	HIMALAYA WELLNESS COMPANY, BENGALURU		
	BATCH MANUFACTURING RECORD		
Product Name	PILEX FORTE OINTMENT GEN		
Document No.	BMR/3003687/1157/01-01	Supersedes Doc. No. & Date	BMR/3003687/1157/01-00 & 07/08/2020
Market	GEN	CML	All Kind
Effective Date	18/01/2022	Standard Batch Size	2,000 Kg
Batch No.		Mfg. Lic. No.	HP-47-Ay LL

PRODUCT NAME : **PILEX FORTE OINTMENT GEN**

SEMI FINISHED PRODUCT CODE/ALTERNATE No. : 3003687/01

REFERENCE MFR No. : **MFR/PH/19/0039/00**

BATCH NUMBER :

ACTUAL BATCH SIZE :

MANUFACTURING DATE :

EXPIRY DATE :

SHELF LIFE : 3 Years

BATCH COMMENCED ON :

BATCH COMPLETED ON :

TOTAL QUANTITY : _____ Kg

MANUFACTURING YIELD : _____ %

ANY BREAK DOWN / DEVIATION / INCIDENT :

EXECUTED BATCH RECORD REVIEWED BY (SIGN/DATE) :

(MANAGER-PRODUCTION)


EXECUTED BATCH RECORD REVIEWED BY (SIGN/DATE) :

(MANAGER-QA)

Prepared by QA	Checked by Production	Authorized by QA
MALLARAJE URS A.N. 17/01/2022	Deepak Kumar 17/01/2022	BALESH KUMAR 18/01/2022

Note:- This document has been generated electronically and is valid without signature.

QL001/F01-04 This document and the contents hereof are considered proprietary and confidential information of The Himalaya Drug Company. Disclosure to unauthorized individuals or dissemination, publication or copying is prohibited without the prior written consent of The Himalaya Drug Company.

	HIMALAYA WELLNESS COMPANY, BENGALURU		
	BATCH MANUFACTURING RECORD		
Product Name	PILEX FORTE OINTMENT GEN		
Document No.	BMR/3003687/1157/01-01	Supersedes Doc. No. & Date	BMR/3003687/1157/01-00 & 07/08/2020
Market	GEN	CML	All Kind
Effective Date	18/01/2022	Standard Batch Size	2,000 Kg
Batch No.		Mfg. Lic. No.	HP-47-Ay LL

1.0 PROCESSING INSTRUCTIONS:

General processing instructions:

- Standard operating procedures are unit operation based & current revision of SOPs shall be followed.
- Observe GMP requirements throughout the manufacturing process.
- Check & ensure that the balances are in calibrated state.
- Ensure that product is labeled at all applicable stages of manufacturing process.
- Ensure that all vessels are clean, dry & odour free. Ensure all equipment's are cleaned as per SOP & affixed with cleaned status label.
- Avoid direct product contact.
- Ensure that secondary gowning of the respective areas is followed.
- Dispense raw materials as per SOP.
- Maintain temperature of the respective area as per requirement
- Dispense ingredients in new double polythene covers / dedicated drums.
- All the ingredients should be weighed & verified accurately as per the approved process order of batch.
- Security sieving of applicable ingredients should be done before addition.

Critical control points:


- Crosscheck the dispensed material against process order
- Melting temperature for waxes
- Filtration of molten phase
- Mixing duration & RPM
- Maintain required temperature condition at each stage
- Filtration: Mesh size, Mesh integrity
- Cooling temperature
- Hold time of bulk

Deviation No: CM/DR/20/0312

Prepared by QA	Checked by Production	Authorized by QA
MALLARAJE URS A.N. 17/01/2022	Deepak Kumar 17/01/2022	BALESH KUMAR 18/01/2022

Note:- This document has been generated electronically and is valid without signature.

QL001/F01-04 This document and the contents hereof are considered proprietary and confidential information of The Himalaya Drug Company. Disclosure to unauthorized individuals or dissemination, publication or copying is prohibited without the prior written consent of The Himalaya Drug Company.

	HIMALAYA WELLNESS COMPANY, BENGALURU		
	BATCH MANUFACTURING RECORD		
Product Name	PILEX FORTE OINTMENT GEN		
Document No.	BMR/3003687/1157/01-01	Supersedes Doc. No. & Date	BMR/3003687/1157/01-00 & 07/08/2020
Market	GEN	CML	All Kind
Effective Date	18/01/2022	Standard Batch Size	2,000 Kg
Batch No.		Mfg. Lic. No.	HP-47-Ay LL

2.0 RAW MATERIALS DISPENSING:

2.1 Clean the area & equipments as per SOP & get line clearance from QA.

2.2 Line clearance for dispensing:

Date: _____

Parameters	Observation (Yes/No)	Ckd. By Stores supervisor	Verified by QA	Dispensing Booth / Cubical No.:_____
Cleanliness of the Dispensing area as per SOP				Previous Product: _____ Batch No.: _____ Dispensing started at:_____ Dispensing completed at:_____
Accessories/scoops/spatula cleaned as per SOP				
Previous batch ACCESSORIES removed from area				
Containers to be used for the batch dispensing are cleaned as per SOP				
New Polybags to be used for each batch dispensing				
Updation of logbook for In-process SS container				
Updation of Dispensing area / equipment cleaning & usage log book				
Weighing balance calibrated as per SOP: _____			Calibration due on date: _____	
a) Weighing balance code: _____, Weighing balance capacity: _____Kg				
RM Dispensing as per SOP No.: _____			Operator: _____	

2.3 Attach CLEANED status label of the equipment to the Batch Record.

2.4 Dispensing Area temperature & % Relative humidity for monitoring:
(Frequency at the initial stage & every two hours \pm 10 minutes)

Date	Time	Thermo-hygrometer ID	Temperature (for monitoring)	% RH (for monitoring)	Checked by	Verified by QA


2.5 Line Clearance Initiated by Stores Supervisor (Sign/date) _____ / time: _____

2.6 Line Clearance SOP No.: _____, by QA (Sign/date) _____ / time: _____

Prepared by QA	Checked by Production	Authorized by QA
MALLARAJE URS A.N. 17/01/2022	Deepak Kumar 17/01/2022	BALESH KUMAR 18/01/2022

Note:- This document has been generated electronically and is valid without signature.

QL001/F01-04 This document and the contents hereof are considered proprietary and confidential information of The Himalaya Drug Company. Disclosure to unauthorized individuals or dissemination, publication or copying is prohibited without the prior written consent of The Himalaya Drug Company.

	HIMALAYA WELLNESS COMPANY, BENGALURU		
	BATCH MANUFACTURING RECORD		
Product Name	PILEX FORTE OINTMENT GEN		
Document No.	BMR/3003687/1157/01-01	Supersedes Doc. No. & Date	BMR/3003687/1157/01-00 & 07/08/2020
Market	GEN	CML	All Kind
Effective Date	18/01/2022	Standard Batch Size	2,000 Kg
Batch No.		Mfg. Lic. No.	HP-47-Ay LL

2.7 Raw Material Indent as Per SAP:

SAP CODE	MATERIAL DESCRIPTION	UOM	STD. BATCH QTY.
2000212	DD 458WN SE IH	KG	295
2000209	DD 458 POWDER IH	KG	159.167
4000539	CAMPOR BP	KG	22.5
4000674	CETOMACROGOL 1000 [NOIGEN CS 1000] BP	KG	61.25
4000949	YELLOW PETROLEUM JELLY IP	KG	182.5
4000750	HEAVY LIQUID PARAFFIN IP	KG	121.667
4001197	PROPYL PARABEN SODIUM IP	KG	2.917
4001192	METHYL PARABEN SODIUM IP	KG	4.583
4000673	CETO STEARYL ALCOHOL IP	KG	165
4000848	PROPYLENE GLYCOL IP	KG	305.417
4000851	PURIFIED WATER IP/PH.EUR/USP/IH	KG	680

NOTE: Production & QA should Check & Verify Raw Materials indent detail against SAP Approved Process order.

Checked by Production: - Sign: _____ & date: _____,


Verified by QA: - Sign: _____ & date: _____

- AR No. of PURIFIED WATER: _____
- Specification No. followed for PURIFIED WATER analysis: _____
- Date of QC approval: _____ pH: _____

Prepared by QA	Checked by Production	Authorized by QA
MALLARAJE URS A.N. 17/01/2022	Deepak Kumar 17/01/2022	BALESH KUMAR 18/01/2022

Note:- This document has been generated electronically and is valid without signature.

QL001/F01-04 This document and the contents hereof are considered proprietary and confidential information of The Himalaya Drug Company. Disclosure to unauthorized individuals or dissemination, publication or copying is prohibited without the prior written consent of The Himalaya Drug Company.

	HIMALAYA WELLNESS COMPANY, BENGALURU		
	BATCH MANUFACTURING RECORD		
Product Name	PILEX FORTE OINTMENT GEN		
Document No.	BMR/3003687/1157/01-01	Supersedes Doc. No. & Date	BMR/3003687/1157/01-00 & 07/08/2020
Market	GEN	CML	All Kind
Effective Date	18/01/2022	Standard Batch Size	2,000 Kg
Batch No.		Mfg. Lic. No.	HP-47-Ay LL

3.0 LINE CLEARANCE FOR MANUFACTURING:

3.1 Clean the area & equipment's as per SOP & get the line clearance from QA.

3.2 Cross verify the dispensed materials against approved process order of the batch.

3.3 Manufacturing Area Cleaned As Per SOP No.: _____ Date: _____

Equipment	Equipment id	Capacity of equipment\ s / vessels	Previous product	Previous batch no.	Cleaned by & cleaned on date	Cleaned as per SOP No.	Checked by prod. / Date
Weighing balance							
Melting kettle							
SS Jacketed Vessel							
SS vessels for dissolution							
Main mixing vessel							
Extraction vessel							
Homogenizer							
Stirrer							
#100 Mesh Nylon Cloth		---					
#60 Mesh		---					
SS Transfer Pump & Hose Pipes		---					
Bulk holding SS vessel							

3.4 Ensure all equipment's are cleaned as per SOP & affixed with cleaned status label.

3.5 Manufacturing Area temperature & %Relative humidity for monitoring: (Frequency at initial stage & every two hours \pm 10 minutes)

Date	Time	Thermo-hygrometer ID	Are Temperature	%RH	Checked by	Verified by QA


3.6 Line Clearance initiated by Production CHEMIST _____ / DATE: _____, TIME: _____

3.7 Line clearance verified by QA _____ / DATE: _____, TIME: _____

Prepared by QA	Checked by Production	Authorized by QA
MALLARAJE URS A.N. 17/01/2022	Deepak Kumar 17/01/2022	BALESH KUMAR 18/01/2022

Note:- This document has been generated electronically and is valid without signature.

QL001/F01-04 This document and the contents hereof are considered proprietary and confidential information of The Himalaya Drug Company. Disclosure to unauthorized individuals or dissemination, publication or copying is prohibited without the prior written consent of The Himalaya Drug Company.

	HIMALAYA WELLNESS COMPANY, BENGALURU		
	BATCH MANUFACTURING RECORD		
Product Name	PILEX FORTE OINTMENT GEN		
Document No.	BMR/3003687/1157/01-01	Supersedes Doc. No. & Date	BMR/3003687/1157/01-00 & 07/08/2020
Market	GEN	CML	All Kind
Effective Date	18/01/2022	Standard Batch Size	2,000 Kg
Batch No.		Mfg. Lic. No.	HP-47-Ay LL

3.7.1 QA Line Clearance SOP No.: _____


3.8 Equipment's Calibration & Operations SOP details:

Equipment	Calibration SOP No. & calibrated on date	Operation SOP No.	Operator name	Checked by Prod.	Verified by QA
Weighing balance					
Melting kettle	---				
Main mixing vessel	---				
Homogenizer	---				
Stirrer	---				
SS Transfer Pump/Hose Pipes	---				
pH Meter					

Prepared by QA	Checked by Production	Authorized by QA
MALLARAJE URS A.N. 17/01/2022	Deepak Kumar 17/01/2022	BALESH KUMAR 18/01/2022

Note:- This document has been generated electronically and is valid without signature.

QL001/F01-04 This document and the contents hereof are considered proprietary and confidential information of The Himalaya Drug Company. Disclosure to unauthorized individuals or dissemination, publication or copying is prohibited without the prior written consent of The Himalaya Drug Company.

	HIMALAYA WELLNESS COMPANY, BENGALURU		
	BATCH MANUFACTURING RECORD		
Product Name	PILEX FORTE OINTMENT GEN		
Document No.	BMR/3003687/1157/01-01	Supersedes Doc. No. & Date	BMR/3003687/1157/01-00 & 07/08/2020
Market	GEN	CML	All Kind
Effective Date	18/01/2022	Standard Batch Size	2,000 Kg
Batch No.		Mfg. Lic. No.	HP-47-Ay LL


3.9 MANUFACTURING:

Date	Step	Procedure	Qty.	Time		Observation	Done by	Ckd. by				
				From	To							
	3.9.1	To melting tank, Transfer	---			Temp.:						
		HEAVY LIQUID PARAFFIN				Temp.:						
		YELLOW PETROLEUM JELLY				RPM:						
		Heat to 80°C ±2°C. Then add	---			Temp.:						
		CETOMACROGOL 1000 [NOIGEN CS 1000] BP				Complete melting of all the materials: YES/NO						
		CETO STEARYL ALCOHOL IP										
		Melt at 80°C ±2°C with mixing at 900 RPM. At 80°C ±2°C, add	---									
		CAMPHOR BP										
		Until it dissolves. Ensure complete melting of all the materials.	---									
	3.9.2	To separate SS jacketed vessel, transfer	---			Temp.:						
		PURIFIED WATER (35.833 % of Batch Size)				Temp.:						
		Heat it to 90°C±2°C, maintain for 30 minutes at 90°C±2°C, & cool it to room temperature.	---			pH:						
		Check pH of Heated & cooled Purified water.										
		Heated and cooled Purified water to be used for manufacturing.										
		To Extraction vessel, transfer heated and cooled	---							Temp.:		
		PURIFIED WATER (33.33 % of Batch Size)								Duration:		
		Add	---							Settling time:		
		DD 458WN SE IH										
		And heat to 60°C±2°C for 20 minutes and allowed to settle for 20 minutes.	---									

Prepared by QA	Checked by Production	Authorized by QA
MALLARAJE URS A.N. 17/01/2022	Deepak Kumar 17/01/2022	BALESH KUMAR 18/01/2022

Note:- This document has been generated electronically and is valid without signature.

QL001/F01-04 This document and the contents hereof are considered proprietary and confidential information of The Himalaya Drug Company. Disclosure to unauthorized individuals or dissemination, publication or copying is prohibited without the prior written consent of The Himalaya Drug Company.

	HIMALAYA WELLNESS COMPANY, BENGALURU		
	BATCH MANUFACTURING RECORD		
Product Name	PILEX FORTE OINTMENT GEN		
Document No.	BMR/3003687/1157/01-01	Supersedes Doc. No. & Date	BMR/3003687/1157/01-00 & 07/08/2020
Market	GEN	CML	All Kind
Effective Date	18/01/2022	Standard Batch Size	2,000 Kg
Batch No.		Mfg. Lic. No.	HP-47-Ay LL


3.9 MANUFACTURING:

Date	Steps	Procedure	Qty.	Time		Observation	Done by	Ckd. by
				From	To			
	3.9.2	Contd...,				Filter integrity of nylon cloth: Before: After:		
		Filter through #100 mesh nylon cloth to main mixing vessel.						
		Use remaining 0.66% of Purified water for rinsing of Extraction vessel and add to the main mixing vessel.						
	3.9.3	To the main mixing vessel, Add	---			Temp.: RPM: Homogenizer RPM: Duration: Lumps Free Yes/No		
		PROPYLENE GLYCOL	---					
		METHYL PARABEN SODIUM						
		PROPYL PARABEN SODIUM						
		Heat the contents up to 65°C±2°C under continuous mixing at 20 RPM.	---					
		Switch on the homogenizer & slowly disperse	---					
		DD 458 POWDER						
		Under continuous homogenization at 1400 RPM for 10 minutes. Ensure free from Lumps.	---					
	3.9.4	At 76° ± 2°C transfer step 3.9.1 to main mixing vessel by filtering through #100 mesh nylon cloth and homogenize for 40 minutes at 1500 RPM.	---			Temp.: Filter integrity of nylon cloth Before: After: Homogenizer RPM: Duration: RPM: Temp.:		
		Stop homogenizer and continue mixing at 20 rpm. Cool the contents of main mixing vessel by cold water circulation.						
		Stop mixing and scrap the walls thoroughly and continue mixing until the temperature of 40° ± 2°C is reached.						

Prepared by QA	Checked by Production	Authorized by QA
MALLARAJE URS A.N. 17/01/2022	Deepak Kumar 17/01/2022	BALESH KUMAR 18/01/2022

Note:- This document has been generated electronically and is valid without signature.

QL001/F01-04 This document and the contents hereof are considered proprietary and confidential information of The Himalaya Drug Company. Disclosure to unauthorized individuals or dissemination, publication or copying is prohibited without the prior written consent of The Himalaya Drug Company.

	HIMALAYA WELLNESS COMPANY, BENGALURU		
	BATCH MANUFACTURING RECORD		
Product Name	PILEX FORTE OINTMENT GEN		
Document No.	BMR/3003687/1157/01-01	Supersedes Doc. No. & Date	BMR/3003687/1157/01-00 & 07/08/2020
Market	GEN	CML	All Kind
Effective Date	18/01/2022	Standard Batch Size	2,000 Kg
Batch No.		Mfg. Lic. No.	HP-47-Ay LL

3.9 MANUFACTURING:

Date	Steps	Procedure	Qty.	Time		Observation	Done by	Ckd. by
				From	To			
	3.9.5	At 40° ± 2°C recirculate the bulk for 5 minutes and apply vacuum of 500 mm Hg for 10 minutes. Bulk should be free from lumps	---			Temp.: Recirculation: Vacuum: Duration: Free from lumps: Yes/No		
	3.9.6	Filter THE BULK through #60 mesh & unload to storage vessel & update the observations						

4.0 BULK SAMPLING: (Production should raise test request form & intimate QA/QC to collect bulk sample)

- Bulk Sampled by QA/QC: Sign: _____ & date: _____ Sample Qty.: _____ (Kg)
- Bulk sample sent with TRF to QC by (Prod.): Sign: _____ & date: _____

4.1 Analyse the bulk sample for the following parameters:

S. No.	Parameter	Specification	Observations
1	Description	Creamish white to buff white colored homogeneous ointment, smooth, non-gritty and easily spreading consistency.	
2	pH (Direct)	5.5 – 7.5	

Bulk Specification: Complies /Doesn't Complies

Checked by Production: Sign: _____ & date: _____,


Verified by QA: Sign: _____ & date: _____

NOTE: (All the in-process parameters included in bulk specification should be analyzed by QC as per bulk specification.)

Prepared by QA	Checked by Production	Authorized by QA
MALLARAJE URS A.N. 17/01/2022	Deepak Kumar 17/01/2022	BALESH KUMAR 18/01/2022

Note:- This document has been generated electronically and is valid without signature.

QL001/F01-04 This document and the contents hereof are considered proprietary and confidential information of The Himalaya Drug Company. Disclosure to unauthorized individuals or dissemination, publication or copying is prohibited without the prior written consent of The Himalaya Drug Company.

	HIMALAYA WELLNESS COMPANY, BENGALURU		
	BATCH MANUFACTURING RECORD		
Product Name	PILEX FORTE OINTMENT GEN		
Document No.	BMR/3003687/1157/01-01	Supersedes Doc. No. & Date	BMR/3003687/1157/01-00 & 07/08/2020
Market	GEN	CML	All Kind
Effective Date	18/01/2022	Standard Batch Size	2,000 Kg
Batch No.		Mfg. Lic. No.	HP-47-Ay LL

5.0 BULK UNLOADING:

5.1 Filter the bulk through the # 60 mesh and unload from main mixing vessel to bulk holding SS vessel.


5.2 Label the status & calculate Bulk yield.

<ul style="list-style-type: none"> Mesh integrity of #60mesh 						
Before use:						
Checked by:			Verified by:			
Previous Product: _____			Batch No.: _____			
Date	SS Vessel No.	Gross wt. (kg)	Tare wt. (kg)	Net. wt. (kg)	Weighed by	Checked by
Total Bulk wt. = _____ Kg						
<ul style="list-style-type: none"> Mesh integrity of #60mesh 						
After use:						
Checked by:			Verified by :			

Prepared by QA	Checked by Production	Authorized by QA
MALLARAJE URS A.N. 17/01/2022	Deepak Kumar 17/01/2022	BALESH KUMAR 18/01/2022

Note:- This document has been generated electronically and is valid without signature.

QL001/F01-04 This document and the contents hereof are considered proprietary and confidential information of The Himalaya Drug Company. Disclosure to unauthorized individuals or dissemination, publication or copying is prohibited without the prior written consent of The Himalaya Drug Company.

	HIMALAYA WELLNESS COMPANY, BENGALURU		
	BATCH MANUFACTURING RECORD		
Product Name	PILEX FORTE OINTMENT GEN		
Document No.	BMR/3003687/1157/01-01	Supersedes Doc. No. & Date	BMR/3003687/1157/01-00 & 07/08/2020
Market	GEN	CML	All Kind
Effective Date	18/01/2022	Standard Batch Size	2,000 Kg
Batch No.		Mfg. Lic. No.	HP-47-Ay LL

6.0 BULK YIELD CALCULATIONS:

Theoretical weight of the batch: _____ Kg.

Total weight of the batch obtained: _____ Kg.

% Yield = $\frac{\text{Total weight obtained (Kg.)} + \text{Sample Qty. (Kg)}}{\text{Theoretical weight (Kg)}} \times 100 = \text{_____} \times 100 = \text{_____} \%$

Done by/date (Prod. Supervisor): Sign: _____ & date: _____,

Verified by QA: Sign: _____ & date: _____

7.0 JUSTIFICATION FOR LESS BULK YIELD (If Applicable):

8.0 DEVIATION / INCIDENT (If Any):

9.0 BATCH SUMMARY:

%Loss		BMR reviewed by	
Section Head-Production Date		Quality Assurance Date	

Prepared by QA	Checked by Production	Authorized by QA
MALLARAJE URS A.N. 17/01/2022	Deepak Kumar 17/01/2022	BALESH KUMAR 18/01/2022

Note:- This document has been generated electronically and is valid without signature.

QL001/F01-04 This document and the contents hereof are considered proprietary and confidential information of The Himalaya Drug Company. Disclosure to unauthorized individuals or dissemination, publication or copying is prohibited without the prior written consent of The Himalaya Drug Company.