



Document:	MC/TTH1234/01.0		
Batch Number:	W071548	Process Order:	071548

MASTER BATCH RECORD

MC 1108 Coated Oral Granules	Issued by Initials/Date
	<i>Ryw</i> 20 Feb 2024

1. BATCH DETAILS

Product Code	Theoretical Master Batch Size	Product ID
100245	19.991 kg	JL019374

2. BATCH FORMULATION

Component	Component Code	Quantity per Sub-lot (kg)	Performed by Initials/Date	Checked by Initials/Date
MC1108 Oral Granule Cores	HQ00075	<i>Ryw</i> 0.8 1.1 (CC ₁)	<i>Ryw</i> 01 Mar 2024 (FD Scientist)	<i>h</i> 1 ~ 2 (Group Leader)
		<i>Ryw</i> 0.9 1.5 (CC ₂)		
		<i>Ryw</i> 0.7 1.5 (CC ₃)		
Rosabella II Rose - 39R220021	HQ00029	177	N/A	N/A
Purified Water Ph.Eur/USP-NF (10L Container) or Purified Water USP/JP/EP	HQ00081 HQ00003	20.400	<i>Lmc</i> 01 Mar 2024	<i>JL</i> 01 Mar 2024
• The quantities for CC ₁ , CC ₂ and CC ₃ will be assigned based on the quantities of MC1108 Oral Granule Cores available.				

PWA 1-8 Follow instruction on Batch Board	Low Humidity Requirement Coating – YES Recombination – YES (Refer to section 0 for humidity requirements for Recombination).	Cold Chain Product NO
Complete SOF/1029 to activate low humidity conditions for the Coating process (≤25.0% RH).		Performed by Initials/Date <i>WAB</i> 01 Mar 2024



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3. DOCUMENTATION REVIEW

This product has been manufactured in accordance with Good Pharmaceutical Manufacturing Practice. Refer to any deviation reports, change requests, etc below (if none, state none).

CR - 2024 - 0871

CR - 2024 - 0870

reference missed in report 27 Feb 2024

Reviewer	Performed by Initials/Date
Manufacturing	PKE 24 Feb 2024
Quality Assurance	JKV 3 Mar 2024



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4. OPERATOR LIST

The Personnel listed below are signing to confirm they have been trained on this MBR, the SOP's and procedures that are appropriate to the tasks they have performed during this process.

Name (Block Capitals)	Signature	Initials	Date
JASPER COLIN		J C	28 Feb 2024
LEANNE MULLINS		LM	28 Feb 2024
HANNA POPSON		HP	28 Feb 2024
MICHAEL QUANDRY		MQ	28 Feb 2024
JIMMY LOKOVO		JL	28 Feb 2024
GEORGE XAVIER		GX	28 Feb 2024
ULYSSES JONES		UJ	01 Mar 2024
ALICE CHUDARO		AC	01 Mar 2024
KELLY OPUNMAN		KO	01 Mar 2024
CHARLES SNARKEY		CS	01 Mar 2024
JOHN LOXSON		JL	03 Mar 2024
KARL ALOINE		KA	03 Mar 2024
PATRICIA CARQUET		PC	06 Mar 2024
MELANIE CHRISTIAN		MC	06 Mar 2024
PAUL DUDD		PD	07 Mar 2024
BRIAN JOHNSON		BJ	07 Mar 2024
ANNIKA PATEL		AP	07 Mar 2024
XI YU		XY	08 Mar 2024
LARRY SMITH		LS	08 Mar 2024
TYLER PASS		TP	08 Mar 2024
TRACY STACY		TS	08 Mar 2024
BYRON JACKSON		BJ	09 Mar 2024

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5. Event Log

Time	Event Number	Section Reference	Event Initials/Date	Reason/Impact Assessment Initials/Date
15:00	01	W1 SECTION 124, 224 & 324	Hand amendment Made for head cold instruction HM 22 FEB 2024	EE HM 22 FEB 2024 SEE CR-2024-0871 HM 22 FEB 2024
10:35	02	W1 SECTION 6.1	Blue 09 room used for dispensing roseanna AH 01 MAR 2024	Additional room used For dispensing roseanna. No impact to batch 06 MAR 2024
10:40	03	W1 SECTION 7	Balance used for Roseanna dispensing: Plant No. 81/754/209 Calibration due: Apr 2024 01 Mar 2024	Additional balance used. No room for Equipment List. No impact to batch. 07 Mar 2024
09:33	04	Page 29 of 145 Step 12- 7 #8.2	Inlet air flow unstable due to fault. Pre-warming stopped. Engineering informed to resolve fault. Extra pages to be ordered + Roseanna to be re-disseised for sublot 1. 02 mar 2024	Issue fixed by Engineering Ref U2024/10/8273 10 Mar 2024
IMPACT ASSESSMENT TO BE UNDERTAKEN BY SCIENTIST (OR MORE SENIOR MEMBER OF F&D TEAM OR OPERATIONS TEAM)				



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6. AREA/EQUIPMENT CHECKS – DISPENSING OF COATING MATERIAL AND ORAL GRANULE CORES

Instructions			Performed by Initials/Date
	Record the Room No.(s) to be used.	Blue B	PFS 28 Feb 2024
	<ul style="list-style-type: none">Enter the batch details into the Room & Equipment Logbooks & verify that the room(s) and equipment are clean by checking the cleaning Logbooks and ensure that they are all within expiration date.Enter details onto board outside room as per SOP/FD/GEN005.Place the appropriate Area Exposure Risk Board on outside of door.Check the Balance Logbooks and ensure that the balances are level and that calibration checks have been carried out in accordance with SOP/PDN/EQU001.Check cleanliness of all materials and consumables, record check on MSD ID Sheet.Complete MSD ID sheet and perform TROPOS transactions as per SOP/TROP/GEN083.Move the Coating material to the processing room.		



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7. EQUIPMENT LIST – DISPENSING OF COATING MATERIAL

Equipment Description	SOP Reference	Plant No. OR Unique Ref.	Calibration Due Date	Performed by Initials/Date
Balance(s)	SOP/PDN/EQU002 SOP/FD/EQU027 SOP/FD/EQU201	2971602931 9281729342	Jul 2023 06 Mar 2024	LMZ 28 Feb 2024

*SEE EVENT 03 ON PAGE 4 OF 145 AW 01 MAR 2024

Instructions		Performed by Initials/Date
Confirm that all equipment listed above is within its calibration due date and will remain within calibration for the duration of the batch and that all equipment is set up correctly.		LMZ 28 Feb 2024

Contamination of additional Equipment in event 3
JS 24 Feb 2024

LIST OF CONSUMABLES

RECORD THE ITEM CODES AND DESCRIPTIONS OF ANY CONSUMABLE ITEMS USED E.G. DISPOSABLE SCOOPS, POLYETHYLENE BAGS.

LOT NUMBERS ARE ONLY REQUIRED FOR POLYETHYLENE BAGS.

Item Code	Material Description	Lot Number	Performed by Initials/Date
NJ2534	250 mL scoop	K102837	LMZ 28 Feb 2024
NP054	medium bags	K102938	LMZ 28 Feb 2024
NP053	Large polybag	K263474	LMZ 28 Feb 2024
NJ2533	300 mL scoop	K019293	LMZ 28 Feb 2024
NJ2532	1000 mL scoop	K672782	RW 02 Mar 2024
NP056	large polybag	K839442	RW 02 Mar 2024
NJ2552	yellow pots	K837492	LMZ 28 Feb 2024



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8. DISPENSING

DISPENSING OF ROSABELLA

8.1.1 SUB LOT 1

**Rosabella II Rose - 39R220021
LQ0971**

Quantity to Dispense 3.600 kg (A₁)

Transfer the material to the weighing area. Weigh the required quantity into a double lined clean, dry polyethylene bag, labelled with the sub lot number. Print a weight ticket and attach below.

MEDICORE PHARMA PBK989 P/N 29/701/023	
DATE	01/Mar/2024
TIME	11:02:06
GROSS	2.745 kg
NET	1.857 kg
TARE	2.984 kg
PRODUCT	ROSABELLA ROSE
W.O.	071548
CODE No.	RM2664
BATCH No.	G165632
SCALE1	
QW 01 Mar 2024	

Performed by Initials/Date	Witnessed and Checked by Initials/Date
QW 01 Mar 2024	BU 01 MAR 2024



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8.1.2 SUB LOT 2

**Rosabella II Rose - 39R220021
LQ0971**

Quantity to Dispense 3.600 kg (A₂)

Transfer the material to the weighing area. Weigh the required quantity into a double lined clean, dry polyethylene bag, labelled with the sub lot number. Print a weight ticket and attach below.

MEDICORE PHARMA		01/Mar/2024		3.205 kg	ROSABELLA ROSE	071548	RM2664	G165632	QW 01 Mar 2024	
PBK989 P/N 29/701/013		15:49:09	2.634 kg	W.O.		CODE No.	BATCH No.			
DATE	TIME	GROSS	TARE	PRODUCT		W.O.	CODE No.	BATCH No.		
		NET								
					ROSABELLA ROSE	W.O.	CODE No.	BATCH No.		
						071548	RM2664	G165632		

Performed by
Initials/Date

QW 01 Mar 2024

Witnessed and Checked by
Initials/Date

BU 01 MAR 2024



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8.1.3 SUB LOT 3

Rosabella II Rose - 39R220021 LQ0971 Quantity to Dispense 3.600 kg (A₃)

Transfer the material to the weighing area. Weigh the required quantity into a double lined clean, dry polyethylene bag, labelled with the sub lot number. Print a weight ticket and attach below.

MEDICORE PHARMA PBK989 P/N 29/701/013	
DATE	01/Mar/2024
TIME	15:49:09
GROSS	3.205 kg
NET	2.634 kg
TARE	3.733 kg
PRODUCT	ROSABELLA ROSE
W.O.	071548
CODE No.	RM2664
BATCH No.	G165632
SCALE1	
QW 01 Mar 2024	

Performed by Initials/Date	Witnessed and Checked by Initials/Date
QW 01 Mar 2024	BU 01 MAR 2024



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Instructions		Performed by Initials/Date	Checked by Initials/Date
	<p>Calculate the quantity of Rosabella II Rose - 39R220021 (LQ0971) dispensed by performing the calculation below.</p> $A = A_1 + A_2 + A_3$ <p>A₁: Ref to Section 8.1.1 A₂: Ref to Section 8.1.2 A₃: Ref to Section 8.1.3</p>	<p><u>18.011</u> kg (A) (3 decimal places)</p>	<p>QW 01 MAR 2024</p> <p>BU 01 MAR 2024</p>