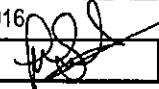
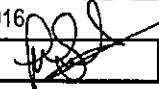


(8-C)

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

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 <i>[Signature]</i>	APPR BY : SIU ANN LIM <i>[Signature]</i> DATE : 21/02/2017

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

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>AB</i>

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"/> NA
13	Changes related to the batch are approved and the recommendations in change control request are compiled.	<input checked="" type="checkbox"/> NA
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

- MA -

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.

Approved

Rejected

Authorised By:

SITI AYU NI NORZAIDA KHAIZIR

Signature:

Siti Ayu

Date:

01/02/18

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tamboi 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 <i>[Signature]</i>	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
Amber Glass 100 ml
Amber Glass 120 ml
Amber Glass 1 Litre

YES
YES
YES
YES

Amber PET 60 ml
Amber PET 100 ml
Amber PET 120 ml

YES
YES
YES

STORAGE :

Store at temperature 25°C

Protect from light.

SHELF LIFE :

3 Years

THEORETICAL YIELD :

98 - 102 %

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tampol 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 <i>DOL</i> DATE : 21/09/2016

Completion : 19/01/18

QC No : DAG 1801066

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 : *DOL*
Date : 21/09/16

Issued by : *DAG*
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

AREA Checklist

GMP Checklist : DISPENSING

Weighing Area Check	Weighing Checklist	Tick (\) where appropriate			Sign		Date	Sign IPQA / Prodn. Pharmacist
		Dispensing Personnel	Dispensing Supervisor					
	All materials from previous batch are removed	<input checked="" type="checkbox"/>	Yes	<input type="checkbox"/>	No	<i>J</i>	<i>J</i>	13/04/18 <i>J</i>
	Room is properly labelled	<input checked="" type="checkbox"/>	Yes	<input type="checkbox"/>	No	<i>J</i>	<i>J</i>	13/04/18 <i>J</i>
	Weighing equipment are cleaned and calibrated	<input checked="" type="checkbox"/>	Yes	<input type="checkbox"/>	No	<i>J</i>	<i>J</i>	13/04/18 <i>J</i>
	Status of dispensing booth	<input checked="" type="checkbox"/>	Clean	<input type="checkbox"/>	Unclean	<i>J</i>	<i>J</i>	13/04/18 <i>J</i>
	Room temperature (not more than 25°C)	21°C				<i>J</i>	<i>J</i>	13/04/18 <i>J</i>
	Room relative humidity (not more than 70%)	67%		NA		<i>J</i>	<i>J</i>	13/04/18 <i>J</i>
	Magnehelic pressure gauge reading (not more than 374 pascal / 1.5 W.C.)	0.3 "wc				<i>J</i>	<i>J</i>	13/04/18 <i>J</i>

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

Equipment Check	Description	Serial No.	Weighing range	Tick (\) where appropriate	Calibration expiry date	Sign		Sign IPQA / Prodn. Pharmacist
						Dispensing Personnel	Date	
	Dispensing booth LOT 1f	W.C-00 -001		<input checked="" type="checkbox"/>	21/03/18	<i>J</i>	13/04/18	<i>J</i>
	Balance name: SHIMADZU UX3200 G	01617 00170	< 3000gm	<input checked="" type="checkbox"/>	05/01/19	<i>J</i>	13/04/18	<i>J</i>
	Balance name: A NO GP-30 F	14#02 520	> 3000gm	<input checked="" type="checkbox"/>	05/01/19	<i>J</i>	13/04/18	<i>J</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 ApproveDate: *12/04/18*

Remarks:

NA



Sunward Pharmaceutical Sdn Bhd

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

Batch Weighing Record

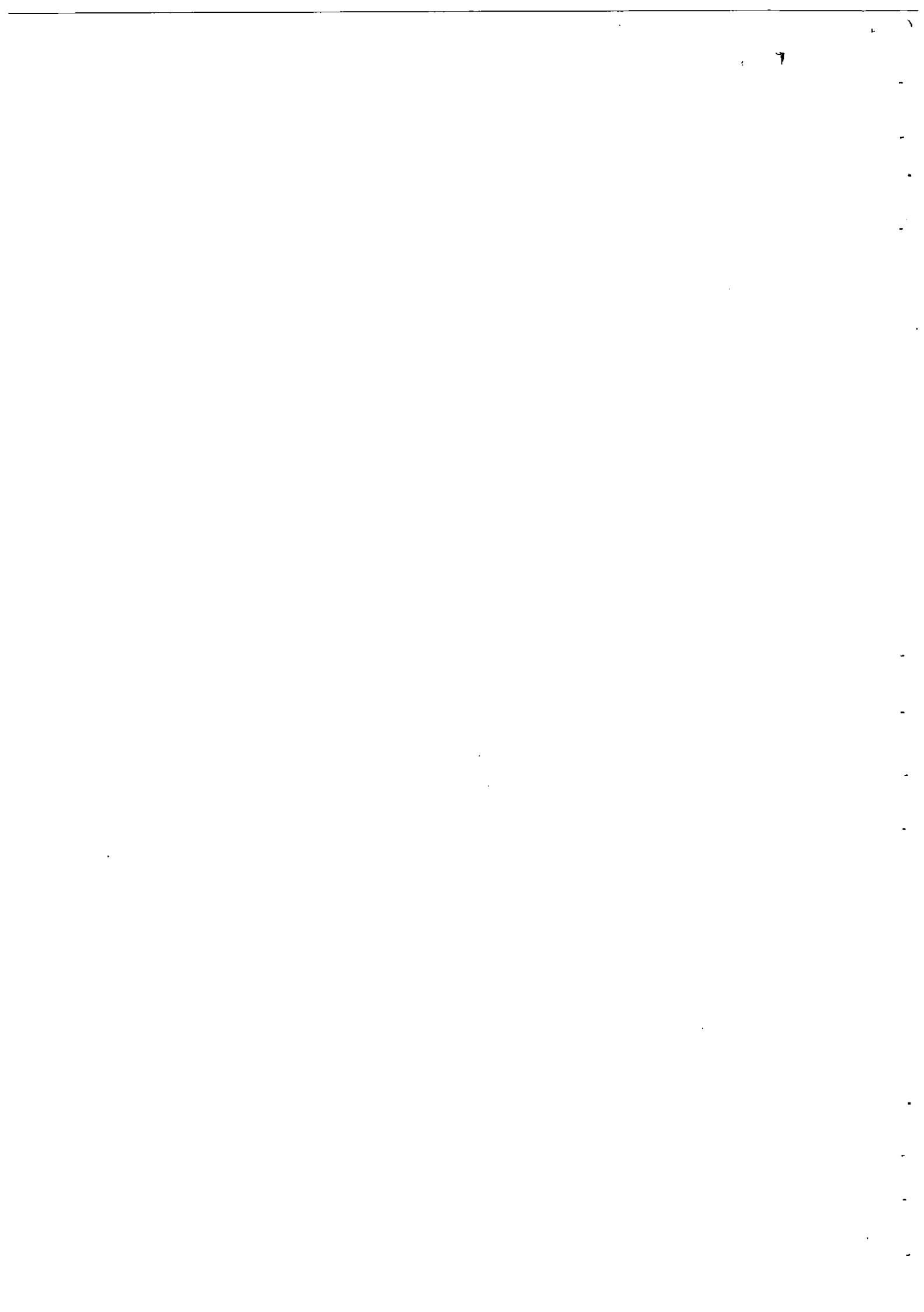
Prod. Order No. MS17-1065-2-
MIX1

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 +50kgx3	KG	↓ 13/01/18	✓ 13/01/18
MAT-NP-0076	Glycerine	337.500	KG	RMJ1710003	33.5 kg x15	KG	✓ 16/01/18	✓ 16/01/18
MAT-NP-0084	Liquid Sorbitol 70%	351.000	KG	RMJ1711053	33.2 kg x15	KG	✓ 15/01/18	✓ 15/01/18
MAT-NP-0092	Propylene Glycol	56.160	KG	RMJ1710007	18.72 kg x3	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: 8

Sunadine Syrup

Raw Material	: Liquid Sorbitol 70%
Net Weight	: 53.1 kg
Q.C No	: RMJ 1711053
Ticket/ B. No	: MS17-1065
Weighing date	: 13/01/18
Weighed By	: ✓ Checked by: 9

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: 10

Sunadine Syrup

Raw Material	: Liquid Sorbitol 70%
Net Weight	: 53.1 kg
Q.C No	: RMJ 1711053
Ticket/ B. No	: MS17-1065
Weighing date	: 13/01/18
Weighed By	: ✓ Checked by: 9

Raw Material	: Spirit Chloroform
Net Weight	: 15.108 kg
Q.C No	: RMJ 1710042
Ticket/ B. No	: MS17-1065
Weighing date	: 15/01/18
Weighed By	: ✓ Checked by: 2

Raw Material	: Liquid Sorbitol 70%
Net Weight	: 53.1 kg
Q.C No	: RMJ 1711053
Ticket/ B. No	: MS17-1065
Weighing date	: 13/01/18
Weighed By	: ✓ Checked by: 2

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: 2

Raw Material	: Liquid Sorbitol 70%
Net Weight	: 53.1 kg
Q.C No	: RMJ 1711053
Ticket/ B. No	: MS17-1065
Weighing date	: 13/01/18
Weighed By	: ✓ Checked by: 2

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: 2

Raw Material	: Liquid Sorbitol 70%
Net Weight	: 53.1 kg
Q.C No	: RMJ 1711053
Ticket/ B. No	: MS17-1065
Weighing date	: 13/01/18
Weighed By	: ✓ Checked by: 2

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: 2

Raw Material	: Liquid Sorbitol 70%
Net Weight	: 53.1 kg
Q.C No	: RMJ 1711053
Ticket/ B. No	: MS17-1065
Weighing date	: 13/01/18
Weighed By	: ✓ Checked by: 2

Sunadine Syrup

Raw Material : Peach PCA 5019 Flavour
 Net Weight : 1840g
 Q.C No : RMJ 1609021
 Ticket/ B. No : MS17-1065
 Weighing date : 13 / 01 / 18
 Weighed By : ✓ Checked by: ⚡

Sunadine Syrup

Raw Material : Sodium Benzoate
 Net Weight : 1153g
 Q.C No : RMJ 1711040
 Ticket/ B. No : MS17-1065
 Weighing date : 13 / 01 / 18
 Weighed By : ✓ Checked by: ⚡

Raw Material : Citric Acid Anhydrous
 Net Weight : 9900g
 Q.C No : RMJ 1710522
 Ticket/ B. No : MS17-1065
 Weighing date : 13 / 01 / 18
 Weighed By : ✓ Checked by: ⚡

Raw Material : Sugar - Coarse Sugar
 Net Weight : 36.4 kg
 Q.C No : RMJ 1801006
 Ticket/ B. No : MS17-1065
 Weighing date : 13 / 01 / 18
 Weighed By : ✓ Checked by: ⚡

Raw Material : Loratadine (Micronised)
 Net Weight : 945 g
 Q.C No : RMJ 1405039
 Ticket/ B. No : MS17-1065
 Weighing date : 13 / 01 / 18
 Weighed By : ✓ Checked by: ⚡

Raw Material : Sugar - Coarse Sugar
 Net Weight : 50kg
 Q.C No : RMJ 1801006 13/01/18 01006
 Ticket/ B. No : MS17-1067
 Weighing date : 13 / 01 / 18
 Weighed By : ✓ Checked by: ⚡

Sunadine Syrup

Raw Material	:	Glycerine
Net Weight	:	25.5 kg
Q.C No	:	RMJ 1410003
Ticket/ B. No	:	MS17-1065
Weighing date	:	16/01/18
Weighed By	:	<i>J</i> Checked by: <i>J</i>

Sunshine syrup

Raw Material	:	Glycerine
Net Weight	:	55.5 g
Q.C No	:	RMJ 1712003
Ticket/ B. No	:	MS17-1065
Weighing date	:	16/01/18
Weighed By	:	<i>[Signature]</i>
		Checked by:

Raw Material	:	Glycerine
Net Weight	:	20-5 kg
Q.C No	:	RMJ 1#1003
Ticket/ B. No	:	MS17-1065
Weighing date	:	16/01/18
Weighed By	:	
		Checked by: 

Material : Glycine
t Weight : 22.5 kg
C No : RMJ 171003
ket/ B. No : MSIF - 1065
eighing date : 16/01/18
eighed By : L Checked by: H

Raw Material	:	Glycerine
Net Weight	:	30.5 g
C No	:	RMJ 1 ^f 12003
Bucket/ B. No	:	MS17-1065
Weighing date	:	16/01/18
Weighed By	:	JL
		Checked by:

Material : Glycerine
Weight : 22.5 g
C No : RMJ 1715003
cket/ B. No : MS17-1065
ighing date : 16/01/18
ighed By : 
Checked by: 

Sunadine Syrup

Raw Material	:	Glycerine
Net Weight	:	22.5 kg
Q.C No	:	RMJ 1#10003
Ticket/ B. No	:	MS17-1065
Weighing date	:	16/01/18
Weighed By	:	<i>[Signature]</i>
		Checked by:

Sunadine Syrup

Raw Material	: Glycerine
Net Weight	: 22.5 kg
Q.C No	: RMJ 171003
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 1#1003
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	:	<i>L</i>
		Checked by:

Raw Material	: Glycerine
Net Weight	: 22.5 kg
Q.C No	: RMJ 1#19003
Ticket/ B. No	: MS17-1065
Weighing date	: 16/01/18
Weighed By	: f Checked by

Raw Material	:	Glycerine
Net Weight	:	22.5 kg
Q.C No	:	RMJ 1(F)9003
Ticket/ B. No	:	MS17-1065
Weighing date	:	16/01/18
Weighed By	:	<i>L</i>
		Checked by:

Sunadine Syrup

Raw Material	: Liquid Sorbitol 70%
Net Weight	: 23.1 kg
Q.C No	: RMJ 1#11053
Ticket/ B. No	: MS17-1065
Weighing date	: 15/01/18
Weighed By	: Checked by: <i>J</i>

Sunadine Syrup

Raw Material	: Liquid Sorbitol 70%
Net Weight	: 23.1 kg
Q.C No	: RMJ 1#11053
Ticket/ B. No	: MS17-1065
date	: 15/01/18
By	: Checked by: <i>J</i>

Raw Material	: Liquid Sorbitol 70%
Net Weight	: 23.1 kg
Q.C No	: RMJ 1#11053
Ticket/ B. No	: MS17-1065
Weighing date	: 15/01/18
Weighed By	: Checked by: <i>J</i>

Raw Material	: Liquid Sorbitol 70%
Net Weight	: 23.1 kg
Q.C No	: RMJ 1#11053
Ticket/ B. No	: MS17-1065
Weighing date	: 15/01/18
Weighed By	: Checked by: <i>J</i>

Raw Material	: Liquid Sorbitol 70%
Net Weight	: 23.1 kg
Q.C No	: RMJ 1#11053
Ticket/ B. No	: MS17-1065
Weighing date	: 15/01/18
Weighed By	: Checked by: <i>J</i>

Raw Material	: Liquid Sorbitol 70%
Net Weight	: 23.1 kg
Q.C No	: RMJ 1#11053
Ticket/ B. No	: MS17-1065
Weighing date	: 15/01/18
Weighed By	: Checked by: <i>J</i>

Raw Material	: Liquid Sorbitol 70%
Net Weight	: 23.1 kg
Q.C No	: RMJ 1#11053
Ticket/ B. No	: MS17-1065
Weighing date	: 15/01/18
Weighed By	: Checked by: <i>J</i>

Raw Material	: Glycerine
Net Weight	: 22.5 kg
Q.C No	: RMJ 1#10003
Ticket/ B. No	: MS17-1065
Weighing date	: 16/01/18
Weighed By	: Checked by: <i>J</i>

Raw Material	: Liquid Sorbitol 70%
Net Weight	: 23.1 kg
Q.C No	: RMJ 1#11053
Ticket/ B. No	: MS17-1065
Weighing date	: 15/01/18
Weighed By	: Checked by: <i>J</i>

Raw Material	: Glycerine
Net Weight	: 22.5 kg
Q.C No	: RMJ 1#10003
Ticket/ B. No	: MS17-1065
Weighing date	: 16/01/18
Weighed By	: Checked by: <i>J</i>

Raw Material	: Liquid Sorbitol 70%
Net Weight	: 23.1 kg
Q.C No	: RMJ 1#11053
Ticket/ B. No	: MS17-1065
Weighing date	: 15/01/18
Weighed By	: Checked by: <i>J</i>

Raw Material	: Glycerine
Net Weight	: 22.5 kg
Q.C No	: RMJ 1#10003
Ticket/ B. No	: MS17-1065
Weighing date	: 16/01/18
Weighed By	: Checked by: <i>J</i>

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)180118	Deionised water to	900 L	900L	18/10/18	-	18/10/18

Received in good order by production:

Checked by 
18/10/18

18/10/18
Date of receipt

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 checked="" type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Overall room condition is satisfactory	<input type="checkbox"/> Yes	<input checked="" 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 ($\geq 8 \text{ Pa}$)	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: 6	/				19/01/18
	Stirring	Stirrer 2 28/04/18	/				19/01/18
		Code: MC-WD-002					
		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 checked="" 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					

Final Approval:

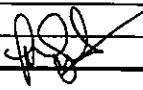
Type of Line Clearance	Approved by	Final Approval		Sign & Date
Minor Line Clearance	Controller / Supervisor / IPQA / Pharmacist / PRP	<input checked="" type="checkbox"/> Approve	<input type="checkbox"/> Not Approve	 19/12/17
Major Line Clearance	IPQA / Pharmacist / PRP	<input type="checkbox"/> Approve	<input type="checkbox"/> Not Approve	

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

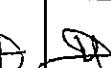
Checked by (sign & date):  19/12/17

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
REMARKS :	EFFECTIVE DATE : 24/10/2016 APPR BY : SIU ANN LIM 

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>9.10 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>9.40 am</u> to <u>10.00 am</u>	 	/ /
14) Filter through a sieve mesh size #100 into covered storage tank(s).	 	/
15) Label storage tank(s).	 	/

Verified by: J Date: 19/10/16

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 <i>[Signature]</i>	APPR BY : SIU ANN LIM <i>[Signature]</i> DATE : 21/09/2016

QC No :

PWJ/1801060

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	3.00	2.0 - 4.0 at 25 deg. C
Viscosity	72.9	40 - 120 cps at 25 deg. C
S.G.	1.25	1.1 - 1.4 at 25 deg. C

Previous item manufactured : SUNADINE SYRUP (331-16001)

Remarks : N/A

Analysed By : *[Signature]* Date : 19/01/18

Checked By: *[Signature]* 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 331-18001	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		M.	M.	19/01/18
Room relative humidity ($\leq 70\%$)	69		M.	M.	19/01/18
Differential pressure ($\geq 8 \text{ Pa}$)	18		M.	M.	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	-			M.	M.	19/01/18
	Others: Code:	-			M.	M.	
Weighing	Weighing Balance Code: 004 (b)	-	27/02/18		M.	M.	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>M.</i> 19/01/18		<i>M.</i> 19/01/18	

SUNWARD PHARMACEUTICALS SDN BHD

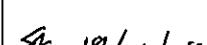
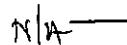
9, 11 & 17 Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Tampoi Johor Bahru, Johor, Malaysia

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

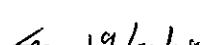
Section B: For Major Line Clearance Use ONLY (After level 2 cleaning)

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 checked="" 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:						
<ul style="list-style-type: none"> Floor, wall, door, other areas that potentially have dust, powder or traces accumulated Supply air grill 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 checked="" 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 checked="" 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 checked="" 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 checked="" type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Sign & Date						
 19/12/18						

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	 19/12/18
Major Line Clearance	IPQA / Pharmacist / PRP	<input type="checkbox"/> Approve	<input type="checkbox"/> Not Approve	 N/A

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

Checked by (sign & date):  19/12/18

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 <i>DJL</i>	APPR BY : SIU ANN LIM <i>PA</i> DATE : 21/09/2016

Bottle Cleaning

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

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

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tamboi 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 For: 60ml, 100ml, 120ml	APPR BY : SIU ANN LIM  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.:

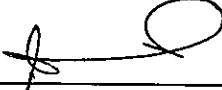
SUNWARD PHARMACEUTICAL SDN BHD

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
REMARKS :	- 60ml, 100ml, 120ml	DATE : 09/01/2018 EFFECTIVE DATE : 09/01/2018 APPR BY : AZHAN DAUD

HOLOGRAM LABEL, LABEL, HOLOGRAM and LEAFLET Requisition Form

Item	Qty Requested	Qty Issued
Hologram Label	NA	NA
Label	1852	2029X1 2024X1 2026X1 773 X1
* Hologram	1510	1510
Leaflet	1501	1501 19/01/18 1501

Requested By : 
 Issued By : /MA
 Date of Issue : 19/01/18
 Quantity Checked and
 Received By : 

* HOLOGRAM Details

	Quantity	Serial Number
	1510	H239 424 32 - H239 499 41 .
Reject		/MA
Total Quantity Issued	1510 .	

Remarks : _____

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

Brought Forward LABEL, HOLOGRAM and LEAFLET Form

Item	Qty Requested	Qty Issued
Label		
Hologram		
Leaflet		

Requested By : _____

Issued By : _____

Date of Issue : _____

Quantity Checked and

Received By _____

* HOLOGRAM Details

	Quantity	Serial Number
Reject		
Total Quantity Issued		

Remarks : _____

Item Picture

SWMY LIVE

Tuesday, January 09, 2018

Page 2

SUN\AZMI

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

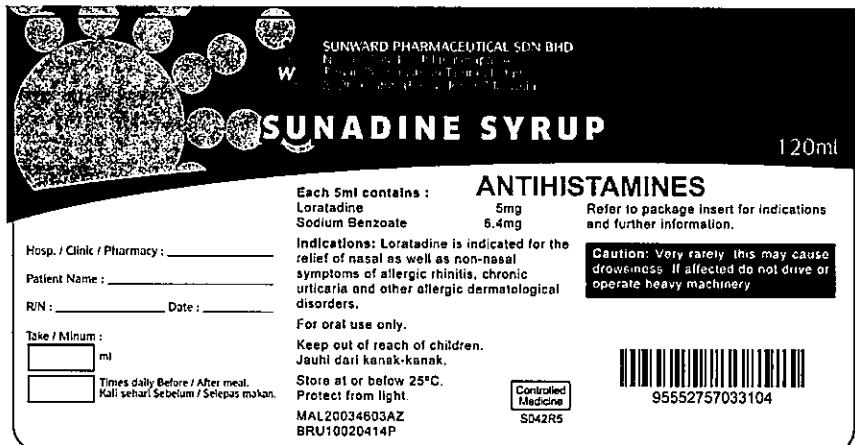
Background : Pan 2935C, T50%

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

Material : ArtPaper - Raflaplus

Packing : Roll Form

Pattern :



Approved by : Culy 09/01/18



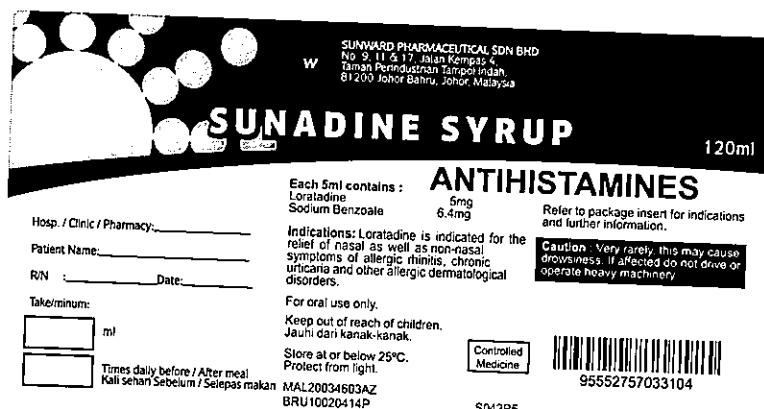
Production Ticket No.:

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 <i>[Signature]</i>	DATE : 21/09/2016

Approved LABEL



QC Reference No. :	Dm31801005		
Activity:	Coded By	Checked and Approved By	
Signature:	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</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



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 <i>[Signature]</i>	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 shown that both loratadine and its metabolite readily cross the blood-brain barrier. It has higher affinity for the peripheral rather than 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. Desmethylloratadine, which is the major metabolite has potent histamine H1-receptor blocking activity. Reported half-lives for loratadine and desmethylloratadine are about 12 and 18 hours respectively. Loratadine is about 98% bound to plasma proteins while its major metabolite, desmethyloratadine 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, alopecia, anaphylaxis, abnormal hepatic function, tachycardia, palpitation, fatigue, headache, somnolence, dry mouth, nervousness, wheezing, abdominal pain, hypertension, 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 asthma, hypertension, 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, cimidine, 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, desmethyloratadine 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 cimidine 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

PWJ 1801079

[Signature]

AS/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 SYRUP 281-18002 100ML	Approved by	AZHAN
Previous Product / Batch No. / Pack Size	SUNWARD SYRUP 281-18001 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.	l	19/01/18
	Room relative humidity ($\leq 70\%$)	54	g.	l	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		✓	Hatched	g.	l	19/01/18
	Komark Labelling Machine 2 Code: MC-PD-006		/	Hatched			
	Foresco-Labelling Machine Code: MC-PD-003		/	Hatched			
	Others: Code:		/	Hatched			
Weighing	Weighing Balance Code: DS 671-1		✓	22/01/18	g.	l	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 SWUP 321-18002 100ML	Approved by	AZHAN
Previous Product / Batch No. / Pack Size	SUNADING SWUP 321-18001 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					
		19/01/18		19/01/18		19/01/18

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	19/01/18

Check all packaging materials are 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 :	For: 60ml, 100ml, 120ml	EFFECTIVE DATE : 21/09/2016 <i>DOL</i>	APPR BY : SIU ANN LIM <i>SAL</i>
			DATE : 21/09/2016

PACKING Job Specifications

Steps	Performed	Checked
1) Set labeling and printing machine.	<i>b</i>	<i>x</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>b</i>	<i>x</i>
3) Printing machine will print batch number, manufacturing date and expiry date onto product labels.	<i>b</i>	<i>x</i>
4) Labeling machine will first paste hologram onto product labels and then label the bottles as they move on the conveyor belt.	<i>b</i>	<i>x</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>b</i>	<i>x</i>
6) Pack labelled bottles into labelled carton(s).	<i>b</i>	<i>x</i>
7) Insert leaflets into carton(s) and seal carton(s) with cellophane tape at the middle and both of the edges.	<i>b</i>	<i>x</i>
8) Check weight of carton(s). Document the results.	<i>b</i>	<i>x</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>b</i>	<i>x</i>

Verified By : *A*Date : 19/09/16

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 <i>[Signature]</i> DATE : 21/09/2016

PACKING Report

QC reference Number

Packing Materials Description

Bottle	: <u>PFY 1713049</u>
Cap	: <u>PFJ 1713049 / 1+12085</u> <small>19/10/14</small>

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 Kempar 4, Taman Perindustrian Templer Indah, 81200 Johor Bahru, Johor, Malaysia

Batch Manufacture Record	
ITEM: Sunadine Syrup	PREP BY : AZMI EFFECTIVE DATE : 09/01/2018
REMARKS : - 60ml, 100ml, 120ml, 1L	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	Reject	Good condition	Transfer Shipment	Supervisor	Controller	Scrap qty	Checked/ destroyed by QC/ date
HOLeGRAM LABEL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
LABEL	1801001	1801	-	400	4	-	1	-	-	-	-	-	10/01/18	✓	39.	✓ 23/01/18
HOLeGRAM	1410014	1401	-	100	-	4	-	-	-	-	-	-	10/01/18	✓	-	✓ 23/01/18
LEAFLET	1801001	1801	-	1500	-	-	1	-	-	-	-	-	10/01/18	✓	1500	✓ 23/01/18
Rejected Hologram No.															-	

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

Remarks:
✓ 100% ✓ 100% ✓ 100%

DATE : 09/01/2018

Production Ticket No.:

SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempar 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	APPR BY : SIU ANN LIM
REMARKS :	For: 60ml, 100ml, 120ml, 1L		DATE : 21/09/2016

PACKAGING MATERIAL Reconciliation

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

Batch No	Ticket No	Verified by controller
~	~	~
~	~	~

Remarks:

-NA-

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
REMARKS :	- 60ml, 100ml, 120ml, 1L

PREP BY : AZMI DATE : 09/01/2018
EFFECTIVE DATE : 09/01/2018
APPR BY : AZHAN DAUD *(Signature)* DATE : 09/01/2018

PHYSICAL CHECKS ON PACKED PRODUCTS

		Packing Personnel	Production Controller	Date
Correct size and colour of bottles and caps	✓	<i>a.</i>	<i>f</i>	19/01/18
Status of Containers	Clean	✓	<i>a.</i>	19/01/18
	Unclean			
Labels are correctly coded with	Batch No. On BMR: 231-18002. On Label: 231-18002	✓	<i>a.</i>	19/01/18
	Date of Mfg. On BMR: 19 JAN 2018 On Label: JAN 18	✓		
	Expiry Date: On BMR: DEC 2020 - On Label: DEC 20.	✓		
Labels correspond to the item produced	Yes	✓	<i>a.</i>	19/01/18
	No			
Labels are printed with "Controlled Medicine" for items containing Schedule Poisons.	Yes	✓	<i>a.</i>	19/01/18
	No			
Containers are	Properly capped	✓	<i>a.</i>	19/01/18
	Sealed with cap seal			
Package insert attached/enclosed		✓	<i>a.</i>	19/01/18

Checked By : *[Signature]*
QC Dept

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 : 21/09/2016
REMARKS :	-	EFFECTIVE DATE : 21/09/2016 APPR BY : SIU ANN LIM	 DATE : 21/09/2016

QC No :

Par1801060

APPROVAL For Release

Date of Manufacture : 19 JAN 2018

Expiry Date : DEC 2020

Quantity Planned : 900 c

Total Quantity Produced :

$$\begin{aligned} & 7506 \times 120ml \\ & 4 \times 120ml taken by us \\ & 4 \times 120ml for testing \end{aligned}$$

Yield (%) : 100.19 %

Item is approved for release

	Signature	Name	Date
QC Manager/Chemist/QC Pharmacist		Harnel Abdullah	28/01/18
Production Pharmacist		Jing Yt	26/01/18

Remarks : - M4 -

ANALYTICAL REPORT FOR LIQUID PREPARATIONS

Effective Date	17/10/2015	Review Date	17/10/2018
Reference Document No.	SOP/QA/0709	Revision	7.0
Prepared By	Ms HIDAYAH	QC Clerk	
Checked By	Ms M.C. ONG	QC Chemist	
Approved By	Ms. H.T.NG	QC Manager	
PRODUCT	SUNADINE SYRUP		
BATCH NO.	331-18002	QC NO.	PWJ 1801066
CONTENTS PER 5ML	Loratadine	5mg	
PRESERVATIVE PER 5ML	Sodium Benzoate	6.4 mg	
DATE OF MANUFACTURE	19/01/18	BATCH SIZE	900L
EXPIRY DATE	13/05/20	PACK SIZE	100M

REFERENCE OF ASSAY METHOD: SUNWARDS

TEST	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 Benzoinic 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 80.0 - 120.0%	Sodium Benzoate : 101.31%
8. ASSAY (content per 5 ml)	Loratadine 90.0 - 110.0%	Loratadine : 100.24%
9. MICROBIAL CONTAMINATION TEST (BP)	TAMC (cfu/ml) TYMC (cfu/ml) Specified Micro-organisms	TAMC : <10 TYMC : <10 Specified Micro-organisms : Complies
10. MICROBIAL CONTAMINATION TEST (NPCB)	Specified Micro-organisms	Absence of <i>D. cecropiae</i> in 1ml Specified Micro-organisms : Complies

TAMC : Total Aerobic Microbial Count

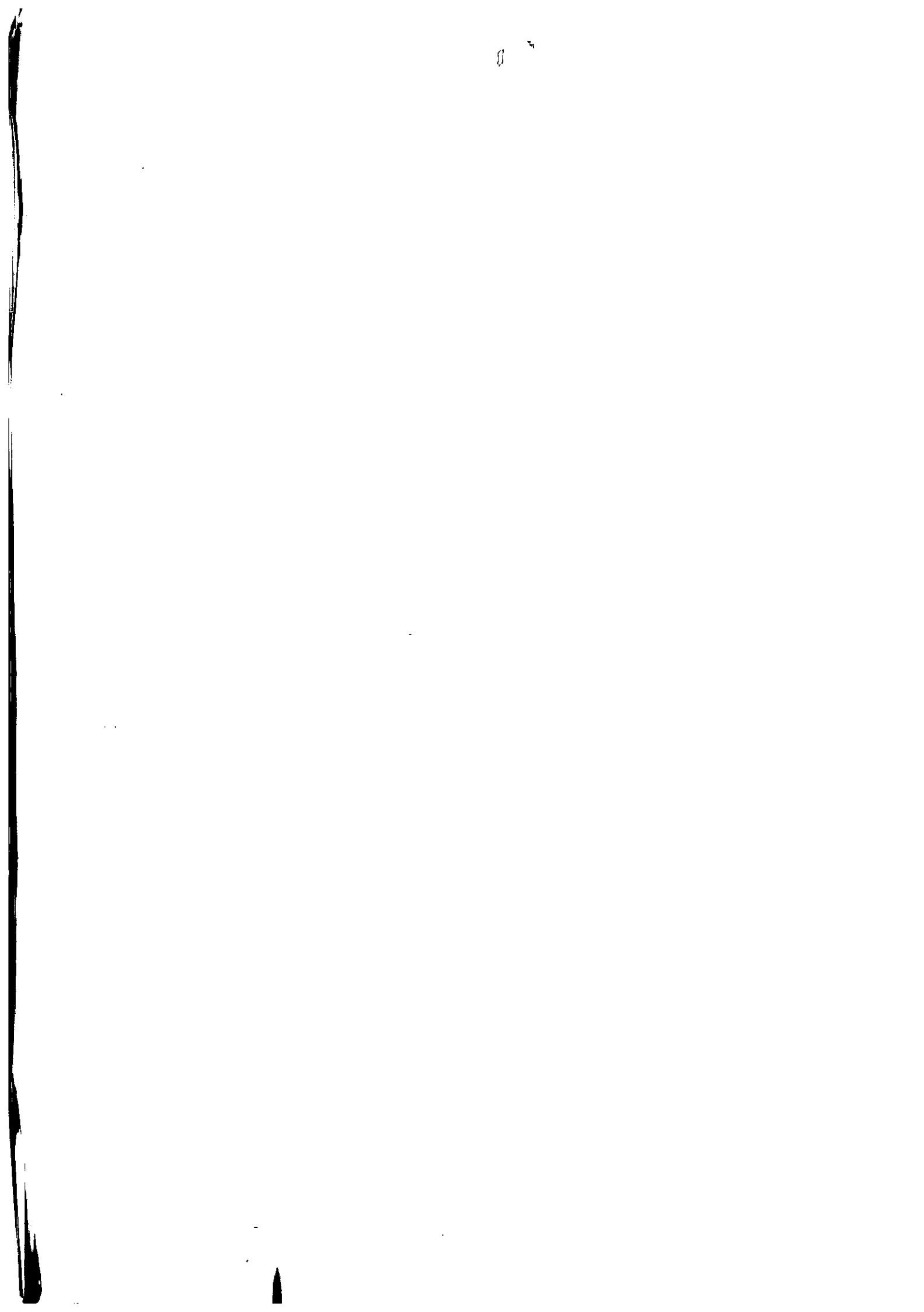
TYMC : Total Combined Yeast/Moulds Count

REMARKS:

ANALYZED BY	DATE
CHECKED BY	DATE
APPROVED BY	DATE

SUNWARD PHARMA JB
COPY
REVISION

SUNWARD PHARMA JB
MASTER COPY
REVISION



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

Production Ticket No.:

SUNWARD PHARMACEUTICAL SDN BHD

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

Manufacturing Manpower Record		
SUBJECT :	ITEM :	PREP BY : AZMI
REMARKS :	Sunadine Syrup	EFFECTIVE DATE : 21/09/2016 <i>[Signature]</i>
	-	APPR BY : SIU ANN LIM <i>[Signature]</i>
	-	DATE : 21/09/2016

Batch No.:

Sunadine Syrup

SYRUP/CREAM				PACKING			
Starting	Ending	Manpower	Starting	Ending	Manpower		
19/01/14			19/01/14				
Preparation / mixing / frosting			Filling				
9.00 am	10.00 am	2	2.45 pm	5.25 pm	3		
Wash and cleaning			Wash and cleaning				
11.00 am	12.00 pm	2	8.25 pm	8.00 pm	3		
Labelling			Labelling				
			2.45 pm	5.25 pm	4		
			WAF				

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

SIGNATURE LIST



SUNWARD PHARMACEUTICAL SDN BHD

No. 9, 11 & 17, Jalan Kempas 4, Taman Perindustrian Tamboi 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





 SUNWARD Pharmaceutical Sdn Bhd

ACTIVITY RECORD





IN-PROCESS SYRUP SMALL PACK FILLING WEIGHING RECORD

Machine :	In-Line Filling & Capping Machine (Monoblock) / EG-2 Filling Machine (Everscan)				Date :	19/01/18	
Product :	Syrup	Batch No:	331 - 18002	Batch Size:	900L	Pack Size:	120ml
Bottle Weight (g)	(1) 17.21 (6) 17.15	(2) 17.17 (7) 17.26	(3) 17.15 (8) 17.25	(4) 17.29 (9) 17.31	(5) 17.24 (10) 17.22	Average weight of 10 bottles (g): 17.22	
Weight of 60ml/610ml/120ml (g):	(1) 147.65	(2) 147.57	(3) 147.58	(4) 147.52	(5) 147.49	Average weight (g): 147.58	

Minimum limit = (Average weight of syrup in 5 measurements) + Average weight of 10 bottles

*FOR METHADONE, Minimum limit = (Average weight of 61ml syrup in 5 measurements) + Average weight of 10 bottles

Maximum limit = Minimum limit + 3%

Tank No.	Time	Weight (g)							Performed by	Supervisor/Controller	Check by QC	Remark
		Noz. 1	Noz. 2	Noz. 3	Noz. 4	Noz. 5	Noz. 6	Noz. 7				
E	2.45 pm	165.29	165.34	165.20	165.27	165.29	165.30	165.42	165.40	✓	✓	
	3.00 pm	165.20	165.42	165.17	165.39	165.40	165.30	165.36	165.34	✓	✓	
	3.15 pm	165.21	165.39	165.50	165.31	165.46	165.57	165.46	165.47	✓	✓	
F	2.30 pm	165.21	165.45	165.54	165.35	165.45	165.35	165.51	165.56	✓	✓	
	3.45 pm	165.28	165.40	165.60	165.40	165.45	165.59	165.42	165.36	✓	✓	
	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 remarks column.

SUNWARD PHARMA. (JB)	SUNWARD PHARMA (JB)
MASTER COPY	COPY <input checked="" type="checkbox"/>
REVISION 0	REVISION <input checked="" type="checkbox"/>



IN-PROCESS SYRUP SMALL PACK WEIGHING RECORD

Tank No.	Time	Weight (g)						Performed by	Supervisor/ Controller	QC	Remark
		Noz. 1	Noz. 2	Noz. 3	Noz. 4	Noz. 5	Noz. 6				
C	4.15 pm	165.30	165.49	165.44	165.65	165.74	165.25	165.21	✓	✓	
C	4.30 pm	165.38	165.57	165.41	165.70	165.78	165.18	165.25	✓	✓	
C	4.45 pm	165.27	165.52	165.60	165.69	165.73	165.32	165.40	✓	✓	
G	5.00 pm	165.34	165.40	165.46	165.73	165.47	165.50	165.34	✓	✓	
G	5.15 pm	165.21	165.28	165.71	165.34	165.26	165.24	165.41	✓	✓	
G	5.30 pm	165.27	165.21	165.82	165.40	165.37	165.25	165.42	✓	✓	

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

SUNWARD PHARMA (JB)
MASTER COPY REVISION
COPY REVISION



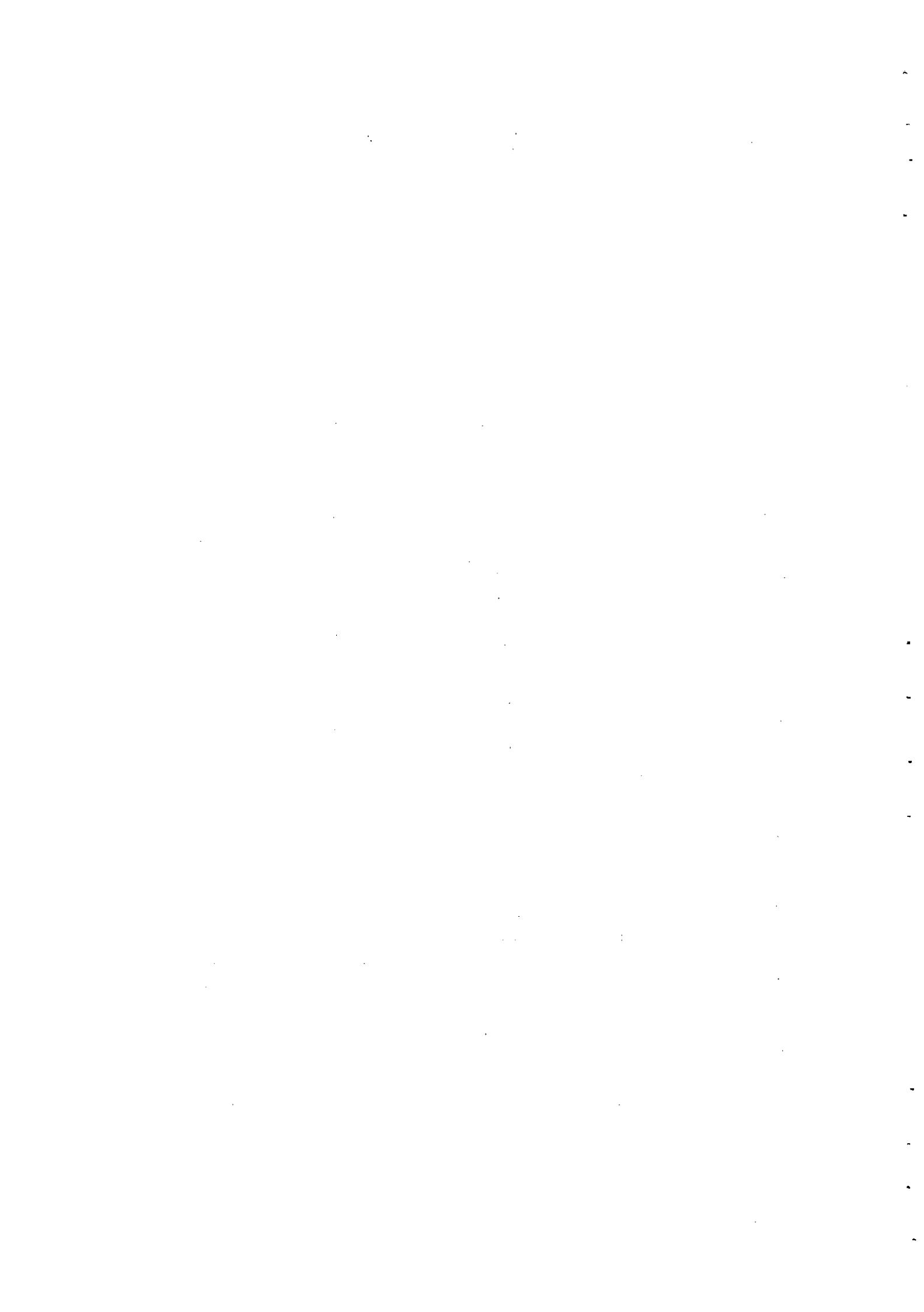
FINISHED PRODUCT WEIGHING RECORD (120ml)

Product:	SUNADINE SYRUP	Batch No:	321-18002
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) :			0.58kg
Specifications: (Weight of 1 bottle x Number of bottles in a carton) + Tare :			Not less than 8.98kg .

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	9.01	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 67-1
Weighed by/date :	NORA - NADIAH 1-151 19/01/18
Verified by/date :	FUJI 1/18



SUNWARD
PHARMACEUTICAL
SDN BHD

PRODUCTION RECORD

Doc. No.: RC/PD/93a
Version no.: 02

CLEANING CHECKLIST

Prepared by: *7/3/2016*

Approved by: *MJ* *7/3/16*

Equipment:	Monoblock Filling Machine		
Previous Product Manufactured:	<i>Sunadine Syr</i>	Batch Number:	331-18001
Cleaned by:	<i>n/a</i>		
Cleaning time/date:	Date: <i>10/01/18</i>	Date: <i>/</i>	
	Time Start: <i>12.40 pm</i>	Time Start: <i>n/a</i>	
	Time End: <i>2.45 pm</i>	Time End: <i>/</i>	

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)

Level 2 Cleaning (*✓ if the part is cleaned*)

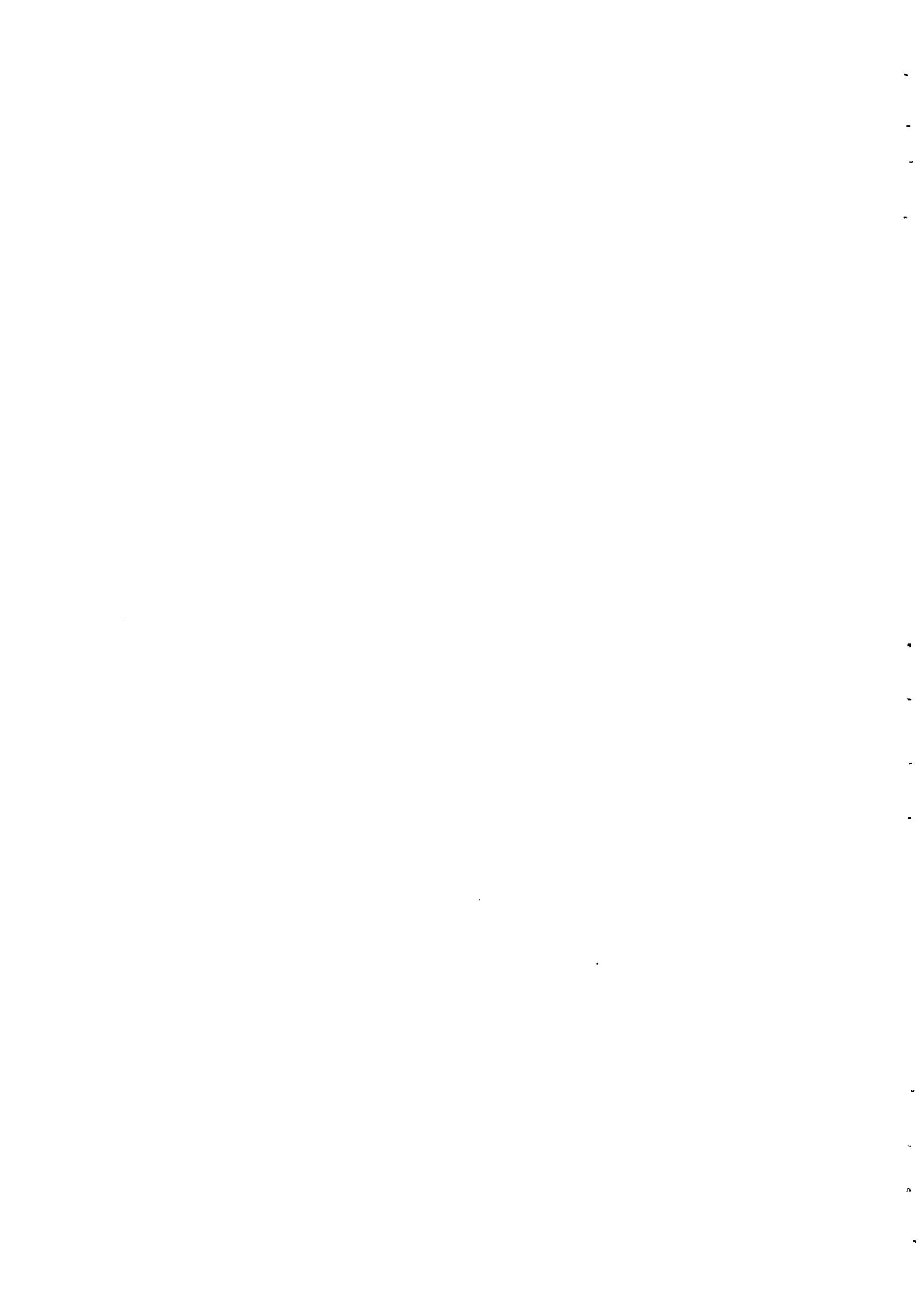
Parts	Cleaned	Parts	Cleaned
Storage Tank		Motor Pump	
Transfer Hose		Syrup Filter Unit	
Volume Sensor		Machine Body	
Hopper (Rinsing)		Wash System	
		Water Temperature:	°C

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 *✓*

Contact:

Ticket No. *331 - 1822*

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
	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
	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
	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
	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
	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
	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
	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
	RM17-M0646	RMJ1710042	DEN097/17	03/08/2019	15.408 KG	15.408	KG Approved

Action	Sign	Date
Received By	<i>JL</i>	<i>17/01/18</i>
Verify By	<i>DR</i>	<i>17/01/18</i>





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

Contact:

Ticket No.

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-	28/02/2022 M	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
REMARKS :		EFFECTIVE DATE : 21/09/2016 APPR BY : SIU ANN LIM

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 :	page 1 of 1000

Issued by : J
Date : 10/01/18

Packer No. :
NADIAH MOOKA, MA, FZ

Packing Details

Quantity	Pack Size	No. of Carton	Units per Carton
<u>7506</u> bottles	120ml	120	50 bottles
		1	6 bottles

Goods received by Store	Signature	Date
Approved label affixed by QC		<u>10/01/18</u>

Entry into :	Signature	Date
Stock Card		
Computer		

Remarks :

