

pharmaxis	FM-359-05	Date Effective: 31-Mar-21	Page 1 of 2
SPRAY DRIED MANNITOL BLEND RELEASE			

Specification Number:	SP-504- <u>09</u>	Blend Lot Number:	<u>M23-032</u>
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Checklist		Initial and Date
Production records have been reviewed and comply with requirements. (PIs, forms and associated records other than LBs)		<i>pliberatore 28 Aug 23</i>
Room/Equipment	LB-133 Blending Room - B1.018	<i>pliberatore 28 Aug 23</i>
Logbook reviewed, entries and cleaning comply with requirements.	LB-134 Solution Prep Room - B1.017 - Logbook	<i>pliberatore 28 Aug 23</i>
	LB-137 Spray Dryer Cyclone Room - B1.011 - Logbook	<i>pliberatore 28 Aug 23</i>
	LB-138 Spray Dryer 1 Bag Filter Room - B1.014 Logbook	<i>pliberatore 28 Aug 23</i>
	LB-145 IBC Tag No. 00410 for 350kg Logbook (spray drying)	<i>pliberatore 28 Aug 23</i>
	LB-145 IBC Tag No. 00410 for 350kg Logbook (blending)	<i>pliberatore 28 Aug 23</i>
Test results conform to specification		<i>pliberatore 28 Aug 23</i>
Raw materials released and within expiry at time of consumption		<i>pliberatore 28 Aug 23</i>

	Record details	Initial and Date
Incident reports appropriately resolved (DR/NCPB/OOS/MTIR/CK/CA/EMS/OOL/EBM)	<i>N/A</i>	<i>pl 29 Aug 23</i>
DOM of first sub-batch	<i>03 Aug 23</i>	<i>pl 25 Aug 23</i>
Expiry date of first sub-batch	<i>03 Sep 23</i>	<i>pl 23 Aug 23</i>
DOM of Blend	<i>09 Aug 23</i>	<i>pl 23 Aug 23</i>
All spray dried mannitol sub-batches within expiry at time of consumption		<i>pl 23 Aug 23</i>
Expiry of Blend	<i>02 Oct 23</i>	<i>pl 23 Aug 23</i>
No restrictions/conditions for release <ul style="list-style-type: none"> All tests required as per SP-504 performed and comply No restrictions/conditions arising from incident reports No restrictions/conditions arising from restrictions/conditions on use of starting material 	<i>No restrictions</i>	<i>pl 29 Aug 23</i>

Details of conditional release/Comments			
Quantity on PI-118 (g)	<i>59227.7g</i>	Quantity entered in Navision (g)	<i>59227.7g</i>

Batch meets requirements for (tick box)	Full release	<input checked="" type="checkbox"/>	Conditional release	<input type="checkbox"/>
QA released by (sign and date):	<i>pliberatore 29 Aug 23</i>			
Production record scanned, ELB-091 completed	<i>pliberatore 29 Aug 23</i>			

Authorisation signature and date: <i>[Signature] 19 Mar 21</i>	Reference: SOP-295
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TE-002-03	

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SPRAY DRIED MANNITOL BLEND RELEASE			

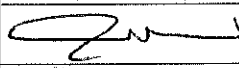
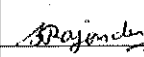

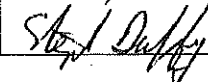
Specification Number:	SP-504- <u>09</u>	Blend Lot Number:	<u>M23-032</u>
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Sub-batch list for manufactured Spray Dried Mannitol Blend					
Sub-batch	Number of fractions produced	Date of Manufacture (DOM)	Incident reports	Acceptable fractions	Production record Reviewed (sign and date)
M23-029	4	3 Aug 23	N/A	4	<i>[Signature]</i> 12 Oct 23
M23-030	4	4 Aug 23	N/A	4	<i>[Signature]</i> 23 Aug 23
M23-031	2	7 Aug 23	N/A	2	<i>[Signature]</i> 23 Aug 23

Raw Material list for manufactured Spray Dried Mannitol Blend			
Material Name	Lot Number	Batch Number	Sign and Date
Raw material mannitol, SP-001	IGN22-053	E326P	<i>[Signature]</i> 23 Aug 23
Raw material mannitol, SP-001		N/A	
Raw material mannitol, SP-001			<i>[Signature]</i> 12 Oct 23

Authorisation signature and date: <i>[Signature]</i> 19 Mar 21	Reference: SOP-295
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TE-002-03	

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PROCESSING INSTRUCTION: SPRAY DRIED MANNITOL BLEND (SP-504)			
Issued By/Date <i>JH</i> 04 Aug 23		Lot Number: M23-032	

	Name	Position	Signature	Date
Author:	Pouria Nooshin	Packaging Leader		26 Nov 21
Checked By:	Rajendra Sambasivam	Production Operator		26 Nov 21
Checked by (QA):	Aaron Dooley	QA Manager		26 Nov 21
Authorised by:	Stephen Duffy	Production Manager		26 Nov 21

1 PRODUCT DESCRIPTION

1.1	Product Description	Spray Dried Mannitol Blend
	Specification Number (Include version number)	SP-504- <u>09</u>
	Strength	N/A
	Batch Size:	60,000
	Blend expiry date (60 days from date of manufacture of oldest sub-batch)	02 OCT 23
	COMPLETED BY/DATE: <i>JAS</i> 07 AUG 23	

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

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Issued By/Date <i>[Signature]</i> 04 Aug 23		Lot Number: M23-032	

2 BILL OF MATERIALS

Prior to processing, the **Production Supervisor** must specify below the lot numbers, fractions & quantities of Spray Dried Mannitol to be included in the blend.

The Production Supervisor must then calculate the total assigned quantity & verify that the total is within the Blender Weight Limits specified.

Material Name	Specification Number	Quantity per unit/ Batch	Lot Number	Fraction Number (s)	Quantity (g)	Expiry date
Spray Dried Mannitol Individual Batch	SP-503	56 kg- 60kg	M23-027	1-4	24 521.0g	03 SEP 23
			M23-030	1-4	24 494.1g	04 SEP 23
			M23-031	1-2	11 380.5g	05 SEP 23
			<i>[Handwritten: 113 SP-09 Aug 23]</i>			
			TOTAL (g):		60,395.6g	Weight Limit: 56 kg- 60kg

COMPLETED BY/DATE: *[Signature]* 07 Aug 23

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Issued By/Date <i>W 04 Aug 23</i>		Lot Number: <i>M23-032</i>	

3 ROOM & PRINCIPAL EQUIPMENT

3.1	Room & Principal Equipment (20RR): <ul style="list-style-type: none"> • Blending Room (B1.018) • Frewitt Coniwitt-150 Conical Mill (Tag: 00405) • Mueller CONT350-CI000-K-08357 350 Kg IBC (Tag: 00410) • Müller Blender Column Lifter (Tag 00412) • Calibrated Balances
3.2	Login to the Blending Room (B1.018) - Logbook (LB-133). COMPLETED BY/DATE: <u><i>SA09FHH23</i></u>

4 CLEANING CHECKS

4.1	<p>Is this the first lot to be manufactured after a major clean? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>If Yes, Check</p> <p>If more than 5 days have elapsed since the equipment was last sanitised, then:</p> <ul style="list-style-type: none"> • Re-sanitise all product contact surfaces with 70%IPA. • Record re-sanitisation on each Equipment Cleaning Tag (FM-231) for the IBC, Mill, Column Lifter & Parts and also in the Blending Logbook (LB-133). • Ensure all surfaces are dry. • Attach each Cleaning Tag (FM-231) & Major Cleaning Records (FM-288, FM-296 & FM-286) for the IBC, Mill & Column Lifter to the processing instructions. <p>If No, this section is not applicable.</p> <p>Sign below when it is confirmed that the equipment is within the sanitisation expiry time.</p> <p>COMPLETED BY/DATE: <u><i>SA09FHH23</i></u></p>
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5 ROOM CONDITIONS

5.1	Check EMS for alarms (as detailed in SOP-244 – from local connection in B1.034). If no alarms are present on the EMS regarding the pressure differential, temperature and relative humidity in Room B1.018, 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: <u><i>SA09FHH23</i></u>
5.2	Confirm that the Nitrogen supply is turned on. COMPLETED BY/DATE: <u><i>SA09FHH23</i></u>

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6 ROOM CLEARANCES

6.1	<p>Ensure the room is clear of all unnecessary material – refer to SOP-142. Room clearance is performed as per FM-391 by the second trained person (not involved in completing the above steps).</p> <p>COMPLETED BY/DATE: <u><i>SA09 Aug 23</i></u></p> <p>ROOM CLEARANCE CHECKED BY/DATE: <u><i>1-09 Aug 23</i></u></p>
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7 BLENDING PROCEDURE

7.1	<p>Complete Blender set-up as per SOP-262. Ensure all safety precautions are adhered to.</p> <p>COMPLETED BY/DATE: <u><i>SA09 Aug 23</i></u></p>
7.2	<p>Install the vibrational hammer on the IBC. Confirm that the vibrator is operational – if not, alert the Production Supervisor and do not proceed with batch until fixed.</p> <p>COMPLETED BY/DATE: <u><i>SA09 Aug 23</i></u></p>
7.3	<p>Set up the Frewitt Coniwitt-150 Conical Mill (Tag 00405) according to SOP-257. Set the Mill speed to 500 rpm and use a 3 mm screen (Serial No. 432501 only). Ensure the Mill is set up correctly by testing it first. Ensure that the screen and rotor are not in contact with each other.</p> <p>COMPLETED BY/DATE: <u><i>SA09 Aug 23</i></u></p> <p>CHECKED BY/DATE: <u><i>1-09 Aug 23</i></u></p>
7.4	<p>Record the balance to be used for weighing step:</p> <p>Balance Used (Tag): <u><i>00127</i></u></p> <ul style="list-style-type: none"> • Weigh each assigned fraction of Spray Dried Mannitol and record the gross weight. • Empty the contents of each bag into the IBC. • Weigh the empty bag and record the tare weight. • Calculate the net weight of each fraction added to the IBC. • Calculate the total net weight of Spray Dried Mannitol fractions added to the IBC. • Verify that the total is within the limits specified. • Complete FM-006 Inventory form for each Spray Dried Mannitol lot used. • All weights & calculations are to be checked by a 2nd Operator.

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PROCESSING INSTRUCTION: SPRAY DRIED MANNITOL BLEND (SP-504)			
Issued By/Date <i>N</i> 04 Aug 23		Lot Number: M23-032	

Lot Number	Fraction Number	Gross Weight (g)	Tare Weight (g)	Net Weight (g)	Completed by/Date	Checked by/Date
M23-029	1	6315.4 g	129.7 g	6185.7 g	SA09PHG23	209 Aug 23
M23-029	2	6500.0 g	123.5 g	6376.5 g	SA09PHG23	209 Aug 23
M23-029	3	6536.0 g	127.3 g	6408.7 g	SA09PHG23	209 Aug 23
M23-029	4	5626.0 g	127.9 g	5498.1 g	SA09PHG23	209 Aug 23
M23-030	1	6380.9 g	128.9 g	6252.0 g	SA09PHG23	209 Aug 23
M23-030	2	6404.0 g	124.4 g	6279.6 g	SA09PHG23	209 Aug 23
M23-030	3	6664.0 g	132.6 g	6531.4 g	SA09PHG23	209 Aug 23
M23-030	4	5502.0 g	128.7 g	5373.3 g	SA09PHG23	209 Aug 23
M23-031	1	6380.8 g	129.6 g	6251.2 g	SA09PHG23	209 Aug 23
M23-031	2	5225.7 g	132.7 g	5093.0 g	SA09PHG23	209 Aug 23
		g	g	g		
		g	g	g		
		g	g	g		
		g	g	g		
		g	g	g		
		g	g	g		
		g	g	g		
		g	g	g		
		g	g	g		
		g	g	g		
Total Powder added to IBC (56kg- 60kg)...(a):					60247.5 62247.5 g SA09PHG23	209 Aug 23

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Issued By/Date <i>JK</i> <i>04 Aug 23</i>		Lot Number: <i>M23-032</i>	

7.5	<p>Login to the control panel. Perform the following steps as per SOP-262.</p> <p>Set the blender speed to 15 rpm. Set the blending time to 10 minutes. Enter the Lot Number of the batch to be blended in the following format MYY-XXX. The checker shall ensure the correct data as recorded below is manually entered on the Blender HMI.</p> <p>Blend Speed Entered: <u>15</u> rpm</p> <p>Blend Time Entered: <u>10</u> minutes</p> <p>Lot Number: <u>M23-032</u></p> <p>COMPLETED BY/DATE: <u>S209PNA23</u></p> <p>CHECKED BY/DATE: <u><i>[Signature]</i> 07 Aug 23</u></p>
7.6	<p>Blend the batch as per SOP-262.</p> <p>If any stoppages are required record the details in the minor incident form.</p> <p>Stoppages: <u>N/A</u> (N/A if not required)</p> <p>Refer to Deviation: <u>N/A</u> (N/A if not required)</p> <p>COMPLETED BY/DATE: <u>S209PNA23</u></p>
7.7	<p>Remove the blender printout. Check that Blend Speed, Blend Time and Lot Number are the same as the Blender HMI. Attach printout to PI.</p> <p>Initiate a Minor Incident Report if there is a difference observed.</p> <p>COMPLETED BY/DATE: <u>S209PNA23</u></p>

8 MILLING PROCEDURE

8.1	<p>Place a tared sterile Size 2 plastic bag (with WIP label attached outlining details of batch and tare weight) underneath outlet funnel and start the Mill.</p> <p>Feed the Spray Dried Mannitol Blend gradually as detailed in SOP- 257 into the Mill hopper (to ensure no grinding of the powder occurs).</p> <p>In order to ensure each bag is closed properly, try to limit each bag maximum quantity to approximately 7,500g. Seal each bag after filling. Change the bag intermittently throughout the process and label bags as 1, 2, 3...</p> <p>COMPLETED BY/DATE: <u>S209PNA23</u></p> <p>CHECKED BY/DATE: <u><i>[Signature]</i> 09 Aug 23</u></p>
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Issued By/Date <i>W 04 Aug 23</i>		Lot Number: <i>M23-032</i>	

- 8.2 Weigh minimum 50g sample from each bag for QC sampling.
Use a clean spatula to sample from different locations in each bag. Immediately reseal each bag after sampling.
Place the samples in tared, labelled sterile plastic containers & close. Care must be taken when placing the lid onto the sample container. Do not use force. Ensure lid sits evenly.
Calculate the total. All weights, calculations & sample labels must be checked by a 2nd Operator.

Balance Used (Tag): 00127

Bag Number	Sample	Gross Weight	Tare Weight	Net Weight
Bag 1	QC:	96.0 g	43.8 g	52.2 g
Bag 2	QC:	95.1 g	43.9 g	51.2 g
Bag 3	QC:	96.3 g	43.8 g	52.5 g
Bag 4	QC:	95.8 g	43.8 g	52.0 g
Bag 5	QC:	95.4 g	43.9 g	51.5 g
Bag 6	QC:	98.7 g	43.9 g	54.8 g
Bag 7	QC:	96.4 g	43.9 g	52.5 g
Bag 8	QC:	95.8 g	43.8 g	52.0 g
Bag 9	QC:		N/A g	
Bag 10	QC:		50.01g 423 g	
Total Weight of Samples.....(b):				418.7 g

COMPLETED BY/DATE: SD09PA423

CHECKED BY/DATE: 1-09 Aug 23

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Issued By/Date <i>AK</i> 04 Aug 23		Lot Number: M23-032	

8.3 Weigh each Spray Dried Mannitol Blend bag & calculate the total. Complete the WIP labels:

- Record the weight on the WIP label.
- Record the expiry date (from section 1 on page 1) on the WIP label

All weights, calculations & bag labels must be checked by a 2nd Operator.

Balance Used (Tag): 00127

Spray Dried Mannitol Blend	Gross Weight	Tare Weight	Net Weight
Bag 1	6788.0 g	111.2 g	6676.8 g
Bag 2	7547.0 g	110.8 g	7436.2 g
Bag 3	7620.0 g	110.9 g	7509.1 g
Bag 4	7687.0 g	110.8 g	7576.2 g
Bag 5	7674.0 g	111.2 g	7562.8 g
Bag 6	7654.0 g	110.6 g	7543.4 g
Bag 7	7602.0 g	110.7 g	7491.3 g
Bag 8	7543.0 g	111.1 g	7431.9 g
Bag 9			
Bag 10			
Total Spray Dried Mannitol Blend.....(c):			59227.7 g

COMPLETED BY/DATE: *SR09PH23*

CHECKED BY/DATE: *109 Aug 23*

8.4 Place each bag in a second sterile plastic bag & seal the second bag.

COMPLETED BY/DATE: *SR09PH23*

8.5 Initiate FM-006 (Inventory Intermediate/WIP) for the Spray Dried Mannitol Blend.

COMPLETED BY/DATE: *SR09PH23*

8.6 Calculate the Lot expiry date below;
The expiry date for Blend (SP-504) is 60days from the date of Spray-Drying of the oldest sub-batch included in the blend.

Lot Expiry Date: 02 Oct 23

COMPLETED BY/DATE: *SR09PH23*

CHECKED BY/DATE: *109 Aug 23*

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Issued By/Date <i>PK</i> 04 Aug 23		Lot Number: M23-032	

9 YIELD

9.1	Calculate the yield. The calculation must be checked by a 2 nd Operator.																				
	<table> <tr> <td>Total Blend Output.....(d):</td> <td>59646.4</td> <td>g</td> <td>= (b) + (c), refer 8.2 & 8.3</td> </tr> <tr> <td>Total Powder added to IBC:</td> <td>62247.5</td> <td>g</td> <td>= (a), refer 7.4 <i>SR09 Aug 23</i></td> </tr> <tr> <td>Yield:</td> <td>99</td> <td>%</td> <td>= [(d) / (a)] x 100</td> </tr> <tr> <td>Yield Limits:</td> <td colspan="3">97 – 101 %</td> </tr> <tr> <td>Yield within limits (circle):</td> <td colspan="3">(Y) / N</td> </tr> </table>	Total Blend Output.....(d):	59646.4	g	= (b) + (c), refer 8.2 & 8.3	Total Powder added to IBC:	62247.5	g	= (a), refer 7.4 <i>SR09 Aug 23</i>	Yield:	99	%	= [(d) / (a)] x 100	Yield Limits:	97 – 101 %			Yield within limits (circle):	(Y) / N		
Total Blend Output.....(d):	59646.4	g	= (b) + (c), refer 8.2 & 8.3																		
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Yield:	99	%	= [(d) / (a)] x 100																		
Yield Limits:	97 – 101 %																				
Yield within limits (circle):	(Y) / N																				
	COMPLETED BY/DATE: <i>SR09 Aug 23</i> CHECKED BY/DATE: <i>PK 09 Aug 23</i>																				
9.2	Photocopy the printout from the blender, sign the copy & attach to the PI.																				
	COMPLETED BY/DATE: <i>SR09 Aug 23</i>																				

10 LABELLING AND STORAGE

10.1	Store the labelled bags in the WIP storage area in the clean room (B1.021). Ensure all bags from the same batch are store on the same rack. All the labels completed must be checked by the 2nd trained person for the accuracy of the details entered.
	<i>SR09 Aug 23</i> COMPLETED BY/DATE: <i>SR09 SR09 Aug 23</i> CHECKED BY/DATE: <i>PK 09 Aug 23</i>

11 CONSUMPTION & OUTPUT

11.1	Calculate the total consumption of all the materials used. All consumptions must be checked by the 2 nd person.																				
	<table border="1"> <thead> <tr> <th>Material</th> <th>Specification Number</th> <th>Lot Number</th> <th>Total quantity used per lot (Kg)</th> </tr> </thead> <tbody> <tr> <td>Spray Dried Mannitol Individual Batch</td> <td>SP-503</td> <td>M23-029</td> <td>24.521 kg</td> </tr> <tr> <td>Spray Dried Mannitol Individual Batch</td> <td>SP-503</td> <td>M23-030</td> <td>24.494 kg</td> </tr> <tr> <td>Spray Dried Mannitol Individual Batch</td> <td>SP-503</td> <td>M23-031</td> <td>11.380 kg</td> </tr> <tr> <td>OUTPUT</td> <td>SP-504</td> <td>M23-032</td> <td>59227.7g</td> </tr> </tbody> </table>	Material	Specification Number	Lot Number	Total quantity used per lot (Kg)	Spray Dried Mannitol Individual Batch	SP-503	M23-029	24.521 kg	Spray Dried Mannitol Individual Batch	SP-503	M23-030	24.494 kg	Spray Dried Mannitol Individual Batch	SP-503	M23-031	11.380 kg	OUTPUT	SP-504	M23-032	59227.7g
Material	Specification Number	Lot Number	Total quantity used per lot (Kg)																		
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OUTPUT	SP-504	M23-032	59227.7g																		
	COMPLETED BY/DATE: <i>SR09 Aug 23</i> CHECKED BY/DATE: <i>PK 10 Aug 23</i>																				

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Issued By/Date	Lot Number:		
N 04 Aug 23	MR3-032		

12 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
			N/A SP207A4423		
			N/A SP210A4423		

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Issued By/Date	<i>JK</i> 04 Aug 23	Lot Number:	M23-032

13 NAVISION & TRENDING UPDATE

13.1	Perform Navision Production Journal transactions as per SOP-165 and enter Trending as per SOP-241. COMPLETED BY/DATE: <u>SR 16 Aug 23</u>
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14 BATCH REVIEW

14.1	Verify Navision Production Journal transactions as per SOP-165. COMPLETED BY/DATE: <u>LT 16 AUG 23</u>		
14.2	Ensure production journal is posted & trending is completed accurately. COMPLETED BY/DATE: <u>SR 17 AUG 23</u>		
14.3	Record any Associated Deviation, CR or CAR – to be completed by Production staff <table border="1" style="width: 100%;"> <tr> <td>Reports</td> <td><u>N/A</u></td> </tr> </table> COMPLETED BY/DATE: <u>LT 16 AUG 23</u>	Reports	<u>N/A</u>
Reports	<u>N/A</u>		
14.4	The Process Instructions & the associated documents have been reviewed as detailed in SOP-291. COMPLETED BY/DATE: <u>LT 16 AUG 23</u>		

15 APPROVAL BY PRODUCTION MANAGER/PRODUCTION SUPERVISOR

These Processing Instructions & associated documents have been reviewed & the lot produced in compliance with GMP.	
Print Name: <u>L. Thuringish</u>	Sign/Date: <u>[Signature] 16 AUG 23</u>

16 ASSOCIATED DOCUMENTS AND QA REVIEW

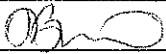
Include details of any associated documents		
Associated Document	Document Number	Initial/Date
EMS OOL		
CAR Number(s)		
DR Number(s)		<u>N/A</u> <u>29 Aug 23</u>
NCPR Number(s)		
CR Number(s)		
OOS Number(s)		
BATCH DOCUMENT QA REVIEWED BY		
Print Name: <u>Joanna Liberatore</u>	Sign/Date: <u>[Signature] 29 Aug 23</u>	

pharmaxis	FM-286-04	Date Effective: 16-Jan-19	Page 1 of 1
MAJOR CLEAN RECORD FOR 350Kg IBC Tag 00410			

IBC Tag no.	00410		
IBC Cleaned after Lot no:	M23-031	70% IPA Lot Number	IPA-0493
Completed By / Date:	Gm 07 Aug 23		

EQUIPMENT AND MACHINE PARTS	
1.	Surfaces – Exterior and Interior Clean IBC lid according to SOP-191, Minor Equipment Cleaning and Sanitising Procedure. Connect and open the butterfly discharge valve on the IBC to the drainage point in Equipment Wash Bay Room (B1.028). Sanitise the IBC Lid with spray ball assembly by spraying all internal/external surfaces with 70% IPA. Inspect spray ball and hose – report any non-conformances to Production Supervisor. Connect the WFI to the spray ball assembly and clean internal surfaces of IBC as detailed in SOP-256. Allow the WFI to flow through the spray ball assembly for a period of at least 3 minutes. Wipe the external surfaces of the IBC using a sterile wipe soaked in WFI. External and internal surfaces are to be sprayed with 70% IPA as practically possible. Confirm by visual inspection that the external surfaces of the IBC are clean and dry. Completed By/ Date: Gm 07 Aug 23

EQUIPMENT INSPECTION AND APPROVAL							
2.	Inspect/check the following:						
	<table border="1"> <tr> <td>The equipment is visually clean, dry and fit for use.</td> <td>Equipment parts are visually clean and dry.</td> </tr> <tr> <td>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.</td> <td>External surfaces of the equipment are clean and dry</td> </tr> <tr> <td>Area surrounding the equipment is clean, dry and free of rubbish.</td> <td>The cleaning tag is attached to the equipment.</td> </tr> </table>	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.	The cleaning tag is attached to the equipment.
	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.	The cleaning tag is attached to the equipment.					
Sign below- only if the checker is fully satisfied that the equipment is clean and fit for use. Report any non-conformities immediately to the Production Supervisor.							
Completed By/ Date: SA 07 Aug 23							

Authorisation signature and date:  16 Jan 19	Reference: SOP-256
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TE-002-03	

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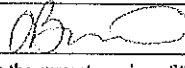
10-10-10

pharmaxis	FM-288-05	Date Effective: 31-Aug-18	Page 1 of 1
FREWITT CONIWITT-150 CONICAL MILL (TAG 00405) CLEANING FORM			

Mill Cleaned after Batch:	Lot Number EXP 502	Lot Number of 70% IPA - (IPA-XXXX):	IPA-0492
Completed By / Date:	SA 25 Jul 23		

EQUIPMENT AND MACHINE PARTS			
1.	Mill Surfaces – External and Internal		
	Cover the electrical plug/cable with a plastic bag (fasten with a cable tie). Avoid direct contact with WFI/IPA.		
	In Wash Bay B1.028, spray WFI into the inlet funnel and up the outlet funnel until all visible mannitol is removed from within the assembled mill housing.		
	Spray the mill's protective casing/enclosure and trolley with WFI until all visible mannitol is removed.		
	Dismantle the Frewitt ConiWitt-150 conical mill as described in SOP-257.		
	Thoroughly spray all minor parts (removed from main body of machine) with WFI until the parts are visually clean. Rinse surfaces again thoroughly with WFI.		
	Spray machine and all parts with 70% IPA and wipe down.		
	Wipe the external surfaces of the mill using a sterile wipe soaked in WFI. Spray and wipe all external surfaces with 70% IPA.		
	Confirm by visual inspection that the machine and all parts are clean. Thoroughly check surfaces of all parts for water marks or any residue.		
	Note: Issue individual FM-231 for the Mill and its detachable parts as per SOP-257.		
Completed By:	SA	Date:	25 Jul 23

2.	EQUIPMENT INSPECTION AND APPROVAL		
	Inspect/check the following:		
	The equipment is visually clean, dry and fit for use.	Equipment parts are visually clean and dry. Ensure that no water marks or any residue on all surfaces.	
	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	Individual cleaning tag(s) attached to the Mill and its detachable parts.	
	Sign below if the checker is fully satisfied that the equipment is clean and fit for use. Report any non-conformities to the Production Manager/Supervisor.		
	Completed By:		Date:

Authorisation signature and date:	 31 Aug 18	Reference: SOP-257
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TE-002-03		

1. 請列明(a) 2019年12月31日及2020年3月31日，本公司之已發行股本及儲備；及(b) 2019年及2020年本公司之溢利及虧損。

$$\begin{aligned} \mathbb{E}(\mathcal{L}_n) &= \mathbb{E}(\mathcal{L}_n^{\text{out}}) + \mathbb{E}(\mathcal{L}_n^{\text{in}}) \\ &= \mathbb{E}(\mathcal{L}_n^{\text{out}}) + \mathbb{E}(\mathcal{L}_n^{\text{in}}) \end{aligned}$$
[illegible]

24, 1972, 1930-1934, 1976

2010年12月10日 星期五

J. Biol. Chem. 260:1798-1804, 1985

Received 15 July 1998; accepted 15 July 1998

[illegible]

3) *Interaktion* der beiden Faktoren: Ist das Verhalten des Individuums durch die Kombination der beiden Faktoren (z.B. Stress und Zeitdruck) beeinflusst?

of human and other vertebrate (PW) diets is dependent on the availability of these dietary resources.

\mathbb{A}^1 -homotopy invariance of the motivic cohomology of the motivic spectrum $\mathbb{H}\mathbb{Z}$ is given by

1. *How do you feel about the fact that you are a woman in a male-dominated field?*

[illegible]

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1. $\frac{1}{2} \times \frac{1}{2} = \frac{1}{4}$

1. 2017年12月31日，甲公司“应付账款”科目贷方余额为100万元，其中明细科目贷方余额有80万元，借方余额有20万元；“预付账款”科目借方余额为20万元，其中明细科目借方余额有15万元，贷方余额有5万元。不考虑其他因素，甲公司12月31日资产负债表“应付账款”项目应填列的金额为（ ）万元。

[illegible]

(continued from page 6)

[illegible]

but could not be prepared to discuss the matter with

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100. The defendant is also in a position to present evidence that the defendant is not a person who is likely to be involved in a criminal enterprise, and that the defendant is not a person who is likely to be involved in a criminal enterprise.

Cheng, H. and H. H. Chen, 1999. A new species of the genus *Chrysomela* from Taiwan. *Acta Zool. Sin.* 26: 103-104.

1. 在 \mathbb{R}^n 中, 设 $\mathbf{A} = (a_{ij})$ 是一个 $n \times n$ 的实对称矩阵, 且 \mathbf{A} 是正定的. 证明: \mathbf{A} 的所有特征值都是正的.

2001-2002-2003-2004-2005-2006-2007-2008-2009-2010-2011-2012-2013-2014-2015-2016-2017-2018-2019-2020-2021-2022-2023-2024-2025-2026-2027-2028-2029-2030-2031-2032-2033-2034-2035-2036-2037-2038-2039-2040-2041-2042-2043-2044-2045-2046-2047-2048-2049-2050-2051-2052-2053-2054-2055-2056-2057-2058-2059-2060-2061-2062-2063-2064-2065-2066-2067-2068-2069-2070-2071-2072-2073-2074-2075-2076-2077-2078-2079-2080-2081-2082-2083-2084-2085-2086-2087-2088-2089-2090-2091-2092-2093-2094-2095-2096-2097-2098-2099-2100-2101-2102-2103-2104-2105-2106-2107-2108-2109-2110-2111-2112-2113-2114-2115-2116-2117-2118-2119-2120-2121-2122-2123-2124-2125-2126-2127-2128-2129-2130-2131-2132-2133-2134-2135-2136-2137-2138-2139-2140-2141-2142-2143-2144-2145-2146-2147-2148-2149-2150-2151-2152-2153-2154-2155-2156-2157-2158-2159-2160-2161-2162-2163-2164-2165-2166-2167-2168-2169-2170-2171-2172-2173-2174-2175-2176-2177-2178-2179-2180-2181-2182-2183-2184-2185-2186-2187-2188-2189-2190-2191-2192-2193-2194-2195-2196-2197-2198-2199-2200-2201-2202-2203-2204-2205-2206-2207-2208-2209-2210-2211-2212-2213-2214-2215-2216-2217-2218-2219-2220-2221-2222-2223-2224-2225-2226-2227-2228-2229-2230-2231-2232-2233-2234-2235-2236-2237-2238-2239-2240-2241-2242-2243-2244-2245-2246-2247-2248-2249-2250-2251-2252-2253-2254-2255-2256-2257-2258-2259-2260-2261-2262-2263-2264-2265-2266-2267-2268-2269-2270-2271-2272-2273-2274-2275-2276-2277-2278-2279-2280-2281-2282-2283-2284-2285-2286-2287-2288-2289-2290-2291-2292-2293-2294-2295-2296-2297-2298-2299-2300-2301-2302-2303-2304-2305-2306-2307-2308-2309-2310-2311-2312-2313-2314-2315-2316-2317-2318-2319-2320-2321-2322-2323-2324-2325-2326-2327-2328-2329-2330-2331-2332-2333-2334-2335-2336-2337-2338-2339-2340-2341-2342-2343-2344-2345-2346-2347-2348-2349-2350-2351-2352-2353-2354-2355-2356-2357-2358-2359-2360-2361-2362-2363-2364-2365-2366-2367-2368-2369-2370-2371-2372-2373-2374-2375-2376-2377-2378-2379-2380-2381-2382-2383-2384-2385-2386-2387-2388-2389-2390-2391-2392-2393-2394-2395-2396-2397-2398-2399-2400-2401-2402-2403-2404-2405-2406-2407-2408-2409-2410-2411-2412-2413-2414-2415-2416-2417-2418-2419-2420-2421-2422-2423-2424-2425-2426-2427-2428-2429-2430-2431-2432-2433-2434-2435-2436-2437-2438-2439-2440-2441-2442-2443-2444-2445-2446-2447-2448-2449-2450-2451-2452-2453-2454-2455-2456-2457-2458-2459-2460-2461-2462-2463-2464-2465-2466-2467-2468-2469-2470-2471-2472-2473-2474-2475-2476-2477-2478-2479-2480-2481-2482-2483-2484-2485-2486-2487-2488-2489-2490-2491-2492-2493-2494-2495-2496-2497-2498-2499-2500-2501-2502-2503-2504-2505-2506-2507-2508-2509-2510-2511-2512-2513-2514-2515-2516-2517-2518-2519-2520-2521-2522-2523-2524-2525-2526-2527-2528-2529-2530-2531-2532-2533-2534-2535-2536-2537-2538-2539-2540-2541-2542-2543-2544-2545-2546-2547-2548-2549-2550-2551-2552-2553-2554-2555-2556-2557-2558-2559-2560-2561-2562-2563-2564-2565-2566-2567-2568-2569-2570-2571-2572-2573-2574-2575-2576-2577-2578-2579-2580-2581-2582-2583-2584-2585-2586-2587-2588-2589-2590-2591-2592-2593-2594-2595-2596-2597-2598-2599-2600-2601-2602-2603-2604-2605-2606-2607-2608-2609-2610-2611-2612-2613-2614-2615-2616-2617-2618-2619-2620-2621-2622-2623-2624-2625-2626-2627-2628-2629-2630-2631-2632-2633-2634-2635-2636-2637-2638-2639-2640-2641-2642-2643-2644-2645-2646-2647-2648-2649-2650-2651-2652-2653-2654-2655-2656-2657-2658-2659-2660-2661-2662-2663-2664-2665-2666-2667-2668-2669-2670-2671-2672-2673-2674-2675-2676-2677-2678-2679-2680-2681-2682-2683-2684-2685-2686-2687-2688-2689-2690-2691-2692-2693-2694-2695-2696-2697-2698-2699-2700-2701-2702-2703-2704-2705-2706-2707-2708-2709-2710-2711-2712-2713-2714-2715-2716-2717-2718-2719-2720-2721-2722-2723-2724-2725-2726-2727-2728-2729-2730-2731-2732-2733-2734-2735-2736-2737-2738-2739-2740-2741-2742-2743-2744-2745-2746-2747-2748-2749-2750-2751-2752-2753-2754-2755-2756-2757-2758-2759-2760-2761-2762-2763-2764-2765-2766-2767-2768-2769-2770-2771-2772-2773-2774-2775-2776-2777-2778-2779-2780-2781-2782-2783-2784-2785-2786-2787-2788-2789-2790-2791-2792-2793-2794-2795-2796-2797-2798-2799-2800-2801-2802-2803-2804-2805-2806-2807-2808-2809-2810-2811-2812-2813-2814-2815-2816-2817-2818-2819

Keywords: child sexual abuse; disclosure; social support

1992, 1993, 1994, 1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025, 2026, 2027, 2028, 2029, 2030, 2031, 2032, 2033, 2034, 2035, 2036, 2037, 2038, 2039, 2040, 2041, 2042, 2043, 2044, 2045, 2046, 2047, 2048, 2049, 2050, 2051, 2052, 2053, 2054, 2055, 2056, 2057, 2058, 2059, 2060, 2061, 2062, 2063, 2064, 2065, 2066, 2067, 2068, 2069, 2070, 2071, 2072, 2073, 2074, 2075, 2076, 2077, 2078, 2079, 2080, 2081, 2082, 2083, 2084, 2085, 2086, 2087, 2088, 2089, 2090, 2091, 2092, 2093, 2094, 2095, 2096, 2097, 2098, 2099, 2100, 2101, 2102, 2103, 2104, 2105, 2106, 2107, 2108, 2109, 2110, 2111, 2112, 2113, 2114, 2115, 2116, 2117, 2118, 2119, 2120, 2121, 2122, 2123, 2124, 2125, 2126, 2127, 2128, 2129, 2130, 2131, 2132, 2133, 2134, 2135, 2136, 2137, 2138, 2139, 2140, 2141, 2142, 2143, 2144, 2145, 2146, 2147, 2148, 2149, 2150, 2151, 2152, 2153, 2154, 2155, 2156, 2157, 2158, 2159, 2160, 2161, 2162, 2163, 2164, 2165, 2166, 2167, 2168, 2169, 2170, 2171, 2172, 2173, 2174, 2175, 2176, 2177, 2178, 2179, 2180, 2181, 2182, 2183, 2184, 2185, 2186, 2187, 2188, 2189, 2190, 2191, 2192, 2193, 2194, 2195, 2196, 2197, 2198, 2199, 2200, 2201, 2202, 2203, 2204, 2205, 2206, 2207, 2208, 2209, 2210, 2211, 2212, 2213, 2214, 2215, 2216, 2217, 2218, 2219, 2220, 2221, 2222, 2223, 2224, 2225, 2226, 2227, 2228, 2229, 2230, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2238, 2239, 2240, 2241, 2242, 2243, 2244, 2245, 2246, 2247, 2248, 2249, 2250, 2251, 2252, 2253, 2254, 2255, 2256, 2257, 2258, 2259, 2260, 2261, 2262, 2263, 2264, 2265, 2266, 2267, 2268, 2269, 2270, 2271, 2272, 2273, 2274, 2275, 2276, 2277, 2278, 2279, 2280, 2281, 2282, 2283, 2284, 2285, 2286, 2287, 2288, 2289, 2290, 2291, 2292, 2293, 2294, 2295, 2296, 2297, 2298, 2299, 2300, 2301, 2302, 2303, 2304, 2305, 2306, 2307, 2308, 2309, 2310, 2311, 2312, 2313, 2314, 2315, 2316, 2317, 2318, 2319, 2320, 2321, 2322, 2323, 2324, 2325, 2326, 2327, 2328, 2329, 2330, 2331, 2332, 2333, 2334, 2335, 2336, 2337, 2338, 2339, 2340, 2341, 2342, 2343, 2344, 2345, 2346, 2347, 2348, 2349, 2350, 2351, 2352, 2353, 2354, 2355, 2356, 2357, 2358, 2359, 2360, 2361, 2362, 2363, 2364, 2365, 2366, 2367, 2368, 2369, 2370, 2371, 2372, 2373, 2374, 2375, 2376, 2377, 2378, 2379, 2380, 2381, 2382, 2383, 2384, 2385, 2386, 2387, 2388, 2389, 2390, 2391, 2392, 2393, 2394, 2395, 2396, 2397, 2398, 2399, 2400, 2401, 2402, 2403, 2404, 2405, 2406, 2407, 2408, 2409, 2410, 2411, 2412, 2413, 2414, 2415, 2416, 2417, 2418, 2419, 2420, 2421, 2422, 2423, 2424, 2425, 2426, 2427, 2428, 2429, 2430, 2431, 2432, 2433, 2434, 2435, 2436, 2437, 2438, 2439, 2440, 2441, 2442, 2443, 2444, 2445, 2446, 2447, 2448, 2449, 2450, 2451, 2452, 2453, 2454, 2455, 2456, 2457, 2458, 2459, 2460, 2461, 2462, 2463, 2464, 2465, 2466, 2467, 2468, 2469, 2470, 2471, 2472, 2473, 2474, 2475, 2476, 2477, 2478, 2479, 2480, 2481, 2482, 2483, 2484, 2485, 2486, 2487, 2488, 2489, 2490, 2491, 2492, 2493, 2494, 2495, 2496, 2497, 2498, 2499, 2500, 2501, 2502, 2503, 2504, 2505, 2506, 2507, 2508, 2509, 2510, 2511, 2512, 2513, 2514, 2515, 2516, 2517, 2518, 2519, 2520, 2521, 2522, 2523, 2524, 2525, 2526, 2527, 2528, 2529, 2530, 2531, 2532, 2533, 2534, 2535, 2536, 2537, 2538, 2539, 2540, 2541, 2542, 2543, 2544, 2545, 2546, 2547, 2548, 2549, 2550, 2551, 2552, 2553, 2554, 2555, 2556, 2557, 2558, 2559, 2560, 2561, 2562, 2563, 2564, 2565, 2566, 2567, 2568, 2569, 2570, 2571, 2572, 2573, 2574, 2575, 2576, 2577, 2578, 2579, 2580, 2581, 2582, 2583, 2584, 2585, 2586, 2587, 2588, 2589, 2590, 2591, 2592, 2593, 2594, 2595, 2596, 2597, 2598, 2599, 2600, 2601, 2602, 2603, 2604, 2605, 2606, 2607, 2608, 2609, 2610, 2611, 2612, 2613, 2614, 2615, 2616, 2617, 2618, 2619, 2620, 2621, 2622, 2623, 2624, 2625, 2626, 2627, 2628, 2629, 2630, 2631, 2632, 2633, 2634, 2635, 2636, 2637, 2638, 2639, 2640, 2641, 2642, 2643, 2644, 2645, 2646, 2647, 2648, 2649, 2650, 2651, 2652, 2653, 2654, 2655, 2656, 2657, 2658, 2659, 2660, 2661, 2662, 2663, 2664, 2665, 2666, 2667, 2668, 2669, 2670, 2671, 2672, 2673, 26

[illegible]

$\frac{1}{2} \leq x \leq 1$, $y = 0$, $z = 0$, $t = 0$, $s = 0$

$\mu_1(\sigma) = \mu_2(\sigma) = \mu_3(\sigma) = 1$ and $\mu_4(\sigma) = \mu_5(\sigma) = \mu_6(\sigma) = \mu_7(\sigma) = \mu_8(\sigma) = \mu_9(\sigma) = \mu_{10}(\sigma) = \mu_{11}(\sigma) = \mu_{12}(\sigma) = \mu_{13}(\sigma) = \mu_{14}(\sigma) = \mu_{15}(\sigma) = \mu_{16}(\sigma) = \mu_{17}(\sigma) = \mu_{18}(\sigma) = \mu_{19}(\sigma) = \mu_{20}(\sigma) = \mu_{21}(\sigma) = \mu_{22}(\sigma) = \mu_{23}(\sigma) = \mu_{24}(\sigma) = \mu_{25}(\sigma) = \mu_{26}(\sigma) = \mu_{27}(\sigma) = \mu_{28}(\sigma) = \mu_{29}(\sigma) = \mu_{30}(\sigma) = \mu_{31}(\sigma) = \mu_{32}(\sigma) = \mu_{33}(\sigma) = \mu_{34}(\sigma) = \mu_{35}(\sigma) = \mu_{36}(\sigma) = \mu_{37}(\sigma) = \mu_{38}(\sigma) = \mu_{39}(\sigma) = \mu_{40}(\sigma) = \mu_{41}(\sigma) = \mu_{42}(\sigma) = \mu_{43}(\sigma) = \mu_{44}(\sigma) = \mu_{45}(\sigma) = \mu_{46}(\sigma) = \mu_{47}(\sigma) = \mu_{48}(\sigma) = \mu_{49}(\sigma) = \mu_{50}(\sigma) = \mu_{51}(\sigma) = \mu_{52}(\sigma) = \mu_{53}(\sigma) = \mu_{54}(\sigma) = \mu_{55}(\sigma) = \mu_{56}(\sigma) = \mu_{57}(\sigma) = \mu_{58}(\sigma) = \mu_{59}(\sigma) = \mu_{60}(\sigma) = \mu_{61}(\sigma) = \mu_{62}(\sigma) = \mu_{63}(\sigma) = \mu_{64}(\sigma) = \mu_{65}(\sigma) = \mu_{66}(\sigma) = \mu_{67}(\sigma) = \mu_{68}(\sigma) = \mu_{69}(\sigma) = \mu_{70}(\sigma) = \mu_{71}(\sigma) = \mu_{72}(\sigma) = \mu_{73}(\sigma) = \mu_{74}(\sigma) = \mu_{75}(\sigma) = \mu_{76}(\sigma) = \mu_{77}(\sigma) = \mu_{78}(\sigma) = \mu_{79}(\sigma) = \mu_{80}(\sigma) = \mu_{81}(\sigma) = \mu_{82}(\sigma) = \mu_{83}(\sigma) = \mu_{84}(\sigma) = \mu_{85}(\sigma) = \mu_{86}(\sigma) = \mu_{87}(\sigma) = \mu_{88}(\sigma) = \mu_{89}(\sigma) = \mu_{90}(\sigma) = \mu_{91}(\sigma) = \mu_{92}(\sigma) = \mu_{93}(\sigma) = \mu_{94}(\sigma) = \mu_{95}(\sigma) = \mu_{96}(\sigma) = \mu_{97}(\sigma) = \mu_{98}(\sigma) = \mu_{99}(\sigma) = \mu_{100}(\sigma) = 1$

$$\frac{1}{2} \left(\frac{1}{2} + \frac{1}{2} \right) = \frac{1}{2}$$
[illegible]

pharmaxis	FM-296-04	Date Effective: 26-Apr-19	Page 1 of 1
MÜLLER BLENDER COLUMN LIFTER (TAG: 00412) CLEANING FORM			

Column Lifter Cleaned After Batch:	Previous Lot Number: <i>EXP 502</i>	Record Lot Number of 70% IPA used (IPA-NNNN) <small>where N is a number</small>	70% IPA Lot Number: <i>IPA - 0492</i>
Completed By / Date:	<i>SR 25 JUL 23</i>		

EQUIPMENT AND MACHINE PARTS	
1.	Surfaces Spray and wipe all external surfaces of the Müller Column Lifter with 70% IPA using the mobile elevating work platform where necessary. Spray and wipe all surfaces of the safety access doors and panels with 70% IPA. Spray and wipe both the operator panels with 70% IPA. Confirm by visual inspection that the external surfaces of the Column Lifter, Safety Doors/ Panels and operator panels are clean and dry. Completed By/ Date: <i>SR 25 JUL 23</i>

2.	EQUIPMENT INSPECTION AND APPROVAL	
	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	The cleaning tag is attached to the equipment.
	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 Manager/Supervisor	
	Completed By/ Date: <i>6 - 25 JUL 23</i>	

Authorisation signature and date: <i>ORA</i> <i>23 Apr 19</i>	Reference: SOP-262
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TB-002-03	

pharmaxis	FM-296-04	Date Effective: 26-Apr-19	Page 1 of 1
MÜLLER BLENDER COLUMN LIFTER (TAG: 00412) CLEANING FORM			

Column Lifter Cleaned After Batch:	Previous Lot Number: EXP 502	Record Lot Number of 70% IPA used (IPA-NNNN) <small>where N is a number</small>	70% IPA Lot Number: IPA-0493
Completed By / Date:	SR08 PUG 23		

EQUIPMENT AND MACHINE PARTS	
1.	Surfaces Spray and wipe all external surfaces of the Müller Column Lifter with 70% IPA using the mobile elevating work platform where necessary. Spray and wipe all surfaces of the safety access doors and panels with 70% IPA. Spray and wipe both the operator panels with 70% IPA. Confirm by visual inspection that the external surfaces of the Column Lifter, Safety Doors/ Panels and operator panels are clean and dry. Completed By/ Date: SR08 PUG 23

2.	EQUIPMENT INSPECTION AND APPROVAL 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	The cleaning tag is attached to the equipment.
	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 Manager/Supervisor Completed By/ Date: <u>SR08 Aug 23</u>	

Authorisation signature and date: <u>SR08 Aug 23</u>	Reference: SOP-262
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TE-002-03	

Date	Description	Amount
1912	To Balance	100.00
1913	By Cash	50.00
1914	To Cash	25.00
1915	By Cash	15.00

The following is a list of the items which have been received from the various sources mentioned in the preceding pages. The items are listed in the order in which they were received, and the amount of each item is given in the right hand column. The total amount of the items is given in the left hand column.

Item	Amount
To Cash	100.00
By Cash	50.00
To Cash	25.00
By Cash	15.00
Total	190.00

The following is a list of the items which have been received from the various sources mentioned in the preceding pages. The items are listed in the order in which they were received, and the amount of each item is given in the right hand column. The total amount of the items is given in the left hand column.

Item	Amount
To Cash	100.00
By Cash	50.00
To Cash	25.00
By Cash	15.00
Total	190.00

pharmaxis	FM-391-04	Date Effective: 16-Jun-22	Page 1 of 1
ROOM CLEARANCE CHECKLIST			
Lot Number: M23-032	Issued By/Date: [Signature] 04 Aug 23		

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: <ul style="list-style-type: none"> Equipment is appropriate to use - cleaning completed as required. Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Equipment is clean & dry (visible inspection only). Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Sanitisation is within the time frame as specified in the PI. Yes <input type="checkbox"/> N/A <input type="checkbox"/> 		✓
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: Room BL018 6-09 Aug 23		
If any of the checks above does not comply, do not proceed with Room Clearance.		
ROOM CLEARANCE COMPLETED BY/DATE: [Signature] 09 Aug 23		

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

Authorisation signature and date: [Signature] 08 Jun 22	Reference: SOP-142
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TE-015-03	

pharmaxis	FM-288-05	Date Effective: 31-Aug-18	Page 1 of 1
FREWITT CONIWITT-150 CONICAL MILL (TAG 00405) CLEANING FORM			

Mill Cleaned after Batch:	Lot Number EYP 502	Lot Number of 70% IPA - (IPA-XXXX):	JPP-0493
Completed By / Date:	SR08AUG23		

EQUIPMENT AND MACHINE PARTS			
1.	Mill Surfaces – External and Internal		
	Cover the electrical plug/cable with a plastic bag (fasten with a cable tie). Avoid direct contact with WFI/IPA.		
	In Wash Bay B1.028, spray WFI into the inlet funnel and up the outlet funnel until all visible mannitol is removed from within the assembled mill housing.		
	Spray the mill's protective casing/enclosure and trolley with WFI until all visible mannitol is removed.		
	Dismantle the Frewitt ConiWitt-150 conical mill as described in SOP-257.		
	Thoroughly spray all minor parts (removed from main body of machine) with WFI until the parts are visually clean. Rinse surfaces again thoroughly with WFI.		
	Spray machine and all parts with 70% IPA and wipe down.		
	Wipe the external surfaces of the mill using a sterile wipe soaked in WFI. Spray and wipe all external surfaces with 70% IPA.		
	Confirm by visual inspection that the machine and all parts are clean. Thoroughly check surfaces of all parts for water marks or any residue.		
Note: Issue individual FM-231 for the Mill and its detachable parts as per SOP-257.			
Completed By:		SR	Date: 08AUG23

2.	EQUIPMENT INSPECTION AND APPROVAL		
	Inspect/check the following:		
	The equipment is visually clean, dry and fit for use.	Equipment parts are visually clean and dry. Ensure that no water marks or any residue on all surfaces.	
	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	Individual cleaning tag(s) attached to the Mill and its detachable parts.	
	Sign below if the checker is fully satisfied that the equipment is clean and fit for use. Report any non-conformities to the Production Manager/Supervisor.		
Completed By:		[Signature]	Date: 08Aug23

Authorisation signature and date:	[Signature] 31 Aug 18	Reference: SOP-257
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TE-002-03		

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— *Journal of the American Medical Association*, 1997

1. 2. 3. 4. 5. 6. 7. 8. 9. 10. 11. 12. 13. 14. 15. 16. 17. 18. 19. 20. 21. 22. 23. 24. 25. 26. 27. 28. 29. 30. 31. 32. 33. 34. 35. 36. 37. 38. 39. 40. 41. 42. 43. 44. 45. 46. 47. 48. 49. 50. 51. 52. 53. 54. 55. 56. 57. 58. 59. 60. 61. 62. 63. 64. 65. 66. 67. 68. 69. 70. 71. 72. 73. 74. 75. 76. 77. 78. 79. 80. 81. 82. 83. 84. 85. 86. 87. 88. 89. 90. 91. 92. 93. 94. 95. 96. 97. 98. 99. 100. 101. 102. 103. 104. 105. 106. 107. 108. 109. 110. 111. 112. 113. 114. 115. 116. 117. 118. 119. 120. 121. 122. 123. 124. 125. 126. 127. 128. 129. 130. 131. 132. 133. 134. 135. 136. 137. 138. 139. 140. 141. 142. 143. 144. 145. 146. 147. 148. 149. 150. 151. 152. 153. 154. 155. 156. 157. 158. 159. 160. 161. 162. 163. 164. 165. 166. 167. 168. 169. 170. 171. 172. 173. 174. 175. 176. 177. 178. 179. 180. 181. 182. 183. 184. 185. 186. 187. 188. 189. 190. 191. 192. 193. 194. 195. 196. 197. 198. 199. 200. 201. 202. 203. 204. 205. 206. 207. 208. 209. 210. 211. 212. 213. 214. 215. 216. 217. 218. 219. 220. 221. 222. 223. 224. 225. 226. 227. 228. 229. 230. 231. 232. 233. 234. 235. 236. 237. 238. 239. 240. 241. 242. 243. 244. 245. 246. 247. 248. 249. 250. 251. 252. 253. 254. 255. 256. 257. 258. 259. 260. 261. 262. 263. 264. 265. 266. 267. 268. 269. 270. 271. 272. 273. 274. 275. 276. 277. 278. 279. 280. 281. 282. 283. 284. 285. 286. 287. 288. 289. 290. 291. 292. 293. 294. 295. 296. 297. 298. 299. 300. 301. 302. 303. 304. 305. 306. 307. 308. 309. 310. 311. 312. 313. 314. 315. 316. 317. 318. 319. 320. 321. 322. 323. 324. 325. 326. 327. 328. 329. 330. 331. 332. 333. 334. 335. 336. 337. 338. 339. 340. 341. 342. 343. 344. 345. 346. 347. 348. 349. 350. 351. 352. 353. 354. 355. 356. 357. 358. 359. 360. 361. 362. 363. 364. 365. 366. 367. 368. 369. 370. 371. 372. 373. 374. 375. 376. 377. 378. 379. 380. 381. 382. 383. 384. 385. 386. 387. 388. 389. 390. 391. 392. 393. 394. 395. 396. 397. 398. 399. 400. 401. 402. 403. 404. 405. 406. 407. 408. 409. 410. 411. 412. 413. 414. 415. 416. 417. 418. 419. 420. 421. 422. 423. 424. 425. 426. 427. 428. 429. 430. 431. 432. 433. 434. 435. 436. 437. 438. 439. 440. 441. 442. 443. 444. 445. 446. 447. 448. 449. 450. 451. 452. 453. 454. 455. 456. 457. 458. 459. 460. 461. 462. 463. 464. 465. 466. 467. 468. 469. 470. 471. 472. 473. 474. 475. 476. 477. 478. 479. 480. 481. 482. 483. 484. 485. 486. 487. 488. 489. 490. 491. 492. 493. 494. 495. 496. 497. 498. 499. 500. 501. 502. 503. 504. 505. 506. 507. 508. 509. 510. 511. 512. 513. 514. 515. 516. 517. 518. 519. 520. 521. 522. 523. 524. 525. 526. 527. 528. 529. 530. 531. 532. 533. 534. 535. 536. 537. 538. 539. 540. 541. 542. 543. 544. 545. 546. 547. 548. 549. 550. 551. 552. 553. 554. 555. 556. 557. 558. 559. 560. 561. 562. 563. 564. 565. 566. 567. 568. 569. 570. 571. 572. 573. 574. 575. 576. 577. 578. 579. 580. 581. 582. 583. 584. 585. 586. 587. 588. 589. 590. 591. 592. 593. 594. 595. 596. 597. 598. 599. 600. 601. 602. 603. 604. 605. 606. 607. 608. 609. 610. 611. 612. 613. 614. 615. 616. 617. 618. 619. 620. 621. 622. 623. 624. 625. 626. 627. 628. 629. 630. 631. 632. 633. 634. 635. 636. 637. 638. 639. 640. 641. 642. 643. 644. 645. 646. 647. 648. 649. 650. 651. 652. 653. 654. 655. 656. 657. 658. 659. 660. 661. 662. 663. 664. 665. 666. 667. 668. 669. 670. 671. 672. 673. 674. 675. 676. 677. 678. 679. 680. 681. 682. 683. 684. 685. 686. 687. 688. 689. 690. 691. 692. 693. 694. 695. 696. 697. 698. 699. 700. 701. 702. 703. 704. 705. 706. 707. 708. 709. 710. 711. 712. 713. 714. 715. 716. 717. 718. 719. 720. 721. 722. 723. 724. 725. 726. 727. 728. 729. 730. 731. 732. 733. 734. 735. 736. 737. 738. 739. 740. 741. 742. 743. 744. 745. 746. 747. 748. 749. 750. 751. 752. 753. 754. 755. 756. 757. 758. 759. 760. 761. 762. 763. 764. 765. 766. 767. 768. 769. 770. 771. 772. 773. 774. 775. 776. 777. 778. 779. 780. 781. 782. 783. 784. 785. 786. 787. 788. 789. 790. 791. 792. 793. 794. 795. 796. 797. 798. 799. 800. 801. 802. 803. 804. 805. 806. 807. 808. 809. 810. 811. 812. 813. 814. 815. 816. 817. 818. 819. 820. 821. 822. 823. 824. 825. 826. 827. 828. 829. 830. 831. 832. 833. 834. 835. 836. 837. 838. 839. 840.

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10. 2009 28 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025 2026 2027 2028 2029 2030 2031 2032 2033 2034 2035 2036 2037 2038 2039 2040 2041 2042 2043 2044 2045 2046 2047 2048 2049 2050 2051 2052 2053 2054 2055 2056 2057 2058 2059 2060 2061 2062 2063 2064 2065 2066 2067 2068 2069 2070 2071 2072 2073 2074 2075 2076 2077 2078 2079 2080 2081 2082 2083 2084 2085 2086 2087 2088 2089 2090 2091 2092 2093 2094 2095 2096 2097 2098 2099 2100 2101 2102 2103 2104 2105 2106 2107 2108 2109 2110 2111 2112 2113 2114 2115 2116 2117 2118 2119 2120 2121 2122 2123 2124 2125 2126 2127 2128 2129 2130 2131 2132 2133 2134 2135 2136 2137 2138 2139 2140 2141 2142 2143 2144 2145 2146 2147 2148 2149 2150 2151 2152 2153 2154 2155 2156 2157 2158 2159 2160 2161 2162 2163 2164 2165 2166 2167 2168 2169 2170 2171 2172 2173 2174 2175 2176 2177 2178 2179 2180 2181 2182 2183 2184 2185 2186 2187 2188 2189 2190 2191 2192 2193 2194 2195 2196 2197 2198 2199 2200 2201 2202 2203 2204 2205 2206 2207 2208 2209 2210 2211 2212 2213 2214 2215 2216 2217 2218 2219 2220 2221 2222 2223 2224 2225 2226 2227 2228 2229 2230 2231 2232 2233 2234 2235 2236 2237 2238 2239 2240 2241 2242 2243 2244 2245 2246 2247 2248 2249 2250 2251 2252 2253 2254 2255 2256 2257 2258 2259 2260 2261 2262 2263 2264 2265 2266 2267 2268 2269 2270 2271 2272 2273 2274 2275 2276 2277 2278 2279 2280 2281 2282 2283 2284 2285 2286 2287 2288 2289 2290 2291 2292 2293 2294 2295 2296 2297 2298 2299 2300 2301 2302 2303 2304 2305 2306 2307 2308 2309 2310 2311 2312 2313 2314 2315 2316 2317 2318 2319 2320 2321 2322 2323 2324 2325 2326 2327 2328 2329 2330 2331 2332 2333 2334 2335 2336 2337 2338 2339 2340 2341 2342 2343 2344 2345 2346 2347 2348 2349 2350 2351 2352 2353 2354 2355 2356 2357 2358 2359 2360 2361 2362 2363 2364 2365 2366 2367 2368 2369 2370 2371 2372 2373 2374 2375 2376 2377 2378 2379 2380 2381 2382 2383 2384 2385 2386 2387 2388 2389 2390 2391 2392 2393 2394 2395 2396 2397 2398 2399 2400 2401 2402 2403 2404 2405 2406 2407 2408 2409 2410 2411 2412 2413 2414 2415 2416 2417 2418 2419 2420 2421 2422 2423 2424 2425 2426 2427 2428 2429 2430 2431 2432 2433 2434 2435 2436 2437 2438 2439 2440 2441 2442 2443 2444 2445 2446 2447 2448 2449 2450 2451 2452 2453 2454 2455 2456 2457 2458 2459 2460 2461 2462 2463 2464 2465 2466 2467 2468 2469 2470 2471 2472 2473 2474 2475 2476 2477 2478 2479 2480 2481 2482 2483 2484 2485 2486 2487 2488 2489 2490 2491 2492 2493 2494 2495 2496 2497 2498 2499 2500 2501 2502 2503 2504 2505 2506 2507 2508 2509 2510 2511 2512 2513 2514 2515 2516 2517 2518 2519 2520 2521 2522 2523 2524 2525 2526 2527 2528 2529 2530 2531 2532 2533 2534 2535 2536 2537 2538 2539 2540 2541 2542 2543 2544 2545 2546 2547 2548 2549 2550 2551 2552 2553 2554 2555 2556 2557 2558 2559 2560 2561 2562 2563 2564 2565 2566 2567 2568 2569 2570 2571 2572 2573 2574 2575 2576 2577 2578 2579 2580 2581 2582 2583 2584 2585 2586 2587 2588 2589 2590 2591 2592 2593 2594 2595 2596 2597 2598 2599 2600 2601 2602 2603 2604 2605 2606 2607 2608 2609 2610 2611 2612 2613 2614 2615 2616 2617 2618 2619 2620 2621 2622 2623 2624 2625 2626 2627 2628 2629 2630 2631 2632 2633 2634 2635 2636 2637 2638 2639 2640 2641 2642 2643 2644 2645 2646 2647 2648 2649 2650 2651 2652 2653 2654 2655 2656 2657 2658 2659 2660 2661 2662 2663 2664 2665 2666 2667 2668 2669 2670 2671 2672 2673 2674 2675 2676 2677 2678 2679 2680 2681 2682 2683 2684 2685 2686 2687 2688 2689 2690 2691 2692 2693 2694 2695 2696 2697 2698 2699 2700 2701 2702 2703 2704 2705 2706 2707 2708 2709 2710 2711 2712 2713 2714 2715 2716 2717 2718 2719 2720 2721 2722 2723 2724 2725 2726 2727 2728 2729 2730 2731 2732 2733 2734 2735 2736 2737 2738 2739 2740 2741 2742 2743 2744 2745 2746 2747 2748 2749 2750 2751 2752 2753 2754 2755 2756 2757 2758 2759 2760 2761 2762 2763 2764 2765 2766 2767 2768 2769 2770 2771 2772 2773 2774 2775 2776 2777 2778 2779 2780 2781 2782 2783 2784 2785 2786 2787 2788 2789 2790 2791 2792 2793 2794 2795 2796 2797 2798 2799 2800 2801 2802 2803 2804 2805 2806 2807 2808 2809 2810 2811 2812 2813 2814 2815 2816 2817 2818 2819 2820 2821 2822 2823 2824 2825 28

(a) The first step in the process of determining the value of the property is to determine the value of the property as if it were sold in the open market. This is done by comparing the property to similar properties that have been sold recently.

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Smallmouth bass (17%) and largemouth bass (14%) had the greatest proportion of young among the age classes in all years (Table 2). Young largemouth bass were more abundant than young smallmouth bass in 1997 and 1998 (Table 2).

They also believe that the world is not a place where people are born to suffer, but a place where people are born to live.

1. *Conductance* is the reciprocal of resistance. It is denoted by G and is measured in Siemens (S).

$$G = \frac{1}{R}$$

1. μ can be extended to a regular probability measure on \mathcal{B} .

2017年1月1日

2000年12月15日

1. The first group of students, who are interested in the study of the history of the country, will be assigned to the first group.

[illegible]

Das Bild zeigt die folgenden Informationen:

The first part of the book is devoted to the study of the properties of the function $f(x)$ which is defined by the equation

polymerization of the monomer in the presence of the initiator.

$$V_{\text{eff}}^{\text{eff}} = 2\pi \int_0^{\infty} V_{\text{eff}}^{\text{eff}}(r) r dr$$

Journal of Management Studies, 19(1), 67-80.

[illegible]

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

EQUIPMENT

| | |
|----------------------|---------------|
| Equipment Name | COLUMN LIFTER |
| Equipment Tag Number | 00412 |

Cleaning Status:

| Type of clean | Completed By | Date |
|--------------------------------------------|--------------|-------------------|
| Minor Clean | | |
| Minor Clean Awaiting Major Clean | | N/A
0808 PM 23 |
| Major Clean | SR | 08 PM 23 |
| Major Clean Approved | GR | 08 Aug 23 |
| Resanitisation?
(Include sign and date) | | N/A
0809 PM 23 |

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Authorisation signature and date: <i>Steph Dally</i> 12 Jul 18 | Reference: SOP-142 |
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| pharmaxis | FM-231-04 | Date Effective:
25-Jul-18 | Page 1 of 1 |
| CLEANING TAG/EQUIPMENT STATUS | | | |

EQUIPMENT

| | |
|----------------------|---------------|
| Equipment Name | COLUMN LIFTER |
| Equipment Tag Number | 00412 |

Cleaning Status:

| Type of clean | Completed By | Date |
|--------------------------------------------|--------------|---------------------------|
| Minor Clean | | |
| Minor Clean Awaiting Major Clean | | N/A
SA 25 JUL 23 |
| Major Clean | SA | 25 JUL 23 |
| Major Clean Approved | G | 25 JUL 23 |
| Resanitisation?
(Include sign and date) | SA | 07 JUL 23
SA 07 JUL 23 |


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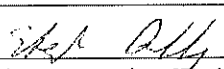
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|-------------------------------|-----------|------------------------------|-------------|
| pharmaxis | FM-231-04 | Date Effective:
25-Jul-18 | Page 1 of 1 |
| CLEANING TAG/EQUIPMENT STATUS | | | |

EQUIPMENT

| | |
|----------------------|--------------|
| Equipment Name | CONICAL MILL |
| Equipment Tag Number | 00405 |

Cleaning Status:

| Type of clean | Completed By | Date |
|--------------------------------------------|-------------------------------------------------------------------------------------|---------------------|
| Minor Clean | | |
| Minor Clean Awaiting Major Clean | | N/A
SR 25 JUL 23 |
| Major Clean | SR | 25 JUL 23 |
| Major Clean Approved |  | 26 JUL 23 |
| Resanitisation?
(Include sign and date) | SR | 07 AUG 23 |

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|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Authorisation signature and date:  12 Jul 18 | Reference: SOP-142 |
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|-------------------------------|-----------|------------------------------|-------------|
| pharmaxis | FM-231-04 | Date Effective:
25-Jul-18 | Page 1 of 1 |
| CLEANING TAG/EQUIPMENT STATUS | | | |

EQUIPMENT

| | |
|----------------------|--------------|
| Equipment Name | CONICPL MILL |
| Equipment Tag Number | 00405 |

Cleaning Status:

| Type of clean | Completed By | Date |
|--------------------------------------------|--------------|-----------------|
| Minor Clean | | |
| Minor Clean Awaiting Major Clean | | N/A
08.08.23 |
| Major Clean | SR | 08 Aug 23 |
| Major Clean Approved | 67 | 08 Aug 23 |
| Resanitisation?
(Include sign and date) | | N/A
08.09.23 |

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

EQUIPMENT

| | |
|----------------------|--------------------------------------------------|
| Equipment Name | MULLER BLENDER / FROE WITT
CONICAL MILL PARTS |
| Equipment Tag Number | 00412/00405 |

Cleaning Status:

| Type of clean | Completed By | Date |
|--------------------------------------------|--------------|------------------|
| Minor Clean | | |
| Minor Clean Awaiting
Major Clean | | NB
30226JUL23 |
| Major Clean | SR | 26JUL23 |
| Major Clean Approved | LS | 26 JUL 23 |
| Resanitisation?
(Include sign and date) | SR | 07 AUG 23 |

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

EQUIPMENT

| | |
|----------------------|-------------------------------------------|
| Equipment Name | MULLER BLENDER / FREWITT
CONICAL PARTS |
| Equipment Tag Number | 00412 / 00405 |

Cleaning Status:

| Type of clean | Completed By | Date |
|--------------------------------------------|--------------|------------------|
| Minor Clean | / | |
| Minor Clean Awaiting
Major Clean | | N/A
08 AUG 23 |
| Major Clean | SB | 08 AUG 23 |
| Major Clean Approved | G | 08 AUG 23 |
| Resanitisation?
(Include sign and date) | / | |
| | | N/A
08 AUG 23 |

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Authorisation signature and date: <i>Shah Ally 12 Jul 18</i> | Reference: SOP-142 |
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|-------------------------------|-----------|------------------------------|-------------|
| pharmaxis | FM-231-04 | Date Effective:
25-Jul-18 | Page 1 of 1 |
| CLEANING TAG/EQUIPMENT STATUS | | | |

EQUIPMENT

| | |
|----------------------|-----------|
| Equipment Name | IBC 350kg |
| Equipment Tag Number | 00410 |

Cleaning Status:

| Type of clean | Completed By | Date |
|--------------------------------------------|--------------|------------------|
| Minor Clean | | |
| Minor Clean Awaiting Major Clean | | |
| Major Clean | LM | 07 Aug 23 |
| Major Clean Approved | SR | 07 Aug 23 |
| Resanitisation?
(Include sign and date) | | N/A
02 Oct 23 |

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Authorisation signature and date: <i>John Duff</i> 12 Jul 18 | Reference: SOP-142 |
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| TE-002-03 | |

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4. August 2023

Production Order - Job Card

Pharmaxis Master Data

Page 1

RowenaG

Production Order

Prod. Order No. 23/076
Status Released

Item Spray Dried Mannitol Blend #20
Item No. 200037
SP No. SP-504-09
Lot No. M23-032

Starting Date 26/12/18
Starting Time 7:45:36 AM
Ending Date 31/12/18
Ending Time 2:00:00 PM

Expected Quantity 56,000 Gram
Output Bin Code 20-G1ACLEAN ROOM ST

Routing

Routing No. SP-504

Operation No. 10
Type Work Center
No. B1.018
Description Blending Room
Time Needed 30.24 HR

Material Requirements

| Item No. | SP No. | Item | Expected Quantity | Unit of Measure Code | Consumed Quantity | Lot No. | Bin Code |
|----------|-----------|------------------------------|-------------------|----------------------|-------------------|---------|----------|
| 200027 | SP-503-06 | Spray Dried Mannitol PSD-5-N | 58,110 | G | | | |

Output

Gross Output _____ Gram
Samples _____ Gram
Net Output _____ Gram

Operator: RAJS
Batch No: M23-032
Blend Time: 00:10:00 Speed: 15
09.08.2023 10:40:39

Operator: RAJS
Batch No: M23-032
Blend Time: 00:10:00 Speed: 15
09.08.2023 10:40:39