

## MASTER FORMULA RECORD



Name of the Product	GENTLE BABY WASH		
MFR No.	MFR/PC/0379	Version	00
Supersedes	NA	Batch Size	100 Kg
Shelf life	3 Years	Mfg. Lic. Category	FDA
Effective Date	16/02/2024		

## 1.0 PRODUCT DETAILS

Name of the Product	GENTLE BABY WASH
Dosage Form	Liquid
Active content	5.0 mg/g
Primary Pack	As per Annexure 01
Unit Pack	As per Annexure 01
Additional Brand Name	As per Annexure 02
Name and address of the company	Himalaya Wellness Company (Formerly known as The Himalaya Drug Company), Makali, Bengaluru 562162, India

Prepared By	Reviewed & Approved By	Reviewed & Approved By	Reviewed & Approved By
CDC	F&D-PC	R&D-TT	R&D-QA
Shrikrishna Hasnale - Research Associate	Nagaveni K.S - SENIOR RESEARCH ASSOCIATE	Manoj Kumar - Associate Manager	Ganesh Uravane - Research Associate
17/01/2024	31/01/2024	02/02/2024	14/02/2024

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## 2.0 BILL OF MATERIAL

Product Code: 3004541

Alt BOM: 1

S. No.	Material Code	Material Description	Grade	INCI Name	Function	CAS NO.	U O M	% ADDN w/w	Qty Per Batch	Qty per g in mg
Active ingredient										
1.	1000741	BG 361 (PBF) Soft Extract	IH	NA	Active	92113-26-3, 84625-40-1	Kg	0.50	0.50	5.00
Inactive ingredients										
2.	4000851	Purified Water	IP/Ph.Eur/ USP/IH	Aqua/Water	Solvent	7732-18-5	Kg	73.46	73.46	7346.00
3.	4000684	Coco Glucoside [Plantacare 818 UP]	IH	Coco-Glucoside	Surfactant-Cleansing Agent	110615-47-9	Kg	10.00	10.00	100.00
4.	4000682	Cocamido Propyl Betaine [Galaxy]	IH	Cocamidopropyl Betaine	Surfactant-Foam Booster	97862-59-4, 61789-40-0, 70851-07-9, 83138-08-3	Kg	8.00	8.00	80.00
5.	4000801	Disodium Cocoamphodi acetate [Miranol C2M Conc NP]	IH	Disodium Cocoamphodi acetate	Surfactant-Cleansing Agent	68650-39-5	Kg	5.00	5.00	50.00

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6.	4000663	Acrylates C 10-30 Alkyl Acrylate Crosspolymer [Carbopol 20]	IH	Acrylates/C10-30 Alkyl Acrylate Crosspolymer	Viscosity Increasing Agent-Aqueous	NA	Kg	0.70	0.70	7.00
7.	4001177	Perfume Sweet Love 288570	IH	Fragrance	Fragrance	NA	Kg	0.70	0.70	7.00
8.	4000819	Phenoxyethanol	IH	Phenoxyethanol	Preservative	122-99-6	Kg	0.50	0.50	5.00
9.	4000678	Citric Acid/ Citric Acid Monohydrate	IH	Citric Acid	pH Adjuster	5949-29-1 77-92-9	Kg	0.35	0.35	3.50
10.	4001199	Sodium Benzoate	IP	Sodium Benzoate	Preservative	532-32-1	Kg	0.30	0.30	3.00
11.	4000884	Sodium Hydroxide Pellets	IP	Sodium Hydroxide	pH Adjuster	1310-73-2	Kg	0.22	0.22	2.20
12.	4000843	Potassium Sorbate	IH	Potassium Sorbate	Preservative	24634-61-5, 590-00-1	Kg	0.20	0.20	2.00
13.	4000708	Disodium EDTA	IP	Disodium EDTA	Chelating Agent	139-33-3	Kg	0.05	0.05	0.50
14.	4000879	Sodium Citrate	IP	Sodium Citrate	Buffering Agent	68-04-2, 6132-04-3	Kg	0.02	0.02	0.20
Total							Kg	100.0	100.00	1000.00

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## 3.0 ACTIVE COMPOSITION

Each g contains:

S. No	Active Preparation	Common Name	INCI Name	Part Used	Quantity (mg)	Functions
<b>BG 361(PBF) Soft Extract*</b>						
1.	Extract	chickpea	Cicer Arietinum Seed Extract	Seed	2.5	Skin Conditioning
2.	Extract	mung bean	Phaseolus Radiatus Seed Extract	Seed	1.5	Skin Conditioning
3.	Extract	fenugreek	Trigonella Foenum-Graecum Seed Extract	Seed	1.0	Moisturization, Skin Conditioning
<b>Total</b>					<b>5.0</b>	<b>NA</b>
<b>Preservative details: * 0.4% Potassium sorbate</b>						

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## Abbreviations:

Alt	: Alternate	No.	: Number
ADDN	: Addition	PET	: Poly Ethylene Terephthalate
BOM	: Bill Of Material	Pdr	: Powder
CAS	: Chemical Abstract Service	PBF	: Paraben Free
cm	: Centimetre	Ph.Eur	: European Pharmacopoeia
CP	: Consumer Products	PC	: Personal care
EDTA	: Ethylene Diamino Tetra Acetic Acid	QA	: Quality Assurance
Ext	: Extract	Qty	: Quantity
g	: Gram	QC	: Quality Control
HDPE	: High-Density PolyEthylene	rpm	: Rotation Per Minute
IH	: In-House	S.	: Serial
INCI	: International Nomenclature of Cosmetic Ingredients	SE	: Soft Extract
IP	: Indian Pharmacopoeia	SS	: Stainless Steel
Kg	: Kilogram	UOM	: Unit of Measurement
L	: Litre	USP	: United States Pharmacopeia
Mfg. Lic.	: Manufacturing Licence	Vol.	: Volume
MC	: Micro Controlled	%	: Percentage
MFR	: Master Formula Record	°C	: Degree Celsius
mg	: Milligram	&t	: And
ml	: Millilitre	w/w	: Weight by Weight
min	: Minutes	#	: Mesh Size
NA	: Not Applicable		

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## 4.0 BRIEF MANUFACTURING AND PACKING PROCEDURE

## Phase separation

Phase	Name of the Raw Material	% ADDN (W/W)
A	Purified Water	5.00
	Disodium EDTA	0.05
A1	Purified Water	56.46
	Acrylates C 10-30 Alkyl Acrylate Crosspolymer [Carbopol 20]	0.70
B	Purified Water	2.00
	Sodium Hydroxid pellets	0.22
C	Disodium Cocoamphodiacetate [Miranol C2M Conc NP]	5.00
	Coco Glucoside [Plantacare 818 UP]	10.00
D	Cocamido Propyl Betaine [Galaxy]	8.00
E	Purified water	2.00
	BG 361 (PBF) Soft Extract	0.50
F	Purified water	2.00
	Potassium Sorbate	0.20
G	Purified water	2.00
	Sodium Benzoate	0.30
H	Purified water	2.00
	Citric Acid/ Citric Acid Monohydrate	0.35
I	Purified water	2.00
	Sodium Citrate	0.02
J	Phenoxyethanol	0.50
K	Perfume Sweet Love 288570	0.70
Total		100.00

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## General Do's &amp; Don'ts:

- All ingredients should be weighed accurately as per the quantity mentioned in BOM.
- Use gloves & masks during production activity.
- Ensure that all vessels are clean, dry & odour free.
- Main mixing vessel will be in continuous mixing from the start phase to end phase.

## Critical Control Points:

- Disperse Carbomer [Carbopol 980] with cowl/stirrer/homogenizer in main vessel. Ensure no lumps should be present.
- Dissolution of Sodium Hydroxide Pellets in Purified Water liberates heat; care should be taken while handling it.
- Add Citric Acid/ Citric Acid Monohydrate solution to the main vessel by passing it through 100 # nylon filter cloth. Check the pH it should be 5.30-5.70
- Add Sodium Citrate solution to the main vessel by passing it through 100 # nylon filter cloth.
- Ensure that no lumps/particles are present in the bulk.
- Store the Bulk in a proper airtight container.
- Ensure mesh integrity of nylon cloth pre and post use.

## A. Manufacturing Procedure

Dispense the tested and approved raw materials as per BOM.

In a separate Jacketed SS vessel, transfer Purified Water (73.46 %) and Heat it to 95°C for 30 min.

Then cool to 35 – 40 °C and use for the batch manufacturing.

**Phase A:** Transfer the Purified Water (5.0%) to separate SS vessel and add Disodium EDTA (0.05 %) and mix well for 5 minutes to get clear solution and transfer to main mixing vessel through 100 # nylon filter cloth with anchor speed at 35-40 rpm. Transfer remaining purified Water (56.46 %) into the main vessel under continuous mixing at 35-40 RPM for 10 minutes. Start cowl/stirrer/homogenizer & add Carbopol Ultrez 20 (0.7 %) into the vortex of the Purified Water. Disperse completely (No lumps should be present).

**Observation:** A translucent gel is formed

**Phase B:** In a separate SS vessel, dissolve Sodium Hydroxide Pellets (0.22 %) in Purified Water (2.00%) using SS Spatula until clear solution obtained.

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**Observation:** A transparent solution is formed which has to be handled properly as the temperature increases during the dissolution process.

Transfer it to the main vessel by passing through #100 nylon filter & continue mixing at 25-30rpm for 15 mins.

**Observation:** A clear transparent thick gel is formed.

**Phase C:** Transfer Disodium Cocoamphodiacetate [Miranol C2M Conc NP] (5.0 %) & Coco Glucoside [Plantacare 818 UP] (10.0 %) into main vessel at 25-30rpm for 10 minutes under stirring. (ensure that no lumps are formed).

**Observation:** Transparent liquid

**Phase D:** Transfer Cocamido Propyl Betaine [Galaxy] (8.0 %) into main vessel under the stirring at 25-30rpm for 10 minutes. (Ensure that no lumps are formed).

**Observation:** Transparent Liquid.

**Phase E:** Take Purified Water (2.0 %) in a side SS vessel and add BG 361 (PBF) Soft Extract (0.5 %) and mix well. Add this by passing through 100 #nylon filter cloth to main vessel. Continue mixing for 10 minutes at 25-30rpm

**Observation:** Transparent Liquid.

**Phase F:** Take Purified Water (2.0 %) in a side SS vessel and add Potassium Sorbate (0.2 %) and mix well. Add this by passing through 100 # nylon filter cloth to main vessel. Continue mixing for 10 minutes at 25-30rpm.

**Observation:** Transparent Liquid.

**Phase G:** Take Purified Water (2.0 %) in a side SS vessel and add Sodium Benzoate (0.3 %) and mix well. Add this by passing through 100 # nylon filter cloth to main vessel. Continue mixing for 10 minutes at 25-30rpm.

**Observation:** Transparent Liquid.

**Phase H:** Take Purified Water (2.0 %) in a side SS vessel and add Citric Acid/ Citric Acid Monohydrate (0.35 %) and mix well. Add this by passing through 100 # nylon filter cloth to main vessel. Continue mixing for 10 minutes at 25-30rpm. Check the pH it should be 5.30-5.70

**Observation:** Slightly Translucent Viscous liquid.

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**Phase I:** Take Purified Water (2.0 %) in a side SS vessel and add Sodium Citrate (0.02 %) and mix well. Add this by passing through 100 # nylon filter cloth to main vessel. Continue mixing for 10 minutes at 25-30rpm.

**Observation:** Slightly Translucent Viscous liquid.

**Phase J:** Add Phenoxyethanol (0.5%) by passing through 100 # nylon filter cloth to main vessel. Continue mixing for 10 minutes at 25-30rpm. Recirculate the mass by removing some materials from the bottom and again add it into the main vessel. (Ensure that all the material has been mixed properly) and De-aerate the bulk under 600-650 mmHg vacuum for 20-30 minutes or until the product is free from air bubbles with continuous mixing.

**Observation:** Translucent Viscous liquid.

**Phase K:** Transfer Perfume Sweet Love 288570 (0.7 %) to main vessel and mix at 15-20 RPM for 20 minutes.

**Observation:** Medium Viscous Translucent Viscous liquid

Submit the sample to QC for analysis.

**In-process checks:**

As per bulk specification

**B. Packing Procedure**

As per Annexure 01.

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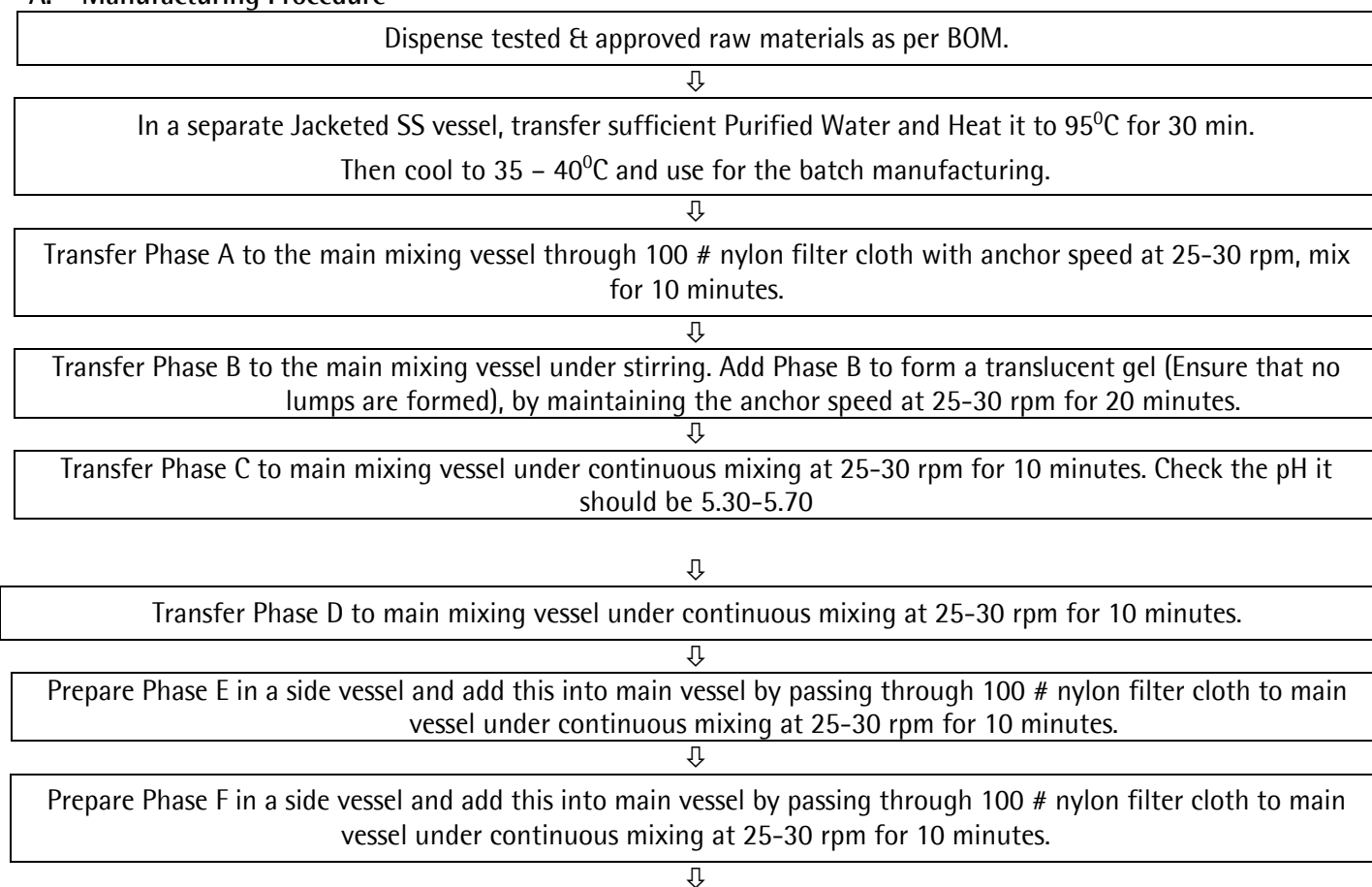
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## 5.0 MANUFACTURING FLOW CHART

## A. Manufacturing Procedure



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Prepare Phase G in a side vessel and add this into main vessel by passing through 100 # nylon filter cloth to main vessel under continuous mixing at 25-30 rpm for 10 minutes.



Prepare Phase H in a side vessel and add this into main vessel by passing through 100 # nylon filter cloth to main vessel under continuous mixing at 25-30 rpm for 10 minutes.



Prepare Phase I in a side vessel and add this into main vessel by passing through 100 # nylon filter cloth to main vessel under continuous mixing at 25-30 rpm for 10 minutes.



Add Phase J into main vessel by passing through 100 # nylon filter cloth to main vessel under continuous mixing at 25-30 rpm for 10 minutes. Recirculate the mass by removing some materials from the bottom and again add into the main vessel. (Ensure that all the material has been mixed properly) and De-aerate the bulk under 600-650 mmHg vacuum for 20-30 minutes or until the product is free from air bubbles with continuous mixing.



Transfer Phase K to the main mixing vessel and mix at 15-20 RPM for 20 minutes.



Send the sample to QC for analysis.



#### B. Packaging Procedure

Packing as per Annexure 01.

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