaign using the same filled capsule us blister packaging lot details:	s as the				
		Previous Blister Lot Number:	NA					
		Previous Blister Description:	NIA NIA					
	COMPLETED BY/DATE: 94 07 SCF 23							
6.2	Co	emplete 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)	23 001 23					
		Bag Numbers Issued	de company de la					
		OMPLETED BY/DATE:						
6.3	Re		ags. Refer SOP-037: with filled capsule lot details). Record the tare we	ight on				
		oel. aste Foil (Label "Reject" with bli	ster lot details)					
		lled Blisters to be Stripped (Label						
	COMPLETED BY/DATE: 39 08 Sep 27							
6.4		t-up of Uhlmann Blisterpacker ass' result was achieved & record	is complete once the blister integrity test is completed	e and a				
	r		ted. It Setup Checklist (FM-301) to the PI.					
	CO	OMPLETED BY/DATE:						
	······································	· ž J						

pharmaxis	PI-122-12	Date Effective: 23-Dec-21	Page 5 of 12
		CTIONS: UHLMAN ER STRIP AU/EU (
Issued By/Date		Lot Number: M23-0	Popular regions in the relative repairment reprint the contraction of the contraction of the relative relative
7 RECIPE & MACH			

7.1	Switch on t	he B12	40 as	described	in	SOP-269	&	login	to	the	B1240	Control	System	&
	VisioChrom	Control	Syste	em.										

Record recipes selected and ensure in compliance with Section 1.1

B1240 Control System recipe (incl. version number):

4 FREINAT 10-02

VisioChrom Control System recipe (incl. version number): Ve Pronchity 105 04

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:

174 °C	179-181°C
40 Cycles/min	SET

Machine Speed:

COMPLETED BY/DATE: M OS SEP 23

ROOM CONDITIONS

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.

PREPARATION FOR START UP

9.1	Re-posi	tion the Con	manation		to the m	inning no	cition
J.1	• Re-posi	mon are con	ipensation.	Cildulain	to the re	mune po	ortion.

• Place the "Waste Foil" bag under the machine reject outlet.

COMPLETED BY/DATE: 39 08 Sep 38 23

Start the machine and perform batch challenge testing for 'Reject Mechanism" as detailed in 9.2 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	785	7 es

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: M 08 Sep 23

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

Issued	By/Date	91 Olseph3	Lot ?	lumber	r: MW-04S	
9.3	the cap A smal Filling Capsul Record	each hopper (in pouches proposules directly from the bag(all amount of capsules should Capsules' container. Labelles' & filled capsule details. If the addition time/date, bales are introduced into the ho	s) into the ho be poured fro the containe ance details,	ppers. om the r with capsul	filled capsule bag i a WIP label refere le details & bag we	nto a sanitised 'Hand encing 'Hand Filling eights on FM-302 as
		Filled Capsule De	escription		Fill Pock	ets By
		40mg Filled Printed C	lear Capsules	3	SIMTAP Feed	ler Hoppers
	COMP	PLETED BY/DATE:				
9.4		he Visio Chrom camera as p		.d		
	СОМЕ	PLETED BY/DATE: 🤫 (8 34 23)		
9.5	СОМР	 Set the SIMTAP Feeder capsules stop feeding. Switch the SIMTAP Feeder capsules stop feeding. Press reset & then start PLETED BY/DATE: 250 Center of the start capsules are supplied to the start capsul	eeder switch	to posi	` '	J
9.6	1	n start of the batch challeng cord the results below when		Visio (Chrom Camera as	detailed in SOP-269
	Test 1 2	Challenge Test Empty Pocket Good Capsules in all	Expected Results Reject	(Pass	Lane 1 sed=Yes/No)	Lane 2 (Passed=Yes/No)
	Supervi Place of bag.	pockets proceed if the test (s) does isor immediately. Sign/date apsules used for camera ver	below when i	it is co blister	minor incident an onfirmed that test(s) rs produced in the) complies.
9.7	Run the	e machine until filled blister	s reach the p	ınchin	g station and stop	immediately.
	СОМР	PLETED BY/DATE: 🧌 🤇	& Sep	23		
9.8	Reset s	tatistical data as detailed in	SOP-269.			
	COMP	PLETED BY/DATE:	08 Sept	2-3		
9.9	Line cl	earance must be performed ist for Blister Packaging Pro	as per SOP-1	42 and	d recorded on FM-	304 (Line Clearance
		CI E AD ANCE DEDECIDM				

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PROCES	SING INSTRU	CTIONS: UHLMAN	IN B1240

240 **BRONCHITOL BLISTER STRIP AU/EU (SP-623)**

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Iss		aD	- 1	n	~	
155	пе	ш п	. v	L,	211	

015ep23

Lot Number: 123-045

10 BATCH MANAFACTURE

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
	As describe	d in section 1.	Samples must b	e taken equally
QC samples	from each la	ane. Label and	handle QC sam	ples as
· •	described in	sop-269.	•	

COMPLETED BY/DATE: 34 12 Sep 23

When the requisite number of blisters has been prepared and the amount obtained in secondary 10.2 is ensured:

Switch the SIMTAP feeder to position zero Ref. CM-23-003-Di 98-12 Sep 2-3 Run off the good blisters to secondary until the SIMTAP feeder is empty Stop the machine as per SOP-269

COMPLETED BY/DATE: 3/12 Sep 23

11 ACTIONS AT COMPLETION OF LOT BLISTER PACKING

_	Test	d in SOP-269 and record the rest Challenge Test	Expected Results	Lane 1 (Passed=Yes/No)	Lane 2 (Passed=Yes/No)
	1	Blister with Empty pockets	Reject	705	YES
	Do not	t proceed if the test does not disor immediately. Sign/date belo	comply recor	d minor incident an confirmed that test(s	d inform production) complies.
	baper.				
	1 -	PLETED BY/DATE: 98 12			

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

н			-	_	• -		 /
	Issued By/Date Discould Lot Number: /	M,	()	- O	-	5	
1							

			Expected	Lane 1	Lane 2
	Test	Challenge Test	Results	(Passed=Yes/No)	(Passed=Yes/No)
	1	Empty Pocket	Reject	Yes	l yes
	2	Good Capsules in all pocl	kets Accept	YES	765
	superv	t proceed if the test (s) doe isor immediately. Sign/date	e below when it is c	confirmed that test(s)	complies.
	bag.	capsules used for camera vo	erification and blist	ers produced in the o	corresponding rejec
		PLETED BY/DATE:			
11.3	Filling corresp	all remaining capsules in the 'container and blisters conding "Reject" labelled b	produced from eag, if applicable.	or Plate, capsules rer nd of batch challe	naining in the 'Hand nge testing in the
	СОМІ	PLETED BY/DATE:	17-Str 23		i .
11.4	The '.ṛ	ne lot Statistical Data to a re odf' file should have the fol at of the B1240 and VisioCl	lowing format: LO	T NUMBER – DAT	
	СОМ	PLETED BY/DATE:	12 Sep 23	######################################	
11.5	Remove by train	ve unused lid foil & form for ned operators. Record tare v unused foil to the Warehou	l from the machine weights on FM-302	. Unused foil is to be	weighed & checked
	СОМІ	PLETED BY/DATE:	12 Sep 25		
11.6	Label of the des	end of the batch, unused ca each recovered capsule bag ecription on WIP label as "F the recovered (i.e. Unused)	with a WIP label, Recovered 40mg Fi	weigh empty and re lled Printed Clear Ca ecord the Gross Weig	ecord tare weight & psules – 20RR". ht below. Calculate
	Weigh	t Weight. ts and calculations must be ce Used (Tag):	checked by a 2nd	Operator. # 12.56	P 73
	Weigh	ts and calculations must be	Gross Weight	Derator. 79 12 Sc Tare Weight	Net Weight
	Weigh	ts and calculations must be ce Used (Tag):			
Annual Control of the	Weigh Baland	ts and calculations must be ce Used (Tag): Description Recovered Unused	Gross Weight	Tare Weight	Net Weight

pharmaxis	PI-122-12	Date Effective: 23-Dec-21	Page 9 of 12
	- , - ,	CTIONS: UHLMAN ER STRIP AU/EU (
والوائد المراجعة أحرافه وواعد فيحود فيحود ويوري والمحادي فالولادة والمواد والمواد والمحادي	@ Sep 23	Lot Number: MR3-00	Andrew Control of the

11.7	Strip the capsules from the "Fi Capsules' bag.	lled Blisters to be St	tripped" blisters and	I place in the 'Reject						
	COMPLETED BY/DATE:	912,SEP 23								
11.8	Weigh the Reject Capsule bag. All weights must be checked by	a 2nd Operator.								
	Balance Used (Tag): 💯 🗎		, popular							
	Description	Gross Weight	Tare Weight	Net Weight						
	Reject Capsules 2304:7 g 42:3 g 27.62.4 g									
	Reject Capsules 2304.7 g 42.3 g 2262.4 g COMPLETED BY/DATE: 413 Sep 23 CHECKED BY/DATE: 413 Sep 23									
11.9	Enter consumption of materials for each material type have been		ventory forms. Tick	(\(\simeq \)) when the values						
		Capsules Lid Foil Blister Form Fo	bil /							
	Also ensure the correct values h	nave been entered on	all forms.							
	COMPLETED BY/DATE: 30 CHECKED BY/DATE:	113 SED 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
	Note: 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: 4 14 Sep 23

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

	Lot Number: Place Color
	Lot Number: バメくへひ45
Issued By/Date // \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	

13 CONSUMPTION & RECONCILIATION

13.1											
	Material	Spec. Number	Lot Number(s)	Total Quantity Used per Lot							
	40mg Filled Printed Clear Capsules	SP-501	M23-039	Total issued on FM-302 – Recovered Capsules							
	Blister Form Foil 160mm	SP-627	Ign22-082	7-7753-2 g							
	(Record different lot numbers separately)	31-02/	N/A N/A	N/A g							
	Bronchitol Foil Australia		Ign 22-041	2320k:5 g							
	and Europe – 20RR (Record different lot numbers	SP-603	141/4	N/A g							
	separately) N/A P/A										
	COMPLETED BY/DATE: 4 13 Sep 23										
	CHECKED BY/DATE:										
13.2	Print a copy of the Statistical data file. Write Lot number and sign/date the printout. Attach to PI.										
	COMPLETED BY/DATE: 38 13 Sep 23										
13.3											
	Outpo	ıt:	Quantity Blisters (E	A)							
	COMPLETED BY/DATE:	为13.5℃	r 23								

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PROCES	SSING INSTRU	PROCESSING INSTRUCTIONS: UHLMANN B1240	NN B1240
BRON(CHITOL BLIST	BRONCHITOL BLISTER STRIP AU/EU (SP-623)	(SP-623)
Issued By/Date	17 015ep23	Lot Number: MAS-OUES	১ পূ ও

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!

Ė					19-17-18-80-18-18-18-18-18-18-18-18-18-18-18-18-18-
Date/I me	Date/Iime Operator Initials	Incident/Observation – briet description/actions	Supervisor Evaluation - root cause, product impact, immediate action	Froduct Quality Impact - Supe If N - provide brief justification If Y - reference deviation report. Sign/	Supervisor Approval – Sign/Date
5 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	X	Start of the Bathan Still the same score of a thing south porter that Lane one and sail could with I considered market	Book 1550ccs and Engineering the production and Engineering the conversion expect that is not so the content of	Might produce endy fortoning M Societies of the october of Societies of the october of	A seems
8//4	4/7	right rank Engly, Manuel for and			7
to diagnose consumino e e e etito de la					
				My Bis sep 23	

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

	SOP-241
	COMPLETED BY/DATE: 34 14 Sep 23
	ATCH REVIEW
1	Verify Navision Production Journal transactions as per SOP-165.
	COMPLETED BY/DATE: 1/1/5E/23
i	Ensure production journal is posted & trending is completed accurately.
	COMPLETED BY/DATE: 199 19 Steep 23
	Record any Associated Deviation, CR or CAR - to be completed by Production staff
	Reports NIA
	COMPLETED BY/DATE: 122 × V2 3 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
	The Process Instructions & the associated documents have been reviewed as detailed in SOP-291
	COMPLETED BY/DATE: 2256723
	PPROVAL BY PRODUCTION MANAGER/PRODUCTION SUPERVISOR
	e Processing Instructions & associated documents have been reviewed & the lot produced

Associated Document	Document Number	Initial/Date
EMS OOL	WA	Al 65 Oct 23
CAR Number(s)	11/8	4/ 05 20# 23
DR Number(s)	1 / 1 · · · · · · · · · · · · · · · · ·	411 05 00 23
NCPR Number(s)	/////	4/ 00 001 83
CR Number(s)	WK.	1/ 05 A. J. 23
OOS Number(s)	1/1/	4N 05 0 1 43 .

pharmaxis	FM-302-11	Date Effective: 30-Mar-21	Page 1 of 6					
PROCESS CONTROL RECORD FOR BLISTER-PACKING PROCESS AT PHARMAXIS								
Issued By/Date: // OUSep & 3		Lot Number: MA3-045						

PRINT ON A3 CLEANROOM PAPER ONLY

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

1. Lid Foil Chang 3. Adjustment-Rai 5. End – end of da 7. Before/after bre	e (End of Roll) se Minor Incident Ro 19/production	PROCESS DETAILS 2. Lid Foil Change (Start of Roll) 4. Start – start of day/ production 6. In-process check – hourly check (and leak test) 8. Form Foil Change (start of roll)	Sealing Plate temp. (°C)	TRAIN CAMERA? (Y/N) (at start of	1	TEST SAI DETAILS		Place ' checking process in	Y/N' in approp – if not satisfac mmediately, coi	ECKS ONLY priate box after ctory (i.e. Y), stop intact Production or Incident Report.	NUMBER O FROM C	F BLISTER – OUNTER	QC SAMPLES		LEAK TEST (to be completed after test co	by Production
Date	Time	Process Record – choose code from above & enter detailed description for any adjustments.	(at start of each day only)	production or when the camera has been powered off)	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	Initials	Pass (P) /Fail (F)	Initials
88 Sep 2.3	12:20	4, &c sample	70	Ý	4	6	A	zanaj.	assects	Y	64	- State of the Sta	52	K	P	33
06 Sep 72,	13,20	6	H/A	and the same of th	7	Ь	B	Learning Control of the Control of t	i francis	Y	3284	55 <i>6</i>	N/A	39		9 f
os Seir 23	03:35	5	NA	7	Y	6	C		anage: Bearing	Y	4104	636	N/A	3%	.P	98
11 SEP 23	06'46	4	179	, cangles I mass	У	(2)	0	t,margh,	. speaker@	¥	4116	994	N/A	38	?	37
119cp 23	07:45	6	H/4	*	Y	6	Lann.	mad tigue.	- American	y	7538	1374	14/4	34	P	30
11Ser 23	09:15	7.6,8	H/A		Y	6	i James	il in common si il il in common si il	No. of the second	Y	10452	1720	N/A	39		99
115473	10:08		H/A) Annual of the state of the st	4	6	G	i jenerali i	a Maria	Y	14108	2 & 36 Y	N/A	35	7	<i>3</i> 5
119ep23	0:19	2,6	H/A	yeary,	Y	6	and descriptions	1		V	1412/	2248	N/A	<i>H</i>		89
11 902	10 ; 5 6	Mid Pro QC samply	41/A	A Company	· constant	H/A	N/A	soniji. Sono	***	Y	15,612	2362	54	B	NA	96
11 Sep23	11:20	6	NA	- consequence of the consequence	Y	6	:pro	isangi.	and a second	Ý	18286	2560	N/A	3%	P	85
11 Ser 23	12:10	No.	N/A	the state of the s	7	6	,	a salari a		<i></i>	18678	2576	N/A	35	P	08
11 Sep 23	3'0	8,	WA	N	7	6	I K	James		>	2402	3026	N/A	3 8	*	39
11 Ser 23	3.10	6	N/A	N	4	6	44///Aus	- Marina Ja	-matrings.	· >/	22122	3048	N/A	31	2	39
11 Sep 23	13.4b		N/A	V	Y	6	M	poten rapid	N	Y	24480	3198	N/A	H	P	H
12 Sep23	(b) (d)	(Survey Comments	- Company	Y		N	i mangari		Special Control of the Control of th	24492	3398	NA	341	Stanton Stanton	A
1254973	07'40	6	N/A	Z.	Ý	6	0	14	C4	Y	27926	3968	N/4	81	P	95
12Se P23	0785:53	5	NA	de de la constante de la const	Y	6	P	N		Y	281/40	CACCA112	152	38	P	K
***************************************	38 7 Sept 3															
			CONTRACTOR OF STREET, ST. ST. STREET, ST. ST. STREET, ST. ST. STREET, ST. ST. ST. STREET, ST. ST. ST. STREET,	***************************************			1	The state of the s	and the same of th	general Francisco de la mode proteche de proteche de moderna de mo						
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pharmaxis	FM-302-11	Date Effective: 30-Mar-21	Page 2 of 6
	PROCESS CONTR	OL RECORD FOR BLISTER-PACKING PROCE	ESS AT PHARMAXIS
Issued By/Date: Step 23		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 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)	TRAIN CAMERA? (Y/N) (at start of production		TEST SAI DETAILS		Place C checking - process in Supervisor	Y/N' in approp - if not satisfac nmediately, co and raise Mine	ECKS ONLY oriate box after ctory (i.e. Y), stop ntact Production or Incident Report.	NUMBER OI FROM CO	DUNTER	QC SAMPLES	Initials	LEAK TEST I (to be completed be after test co.	by Production
Date Fime Process Record – choose code from above & enter detailed description for any adjustments.	(at start of each day only)	or when the camera has been powered off)	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	imitiais	Pass (P) /Fail (F)	Initials
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pharmaxis	FM-302-11	Date Effective: 30-Mar-21	Page 3 of 6
	PROCESS CONTR	OL RECORD FOR BLISTER-PACKING PROCE	SS AT PHARMAXIS
Issued By/Date: // Ol Sepa3	· ·	Lot Number: M23-045	

t. Lid-Foil Change (End of Roll) 5. Adjustment-Raise Minor Incident Report 5. End—end of day/production 7. Before/after break	ESS DETAILS 2. Lid Foil Change (Start of Roll) 4. Start – start of day/ production 6. In-process check – hourly check (and leak test) 8. Form Foil Change (start of roll)	Sealing Plate temp. (°C)	TRAIN CAMERA? (Y/N) (at start of		TEST SAI DETAILS		Place 'I checking - process in Supervisor o	//N' in appropi if not satisfac imediately, con ind raise Mino	ECKS ONLY riate box after story (i.e. Y), stop stact Production or Incident Report.	NUMBER OF FROM CO	UNTER	QC SAMPLES		LEAK TEST (to be completed after test co	by Production
Date Time Proc	cess Record – choose code from above & enter detailed description for any adjustments.	(at start of each day only)	production or when the camera has been powered off)	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	Initials	Pass (P) /Fail (F)	Initials
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bpou	moxis			FM-30	2-11			Effective: Mar-21				Pa	ige 4 of 6		
				PROC	ESS CON	TROL REC	CORD FOR BLI		CKING PI	ROCESS A	T PHARM	IAXIS			
Issued By	/Date:	pr ols	Tepa3					lumber: M							
CAPS	ULE -	record c	apsule le	ot numb	er and we	eights used	d in table belov	V.							
Balance	Tag #:	00011						Comp	leted by/date	34 0	X Sep 23				
Capsule	Type (n	ng): 40 sy	; Capsule	Lot No. M2	3-034	; Expiry Da	te: 23 00 73	Capsule	Type (mg):	; Cap	osule 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)	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)
XC2p73	ì	3405-1	56-2	3348.0	33		KSEP23 10:33								
X Sep 73	Ž.	3407-3	and only	3350 9	36	1/10	USSEP 23 13 1								
R S40 77	3	ZSCY.7	56.4	2409:3	37)	100	115423 07:1h				***************************************	103,000			
K Sep 27	Ų	13.7.9	Tanky, Say	12014	34	140	NSEP 23 07:17								
8 Sep 23	George	3399 y	56.3	3343.1	9th		11 Sep23 05:46					**************************************			
& Ѐp 23	(j	3210.0	560	3540	24		11 Stof 25 01.38					**************************************	1/A Q4	13 Ser 2	<u> </u>
X S40-23	Visional	2410-7	50.1	3354.6	99		n Sep 23, 10:32						<u> </u>		
x (473)	8	3401-7	56.1	3349.6	99		11 Sep 23 11:17								· · · · · · · · · · · · · · · · · · ·
Capsule	Type (n	ng): <u>40 %</u>	; Capsule	Lot No. M2	5-034	; Expiry Da	te: 23007 23	Capsule	Type (mg):	; Cap	sule Lot No.	Amotorrasia (martini martini m	; Expîry	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)	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)
Dev 73	9	2439.0	560	2363.0	15		in Sep 23 13:31								
50023	W. Const.	1128-6	55.3	1075.3	96	2	11 Sep 23 13:33							À	
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pharmaxis		FM-302-11	Date Effective: 30-Mar-21	Page 5 of 6
		PROCESS CONTROL	RECORD FOR BLISTER-PACKING PROCESS	S AT PHARMAXIS
Issued By/Date:	015ep23		Lot Number: Md3-045	

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

Balance Tag	#: (CON					Comple	eted by/date	99 07 Se	477			
Date	Lot No.	Artwork Number/	Expiry Date	Container No.	Gross Weight	Completed by	Checked by (Initials)	Date/Time (Immediately prior to load	Tare Weight	Net Weight	Completed	Checked by

Date	Lot No.	Artwork Number/ Version	Expiry Date	Container No of (foil)	Gross Weight (g)	Completed by (Initials)	Checked by (Initials)	(Immediately prior to load onto the machine)	Tare Weight (g)	Net Weight (g)	Completed by (Initials)	Checked by (Initials)
0188P73	Ign22-041	SP603/02	19 MAY 25	10 OF 13	12410.	85	M	07 Sep 23 10153	178-2	12231-8	H	(a)
67 Sep 23	Ign22-041	SP602/02	19 MAY 25	4 0 = 13	13285.	34	<u> </u>	11 Sep 23	230.3	10974.7	36	M

			The state of the s									
						\V/A	- 99 13 SE	P Z3				
-												

Total (g) 23265

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16 Mar 21

eference: SOP_260

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pharmaxis	FM-302-11	Date Effective: 30-Mar-21	Page 6 of 6
Iggmed Day/Date OC SUC \	PROCESS CONTROL	RECORD FOR BLISTER-PACKING PROCESS	S AT PHARMAXIS
Issued By/Date: M (Sep 23		Lot Number: M23-04S	
FORM FOIL - record detail	s and waights used in tol		

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

	a cora actains and	mergines asea til fyble b	elow.			
Balance Tag #:	(001)					
				Completed by/date	GO 07 SOD 27	
					1 1 21 301 09	

Date	Lot No.	Artwork Number/ Version	Expiry Date	Container No of (foil)	Gross Weight	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)
D7 Sep 23	Jg1122-080	NIA	08 OCT 23	12 4 OF 28 3015413	4536	36	Ma	07 Sep 23 10:56	516.0	4070.1	98	Æ.
75665	IGN 22 TOPO	NIA	ok 00 23	4 0 F 28	28407.	36	Me.	08 Sep 23	516 O	2-1891.		(Mà
x \$40 273	IGN 22-080	MA	05 00 73	(S OF 78	Z\$ 253°	<i>3</i> 6	<u>A</u>	11 Sepzz	515.9		H	
15923	Ign22-080	NA	CC DCT 23	1 0FZ8	28471.	K	<u> </u>	1 SEP 23		277421	31/s	
								12:51	10371,	18100.	K	W.
	The same of the sa											
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						N/A	99 13 Sep 23				·	
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Total (g)

Authorisation signature and date:

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MES-034-05 Reconciliation of Filled Cap	sules After Bliste	erpacking on the U	Jhlmann B1240		
Modified 10-Jul-15					
Excel 2016					
Reference: SOP-269	Capsule Lot Number:	M23-039			
	Capsule Description:	12 210 00 00 00 00 00 00 00 00 00 00 00 00 0	Filled printed Clear Cap	suls	
Capsuid	Specification Number:	SP-501			
Average Gr	oss Capsule Weight (g):	0.08815	(from Encapsulation MES-	031)	
			<u> </u>	*****	
Blister Lot Number:	M23-045	(from PI)			
Number of Capsules per Blister: Weight of Capsules Issued (g):	27,093.1	(from FM-302)			
, orbit of embasses segment (B)		`			
Capsules Issued:	Blisters (Count)	Capsule Weight (g) 27,093.1			
Reject Capsules:			(from PI)		
Recovered Capsules:		0,0	(from PI)		
Leak Test Sample Blisters:	96			isters which contain capsu	ies, from FM-302)
QA Sample Blisters:	158		(from FM-302)		
Good Blisters:	28,134		(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:			(from PI)		
Recovered Capsules:			(from PI)	t a constitue de la constitue	1 C PA (202)
Leak Test Sample Blisters:	Fill-in		(only leak test sample of (from FM-302)	isters which contain capsu	ies, from FM-302)
QA Sample Blisters: Good Blisters:	Fill-in Fill-in		(from Uhlmann .pdf)		
Total Capsules Accounted for:	A SALED DE	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:		The state of the s	(from PI) (from PI)		
Recovered Capsules: Leak Test Sample Blisters:	Fill-in			isters which contain capsu	iles, from FM-302)
QA Sample Blisters:	Fill-in		(from FM-302)		,
Good Blisters:	Fill-in	0.0	(from Uhlmann .pdf)		
Total Capsules Accounted for:		0.0			
		1			
Blister Lot Number: Number of Capsules per Blister:	Control of the contro	(from PI)			
Weight of Capsules Issued (g):		(from FM-302)			
		1			
Capsules Issued:	Blisters (Count)	Capsule Weight (g) 0.0			
Reject Capsules:			(from PI)		
Recovered Capsules:		A CONTRACT OF A	(from PI)		
Leak Test Sample Blisters:			1	listers which contain capsu	iles, from FM-302)
QA Sample Blisters:	state distribution and the state of the stat		(from FM-302)		
Good Blisters:		***************************************	(from Uhlmann .pdf)		
Total Capsules Accounted for:		0.0			
RECONCILIATION OF CAPSUL	ES - UHLMANN				
1	t of Capsules Issued (g):	27,093.1			
	sules Accounted for (g):				
	% Reconcilliation:	99.9	(Limits: 98.0-102.0%)		
	Result:	Pass	(Pass / Fail)		
BLISTERS TO SECONDARY PA	CKACING BOOM				
DEGLERS TO SECONDART FA	Blister Lot Number:	M23-045	N/A	N/A	N/A
Blisters Transferred to Secon			N/A	N/A	N/A
otten (20072				
Completed by/date:	· 5		Refer t	o any DR/CAR/CR/NCP	K etc.
Completed by/date: 9913	5027				



Phormoxis FM-391-04 Date Effective 16-Jun-22 ROOM CLEARANCE CHECKLIST Lot Number: M礼3-04 Issued By/Date: 分

POOM OF ELBANGE CITEDES	✓ each step once complete
ROOM CLEARANCE CHECKS	
Correct area, is in use (as specified in the process instructions).	Y
The outer door of the room is status labelled.	· remainded and
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.	The real management continues and the second c
No alarms on EMS system (ensure alarm and strobe lighting not initiated).	The second secon
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: 31.022	A CARLO DE LA CARL
If any of the checks above does not comply, do not proceed with Room Clearance.	
ROOM CLEARANCE COMPLETED BYDATE: AM or Sep 23	

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

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mply with the current version of the document. Reproductions of this document are uncontrolled and may not be the current version. Not for unauthorised distribution.	ter 12
	Reference: SOP-142
TE-015-03	

Lot Number: Mal3-045 LINE CLEARANCE CHECKLIST FOR BLISTER PACKAGING PROCESSES AT PHARMAXIS pharmaxis FM-304-08 Issued By/Date: Date Effective: 10-May-2023 OLSOPUS Page 1 of 1

		Santa and the sa
	-	LINE CLEARANCE APPROVED BYDATE:
	sfaction.	I declare that the above checks have been completed and are completed to satisfaction.
	d (2 sample blisters – one from each lane).	- Retention samples of compliant blisters taken and included with batch record (2 sample blisters - one from each lane).
The state of the s		- Confirmed that leak test performed and within specification (passed).
	are in the correct position.	- Lid foil is aligned properly with format foil by checking printing on lid foil are in the correct
Control of the Contro	deformed.	- Pockets are aligned properly at sealing tool-check pockets of blister are not deformed
Control of the Contro	4	VERIFY FORMAT/LAYOUT AGAINST BLISTER SPECIFICATION
	23045 Expiry Date: <u>CXP 04/2026</u>	- Batch Number and Expiry Date are correct. Record: Batch Number 401
		Sample Blisters: (2 sample blisters – one from each lane):
The state of the s	ith section 1.1 of the PI.	Ensure recipe version(s) in use for B1240 and Visio Chrom are in compliance with section 1.1 of
	· incanana de la companya de la comp	All set-up materials are rejected – in clearly labelled reject containers.
Annual Control of the	circle as required): WIP / Approved	Materials indicated on bill of materials present only and labelled appropriately (circle as required):
		Daily balance check(s) performed and recorded in associated logbook(s).
English Control of the Control of th	ached to PI.	Cleaning records (FM-231 and FM-297) complete, removed from machine & attached to PI.
		Equipment is clean and dry (visual inspection only).
A contraction of the second		Room Logbook complete (LB-136).
3		No alarms on EMS system (ensure alarm and strobe lighting not initiated).
		No rubbish visible in surrounding area. No tools present from set-up.
		No traces of documentation/materials from previous batch in the area.
1. " " " " " " " " " " " " " " " " " " "	y QA and correct Lot Number identified on each	All processing instructions, associated forms, checklist etc. are present, issued by QA and correct
✓ each step once complete		Line Clearance Checks
80208	M3-045 ST	Bonditol Bloter Strip Rustalia and Europe
Specification Number and Version	Lot Number Specif	Product Blister Description

Authorisation signature and date:

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08May 23

Reference: SOP-269

TE-015-03



FM-301-19

Date Effective: 10-May-23

Page 1 of 3

UHLMANN B1240 FORMAT 10 SETUP CHECKLIST

Issued	Rν	1	Date	1	ΌA`	ì :
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· Ullepa:	W .	0	(.)	P	À	1000
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Lot Number:

M23-645

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

Blister Description:	Branchital Blis	ter Stip Austra	no and Europe
Blister Specification Number:	SP-623-0	\$	
Batch Number to be Embossed on Blister:	Let 23cms		
Expiry Date to be Embossed on Blister: (N/A if no expiry on blister)	EXP 07/3	626	
VisioChrom Recipe to be used (circle):	WC_Bronchitol 10s	VC_RedOpaque 10s	VC_Demo 10s
Lid Foil Description:	Bronokital F	al Australia a	denope 200
Lid Foil Specification Number:	S2-603		
COMPLETED BY/DATE: Prod. Supervisor/Pack. Leader	(M.s.	<u> </u>	

	Task Description	Completed(/		
1.	Trained Operators must issue and weigh lid & form foils record the balance tag- as detailed in SOP-269.	(gross weights only required) &		
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			
	Check condition of following tooling and install.			
	Part Name	Part Number	Completed _(√)	
	Forming Tool	59/1646-1A		
ļ Į	Sealing Tool	59/1646-1A02	En .	
	Presealing Plate	Pharmaxis drg no 097-030 rev2	i.	
	Punching Tool	59/1646-1A		
5.	Punching Tool Guide	59/1646-1A	U	
] .	SIMTAP Feed Tubes	1A (40 off)		
	SIMTAP Sorting Plate	59/1646-1A	V	
	SIMTAP Feed Manifold	59/1646-1A		
	Lid Foil Rollers	(Various)	المراجع	
	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'.		Sandra Comment	
8.	Wipe lid foil rollers with a sterile wipe dampened with 70			
9.	Thoroughly wipe foil stretching station clamping tape with 70% IPA to remove burrs and/or build-up.	n a sterile wipe dampened with	V	

03-

08May 23

Reference: SOP-270

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TE-002-03

FM-301-19

Date Effective: 10-May-23

Page 2 of 3

UHLMANN B1240 FORMAT 10 SETUP CHECKLIST

Issued By / Date (QA): To Olsepa3 Lot Number: Ma3-045

	Т	ask Description		Completed(
	Set positions of equipment to the follow	wing 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	NGMM	**************************************
	Compensation Pendulum	10 mm (adjustable)	10 mm	
	Print Registration	33 mm	38 mm	
and the same of th	Registration Sensor Traverse	29 mm	ZAMW	
	Lid Foil Splice Sensor	107 mm (adjustable)	(07,198)	
	Punching Tool	926.5 mm (adjustable)	926 Smm	
10.	Camera Position	40 mm (adjustable)	Lio m m	
	SIMTAP Sorting Plate Stroke Speed	480	480	
	SIMTAP Base Position	18,3 cm	18-3 Cm	
	SIMTAP Traverse Position	54.5 mm	\$4.5 mm	
	SIMTAP Longitudinal Position	40.0±3.0 mm	UC. Din m	***
	SIMTAP Hopper Outlet	15 mm	15 × 1 × 1	
	SIMTAP Level Sensor	50 mm (left and right)	Somma left sommright	
	SIMTAP Sorting Plate Vibration Pressure	2.4 bar (machine		
	SIMTAP Filling Tube Vibration	stationary) 3.2 bar (machine	2.4 bar	
	Pressure	stationary)	3.2 bg	
	Shaded cells indicate critical parameter	La receiva de Sagra, la regiona de la final de la constantina de la final de la final de la final de la final de		
11	Set embossing type, lot number & expir		MAT/LAYOUT	
11.	AGAINST BLISTER SPECIFICA			
12.	. Feed form foil and lid foil.			
13.	Set B1240 to "Test Run" mode.			1
14.	Install SIMTAP feed manifold.			*Landard
	Start B1240 and check sealing station aligned with blister pockets. Adjust form foil			
15.	position and compensation pendulur	•		
	Check depth of seal knurling. Adjust i	if required – refer SOP-27	70	- Company of the Comp
16.	Position guide before pinhole detector.			
	Login to VisioChrom control system.			
17.	Load VisoChrom Camera control system Recipe Name & Version No loaded and			
	VisioChrom Control System Recipe:	16'5		
	Version Number:			3. marin
18.	Check alignment of seal and pockets by indexing clamps after sealing station.	inspecting blisters. Adju	ast alignment by releasing	~

Authorisation signature and date:

MAC

08May 23

FM-301-19

Date Effective: 10-May-23

Page 3 of 3

UHLMANN B1240 FORMAT 10 SETUP CHECKLIST

Issued By / Date (QA):	N	015cpd3	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.	Enclose and Assessed			
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.	E. Company			
	Run B1240 for approximately 100 cycles and check blisters for:				
24.	 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.				
30.	Additional Comments: MA				
	Assembly and set-up completed according to SOP-270 by:				
31.					
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: 49 08 Sep 23				
	Operator/Maintenance Engineer				

Authorisation signature and date:	MS	08May 27	
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FM-297-09

Date Effective: 28-Aug-20

Page 1 of 2

B1240 UHLMANN BLISTER THERMOFORMER (00407) MAJOR CLEAN CHECKLIST

Machine Cleaned After Lot: M23-034	Batch of 70% IPA used:	1PA-0496
------------------------------------	------------------------	----------

Completed By / Date:

M 06Sep 23

REFER TO SOP-271 FOR FULL CLEANING PROCEDURE

	REFER 10 SOF-2/1 FOR FULL MACHIN	IE PARTS				
_E st, Comovers						
	Wipe with dry non-linting wipe only Form film splice detection sensor					
1	Lid Foil splice detection sensor					
Į.	VisioChrom camera lens					
	COMPLETED BY/DATE: 99 06 Sep 23					
	Wipe with non-linting wipe dampened with 70% IPA					
_	Forming Tools					
2.	Punching Tool					
	COMPLETED BY/DATE: 99 06 SEP ?	3				
	Flush and rinse with WFI; Spray with 70% IPA					
	Shut-Off Housing Dosing Rings	Product Chute Covers				
	Chip Collectors	SIMTAP Manifold (disassemble)				
4	Vibratory Chute	Feeding Hoses				
3.	Sorting Plate and Frame	Perforated Plates				
	Fill Tubes - gently clean internal surfaces with bottle brush.	Hoppers				
	COMPLETED BY/DATE: 90 06 SEP 2	3				
contented (Million MA)	Clean with brass brush; Clear out the film residue using a non-linting wipe; Wipe with non-					
4.	Iinting wipe dampened with 70% IPA Sealing Plates & Product Haloes					
7.		7 ~7				
	COMPLETED BY/DATE: 39 06 SEP 2					
	Clean with WFI/Wipe with non-linting wipe dan	npened with 70% IPA				
	Control Panel					
240	Machine Base					
	Blister Slide					
5.	Punching Tool Conveyor Form Foil Bush					
	(Note: Check for any wear/tear on the bush, any issues show	eld be notified to production supervisor immediately.)				
and the second	Splice Table					
CO SECURITION OF	COMPLETED BY/DATE: 35 06 SEP Z	3				
	Move the cleaned & dried sanitised parts to Clean	Equipment Store Room (B1.026).				
6.	COMPLETED BY/DATE: 360 Sep 23					
Security Contraction						

Authorisation signature and date:

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FM-297-09

Date Effective: 28-Aug-20

Page 2 of 2

B1240 UHLMANN BLISTER THERMOFORMER (00407) MAJOR CLEAN CHECKLIST

	EQUIPMENT INSPECTION & APPROVAL					
	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.					
7.	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 Sec 23					

Authorisation signature and date:

05C

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Reference: SOP-271

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pharmaxis	FM-231-04	Date Effective: 25-Jul-18	Page 1 of 1					
CLEANING TAG/EOUIPMENT STATUS								

Equipment Name	Conveyor Belt
Equipment Tag Number	00910

Cleaning Status:

Type of clean	Completed By	Date
Minor Clean		07 Sep 23
Minor Clean Awaiting Major Clean		
Major Clean		A I R SUR P
Major Clean Approved		<i>(1)</i>
Resanitisation?		
(Include sign and date)		

Authorisation signature and date:	Stel	all	12 Jul 15	Reference: SOP-142			
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CLEANING TAG/EOUIPMENT STATUS								

Equipment Name	UHLMANN BIZYO (Bronchital 10'S)
Equipment Tag Number	

Cleaning Status:

Type of clean	Completed By	Date
Minor Clean		
	N/A	N/A
Minor Clean Awaiting Major Clean		
	NA	NA
Major Clean		
	99	06 Sep 23
Major Clean Approved		06 Sep 23
Resanitisation?		
(Include sign and date)		
	NIA	/V/A

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pharmaxis	FM-231-04	Date Effective: 25-Jul-18	Page 1 of 1					
CLEANING TAG/EQUIPMENT STATUS								

Equipment Name	UHILMAHN BIZ40 (Parts)
Equipment Tag Number	00407

Cleaning Status:

Type of clean	Completed By	Date
Minor Clean		
	NIA	NA
Minor Clean Awaiting Major Clean		
	NA	MA
Major Clean		
	gg	06 SEP 23
Major Clean Approved	ALA	06 Sep 23
Resanitisation?		
(Include sign and date)	N/A.	*N/A

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pharmaxis	FM-231-04	Date Effective: 25-Jul-18	Page 1 of 1
CLI	EANING TAG/E	QUIPMENT STAT	US

Equipment Name	WHLMANN BIZUD
Equipment Tag Number	00407

Cleaning Status:

Type of clean	Completed By	Date
Minor Clean		
	NIA	NA
Minor Clean Awaiting Major Clean		
	NIA	NA
Major Clean		
	39	06 SEP 23
Major Clean Approved		06 Sep 2 3
Resanitisation?		
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	N /A	NIA

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pharmaxis	FM-305-09	Date Effective: 13-Jun-23	Page 1 of 4
OUTP	UT BLISTERS I	ROM UHLMAN	
Lot Number MJ3-04	C	Issued By/Date:	7 015ep 23

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

	M23-045	Expiry Date	Ex? 07/2026
Blister Description	Branchitel Bister Strip An EU	Specification Number(include version)	SP-623-68
Completed By/Date:	John	1 03350023	

SECTION 2 - Perform room clearance.

Room clearance must be performed by an appropriately trained person.	✓ cach step once complete
Correct area (Secondary Packaging – B1.034) is in use.	1
The outer door of the Secondary Packaging room is status labelled.	V
All the documentation, products and materials from the previous production operation have been removed from the Secondary Packaging room.	V
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.	1
LB-180 (Secondary Packaging) and LB-207 (Conveyor Belt) are checked for completeness (eg., Login, batch details, minor clean/ daily clean performed).	V
No alarms on EMS system (ensure alarm and strobe lighting not active).	
Comments: 34	
I declare that the above checks have been completed to my satisfaction. ROOM CLEARANCE APPROVED BY/DATE: 52085623	

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

Authorisation signature and date:	12	13JUN23		Reference: SOP-297	
		Cat 1	Demandrations of this document are unco	strolled and may not be the curre	nt

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phormaxis	FM-305-09	Date Effective: 13-Jun-23	Page 2 of 4
OUTI	PUT BLISTERS F	ROM UHLMANN	B1240
Lot Number: Ma3-04		Issued By/Date:	Olsepas

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	e de la companie de l
3	1/ 50023	07:08	1900	
4	11 58 23	07:36	1700	Same Care
5	11 540 23	07:58	1700	Same Comme
6	11 847 23	08-22	7700	and the second s
7	1154013	0435	1700	, market anguar a
8	11 52023	16200	1700	" Anny magazine
9	1154023	14.335	1700	· Age for the second
10	11 Sep 23	11:05	1700	
11	11 Sep 23	123 /3	1700	Vanish Control of the
12	11 5/40 23	12.39	1700	N. C.
13	11 Sep 23	73 - 73	1700	A Company of Company
14	11 50123	73.554	1700	
15	12500 23	66:59	1700	
16	25423	27.35	1700	*
17	134 23	67:51	456	Tanaman (
18				and the second s
19				and recommend the second secon
20			NA	
21			350	,
22				
23				
24				

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pharmaxis	FM-305-09	Date Effective: 13-Jun-23	Page 3 of 4	
OUT	PUT BLISTERS	FROM UHLMANN	B1240	
Lot Number: M23-	045	Issued By/Date:	O(Sepa3	

Shipper No.	Date	Shipper End Time	Blister Quantity Packed per shipper	Initial
25				and the second s
26	4			
27	Aller Control of the			
28				
29			1 23	
30			759	
31				
32				
33				
34				
35				

SECTION 3. RECONCILIATION

Total number of bliste	rs rejected	during the collection:	
Completed By/Date:	· · · · · · · · · · · · · · · · · · ·	12 Sep 23	·
Ensure that the data re-	corded on	all the shipper labels is accurate.	
Checked By/Date:	1907 / Z	! 5 <i>Ep 23</i>	
PRODUCTION DOC	CUMENT	REVIEW: To be completed by production delegate	+1

Authorisation signature and date: 130 VN23 Reference; SOP-297

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FM-305-09

Date Effective: 13-Jun-23

Page 4 of 4

OUTPUT BLISTERS FROM UHLMANN B1240

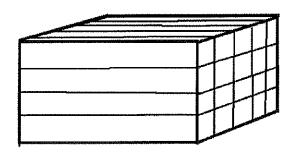
Lot Number:

M23-045

Issued By/Date:

O Sepa3

Aridol /Osmohale Blister Strip 1

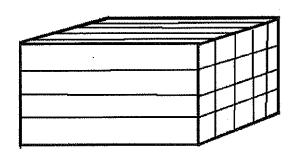


130 Blisters per row

 $5 \text{ rows} = 5 \times 130 \text{ blisters} = 650 \text{ blisters}$

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

Aridol/Osmohale Blister Strip 2 and 3

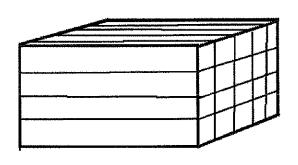


85 Blisters per row

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

Authorisation signature and date:

130 UNZ3

Reference: SOP-297

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Statistic - Thermoformer



Format 4 Format 10-02

MZ3-045 Bronchitali	Blister Strip An/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
\$12 Sep 23	

Statistic - Trompotanies Sacrat - Forest 19-02



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٧.	$+ \left(\Delta \Omega + \zeta_{1} \right) \left(d_{1} \cos \theta + \delta \right) = 0 + \left(\partial_{1} \Omega + \delta \right)^{2}.$
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Gross Output

Samples

Net Output

.	0.1 1.1	OI						31. August 2023
Production (Pharmaxis Mas		Card						Page 1 RowenaG
Production (Order							
Prod. Order No),	23/109						
Status		Released						
Item	Bro	nchitol Blister At	J EU				Starting Date	24/12/18
Item No.	200	045					Starting Time	12:00:00 PM
SP No.	SP-	-623-08					Ending Date	31/12/18
Lot No.	M2:	3-045					Ending Time	2:00:00 PM
Expected Qua	ntity 40,	000	Each					
Output Bin Co	ode 20-	F1K PACK. STA	GGIN					
Routing								
Routing No.		SP-623						
Operation No.		10						
Туре		Work Center						
No.		B1.022						
Description		Primary Packag	ing Room #20					
Time Needed		42	HR					
Material Rec	quirements							
				Expected	Unit of	Consumed	1 .4 ***	Dia Code
Item No.	SP No.	Item		Quantity	Measure Code	Quantity	Lot No.	Bin Code
200042	SP-501-10	40mg Print Cl	ear capsule #20RR	36,452	G			
300144	SP-603-06	Bronchitol Foi	I AU/EU - #20RR	29	KG			
300153	SP-627-04	Blister Form F	oil 160mm -20RR	96	KG		····	
Output								

Each

Each

Each