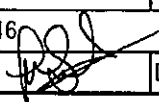


18-C

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT: Batch Manufacture Record		
ITEM: Sunadine Syrup	PREP BY: AZMI	DATE: 21/09/2016
REMARKS: -	EFFECTIVE DATE: 21/09/2016	
-	APPR BY: SIU ANN LIM 	DATE: 21/09/2016

Item : **Sunadine Syrup**Registration No : BRU10020414P MAL20034603AZ

Product Code : 331

Production Ticket No : MS17-1065


Batch No : 331-18002

Mfg Date : 19 JAN 2018

Expiry Date : DEC 2020

Batch Size : 900L

Shelf Life : 3 Years

Verified By : 

Date : 18/01/18

Production Ticket No.:

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT : B.M.R. content Page**ITEM : Sunadine Syrup****PREP BY : AZMI****DATE : 21/02/2017****REMARKS :****EFFECTIVE DATE : 21/02/2017****APPR BY : SIU ANN LIM****DATE : 21/02/2017**

No.	Description				
1	Cover Page	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
2	B.M.R. Content Page	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
3	B.M.R. Checklist	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
4	Product Information Page	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
5	Formulation	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
6	Area Checklist	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
7	Batch weighing Record	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
8	Special Precautions and Remarks	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
9	Cover page: Mixing	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
10	Wet Lab Checklist: Work Area Check and Equipment Check	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
11	Wet Lab Procedure	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
12	Wet Lab QC Report	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
13	Cover page: Primary Packing	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
14	Wet Lab Checklist: Work Area Check and Equipment Check	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
15	Bottle Cleaning	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
16	Syrup Filling and Capping Procedures	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
17	Label, Hologram and Leaflet Requisition Form	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
18	Brought Forward Label, Hologram and Leaflet Requisition Form	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
19	Reference / Approved Label	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
20	Reference / Approved Leaflet	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
21	Cover page: Secondary Packing	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
22	Packing Checklist	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
23	Packing Job Specifications	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
24	Packing Report	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
25	Packaging Materials Reconciliation	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
26	Physical Check on Packed Products	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
27	Approval for Release	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
28	QC Analytical Report	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
29	Manufacturing Manpower Record	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
30	Signature List	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO
31	FPDA / Quarantine Record	<input checked="" type="checkbox"/>	YES	<input type="checkbox"/>	NO

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT : B.M.R. Checklist	
ITEM : Sunadine Syrup	PREP BY : AZMI
REMARKS : -	DATE : 04/08/2017
	EFFECTIVE DATE : 04/08/2017
	APPR BY : AZHAN DAUD <i>[Signature]</i>
	DATE : 04/08/2017

PRODUCT APPROVAL FOR RELEASE (QUALITY ASSURANCE CHECKLIST)

No.	Details	Status
1	Batch record and all attached forms are current and approved	<input checked="" type="checkbox"/>
2	All batch records are signed properly and complying all parameters as per manufacturing instructions	<input checked="" type="checkbox"/>
3	Specified and released components are used in manufacturing	<input checked="" type="checkbox"/>
4	Specified quantities of components are used in manufacturing	<input checked="" type="checkbox"/>
5	Specified product is packed	<input checked="" type="checkbox"/>
6	Specified packaging components are used	<input checked="" type="checkbox"/>
7	Labelling bears the specified control number and product information	<input checked="" type="checkbox"/>
8	Yields are within the limits	<input checked="" type="checkbox"/>
9	In-process results and finished product results are within the specifications	<input checked="" type="checkbox"/>
10	Verify final process testing results	<input checked="" type="checkbox"/>
11	Retention samples and Stability samples as appropriate are taken	<input checked="" type="checkbox"/>
12	All deviations including OOS investigations associated with the batch are closed and listed below. All remedial actions have been performed.	<input checked="" type="checkbox"/>
13	Changes related to the batch are approved and the recommendations in change control request are compiled.	<input checked="" type="checkbox"/>
14	All utilities are within specifications	<input checked="" type="checkbox"/>
15	Process parameters end point (e.g. blending time, compression speed etc.) are within the limits specified in manufacturing instructions	<input checked="" type="checkbox"/>
16	Batch production record is complete and signed by appropriate Production and Quality Control personnel.	<input checked="" type="checkbox"/>
(✓) Correct/Complete and Available (NA) Not Applicable		
List of all Deviations, OOS Investigations and Change Controls		
- NA -		
This batch has been manufactured and tested in compliance with the current good manufacturing practices and conforms to specifications. The batch processing, packaging and analysis records were reviewed and found to be in compliance with current good manufacturing practices.		<input checked="" type="checkbox"/>
Approved		<input checked="" type="checkbox"/>
Rejected		<input type="checkbox"/>
Authorised By:	SITI AYUNI NORDAIDA KHAIR	
Signature:	<i>[Signature]</i>	
Date:	01/02/18	

Production Ticket No.:

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT : **Product Informations**

ITEM : Sunadine Syrup

PREP BY : AZMI

DATE : 21/09/2016

REMARKS :

EFFECTIVE DATE : 21/09/2016

APPR BY : SIU ANN LIM

DATE : 21/09/2016

PRODUCT INFORMATION

NAME OF PRODUCT :

Sunadine Syrup

ACTIVE INGREDIENTS :

Loratadine 5mg / 5ml

REGISTRATION STATUS :

Country	Reg. No.	Country	Reg. No.
Singapore	--	Hong Kong	--
Malaysia	MAL20034603AZ	Myanmar	--
Brunei	BRU10020414P		

DESCRIPTION :

A clear, colourless syrup with peach flavour.

PACKING :

(I) PACK SIZE : 60ml, 100ml, 120ml, 1L

(II) PACKING MATERIAL :

Amber Glass 60 ml

YES

Amber PET 60 ml

YES

Amber Glass 100 ml

YES

Amber PET 100 ml

YES

Amber Glass 120 ml

YES

Amber PET 120 ml

YES

Amber Glass 1 Litre

YES

STORAGE :

Store at temperature 25°C

Protect from light.

SHELF LIFE :

3 Years

THEORETICAL YIELD : 98 - 102 %

Production Ticket No.:

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT : Batch Manufacture Record**ITEM :** Sunadine Syrup**PREP BY :** AZMI**DATE :** 21/09/2016**REMARKS :** -**EFFECTIVE DATE :** 21/09/2016**APPR BY :** SIU ANN LIM**DATE :** 21/09/2016**Completion :** 19/01/18**QC No :** 200 801066 /**FORMULATION**

Materials	Unit Weight 5 ml	Excess (%)
Loratadine (Micronised)	5 mg	5
Propylene glycol	0.3 ml	--
Glycerin	1.5 ml	--
Citric Acid Anhydrous	55 mg	--
Sodium benzoate	6.4 mg	--
Peach PCA 5019 Flavour	0.01 ml	--
Liquid Sorbitol 70%	1.5 ml	--
Spirit chloroform	0.1 ml	--
Coarse Sugar	0.98 g	--
Deionised water to	5 ml	--

Description : A clear, colourless syrup with peach flavour.**Expiry Date on Label:** 3 Years from the date of manufacture.**Approved by :****Date :**

21/09/16

Issued by :**Date :**

13/01/18

MS17-1065

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT: Batch Manufacture Record**ITEM: Sunadine Syrup****PREP BY: AZMI****DATE: 13/04/2017****REMARKS:****EFFECTIVE DATE: 13/04/2017****APPR BY: SIU ANN LIM****DATE: 13/04/2017****AREA Checklist****GMP Checklist: DISPENSING**

	Weighing Checklist	Tick (✓) where appropriate		Sign		Date	Sign
				Dispensing Personnel	Dispensing Supervisor		IPQA / Prodn. Pharmacist
Weighing Area Check	All materials from previous batch are removed	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<i>[Signature]</i>	<i>[Signature]</i>	13/01/18	<i>[Signature]</i>
	Room is properly labelled	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<i>[Signature]</i>	<i>[Signature]</i>	13/01/18	<i>[Signature]</i>
	Weighing equipment are cleaned and calibrated	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<i>[Signature]</i>	<i>[Signature]</i>	13/01/18	<i>[Signature]</i>
	Status of dispensing booth	<input checked="" type="checkbox"/> Clean	<input type="checkbox"/> Unclean	<i>[Signature]</i>	<i>[Signature]</i>	13/01/18	<i>[Signature]</i>
	Room temperature (not more than 25°C)	21°C		<i>[Signature]</i>	<i>[Signature]</i>	13/01/18	<i>[Signature]</i>
	Room relative humidity (not more than 70%)	67%	NA	<i>[Signature]</i>	<i>[Signature]</i>	13/01/18	<i>[Signature]</i>
	Magnehelic pressure gauge reading (not more than 374 pascal / 1.5 W.C.)	0.3 mWC		<i>[Signature]</i>	<i>[Signature]</i>	13/01/18	<i>[Signature]</i>

Note: Status of the weighing room must be fully comply before any weighing can be carried out.

	Description	Serial No.	Weighing range	Tick (✓) where appropriate	Calibration expiry date	Sign	Date	Sign
						Dispensing Personnel		IPQA / Prodn. Pharmacist
Equipment Check	Dispensing booth LOT 1P	MC-00-001		✓	01/03/18	<i>[Signature]</i>	13/01/18	<i>[Signature]</i>
	Balance name: SHIMADZU UX3200 G	0161700170	< 3000gm	✓	05/01/19	<i>[Signature]</i>	13/01/18	<i>[Signature]</i>
	Balance name: AND GP-30 F	11702520	> 3000gm	✓	05/01/19	<i>[Signature]</i>	13/01/18	<i>[Signature]</i>
	Balance name:				NA			
	Balance name:				NA			

Note: Performance check of each electronic balance must be done every working day before commencement of dispensing activity. (Refer to SOP/SA/05001). Fill in the Performance Check Record.

IPQA / Production Pharmacist :



Approve



Not Approve

Date:

[Signature] 12/01/18

Remarks:

NA

Sunward Pharmaceutical Sdn Bhd

9 Jalan Kempas Empat Taman Perindustrian Tampoi Indah Tampoi Johor Bahru, 81200 Malaysia

Batch Weighing Record

Prod. Order No. MS17-1065-2-MIX1

Replan Ref MS17-1065
No.:

Description Sunadine Syrup Mixing

Batch Size 900 LTR or 900L

Item No.	Description	Theoretical Weight	Units	QC Ref. No.	Actual Weight	Units	Weight by Signed & Date	Check By / Date
								QC
MAT0241	Peach PCA 5019 Flavour	1,870.000	GM	RMJ1609021	1870 g	GM	↓ 13/01/18	↓ 13/01/18
MAT-NP-0066	Citric Acid Anhydrous	9,900.000	GM	RMJ1710022	9900g	GM	↓ 13/01/18	↓ 13/01/18
MAT-NP-0039	Sugar - Coarse Sugar	176.400	KG	RMJ1801006	26.4 kg + 50kg x 3	KG	↓ 13/01/18	↓ 13/01/18
MAT-NP-0076	Glycerine	337.500	KG	RMJ1710003	33.5 kg x 15	KG	↓ 16/01/18	↓ 16/01/18
MAT-NP-0084	Liquid Sorbitol 70%	351.000	KG	RMJ1711053	33.4 kg x 15	KG	↓ 13/01/18	↓ 12/01/18
MAT-NP-0092	Propylene Glycol	56.160	KG	RMJ1712007	18.72 kg x 3	KG	↓ 15/01/18	↓ 15/01/18
MAT-NP-0095	Sodium Benzoate	1,152.000	GM	RMJ1711040	1152 g	GM	↓ 13/01/18	↓ 13/01/18
MAT-NP-0233	Spirit Chloroform	15.408	KG	RMJ1710022	15.408 kg	KG	↓ 15/01/18	↓ 15/01/18
MAT-PP-0180	Loratadine (Micronised)	945.000	GM	RMJ1705029	945 g	GM	↓ 13/01/18	↓ 13/01/18

Sunadine Syrup

Raw Material : Sugar - Coarse Sugar
Net Weight : 50kg
Q.C No : RMJ 1801006
Ticket/ B. No : MS17-1065
Weighing date : 13/01/18
Weighed By : Checked by:

Sunadine Syrup

Raw Material : Sugar - Coarse Sugar
Net Weight : 50kg
Q.C No : RMJ 1801006
Ticket/ B. No : MS17-1065
Weighing date : 13/01/18
Weighed By : Checked by:

Raw Material : Spirit Chloroform
Net Weight : 15.408 kg
Q.C No : RMJ 1710042
Ticket/ B. No : MS17-1065
Weighing date : 15/01/18
Weighed By : Checked by:

Raw Material : Propylene Glycol
Net Weight : 18.72 kg
Q.C No : RMJ 1710007
Ticket/ B. No : MS17-1065
Weighing date : 15/01/18
Weighed By : Checked by:

Raw Material : Propylene Glycol
Net Weight : 18.72 kg
Q.C No : RMJ 1710007
Ticket/ B. No : MS17-1065
Weighing date : 15/01/18
Weighed By : Checked by:

Raw Material : Propylene Glycol
Net Weight : 18.72 kg
Q.C No : RMJ 1710007
Ticket/ B. No : MS17-1065
Weighing date : 15/01/18
Weighed By : Checked by:

Sunadine Syrup

Raw Material : Liquid Sorbitol 70%
Net Weight : 23.1 kg
Q.C No : RMJ 1711053
Ticket/ B. No : MS17-1065
Weighing date : 13/01/18
Weighed By : Checked by:

Sunadine Syrup

Raw Material : Liquid Sorbitol 70%
Net Weight : 23.1 kg
Q.C No : RMJ 1711053
Ticket/ B. No : MS17-1065
Weighing date : 13/01/18
Weighed By : Checked by:

Raw Material : Liquid Sorbitol 70%
Net Weight : 23.1 kg
Q.C No : RMJ 1711053
Ticket/ B. No : MS17-1065
Weighing date : 13/01/18
Weighed By : Checked by:

Raw Material : Liquid Sorbitol 70%
Net Weight : 23.1 kg
Q.C No : RMJ 1711053
Ticket/ B. No : MS17-1065
Weighing date : 13/01/18
Weighed By : Checked by:

Raw Material : Liquid Sorbitol 70%
Net Weight : 23.1 kg
Q.C No : RMJ 1711053
Ticket/ B. No : MS17-1065
Weighing date : 13/01/18
Weighed By : Checked by:

Raw Material : Liquid Sorbitol 70%
Net Weight : 23.1 kg
Q.C No : RMJ 1711053
Ticket/ B. No : MS17-1065
Weighing date : 13/01/18
Weighed By : Checked by:

Sunadine Syrup

Raw Material : Peach PCA 5019 Flavour
Net Weight : 1870g
Q.C No : RMJ1609021
Ticket/ B. No : MS17-1065
Weighing date : 13 / 01 / 18
Weighed By : J Checked by: D

Sunadine Syrup



Raw Material : Sodium Benzoate
Net Weight : 1150g
Q.C No : RMJ1711040
Ticket/ B. No : MS17-1065
Weighing date : 13 / 01 / 18
Weighed By : J Checked by: D



Raw Material : Citric Acid Anhydrous
Net Weight : 9900g
Q.C No : RMJ1710022
Ticket/ B. No : MS17-1065
Weighing date : 13 / 01 / 18
Weighed By : J Checked by: D



Raw Material : Sugar - Coarse Sugar
Net Weight : 26.4 kg
Q.C No : RMJ1801006
Ticket/ B. No : MS17-1065
Weighing date : 13 / 01 / 18
Weighed By : J Checked by: D



Raw Material : Loratadine (Micronised)
Net Weight : 945g
Q.C No : RMJ1705039
Ticket/ B. No : MS17-1065
Weighing date : 13 / 01 / 18
Weighed By : J Checked by: D



Raw Material : Sugar - Coarse Sugar
Net Weight : 50kg
Q.C No : RMJ1801006
Ticket/ B. No : MS17-1065
Weighing date : 13 / 01 / 18
Weighed By : J Checked by: D



Sunadine Syrup	
Raw Material	: Glycerine
Net Weight	: 22.5 kg
Q.C No	: RMJ 1712003
Ticket/ B. No	: MS17-1065
Weighing date	: 16/01/18
Weighed By	:  Checked by: 



Sunadine Syrup	
Raw Material	: Glycerine
Net Weight	: 22.5 kg
Q.C No	: RMJ 1712003
Ticket/ B. No	: MS17-1065
Weighing date	: 16/01/18
Weighed By	:  Checked by: 



Raw Material	: Glycerine
Net Weight	: 22.5 kg
Q.C No	: RMJ 1712003
Ticket/ B. No	: MS17-1065
Weighing date	: 16/01/18
Weighed By	:  Checked by: 



Raw Material	: Glycerine
Net Weight	: 22.5 kg
Q.C No	: RMJ 1712003
Ticket/ B. No	: MS17-1065
Weighing date	: 16/01/18
Weighed By	:  Checked by: 



Raw Material	: Glycerine
Net Weight	: 22.5 kg
Q.C No	: RMJ 1712003
Ticket/ B. No	: MS17-1065
Weighing date	: 16/01/18
Weighed By	:  Checked by: 



Raw Material	: Glycerine
Net Weight	: 22.5 kg
Q.C No	: RMJ 1712003
Ticket/ B. No	: MS17-1065
Weighing date	: 16/01/18
Weighed By	:  Checked by: 



Sunadine Syrup	
Raw Material	: Glycerine
Net Weight	: 22.5 kg
Q.C No	: RMJ 1712003
Ticket/ B. No	: MS17-1065
Weighing date	: 16/01/18
Weighed By	:  Checked by: 

Sunadine Syrup	
Raw Material	: Glycerine
Net Weight	: 22.5 kg
Q.C No	: RMJ 1712003
Ticket/ B. No	: MS17-1065
Weighing date	: 16/01/18
Weighed By	:  Checked by: 

Raw Material	: Glycerine
Net Weight	: 22.5 kg
Q.C No	: RMJ 1712003
Ticket/ B. No	: MS17-1065
Weighing date	: 16/01/18
Weighed By	:  Checked by: 

Raw Material	: Glycerine
Net Weight	: 22.5 kg
Q.C No	: RMJ 1712003
Ticket/ B. No	: MS17-1065
Weighing date	: 16/01/18
Weighed By	:  Checked by: 

Raw Material	: Glycerine
Net Weight	: 22.5 kg
Q.C No	: RMJ 1712003
Ticket/ B. No	: MS17-1065
Weighing date	: 16/01/18
Weighed By	:  Checked by: 

Raw Material	: Glycerine
Net Weight	: 22.5 kg
Q.C No	: RMJ 1712003
Ticket/ B. No	: MS17-1065
Weighing date	: 16/01/18
Weighed By	:  Checked by: 

Sunadine Syrup

Raw Material : Liquid Sorbitol 70%

Net Weight : 23.4 kg

Q.C No : RMJ 1711053

Ticket/ B. No : MS17-1065

Weighing date : 12/01/18

Weighed By : Checked by:

Sunadine Syrup

Raw Material : Liquid Sorbitol 70%

Net Weight : 23.4 kg

Q.C No : RMJ 1711053

Ticket/ B. No : MS17-1065

Weighing date : 12/01/18

Weighed By : Checked by:

Raw Material : Liquid Sorbitol 70%

Net Weight : 23.4 kg

Q.C No : RMJ 1711053

Ticket/ B. No : MS17-1065

Weighing date : 12/01/18

Weighed By : Checked by:

Raw Material : Liquid Sorbitol 70%

Net Weight : 23.4 kg

Q.C No : RMJ 1711053

Ticket/ B. No : MS17-1065

Weighing date : 12/01/18

Weighed By : Checked by:

Raw Material : Liquid Sorbitol 70%

Net Weight : 23.4 kg

Q.C No : RMJ 1711053

Ticket/ B. No : MS17-1065

Weighing date : 12/01/18

Weighed By : Checked by:

Raw Material : Liquid Sorbitol 70%

Net Weight : 23.4 kg

Q.C No : RMJ 1711053

Ticket/ B. No : MS17-1065

Weighing date : 12/01/18

Weighed By : Checked by:

Raw Material : Liquid Sorbitol 70%

Net Weight : 23.4 kg

Q.C No : RMJ 1711053

Ticket/ B. No : MS17-1065

Weighing date : 12/01/18

Weighed By : Checked by:

Raw Material : Glycerine

Net Weight : 22.5 kg

Q.C No : RMJ 1712003

Ticket/ B. No : MS17-1065

Weighing date : 16/01/18

Weighed By : Checked by:

Raw Material : Liquid Sorbitol 70%

Net Weight : 23.4 kg

Q.C No : RMJ 1711053

Ticket/ B. No : MS17-1065

Weighing date : 12/01/18

Weighed By : Checked by:

Raw Material : Glycerine

Net Weight : 22.5 kg

Q.C No : RMJ 1712003

Ticket/ B. No : MS17-1065

Weighing date : 16/01/18

Weighed By : Checked by:

Raw Material : Liquid Sorbitol 70%

Net Weight : 23.4 kg

Q.C No : RMJ 1711053

Ticket/ B. No : MS17-1065

Weighing date : 12/01/18

Weighed By : Checked by:

Raw Material : Glycerine

Net Weight : 22.5 kg

C No : RMJ 1712003

et/ B. No : MS17-1065

hing date : 16/01/18

ed By : Checked by:

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT : Batch Manufacture Record**ITEM :** Sunadine Syrup**PREP BY :** AZMI**DATE :** 24/10/2016**REMARKS :****EFFECTIVE DATE :** 24/10/2016**APPR BY :** SIU ANN LIM**DATE :** 24/10/2016**BATCH WEIGHING Record**

QC Reference number	Raw Materials	Net Wt per lot qty : 900 L	Actual Qty Weighed	Weighed By / Date	Checked By / Date	
					QC	Prodn
	Loratadine (Micronised)	945 g				
	Propylene glycol	(56.16kg) 54 L				
	Glycerin	(337.5kg) 270 L				
	Citric Acid Anhydrous	9.9 kg				
	Sodium benzoate	1152 g				
	Peach PCA 5019 Flavour	(1870g) 1800 ml				
	Liquid Sorbitol 70%	(351kg) 270 L				
	Spirit chloroform	(15.408kg) 18 L				
	Coarse Sugar	176.4 kg				
w(2)180119	Deionised water to	900 L	900L	19/10/18	-	19/10/18

Received in good order by production:

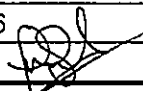
Checked by

Date of receipt

Production Ticket No.:

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT : Batch Manufacture Record			
ITEM :	Sunadine Syrup	PREP BY : AZMI	DATE : 21/09/2016
REMARKS :	-	EFFECTIVE DATE : 21/09/2016	
		APPR BY : SIU ANN LIM 	DATE : 21/09/2016

SPECIAL PRECAUTIONS AND REMARKS

Not applicable.

SUNWARD PHARMACEUTICALS SDN BHD

9, 11 & 17 Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Tampoi Johor Bahru, Johor, Malaysia

Subject	Line Clearance Checklist (Syrup Simplex Area)	Prepared by	AZMI
Room Name		Date	28/12/2017
Product Name & Batch No.		Approved by	AZHAN
		Date	28/12/2017

Instruction: Please fill up all columns. Please write NA if it is blank.

Room Condition & Specification	Reading	Sign		Date
		Operator	Controller / Supervisor / IPQA / Pharmacist / PRP	
Differential pressure (≥ 8 Pa)				

Equipment Check	Process	Equipment & its code	Tick (✓) / fill whichever appropriate	Calibration expiry date	Sign		Date
					Operator	Controller / Supervisor / IPQA / Pharmacist / PRP	
	Stirring	Stirrer 1 Code: MC-WD-001					
		Others: Code:					

☐ For Minor Line Clearance Use ONLY

Work Area Checklist	Tick (✓) where appropriate			
	Operator		Controller / Supervisor / IPQA / Pharmacist / PRP	
Room is properly labelled	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
All materials & documents from previous product has been removed	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Overall room condition is satisfactory	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
All machines have done level 1 cleaning and found to be satisfactory	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
All equipment / utensils have done level 1 cleaning and found to be satisfactory	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
All machines & equipment are labelled	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
All information in the BMR for the previous stages are completely filled	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
All daily recording in the room (example: Room Activity Record) are up-to-date.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Sign & Date				

Final Approval:

Type of Line Clearance	Approved by	Final Approval		Sign & Date
Minor Line Clearance	Controller / Supervisor / IPQA / Pharmacist / PRP	<input type="checkbox"/> Approve	<input type="checkbox"/> Not Approve	

Check all materials are correct as per BMR after line clearance is approved:

Checked by (sign & date): _____

MS17-1065

SUNWARD PHARMACEUTICALS SDN BHD

9, 11 & 17 Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Tampoi Johor Bahru, Johor, Malaysia

Subject	Line Clearance Checklist (Syrup Preparation Area)	Prepared by	AZMI
Room Name	Syrup Preparation 1	Date	28/12/2017
Product Name & Batch No.	sunadine syrup (331-18002)	Approved by	AZHAN
Previous Product & Batch No.	sunadine syrup (331-18001)	Date	28/12/2017

Instruction: Please fill in all columns. Please write NA if it is blank.

Room Condition & Specification	Reading	Sign		Date
		Operator	Controller / Supervisor / IPQA / Pharmacist / PRP	
Differential pressure (≥ 8 Pa)	14			19/01/18

Equipment Check	Process	Equipment & its code	Tick (✓) / fill whichever appropriate	Calibration expiry date	Sign		Date
					Operator	Controller / Supervisor / IPQA / Pharmacist / PRP	
	Sieving	Sieve size: 9	/				19/01/18
	Stirring	Stirrer 2 28/07/18 Code: MC-WD-002	/				19/01/18
		Others: Code:			N/A		
	Weighing	Weighing Balance Code:					




Section A: For Minor Line Clearance Use ONLY (After level 1 cleaning)

Work Area Checklist	Tick(✓) where appropriate			
	Operator		Controller / Supervisor / IPQA / Pharmacist / PRP	
Room is properly labelled	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
All materials & documents from previous product has been removed	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Overall room condition is satisfactory	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
All machines have done level 1 cleaning and found to be satisfactory	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
All equipment / utensils have done level 1 cleaning and found to be satisfactory	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
All machines & equipment are labelled	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
All information in the BMR for the previous stages are completely filled	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
All daily recording in the room (example: Room Activity Record) are up-to-date.	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Sign & Date				
		19/01/18		
			19/01/18	

SUNWARD PHARMACEUTICALS SDN BHD



9, 11 & 17 Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Tampoi Johor Bahru, Johor, Malaysia

Subject	Line Clearance Checklist (Syrup Preparation Area)	Prepared by	AZMI
Room Name		Date	28/12/2017
Product Name & Batch No.	NA	Approved by	 AZHAN
Previous Product & Batch No.		Date	28/12/2017

☐ **Section B: For Major Line Clearance Use ONLY (After level 2 cleaning)**

Work Area Checklist	Tick(✓) where appropriate					
	Operator		Controller / Supervisor		IPQA / Pharmacist / PRP	
Room is properly labelled	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
All materials & documents from previous product has been removed	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Overall room condition is clean & satisfactory:						
• Floor, wall, door, other areas that potentially have dust, powder or traces accumulated	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
• Supply air grill	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
• Return air grill	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Status of the tank is clean	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Status of the stirrer is clean	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
All machines / equipment are cleaned and labelled	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Drums to be used are emptied and clean	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
All information in the BMR for the previous stages / processes are filled	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
All daily recording in the room (example: Room Activity Record, Temperature & RH Record, etc.) are up-to-date	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Sign & Date						
<div style="display: flex; justify-content: space-between;"> <div style="width: 33%;"></div> <div style="width: 33%;"></div> <div style="width: 33%;"></div> </div>						

Final Approval:

Type of Line Clearance	Approved by	Final Approval	Sign & Date
Minor Line Clearance	<u>Controller</u> / Supervisor / IPQA / Pharmacist / PRP	<input checked="" type="checkbox"/> Approve <input type="checkbox"/> Not Approve	 19/01/18
Major Line Clearance	IPQA / Pharmacist / PRP	<input type="checkbox"/> Approve <input type="checkbox"/> Not Approve	 20/1/18































Check all materials are correct as per BMR after line clearance is approved:

Checked by (sign & date):  19/01/18

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT : Batch Manufacture Record**ITEM : Sunadine Syrup****PREP BY : AZMI****DATE : 24/10/2016****REMARKS :****EFFECTIVE DATE : 24/10/2016****APPR BY : SIU ANN LIM****DATE : 24/10/2016****WET LAB Procedure**

Steps	Performed	Checked
Syrup Simplex Preparation		
1) Heat 120L of Deionized (DI) water to 80°C in preparation tank. Time: <u>7:00 am</u> to <u>8:00 am</u>		
2) Check the temperature of the heated water. Temperature: <u>80</u> deg C		
3) Hold the DI water at 80°C for 30 minutes. Time: <u>8:00 am</u> to <u>8:30 am</u>		
4) Dissolve 176.4kg of Coarse Sugar into (3) and stir with stirrer.		
5) Transfer (4) to manufacturing tank using motor pump and syrup transfer hose(s).		
Syrup Preparation		
6) In a stainless steel (SS) container, dissolve 1152g of Sodium Benzoate in 5L of heated DI water. Add into manufacturing tank.		
7) In a SS container, dissolve 9.9kg of Citric Acid Anhydrous in 25L of heated DI water. Add into manufacturing tank.		
8) In a SS container, dissolve 945g of Loratadine (Micronised) in (15.408kg) 18L of Spirit Chloroform. Add (56.16kg) 54L of Propylene Glycol and stir well until clear. Add mixture into manufacturing tank.		
9) Add (337.5kg) 270L of Glycerin and (351kg) 270L of Liquid Sorbitol 70% into manufacturing tank.		
10) Stir mixture with a stirrer for 1 minute while adding (1870g) 1800ml of Peach PCA 5019 Flavour into manufacturing tank. Time: <u>9:19 am</u> to <u>9:20 am</u>		
11) Make up to 890L with DI water and stir for 10 minutes. Time: <u>9:20 am</u> to <u>9:30 am</u>		
12) Take tank samples for QC testing. Make chemical adjustment if necessary.		
13) Make up to 900L with DI water and stir for 1 minute. Time: <u>9:44 am</u> to <u>10:00 9:50 am</u>		
14) Filter through a sieve mesh size #100 into covered storage tank(s).		
15) Label storage tank(s).		

Verified by:  Date: 19/11/18

Production Ticket No.:

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT : **Batch Manufacture Record**

ITEM : Sunadine Syrup

PREP BY : AZMI

DATE : 21/09/2016

REMARKS :

EFFECTIVE DATE : 21/09/2016

APPR BY : SIU ANN LIM

DATE : 21/09/2016

QC No :

PAJ1301068**WET LAB****Quality Control Report**

In Process Report for Syrup/Cream Production, to be completed by QC Dept.

Test	Result	Specification
Description	<i>Complies</i>	A clear, colourless syrup with peach flavour.
pH	<i>3.00</i>	2.0 - 4.0 at 25 deg. C
Viscosity	<i>72.9</i>	40 - 120 cps at 25 deg. C
S.G.	<i>1.251</i>	1.1 - 1.4 at 25 deg. C

Previous item manufactured :

SUNADINE SYRUP (331-15001)

Remarks :

N.A

Analysed By :

Date :

19/01/18

Checked By:

Date :

19/01/18

SUNWARD PHARMACEUTICALS SDN BHD

9, 11 & 17 Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Tampoi Johor Bahru, Johor, Malaysia

Subject	Line Clearance Checklist (Syrup Filling & Packing Area)	Prepared by	AZMI
Room Name	Filling and Capping Room 1	Date	28/12/2017
Product Name & Batch No.	Sunadine Syrup 331-18002	Approved by	AZHAN
Previous Product & Batch No.	Sunadine Syrup 331-18001	Date	28/12/2017

Instruction: Please fill up all columns. Please write NA if it is blank.

Room Condition	Specification	Reading	Sign		Date
			Operator	Controller / Supervisor / IPQA / Pharmacist / PRP	
	Room temperature ($\leq 25^{\circ}\text{C}$)	19.0	<i>Li</i>	<i>Li</i>	19/01/18
	Room relative humidity ($\leq 70\%$)	69	<i>Li</i>	<i>Li</i>	19/01/18
	Differential pressure ($\geq 8\text{ Pa}$)	18	<i>Li</i>	<i>Li</i>	19/01/18

Equipment Check	Process	Equipment & its code	Tick (✓) / fill whichever appropriate	Calibration expiry date	Sign		Date
					Operator	Controller / Supervisor / IPQA / Pharmacist / PRP	
	Packing	Inline Filling & Capping Machine Code: MC-WD-005	✓		<i>Li</i>	<i>Li</i>	19/01/18
		Others: Code:	—		NA	—	
	Weighing	Weighing Balance Code: 004 (b)	✓	27/02/18	<i>Li</i>	<i>Li</i>	19/01/18



Section A: For Minor Line Clearance Use ONLY (After level 1 cleaning)

Work Area Checklist	Tick (✓) where appropriate			
	Operator		Controller / Supervisor / IPQA / Pharmacist / PRP	
Room is properly labelled	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
All materials & documents from previous product has been removed	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Overall room condition is satisfactory	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
All machines have done level 1 cleaning and found to be satisfactory	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
All equipment / utensils have done level 1 cleaning and found to be satisfactory	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
All machines & equipment are labelled	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
All information in the BMR for the previous stages are completely filled	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
All daily recording in the room (example: Room Activity Record) are up-to-date.	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Sign & Date				
<i>Li</i> 19/01/18		<i>Li</i> 19/01/18		

SUNWARD PHARMACEUTICALS SDN BHD

9, 11 & 17 Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Tampoi Johor Bahru, Johor, Malaysia

Subject	Line Clearance Checklist (Syrup Filling & Packing Area)	Prepared by	AZMI
Room Name		Date	28/12/2017
Product Name & Batch No.	NA	Approved by	AZHAN
Previous Product & Batch No.		Date	28/12/2017

**Section B: For Major Line Clearance Use ONLY (After level 2 cleaning)**

Work Area Checklist	Tick(✓) where appropriate					
	Operator		Controller / Supervisor		IPQA / Pharmacist / PRP	
Room is properly labelled	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
All materials & documents from previous product has been removed	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Overall room condition is clean & satisfactory:						
• Floor, wall, door, other areas that potentially have dust, powder or traces accumulated	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
• Supply air grill	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
• Return air grill	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Status of the Filling Machine (example: transfer hose, filling nozzles) is clean	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
All machines / equipment are cleaned and labelled	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Drums to be used are emptied and clean	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
All information in the BMR for the previous stages / processes are filled	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
All daily recording in the room (example: Room Activity Record, Temperature & RH Record, etc.) are up-to-date	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Sign & Date						

Final Approval:

Type of Line Clearance	Approved by	Final Approval	Sign & Date
Minor Line Clearance	Controller / Supervisor / IPQA / Pharmacist / PRP	<input checked="" type="checkbox"/> Approve <input type="checkbox"/> Not Approve	<i>19/01/18</i>
Major Line Clearance	IPQA / Pharmacist / PRP	<input type="checkbox"/> Approve <input type="checkbox"/> Not Approve	<i>NA</i>

Check the product is correct as per BMR after line clearance is approved:

Checked by (sign & date): *19/01/18*

Production Ticket No.:

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT : Batch Manufacture Record			
ITEM :	Sunadine Syrup	PREP BY : AZMI	DATE : 21/09/2016
REMARKS :	-	EFFECTIVE DATE : 21/09/2016	
		APPR BY : SIU ANN LIM	DATE : 21/09/2016

Bottle Cleaning

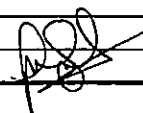
Cleaning Method		Method Used	Operator	Verified By
a) Manual	SOP No.: SWJB2/SOP/PD/00003	n/a		
b) Bottle Air Rinser	SOP No.: SWJB2/SOP/PE/12001	✓	<i>AS</i>	<i>SV</i>

Date of Commencement : 19/01/18Date of Completion : 19/01/18































Production Ticket No.:

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT : Batch Manufacture Record			
ITEM :	Sunadine Syrup	PREP BY : AZMI	DATE : 21/09/2016
REMARKS :	-	EFFECTIVE DATE : 21/09/2016	
		APPR BY : SIU ANN LIM	
	For: 60ml, 100ml, 120ml		DATE : 21/09/2016

Syrup Filling and Capping Procedure

Steps	Performed	Checked
1) Set the Inline Filling and Capping machine.		
2) Load Deionized (DI) Water into hopper and flush machine until all DI water is used up. Check appearance of DI water to ensure that the machine is clean and functioning properly.		
3) Obtain storage tank(s) filled with oral liquid product.		
4) Check against BMR and ensure correct label of oral liquid for product name, label tag and batch number or ticket number.		
5) Connect storage tank to motor pump with a dedicated transfer hose.		
6) Connect motor pump to filter unit with a dedicated transfer hose.		
7) Connect filter unit to hopper with a dedicated transfer hose.		
8) Switch on motor pump to load oral liquid into hopper. Check each nozzle to ensure no leakage.		
9) Obtain empty bottles and caps.		
10) Tare weight of empty bottle and cap.		
11) Load bottles onto turntable and caps into cap hopper.		
12) Set the machine to obtain oral liquid products with required volume.		
13) Perform the volume check at start-up by taking sample from each nozzle and pouring into measuring cylinder. Have the volume verified by controller/supervisor. Nozzle 1 <u>120ml</u> Nozzle 5 <u>120ml</u> Nozzle 2 <u>120ml</u> Nozzle 6 <u>120ml</u> Nozzle 3 <u>120ml</u> Nozzle 7 <u>120ml</u> Nozzle 4 <u>120ml</u> Nozzle 8 <u>120ml</u>		
14) Perform check on cap tightness.		
15) Start filling activity and perform volume check of each nozzle every 30 minutes. Document the results.		

Verified By : 

Date : 19/01/18

Production Ticket No.:

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT : Batch Manufacture Record			
ITEM : Sunadine Syrup		PREP BY : AZMI	DATE : 09/01/2018
REMARKS :		EFFECTIVE DATE : 09/01/2018	
- 60ml, 100ml, 120ml		APPR BY : AZHAN DAUD	DATE : 09/01/2018

**HOLOGRAM LABEL, LABEL, HOLOGRAM and LEAFLET
Requisition Form**

Item	Qty Requested	Qty Issued
Hologram Label	NA	NA
Label	7852	2029 X1 2024 X1 2026 X1 7773 X1
* Hologram	7510	7510
Leaflet	7501	7501 19/01/18 7501

Requested By : _____

Issued By : IMA

Date of Issue : 19/01/18

Quantity Checked and
Received By : _____

*** HOLOGRAM Details**

	Quantity	Serial Number
	7510	H239 424 32 - H239 499 41.
Reject		
Total Quantity Issued	7510	

Remarks :

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

DATE : 21/09/2016

Remarks :

Item Picture

SWMY LIVE

Tuesday, January 09, 2018

Page 2

SUNVAZMI

Item No : PKG1321
Description : Sunadine Syrup 120ml Label (MY/BRU)
S042R5
Replan No : MS17-1065
Item Category : INFO LABEL

Artwork

Information



PKG No. : PKG1321

Part Name : Sunadine Syrup 120ml

Code : S042R5

Colour/ Lettering : Pan 2935C/ Black Lettering

Background : Pan 2935C, T50%

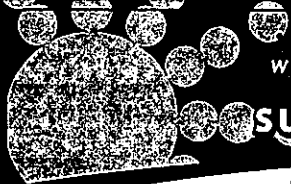
Size : (W)100mm x (H)52mm

Material : ArtPaper - Raflaplus

Packing : Roll Form

Pattern :





SUNWARD PHARMACEUTICAL SDN BHD
No. 1, Jalan 1/1, Taman 1/1, 40100 Shah Alam, Selangor Darul Ehsan, Malaysia
Tel: 03-5123 4567 Fax: 03-5123 4568 Email: info@sunwardpharm.com

SUNADINE SYRUP

120ml

ANTIHISTAMINES

Each 5ml contains :
Loratadine 5mg
Sodium Benzoate 6.4mg

Indications: Loratadine is indicated for the relief of nasal as well as non-nasal symptoms of allergic rhinitis, chronic urticaria and other allergic dermatological disorders.

For oral use only.
Keep out of reach of children.
Jauhkan dari kanak-kanak.
Store at or below 25°C.
Protect from light.
MAL20034603AZ
BRU10020414P

Refer to package insert for indications and further information.

Caution: Very rarely this may cause drowsiness. If affected do not drive or operate heavy machinery.

Controlled Medicine
S042R5

95552757033104

Hosp. / Clinic / Pharmacy : _____

Patient Name : _____

R/N : _____ Date : _____

Take / Minum : _____ ml

Times daily Before / After meal.
Kali sehari Sebelum / Selepas makan.

Approved by : Sulay 09/01/18

Production Ticket No.:

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT : Batch Manufacture Record			
ITEM :	Sunadine Syrup	PREP BY : AZMI	DATE : 21/09/2016
REMARKS :	-	EFFECTIVE DATE : 21/09/2016	
	-	APPR BY : SIU ANN LIM	DATE : 21/09/2016

Approved LABEL

SUNADINE SYRUP 120ml

ANTIHISTAMINES

Each 5ml contains :
Loratadine 5mg
Sodium Benzoate 6.4mg

Indications: Loratadine is indicated for the relief of nasal as well as non-nasal symptoms of allergic rhinitis, chronic urticaria and other allergic dermatological disorders.

For oral use only.
Keep out of reach of children.
Jauhkan dari kanak-kanak.
Store at or below 25°C.
Protect from light.

Refer to package insert for indications and further information.

Caution: Very rarely, this may cause drowsiness. If affected do not drive or operate heavy machinery.

Hosp. / Clinic / Pharmacy: _____
Patient Name: _____
R/N : _____ Date: _____
Take/minum: _____ ml
Times daily before / After meal
Kali sehari Sebelum / Selepas makan

MAL20034603AZ
BRU10020414P

Controlled Medicine

95552757033104

S042R5

QC Reference No. :	PM31801005		
Activity:	Coded By	Checked and Approved By	
Signature:	<i>Sh.</i>	<i>J</i>	<i>2</i>
Date:	19/01/18	19/01/18	19/01/18

Note :

Approved Label - Label which is the coded label approved for the current batch.

MS17-1065

Item Picture

SWMY LIVE

Tuesday, January 09, 2018

Page 1

SUNVAZMI

Item No : PKG0712

Description : Sunadine Syrup/Tablet Leaflet (MY/BRU)
CL356R6

Replan No : MS17-1065

Item Category : INFO LFLET

SUNADINE TABLET / SYRUP

Tablet: Loratadine 10mg / Tablet
Syrup: Loratadine 5mg / 5ml

Pharmacology:

Antihistamines (loratadine) diminish or abolish the main actions of histamine in the body by competitive reversible blockade of histamine receptor sites on tissues. Histamine H1 receptors are responsible for vasodilation, increased capillary permeability, flare and itch reactions in the skin, and to some extent for contraction of smooth muscles in the bronchi and gastrointestinal tract.

Loratadine is a long-acting tricyclic antihistamine with selective peripheral histamine H1-receptor antagonistic activity. Studies have shown that neither loratadine nor its metabolites readily cross the blood-brain barrier. It has higher affinity for the peripheral rather than the central nervous system H1 receptors. Hence, was not found to be sedative and/or to have any effect on the central nervous system. The peak plasma concentration is reached about one hour after oral administration. The peak plasma concentration is reached about one hour after oral administration. The peak plasma concentration is reached about one hour after oral administration.

Loratadine is a rapidly absorbed from the gastrointestinal tract after oral administration. The peak plasma concentration is reached about one hour after oral administration. The peak plasma concentration is reached about one hour after oral administration.

Loratadine is about 96% bound to plasma proteins, while its major metabolite, descarboethoxyloratadine is less extensively bound. Loratadine and its metabolites have been detected in breast milk, but do not appear to cross the blood-brain barrier to a significant extent. Loratadine and its metabolites are excreted in the urine and faeces.

Indications:

Loratadine is indicated for the relief of nasal as well as non-nasal symptoms of seasonal allergic rhinitis, chronic urticaria and other allergic dermatological disorders.

Adverse effects:

Headache, drowsiness, anaphylaxis, abnormal hepatic function, tachycardia, palpitation, fatigue, headache, somnolence, dry mouth, rhinitis, wheezing, abdominal pain, hyperkalemia, nausea, vomiting and rash has been reported.

Precautions/Warnings:

Dose should be lowered (5 mg daily or 10 mg every other day) in patients with liver impairment or renal impairment (GFR < 30 mL/min). It should also be used with caution in patients with prostatic hypertrophy, urinary retention, glaucoma and epilepsy. Children and elderly are more susceptible to side effects.

Safety and efficacy of loratadine in children younger than 2 years of age have not yet been established. Drug known to inhibit hepatic metabolism should be administered with caution until definitive interaction studies can be completed. The number of subjects who concomitantly received loratadine and/or loratadine, cimetidine, ranitidine or theophylline along with loratadine in controlled clinical trials is too small to rule out possible drug interactions.

Use in pregnancy and lactation:

There are no well-controlled studies in pregnant women. Loratadine and its metabolite, descarboethoxyloratadine have been detected in breast milk. Hence, loratadine should only be used when the potential benefit outweighs the potential risk.

Contraindications:

Contraindicated in patients with known hypersensitivity or idiosyncrasy to loratadine or other components in the product.

Drug Interactions:

Loratadine has no potentiating effect when administered concurrently with alcohol. Increase in plasma concentrations of loratadine has been reported with concomitant use of ketoconazole, erythromycin or cimetidine in healthy individuals but without clinically significant changes. Caution should be exercised when administering drugs known to inhibit hepatic metabolism.

Drugs that inhibit hepatic metabolism should be administered with caution until definitive interaction studies can be completed. The number of subjects who concomitantly received loratadine and/or loratadine, cimetidine, ranitidine or theophylline along with loratadine in controlled clinical trials is too small to rule out possible drug interactions.

Dosage:

Category	Dose
Children 2-5 years of age	Two 5ml spoonful (10mg) syrup once daily
Body weight > 30kg	One 5ml spoonful (10mg) syrup once daily
Body weight < 30kg	One 5ml spoonful (10mg) syrup once daily
Children 6-12 years of age	One tablet (10mg)/Two 5ml spoonful (10mg) syrup once daily
Body weight > 30kg	Half a tablet (5mg)/One 5ml spoonful (10mg) syrup once daily
Body weight < 30kg	Half a tablet (5mg)/One 5ml spoonful (10mg) syrup once daily
Adults and children 13 years of age and over	One tablet (10mg)/Two 5ml spoonful (10mg) syrup once daily

The use of loratadine in children under the age of 2 years has not yet been established.

Symptoms and Treatment for overdosage and withdrawal:

In adults, somnolence, tachycardia and headache have been reported with doses greater than 10mg (10-180mg) in children, extrapyramidal side effects and palpitations have been reported in doses greater than 10mg.

General symptomatic and supportive measures should be instituted in the event of overdosage. The treatment should consist of emesis, preferably by administration of ipecac syrup, except in patients with impaired consciousness. Following emesis, activated charcoal should be administered to absorb any remaining drug. However, if emesis is unsuccessful or contraindicated, gastric lavage should be performed using normal saline. Saline cathartics may be of value as a draw water into the bowel by osmosis, hence rapidly diluting the bowel content. Hemodialysis is of no value as loratadine is not eliminated by hemodialysis.

Pack size: Tablet

A bottle of 30 tablets.

Syrup

Bottle pack: A box of 2 x 10 x 10 x 10, 50 x 10 and 100 x 10 tablets per amp.

Pack size (export/bottle only): Tablet: A bottle of 100 tablets and 500 tablets.

Syrup

A bottle of 1 litre.

Storage conditions: Tablet: Store at or below 30°C. Protect from light.

Syrup: Store at or below 25°C. Protect from light.

Shelf-life: 3 years

Description:

Tablet: Oval white convex, bisected tablet with single score on one side only.

Syrup: A clear colourless syrup with peach flavour.

FURTHER INFORMATION CONCERNING THIS DRUG CAN BE OBTAINED FROM YOUR FAMILY PHYSICIAN / LOCAL GENERAL PRACTITIONER / PHARMACEUT.

Manufacturer: Sunward Pharmaceutical Sdn.Bhd.

No. 9, 11 & 17, Jalan Kemuning 4, Taman Perindustrian Tumpu Indah,

81000 Johor Bahru, Johor, Malaysia

Revised Date: 11/6/2012

SIZE : 108 X 72MM

Approved by : Sitiy 09/01/18

Production Ticket No.:

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT : Batch Manufacture Record			
ITEM :	Sunadine Syrup	PREP BY : AZMI	DATE : 21/09/2016
REMARKS :		EFFECTIVE DATE : 21/09/2016	
		APPR BY : SIU ANN LIM	DATE : 21/09/2016

Approved LEAFLET

SUNADINE TABLET / SYRUP

Tablet : Loratadine 10mg / tablet
Syrup : Loratadine 5mg / 5ml

Pharmacology:

Antihistamines (loratadine) diminish or abolish the main actions of histamine in the body by competitive, reversible blockade of histamine receptor sites on tissues. Histamines H1 receptors are responsible for vasodilation, increased capillary permeability, flare and itch reactions in the skin, and to some extent for contraction of smooth muscle in the bronchi and gastrointestinal tract.

Loratadine is a long-acting tricyclic antihistamine with selective peripheral histamine H1-receptor antagonistic activity. Studies have been shown that neither loratadine nor its metabolites readily cross the blood-brain barrier. It has higher affinity for the peripheral rather than the central nervous system H1-receptors. Hence, less problem of daytime sedation for those who have to drive or operate machinery.

It is rapidly absorbed from the gastrointestinal tract after oral administration. The peak plasma concentration is being attained at about one hour. Loratadine undergoes extensive metabolism. Descarboethoxyloratadine, which is the major metabolite has potent histamine H1-receptor blocking activity. Reported half-lives for loratadine and descarboethoxyloratadine are about 12 and 18 hours respectively.

Loratadine is about 98% bound to plasma proteins while its major metabolite, descarboethoxyloratadine is less extensively bound. Loratadine and its metabolites have been detected in breast milk, but do not appear to cross the blood-brain barrier to a significant extent. Loratadine and its metabolites are excreted in the urine and faeces.

Indications:

Loratadine is indicated for the relief of nasal as well as non-nasal symptoms of seasonal allergic rhinitis, chronic urticaria and other allergic dermatological disorders.

Adverse effects:

Gastritis, bloating, anaphylaxis, abnormal hepatic function, tachycardia, palpitation, fatigue, headache, somnolence, dry mouth, nervousness, wheezing, abdominal pain, hyperkinesia, malaise, nausea and rash has been reported.

Precautions/Warnings:

Dose should be lowered (5 mg daily or 10mg every other day) in patients with liver impairment or renal impairment (GFR < 30ml/min). It should also be used with caution in patients with prostatic hypertrophy, urinary retention, glaucoma and epilepsy. Children and elderly are more susceptible to side effects.

Safety and efficacy of loratadine in children younger than 2 years of age have not yet been established. Drug known to inhibit hepatic metabolism should be coadministered with caution until definitive interaction studies can be completed. The number of subject who concomitantly received macrolide antibiotics, ketoconazole, cimetidine, ranitidine, or theophylline along with loratadine in controlled clinical trials is too small to rule out possible drug interactions.

Use in pregnancy and lactation:


There are no well-controlled studies in pregnant women. Loratadine and its metabolite, descarboethoxyloratadine have been detected in breast milk. Hence, loratadine should only be used when the potential benefit outweighs the potential risk.

Contraindications:

Contraindicated in patients with known hypersensitivity or idiosyncrasy to loratadine or other components in the product.

Drug Interactions:

Loratadine has no potentiating effect when administered concurrently with alcohol. Increase in plasma concentrations of loratadine has been reported with concomitant use of ketoconazole, erythromycin or cimetidine in healthy individuals but without clinically significant changes. Caution should be exercised when coadministering drugs known to inhibit hepatic metabolism.

QC Reference No.	Approved By	Date
PMJ 1801049		15/01/18

MS17-1065

SUNWARD PHARMACEUTICALS SDN BHD

9, 11 & 17 Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Tampoi Johor Bahru, Johor, Malaysia

Subject	Line Clearance Checklist (Secondary Packing Area)	Prepared by	AZMI
Packing Line	ROOM 1.	Date	28/12/2017
Product Name / Batch No. / Pack Size	SUNWARD SUNWARD 331-18002 100ML	Approved by	AZHAN
Previous Product / Batch No. / Pack Size	SUNWARD SUNWARD 331-18001 100ML	Date	28/12/2017

Instruction: Please fill up all columns. Please write NA if it is blank.

Room Condition	Specification	Reading	Sign		Date
			Operator	Controller / Supervisor / IPQA / Pharmacist / PRP	
	Room temperature ($\leq 25^{\circ}\text{C}$)	23.9	g.	f	19/01/18
	Room relative humidity ($\leq 70\%$)	54	g.	f	19/01/18

Equipment Check	Process	Equipment & its code	Tick (✓) whichever appropriate	Calibration expiry date	Sign		Date
					Operator	Controller / Supervisor / IPQA / Pharmacist / PRP	
Labelling	Komark Labelling Machine 1 Code: MC-PD-005	✓			g.	f	19/01/18
	Komark Labelling Machine 2 Code: MC-PD-006	✓					
	Foresco Labelling Machine Code: MC-PD-003	NA			NA	NA	
	Others: Code:						
Weighing	Weighing Balance Code: PS 641-1	✓		12/02/18	g.	f	19/01/18
	Weighing Balance Code:				NA		

SUNWARD PHARMACEUTICALS SDN BHD

9, 11 & 17 Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Tampoi Johor Bahru, Johor, Malaysia

Subject	Line Clearance Checklist (Secondary Packing Area)	Prepared by	AZMI
Packing Line	Room 1.	Date	28/12/2017
Product Name / Batch No. / Pack Size	SUNADINE SNUP 331-18002 100ML	Approved by	AZHAN
Previous Product / Batch No. / Pack Size	SUNADINE SNUP 331-18001 100ML	Date	28/12/2017

☐ For Major Line Clearance Use ONLY (during changeover of packaging materials)

Work Area Checklist	Tick(✓) where appropriate					
	Operator		Controller / Supervisor		IPQA / Pharmacist / PRP	
Room / packing line is properly labelled	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
All materials & documents from previous product has been removed	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Overall room / packing line condition is clean & satisfactory:						
• Floor, wall, door, other areas that potentially have dust, powder or traces accumulated	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
• Supply air grill	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
• Return air grill	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Status of labelling machine is clean	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Printing have been set for the next batch	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Conveyor belt (include every fissures) is cleaned	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Line divider is cleaned	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Drum to be used is emptied and cleaned	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
All machines / equipment are cleaned and labelled	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
All information in the BMR for the previous stages / processes are filled	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
All daily recording in the room (example: Room Activity Record, Temperature & RH Record, etc.) are up-to-date	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Sign & Date						
<div style="display: flex; justify-content: space-around;"> <div><i>[Signature]</i> 19/01/18</div> <div><i>[Signature]</i> 19/01/18</div> <div><i>[Signature]</i> 19/01/18</div> </div>						

Final Approval:

Type of Line Clearance	Approved by	Approval	Sign & Date
Major Line Clearance	IPQA / Pharmacist / PRP	<input checked="" type="checkbox"/> Approve <input type="checkbox"/> Not Approve	<i>[Signature]</i> 19/01/18

Check all packaging materials are correct as per BMR after line clearance is approved:

Checked by (sign & date): *[Signature]* 19/01/18

Production Ticket No.:

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT : Batch Manufacture Record			
ITEM : Sunadine Syrup	PREP BY : AZMI	DATE : 21/09/2016	
REMARKS : For: 60ml, 100ml, 120ml	EFFECTIVE DATE : 21/09/2016		
	APPR BY : SIU ANN LIM	DATE : 21/09/2016	

PACKING Job Specifications

Steps	Performed	Checked
1) Set labeling and printing machine.	<i>h</i>	<i>+</i>
2) Check capped bottles for defects as bottles are being transferred from primary packing area to secondary packing area on the conveyer belt.	<i>h</i>	<i>+</i>
3) Printing machine will print batch number, manufacturing date and expiry date onto product labels.	<i>h</i>	<i>+</i>
4) Labeling machine will first paste hologram onto product labels and then label the bottles as they move on the conveyor belt.	<i>h</i>	<i>+</i>
5) Check product label to ensure only one hologram is pasted properly onto one product label. Ensure correct information is clearly and properly printed onto product label(s).	<i>h</i>	<i>+</i>
6) Pack labelled bottles into labelled carton(s).	<i>h</i>	<i>+</i>
7) Insert leaflets into carton(s) and seal carton(s) with cellophane tape at the middle and both of the edges.	<i>h</i>	<i>+</i>
8) Check weight of carton(s). Document the results.	<i>h</i>	<i>+</i>
9) Put and arrange cartons properly onto pallet(s). Wrap cartons with cling wrap and label wrapped cartons with "Quarantine". Transfer pallet with cartons to Quarantine Area.	<i>h</i>	<i>+</i>

Verified By : *h*Date : 19/01/18

Production Ticket No.:

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT : **Batch Manufacture Record**

ITEM : Sunadine Syrup

PREP BY : AZMI

DATE : 21/09/2016

REMARKS :

EFFECTIVE DATE : 21/09/2016

APPR BY : SIU ANN LIM

DATE : 21/09/2016

PACKING Report

QC reference Number

Packing Materials Description

Bottle

: PFJ 1712049

Cap

: PFJ 1712049 1712045
19/09/16**Immediate Packaging :**

Capacity of Packaging : 120ml bottle

Type and Colour : Amber Round PET Bottle

Volume per unit : 120ml

Leaflet requirement : Yes ☒No ☐**Carton :**

Type and Size : 100/120ml Syrup 484x246x138mm Double Wall Carton

No. of Units per Carton : 50 bottles

Labels on Carton : Yes ☒No ☐Carton Sealed : Yes ☒No ☐

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kompass 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia

SUBJECT: Batch Manufacture Record	
ITEM: Sunadine Syrup	PREP BY: AZMI
REMARKS: 60ml, 100ml, 120ml, 1L	EFFECTIVE DATE: 09/01/2018
	DATE: 09/01/2018
	APPR BY: AZHAN DAUD
	DATE: 09/01/2018

PACKAGING MATERIAL Reconciliation

	QC Ref. No.	Transfer order - receipt from PPM store	Brought forward	Quantity used for						Unused Quantity				Sign & Date		Scrap	
				Immediate containers	Carton	QC retention sample	IPQC	BMR	*On Machine	Transfer order - ship to PPM Store			Supervisor	Controller	Scrap qty	Checked/ destroyed by QC/ date	
										Reject	Good condition	Transfer Shipment					
HOLOGRAM LABEL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
LABEL	PM11801001	7822	-	7506	302	4	-	1	-	-	-	-	-	19/01/18	19/01/18	39	23/01/18
HOLOGRAM	PM11801004	7510	-	7506	-	4	-	-	-	-	-	-	-	19/01/18	19/01/18	-	23/01/18
LEAFLET	PM11801009	7501	-	7500	-	-	-	1	-	-	-	-	-	19/01/18	19/01/18	-	23/01/18
Rejected Hologram No.				- Nil -													

Remarks:

JOSE DAWON 6 BOKKS. 2

Brought forward from	Batch No	Ticket No	Verified by controller
*On Machine (Carry forward to)			

Production Ticket No.:

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Peindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT : Batch Manufacture Record	PREP BY : AZMI	DATE : 21/09/2016
ITEM : Sunadine Syrup	EFFECTIVE DATE : 21/09/2016	
REMARKS : For: 60ml, 100ml, 120ml, 1L	APPR BY : SIU ANN LIM	DATE : 21/09/2016

PACKAGING MATERIAL Reconciliation

	QC Ref. No.	Quantity Received		Quantity Used For			Unused Quantity					Sign & Date	
		Transfer order - receipt from store	Brought forward	Packing	QC retention sample	IPQC	*Carry forward to next batch	Transfer order - ship to store				Packing Personnel	Controller
								Scrap	Reject	Good condition	Transfer Shipment		
BOTTLE	PKJ 1712049	7529	-	7506	4	4	-	15	-	-	-	19/01/18	19/01/18
CAP	PKJ 1712045	7544	-	7506	4	4	-	30	-	-	-	19/01/18	19/01/18
CARTON	PKJ1801001	151	-	151	-	-	-	-	-	-	-	19/01/18	19/01/18

Remarks:

-NA-

Brought forward from	Batch No	Ticket No	Verified by controller
*Carry forward to			

Production Ticket No.:

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT : Batch Manufacture Record			
ITEM : Sunadine Syrup		PREP BY : AZMI	DATE : 09/01/2018
REMARKS :		EFFECTIVE DATE : 09/01/2018	
- 60ml, 100ml, 120ml, 1L		APPR BY : AZHAN DAUD	DATE : 09/01/2018

PHYSICAL CHECKS ON PACKED PRODUCTS

			Packing Personnel	Production Controller	Date
Correct size and colour of bottles and caps		✓	A.	f	19/01/18
Status of Containers	Clean	✓	A.	f	19/01/18
	Unclean				
Labels are correctly coded with	Batch No		A.	f	19/01/18
	On BMR: 331-18000	✓			
	On Label: 331-18000				
	Date of Mfg.				
	On BMR: 19 JAN 2018	✓			
	On Label: JAN 18				
	Expiry Date:		A.	f	19/01/18
	On BMR: DEC 2020	✓			
	On Label: DEC 20				
Labels correspond to the item produced	Yes	✓	A.	f	19/01/18
	No				
Labels are printed with "Controlled Medicine" for items containing Schedule Poisons.	Yes	✓	A.	f	19/01/18
	No				
Containers are	Properly capped	✓	A.	f	19/01/18
	Sealed with cap seal				
Package insert attached/enclosed		✓	A.	f	19/01/18

Checked By :
QC Dept

Date : 19/01/18

Production Ticket No.:



SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT : Batch Manufacture Record			
ITEM :	Sunadine Syrup	PREP BY : AZMI	DATE : 21/09/2016
REMARKS :	-	EFFECTIVE DATE : 21/09/2016	
		APPR BY : SIU ANN LIM	DATE : 21/09/2016

QC No : PAW1001060**APPROVAL For Release**Date of Manufacture : 19 JAN 2018Expiry Date : DEC 2020Quantity Planned : 900 LTotal Quantity Produced : 7506 x 120ml4 x 120ml take by uc4 x 120ml for testingYield (%) : 100.19 %

Item is approved for release

	Signature	Name	Date
QC Manager/Chemist/QC Pharmacist		Hameel Abdul	28/01/18
Production Pharmacist		Jing Yi	26/01/18

Remarks :

- MA -

ANALYTICAL REPORT FOR LIQUID PREPARATIONS

Effective Date	17/10/2015	Review Date	17/10/2018
Reference Document No.	SOP/QA/07029	Revision	7.0
Prepared By	Ms. HIDAYAH	QC Clerk	
Checked By	Ms. M.C. ONG	QC Chemist	
Approved By	Ms. B. T. NG	QC Manager	
PRODUCT	SUNADINE SYRUP		
BATCH NO.	331-18002	Q.C. NO.	PWJ 1801066
CONTENTS PER SML	Lorazepam	5mg	
PRESERVATIVE PER SML	Sodium Benzene	6.4 mg	
DATE OF MANUFACTURE	19/01/18	BATCH SIZE	900L
EXPIRY DATE	12/2020	PACK SIZE	100ml

REFERENCE OF ASSAY METHOD : SUNWALDS

TESTS	RELEASE SPECIFICATION	RESULTS
1. PHYSICAL APPEARANCE - Colour - Flavour - Colour	Colourless Peach Clear	Complies Complies Complies
2. pH at 25 degree Celsius	2.0 - 4.0	2.99 /
3. SPECIFIC GRAVITY at 25 degree Celsius	1.10 - 1.40	1.245 /
4. VISCOSITY (cps) at 25 degree Celsius	40 - 120	60.6 /
5. MINIMUM FILL TEST	i. Average net content of the 10 containers not less than the labeled amount. ii. Net content of any single container is :- a) Not less than 90% (labeled amount : < 60ml) b) Not less than 95% (labeled amount within 60ml - 150ml)	complies
6. IDENTIFICATION	A. The retention times of the major peak correspondent to Loratadine in the chromatogram of sample preparation corresponds to that in the chromatogram of the reference preparation, as obtained in the Assay. B. The retention times of the major peak correspondent to Benzoic acid in the chromatogram of sample preparation corresponds to that in the chromatogram of the reference preparation, as obtained in the preservative.	complies
7. CONTENT OF PRESERVATIVE (content per 5 ml)	Sodium Benzoate 90.0 - 120.0%	Sodium Benzoate : 101.31%
8. ASSAY (content per 5 ml)	Loratadine 90.0 - 110.0%	Loratadine : 102.24%
9. MICROBIAL CONTAMINATION TEST (BP) TAMC (cfu/ml) TYMC (cfu/ml) Specified Micro-organisms	Not more than 2.0×10^2 Not more than 2.0×10^1 Absence of E.coli in 1ml	TAMC : <10 TYMC : <10 Specified Micro-organisms : complies
10. MICROBIAL CONTAMINATION TEST (NPCB) Specified Micro-organisms	Absence of B. cepacia in 1ml	Specified Micro-organisms : complies

TAMC : Total Aerobic Microbial Count

TYMC : Total Combined Yeasts-Moulds Count

REMARKS:

ANALYZED BY	DATE
CHECKED BY	DATE
APPROVED BY	DATE

SUNWARD PHARMA JB

COPY ☐ 1
REVISION ☒ 7

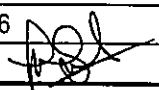
SUNWARD PHARMA JB

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Production Ticket No.:

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT : Batch Manufacture Record			
ITEM :	Sunadine Syrup	PREP BY : AZMI	DATE : 21/09/2016
REMARKS :	-	EFFECTIVE DATE : 21/09/2016	
		APPR BY : SIU ANN LIM 	DATE : 21/09/2016

QC ANALYTICAL Report

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor. Malaysia.

SUBJECT :		Manufacturing Manpower Record	
ITEM :	Sunadine Syrup	PREP BY : AZMI	DATE : 21/09/2016
REMARKS :	-	EFFECTIVE DATE : 21/09/2016	
	-	APPR BY : SIU ANN LIM	DATE : 21/09/2016

Item :

Sunadine Syrup

Prepared By :

nilam, misul

Batch No.:

331-18002

Batch Size :

7006

[illegible]

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

DATE : 21/09/2016

[illegible]

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT : Batch Manufacture Record

ITEM: Sunadine Syrup

PREP BY : AZMI

DATE : 07/03/2017

REMARKS :

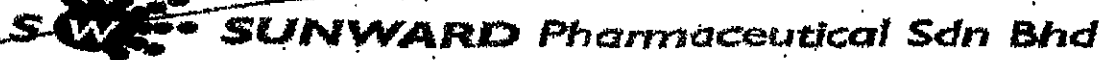
EFFECTIVE DATE : 07/03/2017

APPR BY : SIU ANN LIM

DATE : 07/03/2017

SIGNATURE LIST

[illegible]



ACTIVITY RECORD

PRODUCT NAME:

Sundadine Syrup

BATCH NO.:

331-18002

Date	Time		Process	Operator Name	Sign
	From	To			
19/01/18	9.00 am	10.00 am	preparation	Nazim minn	A.
19/01/18	2.45 pm	5.00 pm	filing.	Nazir Firkam Haidar	M. f.
19/01/18	5.00 pm	5.00 pm	VAREJIAN	LARIAH WORA PA PAS.	Naj HA pas

SUNWARD PHARMACEUTICAL SDN BHD		PRODUCTION RECORD		Doc No: SWMY/PRD/0110 (Appendix 1) Version No: 00 Page: 1 of 2	
IN-PROCESS SYRUP SMALL PACK FILLING WEIGHING RECORD					

Machine :	In-Line Filling & Capping Machine (Monoblock) / FG-2 Filling Machine (Foresco)			Date :	19/01/18
Product :	Sunward Syrup	Batch No:	331 - 18002	Batch Size:	900L
				Pack Size:	120ml

Bottle Weight (g)	(1)	(2)	(3)	(4)	(5)	Average weight of 10 bottles (g):
	(6)	(7)	(8)	(9)	(10)	
	17.21	17.17	17.15	17.29	17.24	172.2
	17.15	17.26	17.25	17.21	17.22	
Weight of 60ml/61ml/120ml (g):	(1)	(2)	(3)	(4)	(5)	Average weight (g):
	147.65	147.67	147.58	147.52	147.49	147.58
Minimum limit = (Average weight of syrup in 5 measurements) + Average weight of 10 bottles						Minimum Limit (g):
*FOR METHADONE, Minimum limit = (Average weight of 61ml syrup in 5 measurements) + Average weight of 10 bottles						164.80
Maximum limit = Minimum limit + 3%						Maximum Limit (g):
						169.74

Tank No.	Time	Weight (g)								Performed by	Check by		Remark
		Noz. 1	Noz. 2	Noz. 3	Noz. 4	Noz. 5	Noz. 6	Noz. 7	Noz. 8		Supervisor/Controller	QC	
E	2.45 pm	165.29	165.34	165.20	165.27	165.29	165.30	165.42	165.40	✓	✓	✓	NA
	3.00 pm	165.20	165.42	165.47	165.29	165.40	165.30	165.36	165.44	✓	✓	✓	
	3.15 pm	165.21	165.39	165.30	165.31	165.46	165.37	165.46	165.47	✓	✓	✓	
F	3.30 pm	165.27	165.45	165.34	165.35	165.45	165.36	165.51	165.56	✓	✓	✓	
	3.45 pm	165.28	165.40	165.60	165.40	165.46	165.39	165.42	165.70	✓	✓	✓	
	4.00 pm	165.30	165.60	165.67	165.39	165.32	165.43	165.49	165.64	✓	✓	✓	

* In process quality inspection should be performed every 15 minutes throughout the packing process and controller/ supervisor should check at random.
Any adjustment done at any time should be recorded at remark column.

SUNWARD PHARMA (JB) MASTER COPY REVISION 01	SUNWARD PHARMA (JB) COPY REVISION 01
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IN-PROCESS SYRUP SMALL PACK WEIGHING RECORD

[illegible]

* In process quality inspection should be performed every 15 minutes throughout the packing process and controller/ supervisor should check at random.

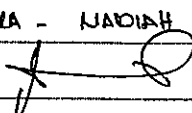
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SUNWARD PHARMACEUTICAL SDN BHD	PRODUCTION RECORD	Doc. No: SWMY/PRD/0110 (Appendix 4) Version No: 00 Page: 1 of 1
FINISHED PRODUCT WEIGHING RECORD (120ml)		

Product:	SUNWARD SYRUP	Batch No:	331-18002
Weight per bottle (Average of 10 bottles):	0.169kg	Quantity of bottles per carton:	50
Tare Weight: (weight of 1 empty carton + partition + pads + leaflet) :			0.53kg
Specifications: (Weight of 1 bottle x Number of bottles in a carton) + Tare :			Not less than 8.98kg.

Ctn No.	Gross Weight (kg)	Ctn No.	Gross Weight (kg)	Ctn No.	Gross Weight (kg)	Ctn No.	Gross Weight (kg)	Ctn No.	Gross Weight (kg)	Ctn No.	Gross Weight (kg)
1	9.04	31	9.06	61	9.03	91	9.04	121	9.06	151	1.55
2	9.04	32	9.06	62	9.03	92	9.04	122	9.04	152	(6 Bottles)
3	9.03	33	9.06	63	9.04	93	9.04	123	9.06	153	
4	9.02	34	9.06	64	9.04	94	9.04	124	9.06	154	
5	9.02	35	9.03	65	9.04	95	9.04	125	9.06	155	
6	9.02	36	9.03	66	9.04	96	9.04	126	9.04	156	
7	9.01	37	9.03	67	9.04	97	9.04	127	9.04	157	
8	9.02	38	9.03	68	9.04	98	9.04	128	9.04	158	
9	9.02	39	9.04	69	9.03	99	9.04	129	9.04	159	
10	9.02	40	9.03	70	9.03	100	9.04	130	9.05	160	
11	9.03	41	9.03	71	9.03	101	9.04	131	9.06	161	
12	9.03	42	9.02	72	9.03	102	9.04	132	9.06	162	
13	9.02	43	9.04	73	9.03	103	9.05	133	9.06	163	
14	9.02	44	9.03	74	9.03	104	9.04	134	9.06	164	
15	9.03	45	9.03	75	9.03	105	9.05	135	9.05	165	
16	9.03	46	9.03	76	9.04	106	9.04	136	9.06	166	
17	9.04	47	9.03	77	9.04	107	9.03	137	9.03	167	
18	9.03	48	9.03	78	9.04	108	9.04	138	9.03	168	
19	9.04	49	9.03	79	9.04	109	9.04	139	9.03	169	
20	9.04	50	9.03	80	9.04	110	9.04	140	9.04	170	
21	9.04	51	9.04	81	9.03	111	9.04	141	9.04	171	
22	9.03	52	9.04	82	9.03	112	9.04	142	9.04	172	
23	9.04	53	9.04	83	9.03	113	9.04	143	9.03	173	
24	9.03	54	9.03	84	9.06	114	9.04	144	9.04	174	
25	9.03	55	9.03	85	9.03	115	9.04	145	9.04	175	
26	9.04	56	9.03	86	9.04	116	9.04	146	9.05	176	
27	9.03	57	9.03	87	9.04	117	9.06	147	9.03	177	
28	9.04	58	9.04	88	9.04	118	9.06	148	9.04	178	
29	9.06	59	9.04	89	9.04	119	9.04	149	9.06	179	
30	9.06	60	9.03	90	9.04	120	9.06	150	9.04	180	

Note: Check underweight cartons for completeness, write "ok", once confirmed as complete.

Weighing Balance code:	DS 671-1
Weighed by/date :	MORA - NADIAH 1-151 19/01/18
Verified by/date :	 19/01/18

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SUNWARD PHARMACEUTICAL SDN BHD	PRODUCTION RECORD	Doc. No.: RC/PD/93a Version no.: 02
CLEANING CHECKLIST		
Prepared by: <i>E 7/3/2016</i>	Approved by: <i>MF 7/3/16</i>	

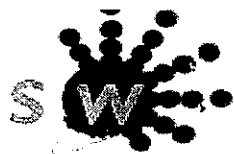
Equipment:	Monoblock Filling Machine		
Previous Product	Sunactive Syu	Batch Number:	331-18001
Cleaned by:	nari		
Cleaning time/date:	Date:	14/01/18	Date:
	Time Start:	12.40 PM	Time Start:
	Time End:	2.45 PM	Time End:

<input checked="" type="checkbox"/> Level 1 Cleaning (✓ if the part is cleaned)			
Parts	Cleaned	Parts	Cleaned
Storage Tank	✓	Motor Pump	✓
Transfer Hose	✓	Syrup Filter Unit	✓
Volume Sensor	✓	Machine Body	✓
Hopper (Rinsing)	✓	Wash System	✓
		Water Temperature:	50 °C
Verified by (Production Supervisor/Controller)		<i>MF</i>	

<input type="checkbox"/> Level 2 Cleaning (✓ if the part is cleaned)			
Parts	Cleaned	Parts	Cleaned
Storage Tank		Motor Pump	
Transfer Hose		Syrup Filter Unit	
Volume Sensor		Machine Body	
Hopper (Rinsing)		Wash System	
		Water Temperature:	°C

As per Step (6) of Level 2 Cleaning of SWJB2/SOP/PE/08002, tick (✓) if comply:			
Parts	Visually clean	Absence of product odour	Absence of product colour
Hopper (Washing)			
Outlet Valve Assembly			
Filling Nozzle Assembly			
Piston Assembly			
Filling Hose			
Verified by (Production Supervisor/Controller)			

Remarks	
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Transfer Receipt

Number : RDIS-29655
 Date : 17. January 2018
 Transfer Order No. : DIS-42628
 Page No. : 1/2

TRANSFER FROM:

Weighed Material Area – (Lot 9,17)

TRANSFER TO:

Production

Production Order MS17-1065-2-MIX1

Replan Ref. No. MS17-1065

Description Sunadine Syrup Mixing *mm*

Contact:

Ticket No.

331-1802

Item No.	Description	Quantity	Unit of Measure	Check by
MAT0241	Peach PCA 5019 Flavour	1,870.000	GM	
	Lot No. QC Ref. No. Batch No. Expired Date Quantity UOM Qty. (Base) BUOM QC Status			
	RM16-M0452 RMJ1609021-RT 119162 05/03/2018 1,870.000 GM 1,870.000 GM Approved			
MAT-NP-0066	Citric Acid Anhydrous	9,900.000	GM	
	Lot No. QC Ref. No. Batch No. Expired Date Quantity UOM Qty. (Base) BUOM QC Status			
	RM17-M0626 RMJ1710022 AA-1706-30323 06/06/2020 9,900.000 GM 9,900.000 GM Approved			
MAT-NP-0039	Sugar - Coarse Sugar	176.400	KG	
	Lot No. QC Ref. No. Batch No. Expired Date Quantity UOM Qty. (Base) BUOM QC Status			
	RM18-M0009 RMJ1801006 M15S17 15/12/2018 176.400 KG 176.400 KG Approved			
MAT-NP-0076	Glycerine	337.500	KG	
	Lot No. QC Ref. No. Batch No. Expired Date Quantity UOM Qty. (Base) BUOM QC Status			
	RM17-M0733 RMJ1712003 BGSXFA9126 25/10/2019 337.500 KG 337.500 KG Approved			
MAT-NP-0084	Liquid Sorbitol 70%	351.000	KG	
	Lot No. QC Ref. No. Batch No. Expired Date Quantity UOM Qty. (Base) BUOM QC Status			
	RM17-M0717 RMJ1711053 0004576262 16/10/2019 351.000 KG 351.000 KG Approved			
MAT-NP-0092	Propylene Glycol	56.160	KG	
	Lot No. QC Ref. No. Batch No. Expired Date Quantity UOM Qty. (Base) BUOM QC Status			
	RM17-M0737 RMJ1712007 A02921U 21/09/2019 56.160 KG 56.160 KG Approved			
MAT-NP-0095	Sodium Benzoate	1,152.000	GM	
	Lot No. QC Ref. No. Batch No. Expired Date Quantity UOM Qty. (Base) BUOM QC Status			
	RM17-M0713 RMJ1711040 20170706B 06/07/2019 1,152.000 GM 1,152.000 GM Approved			
MAT-NP-0233	Spirit Chloroform	15.408	KG	
	Lot No. QC Ref. No. Batch No. Expired Date Quantity UOM Qty. (Base) BUOM QC Status			
	RM17-M0646 RMJ1710042 DEN097/17 03/08/2019 15.408 KG 15.408 KG Approved			

Action	Sign	Date
Received By	<i>[Signature]</i>	17/01/18
Verify By	<i>[Signature]</i>	17/01/18





SUNWARD Pharmaceutical Sdn Bhd (Co. No. 41816-W)

9, 11 & 17 Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia

E-mail : enquiries@sunwardpharma.com Website : www.sunwardpharma.com

Tel : +60 7 2367531 Fax : +60 7 2367532

Transfer Receipt

Number : RDIS-29655
Date : 17. January 2018
Transfer Order No. : DIS-42628
Page No. : 2/2

TRANSFER FROM:

Weighed Material Area – (Lot 9,17)

TRANSFER TO:

Production

Production Order MS17-1065-2-MIX1
Replan Ref. No. MS17-1065
Description Sunadine Syrup Mixing
Ticket No.

Contact:

Item No.	Description				Quantity	Unit of Measure	Check by		
MAT-PP-0180	Loratadine (Micronised)				945.000	GM			
Lot No.	QC Ref. No.	Batch No.	Expired Date	Quantity	UOM	Qty. (Base)	BUOM	QC Status	
RM17-M0286	RMJ1705039	BLRD/1704021-M	28/02/2022	945.000	GM	945.000	GM	Approved	

Action	Sign	Date
Received By		17/01/18
Verify By		17/01/18

Production / QC / Store Copy

Production Ticket No.:

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

SUBJECT : FPDA / Quarantine Record**ITEM :** Sunadine Syrup**PREP BY :** AZMI**DATE :** 21/09/2016**REMARKS :****EFFECTIVE DATE :** 21/09/2016**APPR BY :** SIU ANN LIM**DATE :** 21/09/2016**Item :** Sunadine Syrup**Batch No :** 331-18002**Registration No :** BRU10020414P MAL20034603AZ**Mfg Date :** 19 JAN 2018**Shelf Life :** 3 Years**Expiry Date :** DEC 2020**QC No :** pag 1201 002**Issued by :****Packer No. :****Date :****Packing Details**

Quantity	Pack Size	No. of Carton	Units per Carton
7506 bottles	120ml	150	50 bottles
		1	6 bottles

	Signature	Date
Goods received by Store		20/01/18
Approved label affixed by QC		

Entry into :	Signature	Date
Stock Card		
Computer		

Remarks :

