

CHALLENGE STUDY

MASTER COPY

	BATCH MANUFACTURING RECORD			
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL			BATCH NO.
FILLING LINE	BAG LINE (LINE-2)	PAGE NO.	I OF I	AH250076
BMR NO.	BMR-PA-063-05	BATCH SIZE	4048.0 kg/ 4000 L/ 38446 Units	
PACK SIZE	100 mL			

The Batch Manufacturing Record (BMR) has been prepared, checked, and approved by the undersigned.

FUNCTIONAL AREA	NAME	DESIGNATION	SIGNATURE & DATE
PREPARED BY			
Manufacturing	Amit Sejtre	Officee	Amit 19-feb-25
CHECKED BY			
Manufacturing	Prakash Rayani	Asst. Manager	Prakash 19-Feb-25
Quality Assurance	Mehul Sankalp	Dy. Manager	Mehul 19-feb-25
APPROVED BY			
Quality Assurance	Chirag Patel	Dy. Manager	Chirag 20-Feb-25

	AUTHORIZED COPY	
	QA-SIGN/DATE:	

BMR Issued By QA

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BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL
BMR NO.	BMR-PA-063-05
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)
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Product Name	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL		
Label claim	<u>Each mL contains:</u> Paracetamol IP..... 10.0 mg Mannitol IP..... 36.0 mg Sodium Metabisulfite IP..... 0.2 mg Sodium acetate trihydrate IP..... 1.64 mg Glacial acetic acid IP/USP..... 0.115 mg Glacial acetic acid IP/USP q.s. to pH Sodium Hydroxide IP..... q.s. to pH Water for Injections IP..... q. s		
Description	A clear, colorless to Light brownish yellow color solution		
Location	Bag Line (Line – 2) of Amneal Pharmaceuticals Private Limited (Parenteral Unit-5), Pipan, Sanand.		
Manufacturing License No.	G/28D/LVP/20		
Product code	SIN006		
Market	Domestic		
Batch size	4048.0 kg/ 4000 L (38446 Units)		
Target fill weight	104.04 mL ≈ 104.0 mL (105.3g) (Weight/mL 1.012g/mL)		
BMR Superseded No.	BMR-PA-063-04		
Date of Commencement	02 - May - 25		
Date of Completion	08 - May - 25		
Shelf life	24 months		
Date of Manufacturing (Manufacturing date shall be the date when first two ingredients of the batch are mixed)	06 - May - 25	Assigned by (SM): <i>✓</i> 06 - May - 25	Verified by (QA): <i>PL</i> 06 - May - 25
Date of Expiry	30 - APR - 2027	Assigned by (SM): <i>AJ</i> 06 - May - 25	Verified by (QA): <i>PL</i> 06 - May - 25
Storage Condition	Do not store above 30°C. Do not freeze. Protect from light.		

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BMR NO.	BMR-PA-063-05	
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BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
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1.0 GENERAL INSTRUCTIONS	
<u>General Instructions</u>	
Follow the following instructions.	
<ol style="list-style-type: none"> 1. Follow the line clearance system before starting the operations as per respective SOP PAP-QA-002. 2. Follow the current good manufacturing practices. 3. Follow the approved Standard Operating Procedures. 4. Ensure that Personnel are trained for the allocated job. 5. When you document, ensure that the entry is correct and legible. If any discrepancy or mistake is observed during documentation, correct as per SOP No. IR-QA-002. 6. Ensure that plant utility, RLAF, LAF and AHU units are in running condition. 7. Read the manufacturing instructions before proceeding with operations and follow it and document each operation in BMR. 8. Ensure that all required RM and PPM are approved. 9. Follow entry-exit procedure into respective area as per SOP No. PAP-SM-001 and PAP-SM-002. 10. Ensure the environmental condition %RH, Temperature and Differential pressure are within limit. 11. In case additional pages are required, get the same issued from QA and attach. 12. Attach all dispensing labels / in process weight printouts on Exhibit-VIII (Page for Pasting Labels/ Printouts) as per SOP No. PAP-SM-054 and attach with BMR. 13. Before signature at the specified place, follow the responsibility as per below. 14. Done by: Signature of person actually doing the operation, test, inspection, calculation etc. being recorded. 15. Checked by: The person responsible for observing the actual procedure or witnessing performance of the task or performing an independent check to ensure the task was done correctly. 16. Verified by: A person who ensures or demonstrates that activity performed by doer is true, accurate or justified. 17. Reviewed by: Signature of the person responsible for reviewing and examining the documentation certifying that the record/protocol/report has been reviewed and found completed and in compliance. 18. Ensured by: The person responsible for ensuring the procedure or witnessing performance of the task or performing an independent check to ensure the task was done correctly. 19. Ensure that preventive maintenance, Qualification of equipment and calibration of instruments are within due date. 	

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BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
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1.0 GENERAL INSTRUCTIONS

20. Nitrogen purging is required during the complete manufacturing process and till the end of the filling process (if applicable).
21. Store the bulk solution under nitrogen blanketing (if applicable).
22. Review the Audit trail of equipment's as per respective SOP.

Product Specific Instruction:

1. Paracetamol and sodium metabisulfite are oxygen sensitive, after dispensing materials shall be closed after nitrogen flushing.
2. Dispensing of paracetamol and Sodium metabisulfite should be done very few hours before start of manufacturing.
3. After dispensing paracetamol and Sodium metabisulfite, storage should be done carefully to protect from oxygen.
4. Nitrogen purging and blanketing is required during the complete manufacturing process and till the end of the filling process. Oxygen displacement is necessary throughout the manufacturing process.
5. Packing of filled semi permeable bag should be done immediately after sterilization in Aluminium pouch to protect drug product from atmospheric oxygen. **(Total hold time should be NMT 360 hours (15 days) from completion of sterilization first lot to completion to Aluminium pouching of sterilized bags).**
6. Low viscous (mobile) product.
7. Store the bulk solution under nitrogen blanketing.
8. CIP/SIP of processed fresh new filters (1.2-micron PP and 0.45+0.2-micron PES) shall be used for each batch.
9. 1N NaOH and/or Glacial acetic acid is used for pH adjustment if required.
10. Paracetamol is added carefully to avoid spillage or stick to inner wall of vessel due to its low wettability and high fluffiness. Terminal sterilization should not be less than at 121°C for 12 minutes.

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2.0 ABBREVIATIONS			
Abbreviated Form	Full Name	Abbreviated Form	Full Name
mbar	Millibar	RLAF	Reverse laminar air flow
CAT	Catalogue number	A.R. No.	Analytical report Number /Amneal Receiving Number
API	Active Pharmaceutical Ingredient	G / g	Gram
Ckd	Checked	MM	Material management
RH	Relative Humidity	WFI	Water for Injections
NMT	Not more than	PAP	Amneal Pharmaceuticals Private Limited (Parenteral Unit-5) Pipan, Sanand
QC	Quality Control	CIP	Clean in place
NPVC	Non-Poly Vinyl Chloride	PHT	Pressure hold test
SM	Sterile Manufacturing	RPM	Rotation per minute
Min.	Minimum	IP	Indian Pharmacopeia
Kg	Kilogram	Sr. No./ Nos.	Serial Number / Numbers
Pa	Pascal	QA	Quality Assurance
Q.S./ q.s.	Quantity sufficient	MV	Mixing Vessel
FV	Filtration vessel	°C	Degree Celsius
Hrs.	Hours	Mfg.	Manufacturing
SIP	Steam in Place	Exp.	Expiry
SCADA	Supervisory control and data acquisition	Pa	Pascal
Temp.	Temperature	Req.	Required
&	And	Qty.	Quantity
RM	Raw material	Mtr	Meter
mm	Milimeter	LOD	Loss on Drying
DP	Differential pressure	Eg.	Example
DO	Dissolved oxygen	PPM	Primary packing material
M	Meter	mm WC	millimeters per water column

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3.0 EQUIPMENT TO BE USED			
Equipment to be used by Manufacturing, Filtration and Filling Area personnel:			
Sr. No.	Name of Equipment & Accessories	ID No.	Qualification / Calibration status (OK /Not OK/NA)
1	Dynamic pass box (L215 / G317)	EQP/P1/PRD/027	OK
2	Dynamic pass box (Dispensing L204 / L222)	EQP/P1/PRD/029	OK
3	RLAF (Dispensing Booth)	PA-SM-011	OK
4	pH/DO meter	PA-SM-022	NOT OK
5	Weighing balance 30kg	EQP/P1/PRD/143	OK
6	Weighing balance 320g	EQP/P1/PRD/139	OK
7	Filter integrity testing machine	EQP/P1/PRD/186	-NA-
8	Filter integrity testing machine	EQP/P1/PRD/322	-NA-
9	Filter integrity testing machine	EQP/P1/PRD/045	-NA-
10	Filter integrity testing machine	EQP/P1/PRD/046	OK
11	Mixing vessel – (MV 4000)	EQP/P1/PRD/039	-NOT OK
12	Mixing vessel – (MV 500)	EQP/P1/PRD/040	OK
13	Weighing balance 6kg	EQP/P1/PRD/141	OK
14	Weighing balance 100 kg	EQP/P1/PRD/158	OK
15	Weighing balance 320 g	EQP/P1/PRD/149	OK
16	Weighing balance 6 kg	EQP/P1/PRD/147	OK
17	Weighing Balance 6 kg	EQP/P1/PRD/157	OK
18	Weighing balance 320 g	EQP/P1/PRD/154	OK
19	RLAF for PPM issuance	EQP/P1/PRD/054	OK
20	Disinfectant room LAF	EQP/P1/PRD/119	OK
21			NA
22			22-Nov-25
23			
Checked by (SM): <u>AKT</u> 14-Nov-25			

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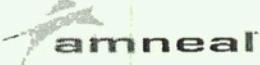
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3.0 EQUIPMENT TO BE USED			
Sr. No.	Name of Equipment & Accessories	ID No.	Qualification / Calibration status (OK /Not OK/NA)
1	Dynamic pass box (L219 / L218)	EQP/P1/PRD/024	OK
2	Dynamic pass box (L216 / G321)	EQP/P1/PRD/025	OK
3	Dynamic pass box (L215 / L208)	EQP/P1/PRD/028	OK
4	Autoclave Unloading LAF	PA-SM-012	OK
5	Bag Form Filing Machine	EQP/P1/PRD/042	OK
6	Filtration vessel – (FV 4000)	EQP/P1/PRD/041	NOT OK
7	Visual Inspection Booth	PA-SM-003	—NIA—
8	Weighing balance 3kg	EQP/P1/PRD/142	OK
9	Lux Meter	PA-SM-122	—NIA—
10	Sterilizer (DC-4)	EQP/P1/PRD/044	NOT OK
11	Bag filling machine LAFs'	EQP/P1/PRD/043	OK
12		EQP/P1/PRD/043A	OK
13		EQP/P1/PRD/043B	OK
14		EQP/P1/PRD/043C	OK
15	Online Checkweigher with Conveyor belt & Dropout Rejector unit	PA-SM-209	OK
16			
17			
18		NIA	
19		QEB	
20		27-Nov-25	
21			
Checked By (SM): <u>Ashutosh</u> -N44-25			

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4.0	AREA REQUIRED FOR BATCH MANUFACTURING					
Sr. No.	Name of operation	Name of Area where operation to be performed	Room No.	%RH NMT	Temperature Range	Classification
1.	Dispensing of Excipient, PPM, API	<input checked="" type="checkbox"/> Dispensing room <input type="checkbox"/> Sampling room	L204 W106	60%	15.0-25.0°C	Under RLAf
2.	Bulk Manufacturing	Bag Manufacturing room	L206	60%	15.0-25.0°C	Grade C
3.	Filtration	Bag Filtration room	L217	60%	15.0-25.0°C	Grade C
4.	Bulk printing, filling, stoppering.	Bag Filling room	L216	60%	15.0-25.0°C	Under LAF surrounded by Grade-C
5.	Bag Collection	Bag Collection	N/A	N/A	15.0-25.0°C	Controlled-Not Classified
6.	Terminal Sterilization	Bag-Loading area	N/A	N/A	15.0-25.0°C	Controlled-Not Classified

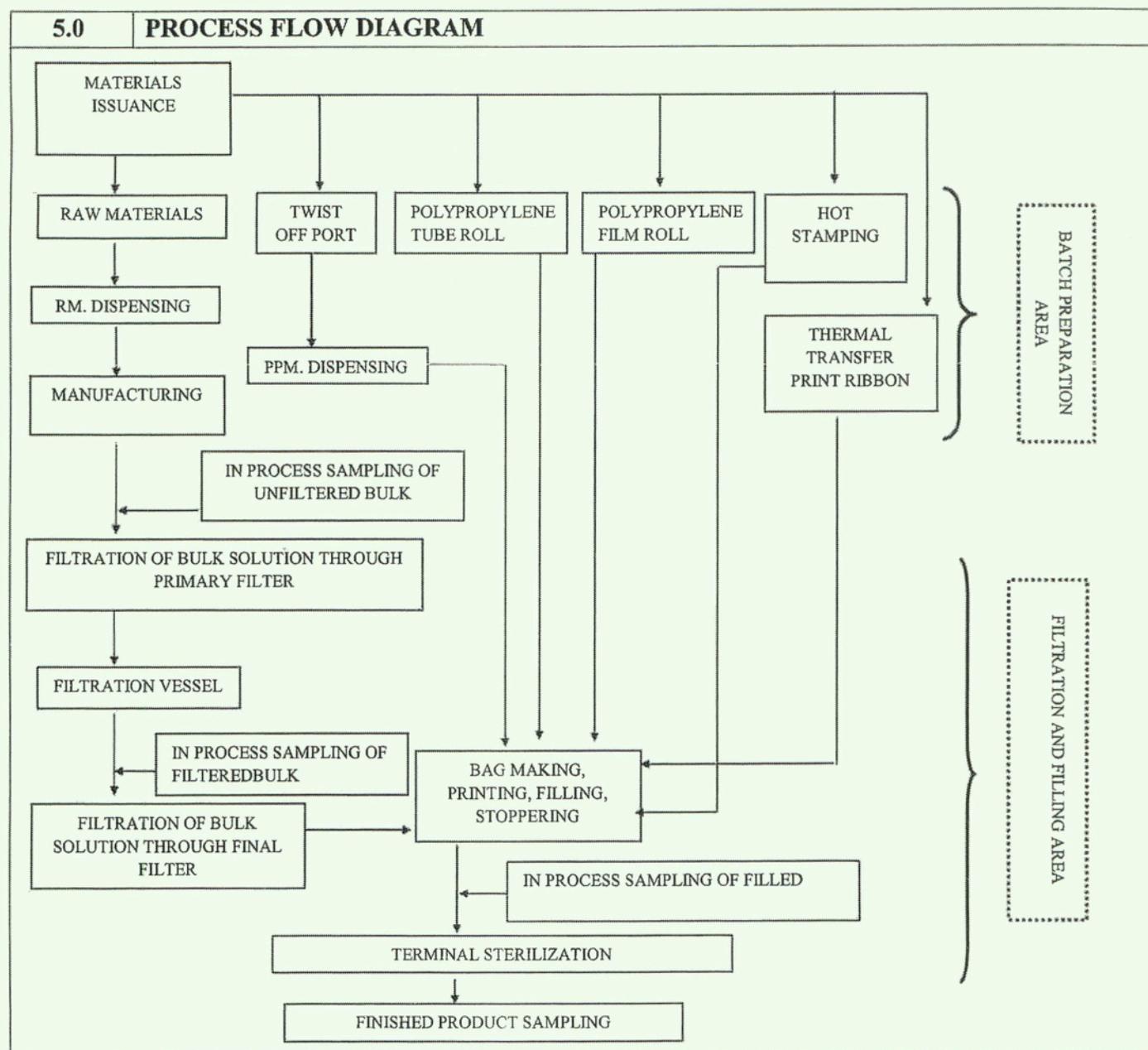
Put a tick mark “√” in “□” which is applicable.

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6.0 SIGNATURE LOG (DISPENSING AREA ACTIVITY)				
Record the name of persons involved in Dispensing area activity.				
Sr. No.	Name	Employee Code	Department	*Signature
1.	Umesh Dubhi	323886	MM	Cole 02-may-25
2.	Yatni Patel	302202	SM	Yatni 06-nun-25
3.	Vasundhara Patil	349988	SM	Vasundhara 06-May-25
4.	Renuka Patil	315799	QA	Renuka 10-may-25
5.				
6.				
7.				
8.				
9.				
10.				
11.				
12.				
13.				
14.				
15.				
16.				
17.				
18.				
19.				CP 10-May-25

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6.0 SIGNATURE LOG (DISPENSING AREA ACTIVITY)				
Record the name of persons involved in Dispensing area activity.				
*Declaration: I undersigned, hereby declare that I am trained in all relevant procedure and activity(s) that I am performing in this batch.				
Sr. No.	Name	Employee Code	Department	*Signature
20.				
21.				
22.				
23.				
24.				
25.				
26.				
27.				
28.				
29.				
30.				
31.				
32.				NIA
33.				
34.				
35.				
36.				
37.				CP 10-May-25

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7.0		MASTER FORMULA				
Raw Material:						
Sr. No.	Material Code	Material Description	Label Claim Qty. mg /mL	Qty.(mg) /Unit (100 mL)	% W/V	Qty./ Batch
1.	RMI-0394	Paracetamol IP *	10.0	1000 mg	1.0 %	40.0 Kg
2.	RMI-0378	Mannitol IP	36.0	3600 mg	3.6%	144.0 Kg
3.	RMI-0341	Sodium metabisulfite NF/ Ph. Eur/BP/IP	0.20	20 mg	0.02%	0.800 Kg
4.	RMI-0391	Sodium acetate trihydrate IP	1.64	164 mg	0.164%	6.560 Kg
5.	RMI-0417	Glacial acetic acid USP	0.115	11.5 mg	0.0115%	460 gm/ 438.0 ml
6.	RMI-0417	Glacial acetic acid USP	q.s. to adjust pH	q.s. to adjust pH	q.s. to adjust pH	200 gm/ 190.84ml
7.	RMI-0389	Sodium Hydroxide IP	q.s. to adjust pH	q.s. to adjust pH	q.s. to adjust pH	0.240 Kg
8.	WIH-0004	Water for Injections IP	q.s	q.s.	q.s.	q.s. up to 4000 L
9.	RMI-0082	Nitrogen Ph.Eur./NF @	q.s	q.s.	q.s.	(q.s.)

Note:

- *Actual quantity to be dispensed after potency calculation for this quantity.
- @ Nitrogen gas to be used as inert gas as required for purging/blanketing during manufacturing, filtration and filling.

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7.0		MASTER FORMULA		
Primary Packing Material:				
Sr. No.	Material Code	Item	Qty/ Bag	Unit
1.	PMI-0998	Polypropylene Film APP114-S-135-200-F	115.0 mm	Mtr
2.	PMI-0996	Polypropylene Tube APP107-S-8.20 X 6.20 #	48.00 mm	Mtr
3.	PMI-0996	Polypropylene Tube APP107-S-8.20 X 6.20 #		Mtr
4.	PMI-0985	Twist-Off Port 823 pp inerta 016+plug (tp823.007_a) (twist-off port 823 pp-in016-tp823.007_a)	01 Nos.	Nos.
5.	MMI-0358	Hot Stamping Foil, Colorit 34973 Black,220 Mm	45.00 mm	Mtr.
6.	MMI-0368	Thermal Transfer Print Ribbon. 53 MM X 450 Mtr Black CFC\$	35.00 mm	Mtr.
*Issue the material approx. 20% excess to compensate the process loss and as per pack size. # Equipment is required to run in 2 UP, two roll of polypropylene tube are required in BOM, required quantity for batch size remain same. \$Preferably Thermal Transfer Print Ribbon, 53 mm will be used for printing purposes. However, based on the requirement & feasibility, stereo printing can also be used. If stereo printing need to be used for printing, then no need to issuance of Thermal Transfer Print Ribbon."				
Primary Packing Material (Filters):				
Sr. No.	Material Code	Material Details	Unit	Standard Qty
1	MMI-0372	Solution Cartridge Filter -1.2 μm -10 INCH	Nos.	01
2	MMI-0367	Solution Cartridge Filter - 0.2 μ - 10 inch	Nos.	01
3	MMI-0366*	TU- Silicone Tube – 8.0 (ID) X 12.8 (OD) Imapure	Meter	07
*This tubing to be used for water transfer.				

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8.0 DISPENSING OF MATERIALS

Issue raw material as per SOP No.: PAP-MM-005.

Balance I.D. No.:

Sr. No.	Material Code	Materials	Std. Qty. Req.	A.R. No.	Net Wt.	Issued By (MM)	Checked By (SM)
1	RMI-0394	Paracetamol IP*	40.0 Kg				
2	RMI-0378	Mannitol IP	144.0 Kg				
3	RMI-0341	Sodium metabisulfite NF /Ph. Eur/BP /IP	0.800 Kg				
4	RMI-0391	Sodium acetate trihydrate IP	6.560 Kg				
5	RMI-0417	Glacial acetic acid USP	438.0 ml/ 460 gm			NIA	
6	RMI-0417	Glacial acetic acid USP	190.84ml/ 200 gm			VS	
7	RMI-0389	Sodium Hydroxide IP	0.240 Kg			05-May-25	

* Quantity should be excess issued considering after potency calculation.

Note: In case, the dispensing activity done by MM person as per SOP No. PAP-MM-005 and PAP-SM-008 then issuance activity does not require.

Check the area is cleaned as per SOP No. PAP-SM-006 for RM dispensing activities.

Record the temperature and %RH as per SOP No. PAP-SM-006 in below mentioned table:

Record the differential pressure of RLAf in below mentioned table.

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8.0 DISPENSING OF MATERIALS

Dispensing of RM/ Excipients in Bag line Dispensing Room

Previous product Calcium Chloride in Sodium Chloride Injection

20 mg/ml (2000 mg/100 mL)

Previous Batch Number AH250073

Room No: L204

Date: 05-May-25

Start Time: 10:23

DP of dispensing room (Limit: NLT 06 Pa)	Temp. (15.0 - 25.0°C)	%RH (NMT 60)	RLAF Equipment ID: PA-SM-011			Remark
			HEPA filter (Limit: 8 – 18 mm WC)	Fine Filter (Limit: 2 – 8 mm WC)	Pre filter (Limit: 0.5 – 5 mm WC)	
05 Pa	21.6	62%	014.0	1007.1	002.3	NA

End Time: 10:26

Recorded by (SM/MM): - Coule 05-May-25

Checked by (SM): - AS 05-May-25

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ADDITIONAL COPY
QA-SIGN/DATE: MFB 24-Dec-24

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 amneal	BATCH MANUFACTURING RECORD	
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BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
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8.0 DISPENSING OF MATERIALS

Dispensing of RM/ Excipients in Bag line Dispensing Room

Previous product — NA —

— NA —

Previous Batch Number — NA —

Room No: L204

Date: 05-May-25 Start Time: 23:10

DP of dispensing room (Limit: NLT 06 Pa)	Temp. (15.0 - 25.0°C)	%RH (NMT 60)	RLAF Equipment ID: PA-SM-011			Remark
			HEPA filter (Limit: 8 – 18 mm WC)	Fine Filter (Limit: 2 – 8 mm WC)	Pre filter (Limit: 0.5 – 5 mm WC)	
<u>25</u>	<u>21-22°C</u>	<u>39%</u>	<u>013.8</u>	<u>007.1</u>	<u>015.3</u>	<u>NA</u>

End Time: 23:13

Recorded by (SM/MM): - Cgul 05-May-25

Checked by (SM): - AB 05-May-25

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CHALLENGE STUDY

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amneal		BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.	
BMR NO.	BMR-PA-063-05		
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)		AH250076
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8.0 DISPENSING OF MATERIALS

Dispensing of RM/ Excipients in RM Sampling room

Check the area is cleaned as per SOP for RM dispensing activities.

Previous product _____ Batch Number _____

Record temperature and %RH of sampling Room as per SOP No.: PAP-QCC-001, in below mention table:

Date	Time	Temperature 15.0°C to 25.0°C	%RH NMT 60 %	Recorded By (MM/SM)	Checked By (SM)

Ensure the cleaning & record in the given below provision:

Date	sampling area & RLAF cleaning	Observation (OK/Not Ok)	Checked By (MM/SM)	Verified by (SM)

Record the differential pressure of RLAf Equipment ID.: RA-MM-001 in below table:

Date	Time	RLAF	Limit in mm wc	Observation in mm wc	Recorded By (MM/SM)	Checked By (SM)
		Pre Filter	0.5 to 5 mm wc		AS 05-May-25	
		Intermediate/ Fine Filter	2 to 8 mm wc			
		HEPA Filter	8 to 18 mm wc			

Fill the check list for line clearance as per SOP: 'Procedure for line clearance' SOP No.: PAP-QA-002 for Sampling area and attach with BMR.

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		BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.	
BMR NO.	BMR-PA-063-05		
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)		AH250067
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9.0 POTENCY CALCULATION FOR API	
<i>Note: If the potency or assay of an API is more than 100 % considered it as 100 %. If the potency or assay of an API is less than 100% calculation shall be done considering actual assay or potency of an API.</i>	
Raw material	A. R. No.
	A1 A2
Paracetamol IP	ARM158896 ARM210047
Recorded By (SM/MM)	<i>Carey OS-Merritt-25</i>
Checked By (SM)	<i>TDS</i>

OPTION 1: If API from single lot, do the following calculation:

Actual Quantity of Paracetamol (g) = A

$$A = \frac{10.0 \text{ g}}{1.0 \text{ L}} \times \text{Batch Size (L)} \times \frac{100}{(\% \text{ of Assay on dried basis})} \times \frac{100}{(100-\text{LOD})}$$

Space for calculation:

$$A = \frac{10.0 \text{ g}}{1.0 \text{ L}} \times \underline{\text{NA}} \text{ (L)} \times \frac{100}{(\underline{\text{NA}})} \times \frac{100}{(100-\underline{\text{NA}})}$$

$$= \underline{\text{NA}} \text{ kg.}$$

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
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9.0	POTENCY CALCULATION FOR API	
Total quantity of Paracetamol for batch (A) (in Kg): =	NA	g/ 1000 = NA Kg.
Calculated By (SM/MM) (Sign & Date)	Checked By (SM) (Sign & Date)	
NA		

OPTION 2: If API from two different lots, perform the calculation as below:

Total Quantity of Paracetamol (g) = A

Lot 1:

$$\frac{\text{..... g}}{(\text{Actual qty. of Lot 1})} \times \frac{1.0 \text{ L}}{10.0 \text{ g}} \times \frac{\% \text{ of Assay on dried basis lot 1}}{100} \times \frac{(100 - \text{LOD})}{100} = \text{..... L1}$$

(Batch Size in Liter)

Space for calculation:

$$\frac{18800 \text{ g}}{1863.115 \text{ L1}} \times \frac{1.0 \text{ L}}{10.0 \text{ g}} \times \frac{99.4}{100} \times \frac{(100 - 0.3)}{100} =$$

(Batch Size in Liter)

CHALLENGE STUDY

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
PAGE NO.	Page 20 of 133	

9.0 POTENCY CALCULATION FOR API	
Lot 2:	
$L_2 = \frac{L_1(\text{Batch size in Liter based on actual quantity of lot 1})}{\text{Liter}} - \frac{\text{% of Assay on dried basis lot 2}}{100}$	
$\frac{10.0 \text{ g}}{1.0 \text{ L}} \times L_2 \times \frac{100}{\text{% of Assay on dried basis lot 2}} \times \frac{100}{(100 - \text{LOD})} = \dots \text{g (calculated quantity of Lot 2)}$	
Space for calculation:	
$L_2 = \frac{L_1(1863.114)}{1000} = 1.863.114 \text{ Liter}$	
$\frac{10.0 \text{ g}}{1.0 \text{ L}} \times 1.863.114 \times \frac{100}{100} \times \frac{100}{(100 - 0.4)} = 21454.679 \text{ g}$	
$\text{Total quantity of Paracetamol for batch (A)} = \text{Actual quantity of Lot 1 (g)} + \text{Calculated quantity of Lot 2 (g)}$	
Space for calculation:	
$\text{Total quantity of Paracetamol for batch (A)} = 18800 \text{ (g)} + 21454.679 \text{ (g)} = 40254.679 \text{ (g)}$	
$\text{Total quantity of Paracetamol for batch (A) (in Kg)} = 40254.679 \text{ g/ 1000} = 40.255 \text{ Kg.}$	
Calculated By (SM/MM) (Sign & Date)	Checked By (SM) (Sign & Date)
<i>SM</i> 05-May-25	<i>AS</i> 05-May-25

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		BATCH MANUFACTURING RECORD	
NAME OF PRODUCT		Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	
BMR NO.		BMR-PA-063-05	
BATCH SIZE		4048.0 kg/ 4000 L (38446 Units)	
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10.0 | RAW MATERIAL DISPENSING

(AS PER SOP: Dispensing of Material, SOP No. PAP-SM-008 & PAP-MM-029)

Note: Fill the check list for line clearance as per SOP No.: PAP-QA-002 for Fume Chamber area and attach with BMR for dispensing Glacial acetic acid.

Dispensing Start Date and Time: 05-May-25 & 11:16

Sr. No.	Ingredients	Material Code	A.R. No.	Balance ID	Qty. Required	Quantity Dispensed	Done By (SM/MM) (Sign/Date)	Checked by (SM) (Sign/Date)
1.	Glacial acetic acid USP	RMI-0417	24604998	EOP1P1PRD1157	438.0mL/ 460 gm	510 gm	Cole 05-May-25	AS 05-May-25
2.	Glacial acetic acid USP*	RMI-0417	246004938240084	EOP1P1PRD157	190.84mL/ 200 gm	116 gm 84.0000 gm	Cole 05-May-25	AS 05-May-25

Dispensing End Date and Time: 05-May-25 & 11:54 * Used for pH adjustment.

Note: Fill the check list for line clearance as per SOP No.: PAP-QA-002

Dispensing Start Date and Time: 05-May-25 & 13:20, 06-May-25 & 00:10

Sr. No.	Ingredients	Material Code	A.R. No.	Balance ID	Qty. Required	Quantity Dispensed	Done By (SM/MM) (Sign/Date)	Checked by (SM) (Sign/Date)
					Calculated			
1.	Paracetamol IP	RMI-0394	ARM2000041 ARM2100047	EOP1P1PRD143	40.0 Kg. 40.255 Kg.	18.800 Kg 21.456 Kg	Cole 06-May-25	AS 06-May-25
2.	Mannitol IP	RMI-0378	24004160	EOP1P1PRD143	144.0 Kg	144.000 Kg	Cole 06-May-25	AS 05-May-25
3.	Sodium metabisulfite NF /Ph. Eur/BP /IP	RMI-0341	24005366	EOP1P1PRD143	0.800 Kg	0.800 Kg	Cole 06-May-25	AS 06-May-25
4.	Sodium acetate trihydrate IP	RMI-0391	23004070	EOP1P1PRD143	6.560 Kg	7.200 Kg	Cole 05-May-25	AS 05-May-25
5.	Sodium Hydroxide IP	RMI-0389	23009910	EOP1P1PRD143	0.240 Kg	0.240 Kg	Cole 05-May-25	AS 05-May-25

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		BATCH MANUFACTURING RECORD
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
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10.0 RAW MATERIAL DISPENSING							
Sr. No.	Ingredients	Material code	A.R. No.	Qty. Required	Quantity Dispensed	Done By (SM) (Sign/ Date)	Ckd. by (SM) (Sign/ Date)
1	Water for Injection IP	WIH-0004	RX34CV78BN	q.s. to 4000 L	q.s. to 4000 L	✓ SS 06-May-25	✓ ACT 06-May-25
2	Nitrogen Ph. Eur.	RMI-0082	25012647	q.s.	q.s.	✓ SS 05-May-25	✓ ACT 06-May-25

Remark: -

—N/A—

—N/A—

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
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11.0 PRIMARY PACKING MATERIAL ISSUANCE AND DISPENSING

ISSUANCE AND VERIFICATION OF FILTERS

Fill the check list for line clearance as per SOP No.: PAP-QA-002 for issuance of filters and attach with BMR.

Fill the check list for line clearance of issuance and verification of primary packaging materials & attach with BMR.

Cleaning details of area as per SOP No.: PAP-MM-008

Name of previous product	NA
Batch No. of previous product	NA
Room No.	W204
Date of cleaning performed	02-May-25
Recorded By (MM) <i>Gaur</i> 02-May-25	Checked By (SM) <i>AS</i> 02-May-25

Remark:

—N/A—

—N/A—

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CHALLENGE STUDY

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		BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.	
BMR NO.	BMR-PA-063-05		AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)		
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11.0 PRIMARY PACKING MATERIAL ISSUANCE AND DISPENSING								
FILTERS:								
Issuance Start Date & Time: <u>02-May-25</u> + 15:55				Recorded by Sign/ Date (MM): <u>Clerk 02-May-25</u>				
Sr. No.	Material	Material code	Part / Cat. No.	Std. Qty.	Actual issued Qty.	A.R. No.	Quantity Issued By (MM)	Checked By (SM)
1	Solution Cartridge Filter - 1.2 μm-10 INCH	MMI-0372	5052503P1 (Sartopure PP3)	01 Nos.	05 NO.	APM 2000195	Clerk 02-May-25	AS 02-May-25
2	Solution Cartridge Filter - 0.2 μ - 10 inch	MMI-0367	5442507H1 (Sartopore 2)	01 Nos	01 NO.	APM 2100 182	Clerk 02-May-25	AS 02-May-25
3	TU- Silicone Tube – 8.0 (ID) X 12.8 (OD) Imapure*	MMI-0366	NA	07 M	10 M	2300 4869	Clerk	AS 02-May-25
*This tubing is to be used for water transfer.								

Issuance End Date & Time: <u>02-May-25</u> <u>18:16</u>	Recorded by Sign/ Date: (MM) <u>Clerk 02-May-25</u>
Attach filter certificates with BMR. Filter certificate Attached By (Sign/Date): <u>Olely 02-May-25</u>	

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CHALLENGE STUDY

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 amneal	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 25 of 133	

11.0 PRIMARY PACKING MATERIAL ISSUANCE AND DISPENSING	
ISSUANCE AND VERIFICATION OF PRIMARY PACKING MATERIALS	
<p>Perform line clearance activity as per SOP No. PAP-QA-002. Fill the check list for line clearance of issuance and verification of primary packaging materials. Attach with BMR.</p>	
Cleaning details of area as per SOP No.: PAP-MM-008	
Name of previous product	~NIA~
Batch No. of previous product	~NIA~
Room No.	W204
Date of cleaning performed	02-May-25
Recorded By (MM) <i>John</i> 02-May-25	Checked By (SM) <i>VS</i> 02-May-25

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CHALLENGE STUDY

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
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11.0 PRIMARY PACKING MATERIAL ISSUANCE AND DISPENSING						
PRIMARY PACKING MATERIALS:						
Sr. No.	Material	Material code	Qty. Req.	AR No.	Issued Qty	Issued By (MM) Checked By (SM)
1.	Polypropylene Film APP114-S-135-200-F	PMI-0998	5305 Mtr. (Required Qty.) = 259.945 Kg. (Converted Qty.)	2400042 42	272.950 Kg	CGML 02-may-25 ✓TS 02-may-25
2.	Polypropylene Tube APP107-S-8.20 X 6.20	PMI-0996	1107 Mtr. (Required Qty.) = 23.247 Kg (Converted Qty.)	240004243	25.580 Kg	CGML 02-may-25 ✓TS 02-may-25
3.	Polypropylene Tube APP107-S-8.20 X 6.20	PMI-0996	1107 Mtr. (Required Qty.) = 23.247 Kg (Converted Qty.)	240004243 24011632	19.875 Kg 8.965 Kg	CGML 02-may-25 ✓TS 02-may-25
4.	Twist-Off Port 823 pp inerta 016+plug (tp823.007_a) (twist-off port 823 pp-in016-tp823.007_a)	PMI-0985	46135 Nos.	NA	NA	NA
5.	Hot Stamping Foil, Colorit 34973 Black,220 MM	MMI-0358	2076 Mtr. (Required Qty.) = 8.304 Kg (Converted Qty.)	27800784	8.955 Kg	CGML 02-may-25 ✓TS 02-may-25
6.	Thermal Transfer Print Ribbon. 53 MM X 450 Mtr Black CFC#	MMI-0368	1614 Mtr. (Required Qty.) = 0.6456 Kg (Converted Qty.)	NA	NA	NA

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BATCH MANUFACTURING RECORD		
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
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11.0 PRIMARY PACKING MATERIAL ISSUANCE AND DISPENSING	
<p># Preferably Thermal Transfer Print Ribbon, 53 mm will be used for printing purposes. However, based on the requirement & feasibility, stereo printing can also be used. If stereo printing need to be used for printing, then no need to issuance of Thermal Transfer Print Ribbon.”</p> <ul style="list-style-type: none"> • Ensure the Printing matter is printed from Domino Printer <input type="checkbox"/> or Stereo Printing <input checked="" type="checkbox"/> (Put the tick mark whichever is applicable) 	
Done By (SM): <u>02-MAY-25</u>	Checked By (SM): <u>AS 02-MAY-25</u>

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
PAGE NO.	Page 28 of 133	

11.0 PRIMARY PACKING MATERIAL ISSUANCE AND DISPENSING				
Balance ID:				
POLYPROPYLENE FILM APP114-S-135-200-F (PMI-0998):				
1 Meter (A) = 0.049 Kg		Weight of Cone = 0.515 Kg		
Roll No.	Required quantity in Kg = 5305 meter x (A) Kg	Actual Issued gross quantity in Kg	Actual issued net quantity in Kg = Actual Issued gross Qty in Kg - Weight of cone	Actual issued quantity in meter = (Actual issued net quantity in Kg) / (A)
1	= <u>5.305</u> X <u>0.049</u> Kg = <u>259.945</u> Kg	2.330	= <u>2.330</u> - <u>0.515</u> = <u>1.815</u> Kg.	= <u>1.815</u> / <u>0.049</u> = <u>37.041</u> meter.
2	= <u>5.305</u> X <u>0.049</u> Kg = <u>259.945</u> Kg	23.630	= <u>23.630</u> - <u>0.515</u> = <u>23.115</u> Kg.	= <u>23.115</u> / <u>0.049</u> = <u>471.735</u> meter.
3	= <u>5.305</u> X <u>0.049</u> Kg = <u>259.945</u> Kg	28.130	= <u>28.130</u> - <u>0.515</u> = <u>27.615</u> Kg.	= <u>27.615</u> / <u>0.049</u> = <u>563.571</u> meter.
4	= <u>5.305</u> X <u>0.049</u> Kg = <u>259.945</u> Kg	28.190	= <u>28.190</u> - <u>0.515</u> = <u>27.675</u> Kg.	= <u>27.675</u> / <u>0.049</u> = <u>564.796</u> meter.
5	= <u>5.305</u> X <u>0.049</u> Kg = <u>259.945</u> Kg	28.155	= <u>28.155</u> - <u>0.515</u> = <u>27.640</u> Kg.	= <u>27.640</u> / <u>0.049</u> = <u>564.082</u> meter.
6	= <u>5.305</u> X <u>0.049</u> Kg = <u>259.945</u> Kg	28.185	= <u>28.185</u> - <u>0.515</u> = <u>27.670</u> Kg.	= <u>27.670</u> / <u>0.049</u> = <u>564.694</u> meter.
7	= <u>5.305</u> X <u>0.049</u> Kg = <u>259.945</u> Kg	27.850	= <u>27.850</u> - <u>0.515</u> = <u>27.335</u> Kg.	= <u>27.335</u> / <u>0.049</u> = <u>557.857</u> meter.
8	= <u>5.305</u> X <u>0.049</u> Kg = <u>259.945</u> Kg	28.075	= <u>28.075</u> - <u>0.515</u> = <u>27.560</u> Kg.	= <u>27.560</u> / <u>0.049</u> = <u>562.449</u> meter.

CHALLENGE STUDY

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
PAGE NO.	Page 29 of 133	

11.0 PRIMARY PACKING MATERIAL ISSUANCE AND DISPENSING				
POLYPROPYLENE FILM APP114-S-135-200-F (PMI-0998):				
1 Meter (A) = 0.049 Kg		Weight of Cone = 0.515 Kg		
Roll No.	Required quantity in Kg = 5305 meter x (A) Kg	Actual Issued gross quantity in Kg	Actual issued net quantity in Kg = Actual Issued gross Qty in Kg - Weight of cone	Actual issued quantity in meter = (Actual issued net quantity in Kg) / (A)
9	= <u>5.305 X 0.049</u> Kg = <u>259.945</u> Kg	<u>27.855</u>	= <u>27.855 - 0.515</u> = <u>27.340</u> Kg.	= <u>27.340 / 0.049</u> = <u>557.959</u> meter.
10	= <u>5.305 X 0.049</u> Kg = <u>259.945</u> Kg	<u>27.865</u>	= <u>27.865 - 0.515</u> = <u>27.350</u> Kg.	= <u>27.350 / 0.049</u> = <u>558.163</u> meter.
11	= <u>5.305 X 0.049</u> Kg = <u>259.945</u> Kg	<u>27.850</u>	= <u>27.850 - 0.515</u> = <u>27.335</u> Kg.	= <u>27.335 / 0.049</u> = <u>557.857</u> meter.
12	X Kg		= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.
13	X Kg		= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.
14	X Kg		= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.
15	X Kg		= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.
16	X Kg		= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.
Done By (SM/MM): <u>Coral</u> <u>02-May-25</u>		Checked By (SM): <u>AS</u> <u>02-May-25</u>		

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 30 of 133	

11.0 PRIMARY PACKING MATERIAL ISSUANCE AND DISPENSING				
Balance ID: F00P1P11PR01157				
POLYPROPYLENE TUBE APP 107-S-8.20 X 6.20 (PMI-0996):				
1 Meter (A) = 0.021 Kg		Weight of Cone = 0.325 Kg		
Roll No.	Required quantity in Kg = 2214-meter x (A) Kg	Actual Issued gross quantity in Kg	Actual issued net quantity in Kg = Actual Issued gross Qty in Kg - Weight of cone	Actual issued quantity in meter = (Actual issued net quantity in Kg) / (A)
1	= <u>2214</u> X <u>0.021</u> Kg = <u>46.494</u> Kg	6.607	= <u>3.105</u> - <u>0.325</u> = <u>2.780</u> Kg.	= <u>2.780</u> / <u>0.021</u> = <u>132.381</u> meter.
2	= <u>2214</u> X <u>0.021</u> Kg = <u>46.494</u> Kg	6.290	= <u>6.290</u> - <u>0.325</u> = <u>5.965</u> = <u>2.780</u> Kg.	= <u>5.965</u> / <u>0.021</u> = <u>284.048</u> meter.
3	= <u>2214</u> X <u>0.021</u> Kg = <u>46.494</u> Kg	8.195	= <u>8.195</u> - <u>0.325</u> = <u>7.870</u> Kg.	= <u>7.870</u> / <u>0.021</u> = <u>374.762</u> meter.
4	= <u>2214</u> X <u>0.021</u> Kg = <u>46.494</u> Kg	9.290	= <u>9.290</u> - <u>0.325</u> = <u>8.965</u> Kg.	= <u>8.965</u> / <u>0.021</u> = <u>426.905</u> meter.
5	= <u>2214</u> X <u>0.021</u> Kg = <u>46.494</u> Kg	1.770	= <u>1.770</u> - <u>0.325</u> = <u>1.445</u> Kg.	= <u>1.445</u> / <u>0.021</u> = <u>68.810</u> meter.
6	= <u>2214</u> X <u>0.021</u> Kg = <u>46.494</u> Kg	9.555	= <u>9.555</u> - <u>0.325</u> = <u>9.230</u> Kg.	= <u>9.230</u> / <u>0.021</u> = <u>439.524</u> meter.
7	= <u>2214</u> X <u>0.021</u> Kg = <u>46.494</u> Kg	9.525	= <u>9.525</u> - <u>0.325</u> = <u>9.200</u> Kg.	= <u>9.230</u> / <u>0.021</u> = <u>439.524</u> = <u>9.200</u> / <u>0.021</u> = <u>438.095</u> meter.
8	= <u>2214</u> X <u>0.021</u> Kg = <u>46.494</u> Kg	9.290	= <u>9.290</u> - <u>0.325</u> = <u>8.965</u> Kg.	= <u>8.965</u> / <u>0.021</u> = <u>426.905</u> meter.

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CHALLENGE STUDY

MASTER COPY

	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
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11.0 PRIMARY PACKING MATERIAL ISSUANCE AND DISPENSING				
POLYPROPYLENE TUBE APP 107-S-8.20 X 6.20 (PMI-0996):				
1 Meter (A) = 0.021 Kg		Weight of Cone = 0.325 Kg		
Roll No.	Required quantity in Kg = 2214 meter x (A) Kg	Actual Issued gross quantity in Kg	Actual issued net quantity in Kg = Actual Issued gross Qty in Kg - Weight of cone	Actual issued quantity in meter = (Actual issued net quantity in Kg) / (A)
9	= _____ X _____ Kg = _____ Kg		= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.
10	= _____ X _____ Kg = _____ Kg		= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.
11	= _____ X _____ Kg = _____ Kg		= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.
12	= _____ X _____ Kg = _____ Kg		= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.
13	= _____ X _____ Kg = _____ Kg		= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.
14	= _____ X _____ Kg = _____ Kg		= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.
15	= _____ X _____ Kg = _____ Kg		= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.
16	= _____ X _____ Kg = _____ Kg		= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.
Done By (SM/MM): <i>02-May-25</i>		Checked By (SM): <i>AS 02-May-25</i>		

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 32 of 133	

11.0 PRIMARY PACKING MATERIAL ISSUANCE AND DISPENSING				
Balance ID: EOP P1 PPD 156				
HOT STAMPING FOIL, COLORIT 34973 BLACK, 220 MM (MMI-0358):				
1 Meter (A) = 0.004 Kg		Weight of Cone = 0.435 Kg		
Roll No.	Required quantity in Kg = 2076 meter x (A) Kg	Actual Issued gross quantity in Kg	Actual issued net quantity in Kg = Actual Issued gross Qty in Kg - Weight of cone	Actual issued quantity in meter = (Actual issued net quantity in Kg) / (A)
1	$= 2076 \times 0.004 \text{ Kg}$ $= 8.304 \text{ Kg}$	0.850	$= 0.850 - 0.435$ $= 0.415 \text{ Kg.}$	$= 0.415 / 0.004 =$ 103.750 meter.
2	$= 2076 \times 0.004 \text{ Kg}$ $= 8.304 \text{ Kg}$	1.255	$= 1.255 - 0.435$ $= 0.820 \text{ Kg.}$	$= 0.820 / 0.004 =$ 205.000 meter.
3	$= 2076 \times 0.004 \text{ Kg}$ $= 8.304 \text{ Kg}$		$= 1.980 - 0.435$ $= 1.545 \text{ Kg.}$	$= 1.545 / 0.004 =$ 386.250 meter.
4	$= 2076 \times 0.004 \text{ Kg}$ $= 8.304 \text{ Kg}$	1.970	$= 1.970 - 0.435$ $= 1.535 \text{ Kg.}$	$= 1.535 / 0.004 =$ 383.750 meter.
5	$= 2076 \times 0.004 \text{ Kg}$ $= 8.304 \text{ Kg}$	1.975	$= 1.975 - 0.435$ $= 1.540 \text{ Kg.}$	$= 1.540 / 0.004 =$ 385.000 meter.
6	$= 2076 \times 0.004 \text{ Kg}$ $= 8.304 \text{ Kg}$	1.980	$= 1.980 - 0.435$ $= 1.545 \text{ Kg.}$	$= 1.545 / 0.004 =$ 386.250 meter.
7	$= 2076 \times 0.004 \text{ Kg}$ $= 8.304 \text{ Kg}$	1.990	$= 1.990 - 0.435$ $= 1.555 \text{ Kg.}$	$= 1.555 / 0.004 =$ 388.750 meter.
Done By (SM/MM): <i>Cewu</i> 02-May-25		Checked By (SM): <i>VJS</i> 02-May-25		

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CHALLENGE STUDY

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 amneal	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 33 of 133	

11.0 PRIMARY PACKING MATERIAL ISSUANCE AND DISPENSING				
Thermal Transfer Print Ribbon. 53 MM X 450 Mtr Black CFC (MMI-0368):				
1 Meter (A) = 0.0004 Kg		Weight of Cone = 0.0147 Kg		
Roll No.	Required quantity in Kg = 1614 meter x (A) Kg	Actual Issued gross quantity in Kg	Actual issued net quantity in Kg = Actual Issued gross Qty in Kg - Weight of cone	Actual issued quantity in meter = (Actual issued net quantity in Kg) / (A)
1	= <u> </u> X <u> </u> Kg = <u> </u> Kg		= <u> </u> - <u> </u> = <u> </u> Kg.	= <u> </u> / <u> </u> = <u> </u> meter.
2	= <u> </u> X <u> </u> Kg = <u> </u> Kg		= <u> </u> - <u> </u> = <u> </u> Kg.	= <u> </u> / <u> </u> = <u> </u> meter.
3	= <u> </u> X <u> </u> Kg = <u> </u> Kg		= <u> </u> - <u> </u> = <u> </u> Kg.	= <u> </u> / <u> </u> = <u> </u> meter.
4	= <u> </u> X <u> </u> Kg = <u> </u> Kg		= <u> </u> - <u> </u> = <u> </u> Kg.	= <u> </u> / <u> </u> = <u> </u> meter.
5	= <u> </u> X <u> </u> Kg = <u> </u> Kg		= <u> </u> - <u> </u> = <u> </u> Kg.	= <u> </u> / <u> </u> = <u> </u> meter.
6	= <u> </u> X <u> </u> Kg = <u> </u> Kg		= <u> </u> - <u> </u> = <u> </u> Kg.	= <u> </u> / <u> </u> = <u> </u> meter.
7	= <u> </u> X <u> </u> Kg = <u> </u> Kg		= <u> </u> - <u> </u> = <u> </u> Kg.	= <u> </u> / <u> </u> = <u> </u> meter.
8	= <u> </u> X <u> </u> Kg = <u> </u> Kg		= <u> </u> - <u> </u> = <u> </u> Kg.	= <u> </u> / <u> </u> = <u> </u> meter.
Done By (SM/MM): ~ NIA ~			Checked By (SM): ~ NIA ~	
06-May-25				

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CHALLENGE STUDY

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
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11.0 PRIMARY PACKING MATERIAL ISSUANCE AND DISPENSING

Check the area is cleaned as per SOP No. PAP-SM-006 for PPM dispensing activities.

Record the room temperature and %RH as per SOP No. PAP-SM-006 in below mentioned table:

Record the differential pressure of RLAf in below mentioned table.

Dispensing of PPM in Bag Line Dispensing Room

Previous product Paracetamol Infusion I.P. 1% W/V
(Parauniport) 100 mL

Previous Batch Number AH250076

Room No: L204

Date: 06-May-25 Start Time: 04:51

DP of dispensing room (Limit: NLT 06 Pa)	Temp. (15.0-25.0°C)	%RH NMT 60 %	RLAF Equipment ID: PA-SM-011			Remark
			HEPA filter (Limit: 8 – 18 mm WC)	Fine Filter (Limit: 2 – 8 mm WC)	Pre filter (Limit: 0.5 – 5 mm WC)	
<u>26</u>	<u>35.7</u>	<u>41%</u>	<u>013.7</u>	<u>007.1</u>	<u>002.3</u>	<u>- N/A -</u>

End Time: 04:53

Recorded by (SM/MM): Cau 06-May-25

Checked by (SM): AS 06-May-25

Fill the check list for line clearance as per SOP: 'Procedure for line clearance' SOP No.: PAP-QA-002 for dispensing area and attach with BMR.

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH25006
PAGE NO.	Page 35 of 133	

11.0 PRIMARY PACKING MATERIAL ISSUANCE AND DISPENSING						
<u>Dispensing of PPM in Sampling room</u>						
Check the area is cleaned as per SOP for PPM dispensing activities.						
Previous product _____	Batch Number _____					
Record temperature and %RH of sampling Room as per SOP No.: PAP-QCC-001, in below mention table:						
Date	Time	Temperature 15.0°C to 25.0°C	%RH NMT 60 %	Recorded By (MM/SM)	Checked By (SM)	
Ensure the cleaning & record in the given below provision:						
Date	sampling area & RLAF cleaning	Observation (OK/Not Ok)	Checked By (MM/SM)	Verified by (SM)		
Record the differential pressure of RLAf Equipment ID.: PA-MM-001 in below table:						
Date	Time	RLAF	Limit in mm wc	Observation in mm wc	Recorded By (MM/SM)	Checked By (SM)
		Pre Filter	0.5 to 5 mm wc		21A RP 06-May-25	
		Intermediate/ Fine Filter	2 to 8 mm wc			
		HEPA Filter	8 to 18 mm wc			

Fill the check list for line clearance as per SOP: 'Procedure for line clearance' SOP No.: PAP-QA-002 for Sampling area and attach with BMR.

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 36 of 133	

11.0 PRIMARY PACKING MATERIAL ISSUANCE AND DISPENSING					
Primary packing material dispensing details as per SOP No. PAP-SM-008.					
Item	UOM	Material Code	A.R. No.	Quantity Required	Quantity Dispensed
Twist-Off Port 823 pp inerta 016+plug (tp823.007_a) (twist-off port 823 pp-in016- tp823.007_a)	Nos.	PMI-0985	24008161	46135	46145 nos.
Done By (SM/MM): (Sign & Date) <i>Ques</i> <i>06 May -25</i>			Checked by (SM): (Sign & Date)		
Remark: <i>Not OK</i> .					
Dispensing Part Reviewed By QA <i>R.P 07-May-25.</i>					

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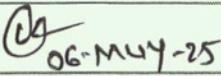
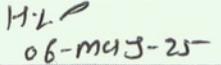
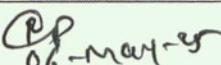
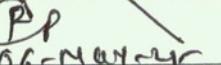
MASTER COPY

 amneal	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 37 of 133	

12.0 | SIGNATURE LOG (MANUFACTURING AREA ACTIVITY)

Record the name of persons involved in Manufacturing area activity.

*Declaration: I undersigned, hereby declare that I am trained on all relevant procedure and activity(s) that I am performing in this batch.

Sr. No.	Name	Employee Code	Department	*Signature
1	Ummerly Bejapati	339516	SM	 06-May-25
2	Heldik Patel	343466	SM	 06-May-25
3	Ronak Patel	315749	QA	 06-May-25
4				
5				
6				
7				
8				
9				
10				N/M
11				
12				
13				
14				 06-May-25

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CHALLENGE STUDY

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
PAGE NO.	Page 38 of 133	

12.0 | SIGNATURE LOG (MANUFACTURING AREA ACTIVITY)

Record the name of persons involved in Manufacturing area activity.

*Declaration: I undersigned, hereby declare that I am trained on all relevant procedure and activity(s) that I am performing in this batch.

Sr. No.	Name	Employee Code	Department	*Signature
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				

~IA

(P.P)
06-MAY-25

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amneal		BATCH MANUFACTURING RECORD
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 39 of 133	

13.0 PREPARATION FOR MANUFACTURING

LOOP NUMBER DETAILS.

Loop 1: Mixing Vessel (500L, EQP/P1/PRD/040) → Product piping → Centrifugal Pump →
Pre-filter (1.2 μ) → Filter housing

Loop 2: Mixing Vessel (4000L, EQP/P1/PRD/039) → Product piping → Centrifugal Pump →
Pre-filter (1.2 μ) → Filter housing

Loop 3: Filtration Vessel (4000L, EQP/P1/PRD/041) → Product Piping → Centrifugal Pump →
Final filter (0.2 μ) → Filter housing → Product Piping → Diaphragm Valves
(6 Ways Block Valves)

Loop 4: Automatic Bag Filling Machine (Filling Station and Insertion station, EQP/P1/PRD/042)

Loop 5: Block Valve → Product Piping → Diaphragm Valves (6 Ways Block Valves)

Note: Verify CIP/PHT/SIP Parameters from SOP No.: PAP-SM-021 (Wherever applicable)

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CHALLENGE STUDY

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 40 of 133	

13.0	PREPARATION FOR MANUFACTURING							
Loop – 1 CIP Details (Perform CIP as per SOP: PAP-SM-021 and attach SCADA report to BMR.)								
Previous Product Name: <u>N/A</u>								
Batch No: <u>N/A</u>								
Test Parameters for CIP: Acceptance Criteria Conductivity: NMT 1.3 µs/ cm.								
Verify the recipe parameter before starting of the CIP cycle as per SOP No.: PAP-SM-021								
Recipe ID.: <u>001</u> Recipe parameter verified by (SM) (Sign/Date): _____								
Note: <ul style="list-style-type: none"> • Select the Recipe ID according to the previous product as mentioned in SOP No. PAP-SM-021. • Perform the CIP with Recipe ID of loop-1 (Recipe ID: 1) if the shutdown CIP was already executed after proceeding previously manufacturing product batch and mentioned "N/A" in previous product. 								
CIP Start Detail		Sampling valve flushing done	CIP End Detail					
Date & Time	Done By (SM)	Checked By (SM)	Yes / No	Done By (SM)	Checked By (SM)	Date & Time	Done By (SM)	Checked By (SM)
05-MAY-25 06:05	H.L. 05-MAY-25	✓ 05-MAY-25	Yes	H.L. 05-MAY-25	✓ 05-MAY-25	05-MAY-25 7:30	H.L. 05-MAY-25	✓ 05-MAY-25
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Verify the SCADA report printout for the CIP process.								
CIP (Complies / Does not Complies)				Reviewed By (SM)				
Does not Complies				S 05-may-25 NA				
N/A								
Note: Attach all the signed and verified CIP Cycle printouts with BMR.								

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CHALLENGE STUDY

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amneal	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
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13.0	PREPARATION FOR MANUFACTURING							
Loop – 2 CIP, PHT, SIP Details (Perform CIP, PHT & SIP as per SOP: PAP-SM-021 and attach SCADA report to BMR.)								
Previous Product Name: <u>-n/a-</u> Batch No: <u>n/a</u> Test Parameters for CIP: Acceptance Criteria Conductivity: NMT 1.3 µs/ cm. Test Parameters for PHT: Acceptance Criteria: Pressure Drop should not go below 0.90 bar pressure. Test Parameters for SIP: Acceptance Criteria: Sterilization Temperature: 121.0°C to 142.0°C for 30 minutes. Verify the recipe parameter before starting of the CIP cycle as per SOP No.: PAP-SM-021. Recipe ID.: <u>001</u> Recipe parameter verified by (SM) (Sign/Date): _____ Note: <ul style="list-style-type: none"> • Select the Recipe ID according to the previous product as mentioned in SOP No. PAP-SM-021. • Perform the CIP with Recipe ID of loop-2 (Recipe ID: 1) if the shutdown CIP was already executed after proceeding previously manufacturing product batch and mentioned “N/A” in previous product. 								
CIP Start Detail		Sampling valve flushing done	CIP End Detail					
Date & Time	Done By (SM)	Checked By (SM)	Yes / No	Done By (SM)	Checked By (SM)	Date & Time	Done By (SM)	Checked By (SM)
05-May-25 02:55	H-LP	05-May-25	Yes	H-LP 05-May-25	05-May-25	05-May-25 05:46	H-LP 05-May-25	05-May-25
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Verify the SCADA report printout for the CIP process.								
CIP (Complies / Does not Complies)				Reviewed By (SM)				
<u>Does Not Complies</u>				<u>G</u>				
<u>N/A</u>				<u>N/A</u>				
Note: Attach all the signed and verified CIP Cycle printouts with BMR.								

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250075
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13.0	PREPARATION FOR MANUFACTURING					
Verify that the vent filter and Nitrogen/compressed Air filter integrity of vessel is complying as per SOP No.: PAP-SM-015 before start of SIP.						
Verified By (SM): _____.						
Start the assembling of 1.2-micron filter as per below mentioned steps as per SOP No.: PAP-SM-015						
Sr. No.	Assembling steps	Date	Start Time	End Time	Assembled By (SM)	Checked By (SM)
1	Assemble the filter in Prefilter housing at product transfer line (from mixing vessel to filtration vessel) in filtration area. (CAT No.: <u>505250391</u>)	05-May-25	09:21	09:30	H.L. 05-May-25	09 05-May-25
Note: During assembling verify arrow (From filter housing) direction and fix in such a way that product flow from Mixing vessel to Filtration vessel.						
Verify the recipe parameter before starting of the PHT cycle as per SOP No.: PAP-SM-021.						
Recipe ID.: <u>001</u> PHT Recipe parameter verified by (SM) <u>H.L 05-May-25</u> (Sign/Date).						
PHT Start Detail			PHT End Detail			
Date & Time	Done By (SM)	Checked By (SM)	Date & Time	Done By (SM)	Checked By (SM)	
05-May-25 09:37	H.L 05-May-25	09 05-May-25	05-May-25 10:04	H.L 05-May-25	09 05-May-25	
N/A	N/A	N/A	N/A	N/A	N/A	
Verify the SCADA report printout for the PHT process.						
PHT (Complies / Does not Complies)			Reviewed By (SM)			
Complies			<u>05-May-25</u>			
N/A			N/A			
Note: Attach all the signed and verified PHT Cycle printouts with BMR.						

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
PAGE NO.	Page 43 of 133	

13.0 PREPARATION FOR MANUFACTURING					
SIP Start Detail			SIP End Detail		
Date & Time	Done By (SM)	Checked By (SM)	Date & Time	Done By (SM)	Checked By (SM)
05-MAY-25 10:33	H.L 05-MAY-25	② 05-MAY-25	05-MAY-25 13:05	H.L 05-MAY-25	② 05-MAY-25
N/A	N/A	N/A	N/A	N/A	N/A

Verify the SCADA report printout for the SIP process.

SIP (Complies / Does not Complies)	Reviewed By (SM)
complies	GL 05-MAY-25
-N/A-	-N/A-

Note: Attach all the signed and verified SIP Cycle printouts with BMR.

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 amneal		BATCH MANUFACTURING RECORD
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 44 of 133	

14.0 CLEANING OF ACCESSORIES				
Ensure washing & drying the supporting accessories for manufacturing like SS container, measuring cylinder, glass beaker/container, processing tubing, glass bottle and pressure vessels etc. as per respective SOP No.: PAP-SM-009 & PAP-SM-007.				
Cleaning performed on Date: <u>05-MAY-25</u> & Time: from <u>10:40</u> to <u>11:54</u>				
Done By (SM): <u>H.L</u> <u>05-may-25</u> Checked By (SM): <u>DL</u> <u>05-may-25</u> .				
Sr. No.	Accessories	Cleaning Status (Satisfactory/Not Satisfactory/NA)	Checked By (SM)	Verified By (SM)
1	SS Container	Satisfactory	<u>H.L</u> <u>06-may-25</u>	<u>DL</u> <u>06-may-25</u>
2	Pressure vessels I.D. No.: <u>NA</u> <u>NA</u> <u>NA</u>	NA		
3	Glass breaker/ container	Satisfactory		
4	Measuring cylinder	Satisfactory		
5	Glass bottle	Satisfactory		
6	Sampler ID No. <u>PA-0A-002</u>	Satisfactory		
7	Processing Tubing	Satisfactory		
8	Other Accessories	Satisfactory		

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CHALLENGE STUDY

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amneal		BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.	
BMR NO.	BMR-PA-063-05		
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)		AH250076
PAGE NO.	Page 45 of 133		

15.0 PRE-CHECKS AND APPROVAL FOR MANUFACTURING PROCESS						
Record differential pressure of following rooms as per SOP No. PAP-SM-006.						
Date	Time	Room	Limit in Pascal	Observation in Pascal	Recorded By (SM)	Checked By (SM)
06-May-25	05:10	Corridor v/s Air lock-1 (L201)	NLT 15	32	H.L. 06-May-25	Qa 06-May-25
	05:12	Air lock-1 (L201) v/s Air lock-2 (L202)	NLT 15	28	H.L. 06-May-25	Qa 06-May-25
	05:18	Air lock-2 (L202) v/s Dispensing room (L204)	NLT 06	25	H.L. 06-May-25	Qa 06-May-25
	05:19	Air lock-2 (L202) v/s Air lock-3 (L203)	NLT 06	14	H.L. 06-May-25	Qa 06-May-25

PRECOMMENCEMENT CHECK OF MANUFACTURING AREA

Date	Time	DP (Limit NLT 06 Pa)	Temperature (15.0-25.0°C)	%RH (NMT 60 %)	Recorded By (SM)	Checked By (SM)
5 OCT '25	05:23	16	23.2	55	H.L. 06-May-22	Qa 06-May-25

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		BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.	
BMR NO.	BMR-PA-063-05		
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)		AH250076
PAGE NO.	Page 45/133		

15.0 PRE-CHECKS AND APPROVAL FOR MANUFACTURING PROCESS					
PRESTART UP CHECK					
Date	Time	Pre-start up activity	Results	Done By (SM)	Checked By (SM)
06-May-25	05:27	Ensure the Load cell verification as per SOP No.: PAP-SM-046.	<input checked="" type="checkbox"/> OK/ <input type="checkbox"/> Not OK	H.L 06-May-25	06-May-25
06-May-25	05:29	Ensure the calibration of pH/DO meter is as per SOP No.: PAP-SM-058	<input checked="" type="checkbox"/> OK/ <input type="checkbox"/> Not OK	H.L 06-May-25	06-May-25
06-May-25	05:48	Transfer the RM from Dispensing Room to Mixing room and verify the RM dispensing details.	<input checked="" type="checkbox"/> OK/ <input type="checkbox"/> Not OK	H.L 06-May-25	06-May-25
06-May-25	05:51	Ensure the Jacket weight of mixing vessel is 212 Kg and Set time fill jacket is 120 sec from HMI.	<input checked="" type="checkbox"/> OK/ <input type="checkbox"/> Not OK	H.L 06-May-25	06-May-25

Put a tick mark “√” in “□” which is applicable.

Perform line clearance activity as per SOP No. PAP-QA-002.

Fill the checklist for line clearance of manufacturing area and attach it with BMR.

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		BATCH MANUFACTURING RECORD
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
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16.0 MANUFACTURING PROCESS				
Record the AR No. of WFI from WFI Analysis Report:				
AR No. of WFI: <u>WF 250505</u>	Recorded By (SM): <u>H.L 06-MUJ-25</u>			
PRE-STARTUP ACTIVITY				
Date	Start Time	Manufacturing instruction	End Time	Done By (SM)
06-May-25	07:28	Start nitrogen flushing to manufacturing vessel EQP/P1/PRD/039 with 0.2μ filtered Nitrogen continuously for at least 10 minutes. Nitrogen flushing Applied: <input checked="" type="checkbox"/> Yes/ <input type="checkbox"/> No	07:38	<u>H.L</u> <u>06-MUJ-25</u>
06-May-25	07:39	Start the cool water circulation in jacket of mixing vessel (Equipment ID: EQP/P1/PRD/039) using Fill Jacket control in IPC. Fill the jacket and when load cell display reading becomes stable. Jacket weight of mixing vessel: <u>214</u> Kg Tare the weight of mixing vessel to zero. Record displayed tare weight of mixing vessel: <u>0</u> Kg.	07:42	<u>H.L</u> <u>06-MUJ-25</u>
06-May-25	07:43	Collect approx. 4070.0 Kg of WFI in mixing vessel ID No. EQP/P1/PRD/039 using WFI Collection control in IPC. Qty. of WFI Collected <u>4070</u> Kg. Stirrer Speed: <u>300</u> (Limit:200-400 RPM). Temperature of WFI <u>39.93</u> °C.	09:05	<u>H.L</u> <u>06-MUJ-25</u>
06-May-25	09:10	Cool down WFI up to below 40°C of mixing vessel by supplying cool water circulation in jacket using Temperature control in IPC, under continuous stirring and nitrogen sparging. Stirrer Speed: <u>300</u> (Limit: 200-400 RPM). Total time for cooling: <u>75</u> Minutes. Temperature of WFI in mixing vessel: <u>38.72</u> °C. (Limit: Below 40°C)	10:25	<u>H.L</u> <u>06-MUJ-25</u>
Checked by (SM): - <u>19 06-MUJ-25</u>				

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 48 of 133	

16.0		MANUFACTURING PROCESS		
Date	Start time	Manufacturing instruction	End Time	Done By (SM)
12-MAY-25	10:30	Start Nitrogen purging using Nitrogen sparging control in IPC for NLT 30 min with continuous stirring. Check and record the DO level Continue nitrogen purging till the DO level is less than 1 PPM. Stirrer Speed: <u>300</u> RPM (Limit: 200-400 RPM) DO: <u>0.76 mg/l</u> (Limit: Less than 1 PPM) Note: 1 mg/L = 1 ppm	11:10 12:05	M.I.P 06-MAY-25
N/A	N/A	Continue nitrogen purging further and withdraw sample again (if applicable). Stirrer Speed: <u>NA</u> RPM (Limit: 200-400 RPM) DO: <u>NA</u> (Limit: Less than 1 PPM)	N/A	N/A
06-MAY-25	11:12	Upon Achieving the required DO, stop the stirring, connect outlet of mixing vessel to inlet of pressure vessel and transfer cooled WFI from mixing vessel (EQP/P1/PRD/039) to mixing vessel (EQP/P1/PRD/040) through silicon tube by applying Nitrogen pressure in such a way that remaining quantity of cooled WFI in mixing vessel (EQP/P1/PRD/039) will be approx. 3600.0 Kg. Nitrogen blanketing for head space in Mixing vessel (EQP/P1/PRD/040) Use this transferred cool WFI for rinsing the container / Bag, volume make up etc. Remaining quantity of WFI in mixing vessel (EQP/P1/PRD/039) <u>3600</u> Kg.	12:57	M.I.P 06-MAY-25
Checked By (SM): <u>09-06-MAY-25</u> .				

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 amneal	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
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16.0		MANUFACTURING PROCESS			
MANUFACTURING STEP - 1					
Date	Manufacturing Instruction	Start Time	Actual process	End Time	Done By (SM)
* 05-May-25 06-May-25	Add and dissolve dispensed batch quantity of Mannitol to the mixing vessel of above step with continuous stirring. Rinse the container/polybag with WFI after addition for complete mass transfer.	14:11	Qty. of Mannitol added <u>144.000</u> kg.	14:28	H.L. ob-MUJ-25
	After addition stirring & nitrogen purging shall be continued for 10 minutes or till to achieve clear solution and record Stirring speed and Mixing time	14:29	Nitrogen Purging: <u>10</u> Minutes (Limit: NLT 10 minutes or till to achieve clear solution)	14:39	H.L. ob-MUJ-25
		14:29	Stirrer speed <u>360</u> RPM (Limit: 200-400 RPM) Mixing time: <u>10</u> Minutes (Limit: 10 minutes)	14:39	H.L. ob-MUJ-25
06-May-25	Check description of bulk solution. (Clarity should be checked from view glass from vessel)	14:40	Clarity: <u>clear solution</u> (Clear solution)	14:41	H.L. ob-MUJ-25
Note: After manufacturing step-1 record the date of manufacturing and expiry of batch on page No. 01 Checked by (SM): - <u>06-May-25</u>					

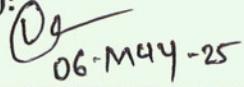
* wrong date written hence corrected.

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CHALLENGE STUDY

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
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16.0	MANUFACTURING PROCESS				
MANUFACTURING STEP – 2					
Date	Manufacturing Instruction	Start Time	Actual process	End Time	Done By (SM)
06-MAY-25	Add and dissolve dispensed weighed batch quantity of Paracetamol to the solution of above step with continuous stirring. Rinse the container with WFI after addition for complete mass transfer.	14:44	Qty. of Paracetamol added <u>40.256</u> kg. Qty. of WFI used for Rinsing: <u>2000</u> mL (Approx.)	14:53	H.L.P 06-MUJ-25
	After addition stirring & nitrogen purging shall be continued for 30 minutes or till complete clear solution obtained and record Stirring speed and Mixing time	14:51	Nitrogen purging: <u>30</u> Minutes (Limit: NLT 30 minutes or till to achieve clear solution)	15:21	H.L.P 06-MUJ-25
		14:54	Stirrer speed <u>300</u> RPM (Limit: 200-400 RPM) Mixing time: <u>30</u> Minutes (Limit: 30 minutes)	15:10	H.L.P 06-MUJ-25
	Check description of bulk solution. (Clarity should be checked from view glass from vessel)	15:00	Clarity: <u>clear solution</u> (Clear solution)	15:26	H.L.P 06-MUJ-25
Checked by (SM):  <u>06-MAY-25</u>					

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		BATCH MANUFACTURING RECORD		
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.		
BMR NO.	BMR-PA-063-05	AH250076		
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)			
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16.0	MANUFACTURING PROCESS				
MANUFACTURING PROCESS STEP-3					
Date	Manufacturing instruction	Start time	Actual process	End time	Done by (SM)
06-MAY-25	Cool down bulk solution up to below 35°C of mixing vessel by supplying cool water circulation in jacket using Temperature control in IPC and under stirring.	15:31	Temperature of solution in mixing vessel: <u>30.48</u> °C (Preferably 30°C) (Limit: NMT 35°C) Total time for cooling: <u>19</u> Minutes.	15:56	H.V. 06-MAY-25
Checked by (SM): - <u>06-MAY-25</u>					

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		BATCH MANUFACTURING RECORD
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
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16.0		MANUFACTURING PROCESS				
MANUFACTURING STEP - 4						
Date	Manufacturing Instruction	Start Time	Actual process		End Time	Done By (SM)
06-MAY-25	Add and dissolve dispensed weighed batch quantity of Sodium metabisulfite (SMBS) to the solution of above step with continuous stirring. Rinse the container with WFI after addition for complete mass transfer. After addition stirring & nitrogen purging shall be continued for 10 minutes or till to achieve complete clear solution obtained and record Stirring speed and Mixing time	15:54	Qty. of Sodium metabisulfite (SMBS) added: <u>0.800</u> kg,		15:52	H.L / 06-MAY-25
		15:55	Qty. of WFI used for Rinsing: <u>500</u> mL (Approx.)		16:05	H.L / 06-MAY-25
		15:55	Nitrogen purging: <u>10</u> Minutes (Limit: NLT 10 minutes or till to achieve clear solution)		16:05	H.L / 06-MAY-25
		15:55	Stirrer speed <u>300</u> RPM (Limit: 200-400 RPM) Mixing time: _____ Minutes (Limit: 10 minutes)		16:05	H.L / 06-MAY-25
06-MAY-25	Check description of bulk solution. (Clarity should be checked from view glass from vessel)	16:06	Clarity: <u>clear solution</u> (Clear solution)		16:07	H.L / 06-MAY-25
Checked by (SM): - <u>06-MAY-25</u>						

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		BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.	
BMR NO.	BMR-PA-063-05		
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)		AH250076
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16.0		MANUFACTURING PROCESS			
MANUFACTURING STEP - 5					
Date	Manufacturing Instruction	Start Time	Actual process	End Time	Done By (SM)
07-May-25	Add and dissolve dispensed weighed batch quantity of Sodium Acetate trihydrate to the solution of above step with continuous stirring. Rinse the container with WFI after addition for complete mass transfer. After addition stirring & nitrogen purging shall be continued for 10 minutes or till to achieve complete clear solution obtained and record Stirring speed and Mixing time	16:10	Qty. of Sodium Acetate trihydrate added <u>6.560</u> kg, Qty. of WFI used for Rinsing: <u> </u> mL (Approx.)	16:14	H.L 07-MAY-25
		16:15	Nitrogen Purging: <u> </u> Minutes (Limit: NLT 10 minutes or till to achieve clear solution)	16:25	H.L 07-MAY-25
		16:15	Stirrer speed <u>300</u> RPM (Limit: 200-400 RPM) Mixing time: <u>10</u> Minutes (Limit: 10 minutes)	16:25	H.L 07-MAY-25
	Check description of bulk solution. (Clarity should be checked from view glass from vessel)	16:26	Clarity: <u>Clear</u> (Clear solution)	16:27	H.L 07-MAY-25
Checked by (SM): - <u>Qe</u> <u>06-MAY-25</u>					

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
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16.0 MANUFACTURING PROCESS					
MANUFACTURING STEP - 6					
Date	Manufacturing Instruction	Start Time	Actual process	End Time	Done By (SM)
06-May-25	Add and dissolve dispensed batch quantity of Glacial acetic acid (438.0 mL) to the solution of above step with continuous stirring. Rinse the container with WFI after addition for complete mass transfer.	16:28	Qty. of Glacial acetic acid added <u>460</u> gm	16:31	H.L. 06-MAY-25
			Qty. of WFI used for Rinsing: <u>500</u> mL (Approx.)		
		After addition stirring & nitrogen purging shall be continued for 10 minutes or till to achieve complete clear solution obtained and record Stirring speed and Mixing time	16:32	Nitrogen Purging: <u>10</u> Minutes (Limit: NLT 10 minutes or till to achieve clear solution)	16:46
		16:32	Stirrer speed <u>300</u> RPM (Limit: 200-400 RPM) Mixing time: _____ Minutes (Limit: 10 minutes)	16:42	H.L. 06-MAY-25
06-May-25	Check description of bulk solution. (Clarity should be checked from view glass from vessel)	16:43	Clarity: _____ (Clear solution)		H.L. 06-MAY-25
06-May-25	Check the initial pH of bulk solution	16:47	Initial pH: <u>5.60</u>	16:51	H.L. 06-MAY-25
Checked by (SM): - <u>D9 06-MAY-25</u> .					

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
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16.0	MANUFACTURING PROCESS																						
MANUFACTURING STEP - 7																							
Date	Manufacturing Instruction	Start Time	Actual process		End Time																		
06-MAY-25	Preparation of 1 N sodium hydroxide solution: Take 4800 ml WFI from previously collected WFI (From Mixing vessel Equipment ID: (EQP/P1PRD/040) in cleaned glass bottle. Add and dissolved dispensed quantity of sodium hydroxide (240gm) in collected WFI Quantity 4800 mL. Make up the volume up to 6000 mL to make 1 N Sodium Hydroxide solution.	16:49	Quantity of NaOH <u>240</u> g Quantity of WFI used <u>4800</u> ml. Total 1 N NaOH solution prepared: <u>6000</u> mL		17:56 M.L.P 06-MAY-25																		
06-MAY-25	Adjust the pH of solution with freshly prepared 1.0 N NaOH or Glacial acetic acid (if required) (Limit: 5.55 to 5.70) Preferably 5.65 After each addition stir the solution for NLT 5 minutes .	17:05	Quantity of 1N NaOH added: <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th rowspan="2">mL</th> <th colspan="2">Stirring time (NLT 5 Min)</th> <th rowspan="2">pH</th> </tr> <tr> <th>From</th> <th>To</th> </tr> </thead> <tbody> <tr> <td>500</td> <td>17:05</td> <td>17:15</td> <td>5.65</td> </tr> <tr> <td colspan="4">N/A</td> </tr> <tr> <td colspan="4">CP 06-may-25</td> </tr> </tbody> </table> Total 1N NaOH used: <u>500</u> mL Stirrer speed: 200-400 RPM Stirrer Speed: <u>300</u>	mL	Stirring time (NLT 5 Min)		pH	From	To	500	17:05	17:15	5.65	N/A				CP 06-may-25				17:20	M.L.P 06-MAY-25
mL	Stirring time (NLT 5 Min)		pH																				
	From	To																					
500	17:05	17:15	5.65																				
N/A																							
CP 06-may-25																							
Checked by (SM): - <u>06-MAY-25</u>																							

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NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
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16.0	MANUFACTURING PROCESS																							
Date	Manufacturing Instruction	Start Time	Actual process		End Time																			
					Done By (SM)																			
06-May-25	After pH adjustment discard the remaining quantity of prepared 1.0 N NaOH and Glacial acetic acid.	17:22	<p>Quantity of Glacial acetic acid added:</p> <table border="1" style="margin-bottom: 10px;"> <thead> <tr> <th rowspan="2" style="width: 30%;">mL</th> <th colspan="2" style="width: 40%;">Stirring time (NLT 5 Min)</th> <th rowspan="2" style="width: 30%;">pH</th> </tr> <tr> <th style="width: 20%;">From</th> <th style="width: 20%;">To</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">N/A</td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p>Total Glacial acetic acid used: <u>N/A</u> mL</p> <p>Final pH of solution: <u>5.87</u> (Limit: 5.55 to 5.70)</p> <p>Stirrer speed: 200-400 RPM</p> <p>Stirrer Speed: <u>N/A</u></p> <p>Remaining Quantity of Sodium Hydroxide Discarded: <u>500 mL</u></p> <p>Remaining Qty. of Glacial acetic acid Discarded: <u>200 gm</u></p>		mL	Stirring time (NLT 5 Min)		pH	From	To	N/A												17:25	H.I.P 06-May-25
mL	Stirring time (NLT 5 Min)		pH																					
	From	To																						
N/A																								
<p>Checked by (SM): - <u>Vg</u> 06-May-25</p>																								

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
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16.0	MANUFACTURING PROCESS
Note: - Make up to 100% of batch size: Make up the volume in SS 316L 4000L manufacturing vessel (EQP/P1/PRD/039) to 100% batch size by using the WFI (which is kept separately in suitable vessel as per calculation given below). Note: Weight per mL of final bulk solution: 1.012 g/mL at 25°C±5°C. Calculation: Volume Make up in Kg = Std. Wt. /mL of bulk × B. Size (L) $= 1.012 \times 4000 \text{ L}$ $= 4048 \text{ Kg}$ Checked By (SM): - <u>06-May-25</u>	

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NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
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16.0 MANUFACTURING PROCESS					
MANUFACTURING PROCESS STEP-8					
Date	Manufacturing instruction	Start time	Actual process	End time	Done by (SM)
06-May-25	Finally, make up the volume to 100 % of the total batch size (4048 kg) as per load cell with cool WFI previously collected in Mixing vessel Equipment ID: (EQP/P1PRD/040)	17:28	Final weight: <u>4048</u> Kg (Verified from load cell display)	17:57	H.L P 06-May-25
06-May-25	Continue stirring and Nitrogen purging for NLT 20 min. To get clear, uniform solution.	17:57	Stirrer speed: <u>300</u> RPM (Limit: 200-400 RPM) Mixing time: <u>20</u> Minutes (Limit: 20 minutes) Nitrogen purging Time <u>20</u> Minutes. (Limit: NLT 20 minutes) Temperature of Bulk solution: <u>29.84</u> °C.	29:16	H.L P 06-May-25

Checked By (SM): - 06-May-25
After completion of mfg. activity, carry out dumping of bulk solution from sampling valve of manufacturing vessel.

Dumping Date/ Start Time: 06-May-25 | 18:18
Quantity of Bulk Solution (Dumping from sampling valve): 2500 mL (At least 2000 mL)
Dumping Date /End Time: 06-May-25 | 18:20
Done By (SM): H.L P 06-May-25 Checked By (SM): - 06-May-25

* During activity of stirring and nitrogen purging activity stopped from 17:54 to 17:57 due to power failure

06-May-25

CHALLENGE STUDY

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BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
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16.0	MANUFACTURING PROCESS			
SAMPLING: Collect the sample as per SOP No.: PAP-QA-004 or as per Sampling protocol.				
Sample Details	Sampled Qty. (mL)	Sampling Date & Time	Sampling done by (QA)	Verified by (SM)
Unfiltered bulk solution	400 + 100 + 100	06-May-25 18:31	PL	H.L. 06-MAY-25
			NIA	
				PL 06-may-25
Total Sample	620 mL	Verified by (SM): H.L. 06-MAY-25		
Total sample after manufacturing (In Kg): $\frac{600 \text{ mL} \times (\text{Bulk density } 1.012 \text{ g/mL})}{1000} = 0.612 \text{ Kg.}$		Calculated by (SM): - H.L. 06-MAY-25		

Process Loss (After volume makeup if any) 0.0 mL X (Bulk density 1.012 g/mL) / 1000 = 0.0 Kg.
 Done By (Sign/Date): H.L. 06-MAY-25.

SAMPLING: Perform the sampling of bulk solution as per Hold time study protocol.				
Sample Details	Sampled Qty. (mL)	Sampling Date & Time	Sampling done by (QA)	Verified by (SM)
			NIA	
Total Sample		Verified by (SM): H.L. 06-MAY-25		
Total sample after manufacturing (In Kg): $\frac{600 \text{ mL} \times (\text{Bulk density } 1.012 \text{ g/mL})}{1000} = 0.612 \text{ Kg.}$		Calculated by (SM): - N/A		

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CHALLENGE STUDY

MASTER COPY

amneal	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 60 of 133	

16.0 MANUFACTURING PROCESS																								
Store the bulk solution in manufacturing vessel under 0.2μ filtered Nitrogen blanketing at pressure: <u>1.00</u> bar (NLT 0.5 bar) till future process.			Applied By (SM): <u>H.L.P</u> <u>06-MAY-25</u>	Checked By (SM): <u>00</u> <u>06-MAY-25</u>																				
Record the details in below table. Frequency: Start and twice in a shift. <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center; width: 10%;">Sr. No.</th> <th style="text-align: center; width: 20%;">Date</th> <th style="text-align: center; width: 20%;">Time</th> <th style="text-align: center; width: 30%;">Nitrogen pressure (NLT 0.5 bar).</th> <th style="text-align: center; width: 30%;">Recorded By (SM)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">01</td> <td style="text-align: center;"><u>06-MAY-25</u></td> <td style="text-align: center;"><u>18:23</u></td> <td style="text-align: center;"><u>1.05</u></td> <td style="text-align: center;"><u>H.L.P</u> <u>06-MAY-25</u></td> </tr> <tr> <td style="text-align: center;">02</td> <td style="text-align: center;"><u>06-MAY-25</u></td> <td style="text-align: center;"><u>23:28</u></td> <td style="text-align: center;"><u>0.49</u></td> <td style="text-align: center;"><u>H.L.P</u> <u>06-MAY-25</u></td> </tr> <tr> <td colspan="5" style="height: 100px; vertical-align: top; padding-top: 10px;"> <p style="text-align: right; margin-right: 10px;">P.S.</p> <p style="text-align: right; margin-right: 10px;">P.L. <u>06-MAY-25</u></p> </td> </tr> </tbody> </table>					Sr. No.	Date	Time	Nitrogen pressure (NLT 0.5 bar).	Recorded By (SM)	01	<u>06-MAY-25</u>	<u>18:23</u>	<u>1.05</u>	<u>H.L.P</u> <u>06-MAY-25</u>	02	<u>06-MAY-25</u>	<u>23:28</u>	<u>0.49</u>	<u>H.L.P</u> <u>06-MAY-25</u>	<p style="text-align: right; margin-right: 10px;">P.S.</p> <p style="text-align: right; margin-right: 10px;">P.L. <u>06-MAY-25</u></p>				
Sr. No.	Date	Time	Nitrogen pressure (NLT 0.5 bar).	Recorded By (SM)																				
01	<u>06-MAY-25</u>	<u>18:23</u>	<u>1.05</u>	<u>H.L.P</u> <u>06-MAY-25</u>																				
02	<u>06-MAY-25</u>	<u>23:28</u>	<u>0.49</u>	<u>H.L.P</u> <u>06-MAY-25</u>																				
<p style="text-align: right; margin-right: 10px;">P.S.</p> <p style="text-align: right; margin-right: 10px;">P.L. <u>06-MAY-25</u></p>																								
Reviewed By (SM): <u>H.L.P</u> <u>06-MAY-25</u>																								
Note: Continue recording of nitrogen blanketing till bulk solution transfer from MV to FV. Note: After completion of transfer activity fill line closure checklist as per SOP No.: PAP-QA-002																								

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CHALLENGE STUDY

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 61 of 133	

16.0	MANUFACTURING PROCESS		
RECONCILIATION			
Page No.	Stage	Qty. (kg)	Remarks
	Theoretical Batch Size	4048	
58	Final Weight after volume makeup (A) (As per load cell)	5500	
59	QC Samples of bulk solution (from manufacturing vessel) (B)	0.845	
59	Process Loss (if any) (C)		✓
	Bulk solution available for filtration (D) = [A-(B+C)]	4047.393	
	%Yield (E) = [B+D] / A X 100 (Limit: NLT 90%)	98.5%	H.L. 06-MAY-25
	% Reconciliation (F) = [(B + C + D)/A] × 100	99%	
Reconciliation by (SM): H.L. 06-MAY-25		Verified By (SM): 06-MAY-25	
Bulk manufacturing Date: <u>06-MAY-25</u> Start time: <u>19:11</u> (Start time from manufacturing step-1 First Material addition time)			
Bulk manufacturing Date: <u>06-MAY-25</u> End time: <u>17:53</u> (End time of manufacturing step-8 Final Stirring end time)			
Total time for manufacturing: <u>03:42</u> Hrs.			
Total time calculated by (SM): <u>H.L. 06-MAY-25</u> . Checked by (SM): <u>06-MAY-25</u> .			
Manufacturing Part Reviewed By (QA): <u>R.08-MAY-25</u>			

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CHALLENGE STUDY

MASTER COPY

 amneal	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 62 of 133	

17.0 SIGNATURE LOG (FILTRATION, FILLING & STOPPERING)				
Record the name of persons who are involved in Filtration and Filling area activity.				
*Declaration: I undersigned, hereby declare that I am trained on all relevant procedure and activity(s) that I am performing in this batch.				
Sr. No.	Name	Employee Code	Department	*Signature
1	Piyush Panchal	317493	SM	906-May-25
2	Tarun Koshti	316080	SM	tar 06-May-25
3	Dhronit Patel	316092	SM	DB 06-May-25
4	Sanjay Agarwal	316328	SM	SA 06-May-25
5	Kavishree Vaghela	316213	QA	KV 06-May-25
6	Ronak Patel	315799	QA	RP 06-May-25
7	Vasundhara Patil	349908	SM	VP 06-May-25
8				
9				
10				
11				
12				
13				
14				
15			N/A	
16				
17				
18				
19				

QA AUTHORIZED COPY

(P)
10-May-25

CHALLENGE STUDY

MASTER COPY

	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
PAGE NO.	Page 63 of 133	

17.0	SIGNATURE LOG (FILTRATION, FILLING & STOPPERING)
-------------	-------------------------------------------------------------

Record the name of persons who are involved in Filtration and Filling area activity.

*Declaration: I undersigned, hereby declare that I am trained on all relevant procedure and activity(s) that I am performing in this batch.

Sr. No.	Name	Employee Code	Department	*Signature
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				
31				
32				
33				
34				
35				
36				
37				
38				

NIA

QP
10-May-25

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CHALLENGE STUDY

MASTER COPY

amneal		BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.	
BMR NO.	BMR-PA-063-05		AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)		
PAGE NO.	Page 64 of 133		

18.0	FILTRATION PROCESS							
<u>Loop – 3 CIP, PHT, SIP Details</u>								
Verify the CIP, PHT and SIP parameters:								
Previous Product Name: <u>N/A</u>								
Batch No: <u>N/A</u>								
Test Parameters for CIP: Acceptance Criteria Conductivity: NMT 1.3 μ s/cm.								
Test Parameters for PHT: Acceptance Criteria: Pressure Drop should not go below 0.90 bar pressure.								
Test Parameters for SIP: Acceptance Criteria: Sterilization Temperature: 121.0°C to 142.0°C for 30 minutes.								
Verify the recipe parameter along with the respective SOP No.: PAP-SM-021.								
Recipe ID.: <u>01</u>	Recipe parameter verified by (SM) (Sign/Date): <u>406-May-25</u>							
Note:								
<ul style="list-style-type: none"> Select the Recipe ID according to the previous product as mentioned in SOP No. PAP-SM-021. Perform the CIP with Recipe ID of respective loop-3 (Recipe ID: 1) if the shutdown CIP was already executed after proceeding previously manufacturing product batch and mentioned "N/A" in previous product. 								
CIP Start Detail		Sampling valve flushing Detail	CIP End Detail					
Date & Time	Done By (SM)	Checked By (SM)	Yes/ No	Done By (SM)	Checked By (SM)	Date & Time	Done By (SM)	Checked By (SM)
<u>06-May-25 07:07</u>	<u>8 06-May-25</u>	<u>DB 06-May-25</u>	<u>Yes</u>	<u>8 06-May-25</u>	<u>DB 06-May-25</u>	<u>06-May-25 12:06</u>	<u>8 06-May-25</u>	<u>DB 06-May-25</u>
				<u>N/A</u>		<u>406-May-25</u>		
Verify the SCADA report printout for the CIP process.								
CIP (Complies / Does not Complies)			Reviewed By (SM)					
<u>Complies write word output</u>			<u>DB 06-May-25</u>					
<u>- N/A -</u>			<u>- N/A -</u>					
Note: Attach all the signed and verified CIP Cycle printouts with BMR.								

QA AUTHORIZED COPY

CHALLENGE STUDY

MASTER COPY

	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
PAGE NO.	Page 65 of 133	

18.0 FILTRATION PROCESS

FILTER INTEGRITY DETAILS:

Perform the Pre integrity of the 0.2 μ product filter as per SOP No.PAP-SM-015 "Integrity testing of various filters".

Filter Integrity Testing Details:

Description	Filter Integrity Detail
Filter integrity testing machine ID No.	<input type="checkbox"/> EQP/P1/PRD/045 / <input type="checkbox"/> EQP/P1/PRD/322/ <input checked="" type="checkbox"/> EQP/P1/PRD/046 <input type="checkbox"/> If any other Id No. <u>n/a</u>
Date of test	<u>06-may-25</u>
Make	Sartorius
Catalogue No.	5442507H1(Sartopore 2)
Lot No.	<u>211146009</u>
Serial No.	<u>501120688 2747</u>
Limit	NLT 3200 mbar
Wetting medium	WFI
Observed Bubble point value (mbar)	_____ mbar
Test Result	Pass <input checked="" type="checkbox"/> Fail <input type="checkbox"/>
Done by (SM)	<u>206-may-25</u>
Checked by (SM)	<u>206-may-25</u>
Put "✓" mark on applicable filter integrity testing result of filter integrity.	

NOTE: Paste the signed and verified filter integrity printout on Exhibit-VIII (Page for pasting labels/ Printouts) as per SOP No.: PAP-SM-054 and attach with BMR.

After Completion of filter integrity, perform the drying of filter using 0.2 μ filtered compressed air for NLT 10 minutes.

Applied Pressure: <u>3.8 bar (NLT 3.5 bar)</u>	From: <u>13:52</u>	To: <u>14:03</u>
Done By (SM): <u>206-may-25</u>	Checked By (SM): <u>206-may-25</u>	

**wrong entry corrected*

CHALLENGE STUDY

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 66 of 133	

18.0 FILTRATION PROCESS

Verify that the vent filter and Nitrogen/compressed Air filter integrity of vessel is complying as per SOP No.: PAP-SM-015 before start of SIP.

Verified By (SM): AB 06-May-25.

After completion of the filter integrity, transfer the housing along with filter to filtration room through pass box. Fix the housing at the respective place and perform the PHT and SIP of the respective looping system along with the filter.

Start the assembling of 0.2-micron filter as per below mentioned steps as per SOP No.: PAP-SM-015

Sr. No.	Assembling steps	Date	Start Time	End Time	Assembled By (SM)	Checked By (SM)
1	Assemble the filter (CAT No.: <u>5442507H1</u>) in product transfer line in filtration area.	06-May-25	14:15	14:25	AB 06-May-25	AB 06-May-25

Note: During assembling verify arrow (From filter housing) direction and fix in such a way that product flow from Filtration vessel to filling machine.

Verify the recipe parameter along with the respective SOP No.: PAP-SM-021.

Recipe ID.: 01 **PHT Recipe parameter verified by (SM)** AB 06-May-25 (Sign/Date).

PHT Start Detail			PHT End Detail		
Date & Time	Done By (SM)	Checked By (SM)	Date & Time	Done By (SM)	Checked By (SM)
06-May-25 14:32	AB 06-May-25	AB 06-May-25	06-May-25 15:09	AB 06-May-25	AB 06-May-25
	N/A				AB 06-May-25

Verify the SCADA report printout for the PHT process.

PHT (Complies / Does not Complies)	Reviewed By (SM)
Does not Complies - N/A -	AB 06-May-25
	- N/A -

Note: Attach all the signed and verified PHT Cycle printouts with BMR.

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		BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.	
BMR NO.	BMR-PA-063-05		
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)		AH2500076
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18.0 FILTRATION PROCESS

Verify the recipe parameter along with the respective SOP No.: PAP-SM-021.

Recipe ID.: 01 SIP Recipe parameter verified by (SM) ✓ 06-May-25 (Sign/Date).

SIP Start Detail			SIP End Detail		
Date & Time	Done By (SM)	Checked By (SM)	Date & Time	Done By (SM)	Checked By (SM)
06-May-25 15:20	✓ 06-May-25	✓ 06-May-25	06-May-25 18:52	✓ 06-May-25	✓ 06-May-25
		NIA			✓ 06-May-25

Verify the SCADA report printout for the SIP process.

SIP (Complies / Does not Complies)	Reviewed By (SM)
Complies	✓ 06-May-25
NIA	NIA

Note: Attach all the signed and verified SIP Cycle printouts with BMR.

Verify the cleaning of filtration vessel prior to start of filtration process and record the details of observation in below table.

Sr. No.	Equipment description	Filtration vessel ID.	Cleaning Observation		Ensured By
1.	Filtration Vessel	EQP/P1/PRD/041	OK <input checked="" type="checkbox"/>	Not OK <input type="checkbox"/>	✓ 06-May-25

Put a tick mark “✓” in “□” which is applicable.

Record differential pressure, % RH and Temperature of Bag filtration room (L217) rooms as per SOP No. PAP-SM-006 in below mentioned table.

Date	Time	Differential pressure NLT 06 Pa	Temperature 15.0-25.0°C	%RH NMT 60	Recorded By (SM)	Checked By (SM)
06-May-25	21:06	25	23	48	✓ 06-May-25	✓ 06-May-25

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CHALLENGE STUDY

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 amneal	BATCH MANUFACTURING RECORD		
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.	
BMR NO.	BMR-PA-063-05		AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)		
PAGE NO.	Page 68 of 133		

18.0 FILTRATION PROCESS

FILTRATION ACTIVITY:

Activity	Date	Time		Done By (SM)	Checked By (SM)
		From	To		
Verify the filtration vessel (FV-4000) for its readiness for the filtration and ensure the zero display on the load cell of the filtration vessel.	06-May-25	21:08	21:10	✓ 06-May-25	DB 06-May-25
Ensure the verification of Filtration vessel load cell as per SOP: PAP-SM-046.					

Perform line clearance activity as per SOP No. PAP-QA-002 and attach the respective format with BMR.
Fill the check list for line clearance of manufacturing area and attach it with BMR.

Note: Perform the product transfer (filtration) activity by filtering the solution through 1.2 μ cartridge filter into the filtration vessel using 0.2 μ filtered nitrogen and stored under nitrogen blanketing as per SOP.: PAP-SM-022.

Remove the entrapped air through filter housing vent if required.

Done by (SM): N/A

Checked By (SM): N/A

CHALLENGE STUDY

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 amneal	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
PAGE NO.	Page 69 of 133	

18.0	FILTRATION PROCESS					
Flushing Details: Fill the filter completely with bulk solution and flush with approx. 400 mL bulk solution each for 2 times. Discard the 1 st and 2 nd filter flushes. Fill the filter completely with bulk solution and hold the solution for 10 Min.						
Done by (SM): <u>806-May-25</u>			Checked By (SM): <u>806-May-25</u>			
Date <u>06-May-25</u>	Time <u>23:43</u>	No. of Filter Flush <u>1st Flush</u>	Flush Qty. <u>400 mL</u>	Approx discarded Qty. <u>400 mL</u>	Discarded By (SM) <u>806-May-25</u>	Verified By (SM) <u>806-May-25</u>
<u>25</u>	<u>23:45</u>	<u>2nd Flush</u>	<u>400 mL</u>	<u>400 mL</u>	<u>806-May-25</u>	<u>806-May-25</u>

Total quantity discarded for filter flush = 800 mL X Bulk density (1.012 g/mL)/1000
= 0.810 Kg (Approx.)

Done By: 806-May-25.

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CHALLENGE STUDY

MASTER COPY

	BATCH MANUFACTURING RECORD		
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.	
BMR NO.	BMR-PA-063-05		
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)		AH250076
PAGE NO.	Page 70 of 133		

18.0 FILTRATION PROCESS					
FILTRATION ACTIVITY:		Date	Time		Done by (SM)
Sr. No.	Activity		From	To	
1	After filter flush continue the filtration activity from mixing vessel to Filtration vessel.	06-May-25	23:46	00:21	E 06-May-25
2	After completion of filtration from batch semi auto, manually open the required valve for the product transfer from MV to FV and flush the nitrogen (NMT 2.5 bar) in the manufacturing vessel for NLT 10 minutes to recover the solution available in the respective line loops.	07-May-25	00:24	00:34	E * 06-May-25 07-May-25
3	Stop the nitrogen flushing, close all the open valves and release the nitrogen pressure from the MV.	07-May-25	00:35	00:37	E 07-May-25

Checked by (SM): OB 06 May 25

Leftover solution in Mixing vessel for hold time study (If any) = N/A Kg (Approx.)

Total filtered Bulk: 4006 Kg (From load cell).

Done By (Sign/Date) = E 07-May-25, Verified by (SM): OB 07 May 25

*wrong date corrected,

E
07-May-25

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CHALLENGE STUDY

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
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18.0 FILTRATION PROCESS

Sampling details from the Filtration Vessel: Perform the sampling of bulk solution after filtration as per SOP: PAP-QA-004 or respective sampling protocol and send to further analysis.

Note: Discard the approximate 50 mL of initial bulk solution from sampling valve of filtration vessel and then collect bulk sample from sampling valve of filtration vessel" as per SOP No. PAP-QA-004.

Initial bulk solution discarded from Sampling valve of filtration vessel before sampling. (Rinsing before sampling)	Discarded Solution: <u>10</u> mL X 1.012 g/ mL / 1000 = <u>0.25</u> Kg (Approx. 50 mL)	Discarded By (QA): <u>NA</u>
---------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------	------------------------------

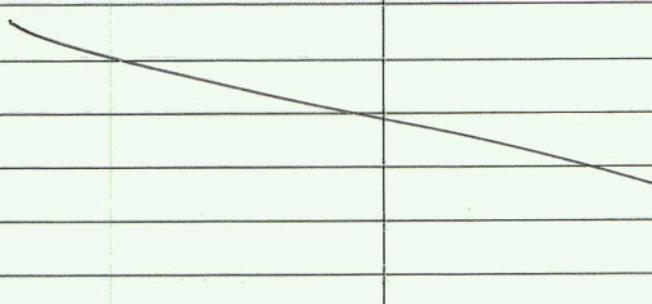
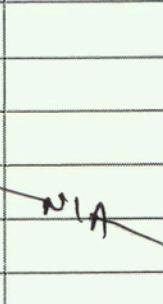
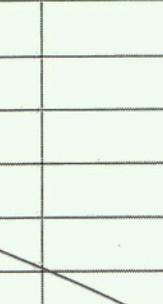
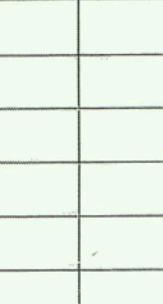
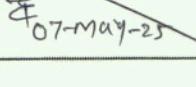
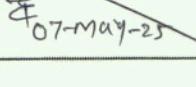
Sample Details	Sampled Qty. (mL)	Sample Date	Time	Sampling done by (QA)	Verified by (SM)
Total Sampled Qty <u>NA</u> mL = <u>NA</u> Kg.					
(Conversion mL to Kg= mL of solution x Bulk density 1.012 g/mL /1000)					
Checked By (SM): <u>NA</u>					
				<u>NA</u>	<u>07-May-25</u>

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CHALLENGE STUDY

MASTER COPY

	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 72 of 133	

18.0	FILTRATION PROCESS			
SAMPLING: Perform the sampling of bulk solution as per Hold time study protocol .				
Sample Details		Sampled Qty. (mL)	Sampling Date & Time	Sampling done by (QA)
				
Total Sample		Verified by (SM):		
Total sample after manufacturing (In Kg): $\text{_____ mL} \times (\text{Bulk density } 1.012 \text{ g/mL}) / 1000$ $= \text{_____ Kg.}$		Calculated by (SM): - 		

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CHALLENGE STUDY

MASTER COPY

		BATCH MANUFACTURING RECORD
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 73 of 133	

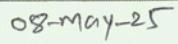
18.0 FILTRATION PROCESS				
Store the bulk solution under 0.2μ filtered Nitrogen blanketing at pressure NLT 0.5 bar. Record the detail in below table. Frequency: Start and every 1 hrs. ± 15 min.				
Sr. No.	Date	Time	Nitrogen pressure (NLT 0.5 bar)	Recorded By (SM)
01	07-May-25	00:39	1.13	✓ 07-may-25
02	07-May-25	01:47	0.90	✓ 07-may-25
03	07-May-25	02:51	1.01	✓ 07-may-25
04	07-May-25	04:00	1.01	✓ 07-may-25
05	07-May-25	05:02	1.03	✓ 07-may-25
06	07-May-25	06:01	0.96	✓ 07-may-25
07	07-May-25	06:59	0.99	✓ 07-may-25
08	07-May-25	07:50	0.81	✓ 07-may-25
09	07-May-25	09:00	0.41	✓ 07-may-25
10	07-May-25	10:00	0.81	✓ 08-may-25
11	07-May-25	10:55	0.80	✓ 07-may-25
12	07-May-25	12:05	0.86	✓ 07-may-25
13	07-May-25	13:13	0.89	✓ 07-may-25
14	11-June-25	14:07	0.85	✓ 07-may-25
15	07-May-25	15:05	0.79	✓ 07-may-25
16	07-May-25	16:05	0.77	✓ 07-may-25
17	07-May-25	17:00	0.86	✓ 07-may-25
18	07-May-25	17:56	0.85	✓ 07-may-25
19	07-May-25	18:54	0.89	✓ 07-may-25

Reviewed By (SM): SG 08-may-25

CHALLENGE STUDY

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		BATCH MANUFACTURING RECORD
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
PAGE NO.	Page 74 of 133	

18.0 FILTRATION PROCESS				
Store the bulk solution under 0.2μ filtered Nitrogen blanketing at pressure NLT 0.5 bar. Record the detail in below table. Frequency: Start and every 1 hrs. ± 15 min.				
Sr. No.	Date	Time	Nitrogen pressure (NLT 0.5 bar)	Recorded By (SM)
20	07-May-25	19:55	0.90	AB 07May-25
21	07-May-25	21:25	0.72	AB 07May-25
22	07-May-25	22:16	1.01	AB 07May-25
23	07-May-25	23:26	0.72	AB 07May-25
24	08-May-25	00:27	0.80	AB 08May-25
25	08-May-25	01:34	0.78	AB 08May-25
26	08-May-25	02:42	0.84	AB 08May-25
27	08-May-25	03:48	0.72	AB 08May-25
  				
Reviewed By (SM): <u>AB</u> 08-May-25				

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CHALLENGE STUDY

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
PAGE NO.	Page 75 of 133	

18.0	FILTRATION PROCESS		
RECONCILIATION:			
Page No.	Stage	Qty. (Kg)	Remarks
61	Bulk solution available for filtration in MV (A)	4047.393	NA
70	Left Over solution in mixing vessel for hold time study (If any) (As per load cell after filtration) (B)		NA
69	Solution discarded for filter flush (Approx.) (C)	0.810	NA
70	Actual filtered bulk available in filtration vessel after completion of filtration (As per load cell) (D)	4006	NA
	Process loss (MV to FV) E = A - (B+C+D)	40.583	NA
71	Rinsing before sampling (If any) (Approx.) (F)	00	NA
71	QC Samples of bulk solution (from filtration vessel) (G)	00	NA
	Actual filtered bulk available in filtration vessel for filling H = D-(F+G)	4006	NA
	% Yield (I) = G+H/A x 100 (Limit: NLT 90%)	98.98%	NA
	% Reconciliation (J) = [(B+C+E+F+G+ H)/A] x 100	100.00%	NA
Reconciliation by (SM):		Verified By (SM):	

Solution available for Filling Conversion of Kg to Ltr.

Filtered Bulk solution to be used for filling = 4006 Kg = 4006 Kg / 1.012 = 3958.498 Ltrs.

Note: - To convert Filtered Bulk solution to number of filled Bags refer below formula for calculation.
 $(\frac{4006}{105.3} \text{ g}) \times 1000$ Nos. of Bags = 38043

Reconciled by (SM): <u>7 May 8th 25</u>	Verified By (SM): <u>AB08 MAY 25</u>
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Filtration part reviewed by QA: P 08-May-25

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amneal		BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.	
BMR NO.	BMR-PA-063-05		AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)		
PAGE NO.	Page 76 of 133		

19.0	FILLING LINE PROCESS		
LOOP 4 CIP AND SIP DETAILS:			
Previous Product Name: <u>N/A</u>			
Batch No: <u>N/A</u>			
Test Parameters for CIP: Acceptance Criteria Conductivity: NMT 1.3 μ s/ cm.			
Test Parameters for SIP: Acceptance Criteria: Sterilization Temperature: 121.0°C to 142. 0°C for 31 min.			
CIP Start Detail			CIP End Detail
Date & Time	Done By (SM)	Checked By (SM)	Date & Time
06-May-25 11:46	<u>E</u> 06-May-25	<u>Jar</u> 06-May-25	06-May-25 13:20
			<u>N/A</u>
			<u>PL</u> 06-May-25
Verify report printout for the CIP process.			
CIP (Complies / Does not Complies)		Reviewed By (SM)	
<u>Complies</u>		<u>Q</u> 06-May-25	
<u>N/A</u>		<u>N/A</u>	
Note: Attach all the signed and verified CIP Cycle printouts with BMR.			
SIP Start Detail			SIP End Detail
Date & Time	Done By (SM)	Checked By (SM)	Date & Time
06-May-25 17:19	<u>E</u> 06-May-25	<u>Jar</u> 06-May-25	7 May 10:05
			<u>N/A</u>
			<u>PL</u> 06-May-25
Verify the printout for the SIP process.			
SIP (Complies / Does not Complies)		Reviewed By (SM)	
<u>Complied</u>		<u>Q</u> 06-May-25	
<u>N/A</u>		<u>N/A</u>	
Note: Attach all the signed and verified SIP Cycle printouts with BMR.			

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CHALLENGE STUDY

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amneal		BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.	
BMR NO.	BMR-PA-063-05		AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)		
PAGE NO.	Page 77 of 133		

19.0	FILLING LINE PROCESS
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LOOP 5 CIP AND SIP DETAILS:

Test Parameters for SIP: Acceptance Criteria: Sterilization Temperature: 121.0°C to 148.0 °C for 30 min.

Previous Product Name: N/A Batch No.: N/A

Recipe ID.: 01 Recipe parameter verified by (SM) (Sign/Date): 06-May-25.

Note:

- Select the Recipe ID according to the previous product as mentioned in SOP No. PAP-SM-021.
- Perform the CIP with Recipe ID of respective loop-5 (**Recipe ID: 1**) if the shutdown CIP was already executed after proceeding previously manufacturing product batch and mentioned "N/A" in previous product.

CIP Start Detail			CIP End Detail		
Date & Time	Done By (SM)	Checked By (SM)	Date & Time	Done By (SM)	Checked By (SM)
06-May-25 06:23	✓ 06-May-25	Jar 06-May-25	06-May-25 06:43	✓ 06-May-25	Jar 06-May-25
—		N/A	—		CP 06-May-25

Verify report printout for the CIP process.

CIP (Complies / Does not Complies)	Reviewed By (SM)
Does not complies	✓ 06-May-25
N/A	N/A

Recipe ID.: 01 Recipe parameter verified by (SM) 06-May-25 (Sign/Date)

SIP Start Detail			SIP End Detail		
Date & Time	Done By (SM)	Checked By (SM)	Date & Time	Done By (SM)	Checked By (SM)
06-May-25 21:56	✓ 06-May-25	Jar 06-May-25	06-May-25 22:42	✓ 06-May-25	Jar 06-May-25
—		N/A	—		CP 06-May-25

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		BATCH MANUFACTURING RECORD
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 78 of 133	

19.0	FILLING LINE PROCESS	
Verify the printout for the SIP process.		
SIP (Complies / Does not Complies)		Reviewed By (SM)
Does not complies ~N/A~		⑪ ✓ 06-May-25 ~N/A~

Note: Attach all the signed and verified CIP Cycle printouts with BMR.

Record differential pressure of following rooms as per SOP No. PAP-SM-006 in below mentioned table.

Date	Time	Room	Limit in Pascal	Observation in Pascal	Recorded By (SM)	Checked By (SM)
06-May-25	22:50	Corridor (G321) v/s Air lock-1 (L209)	NLT 15	24	✓ 06-May-25	✓ 06-May-25
		Air lock-1 (L209) v/s Air lock-2 (L210)	NLT 20	18	✓ 06-May-25	✓ 06-May-25
		Air lock-2 (L210) v/s Air lock-3 (L211)	NLT 06	11	✓ 06-May-25	✓ 06-May-25
		Air lock-3 (L211) v/s Buffer area (L212)	NLT 06	12	✓ 06-May-25	✓ 06-May-25
		Buffer area (L212) v/s Bag filling room (L216)	NLT 06	42	✓ 06-May-25	✓ 06-May-25
		Buffer area (L212) v/s Filtration room (L217)	NLT 06	24	✓ 06-May-25	✓ 06-May-25
		Buffer area (L212) v/s Autoclave unloading (L218)	NLT 06	26	✓ 06-May-25	✓ 06-May-25
		Bag Filling room (L216) v/s Die storage room (L207)	NLT 06	16	✓ 06-May-25	✓ 06-May-25
		Bag Filling room (L216) v/s Stagging room (L208)	NLT 06	18	✓ 06-May-25	✓ 06-May-25
		Buffer area (L212) v/s Air lock-4 (L213)	NLT 06	16	✓ 06-May-25	✓ 06-May-25
		Air lock-4 (L213) v/s Air lock-5 (L214)	NLT 15	20	✓ 06-May-25	✓ 06-May-25
		Air lock-5 (L214) v/s Air lock-1 (L209)	NLT 06	10	✓ 06-May-25	✓ 06-May-25

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CHALLENGE STUDY

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 amneal	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 79 of 133	

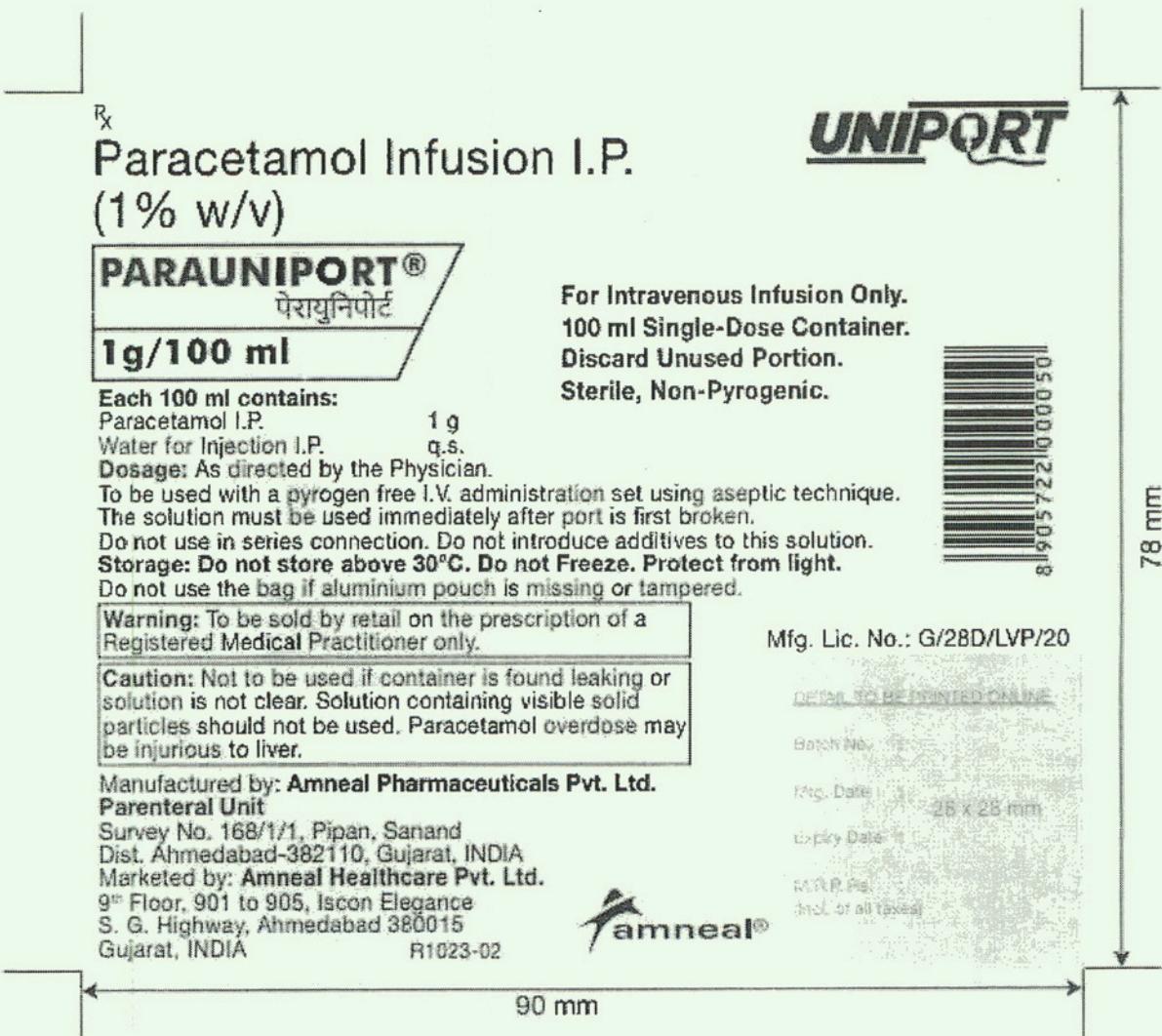
19.0	FILLING LINE PROCESS				
PRECOMMENCEMENT CHECK FILLING ROOM:					
Date	Time	Temp. 15.0-25.0°C	%RH NMT 60	Recorded By (SM)	Checked By (SM)
06-May-25	22:53	21.2 °C	57%	✓ 06-May-25	✓ 06-May-25
Perform line clearance activity as per SOP No. PAP-QA-002 and attach the respective format with BMR. Perform the bag making and filling activity as per SOP No. PAP-SM-022. Recipe Name (Format Name): <u>100 mL NDC Bag, Stereos</u>					
Verified by: <u>✓ 06-May-25</u>					
MACHINE SETTING:					
Empty bags rejected during Machine setup. (From Filling HMI)	Total Quantity of Bags		Done By (SM)	Checked By (SM)	
	188		✓	✓ 06-May-25	
PRECHECK BEFORE FILLING START					
Details	Observation (Satisfactory/ Not Satisfactory/NA)		Done By (SM)	Verified By (QA)	
Ensure correct issuance of printing Die with respect to printing matter.	Satisfactory		✓ 06-May-25	QP 06-May-25	
Verify the batch details in printing matter against the BMR (e.g., Product name & strength, Batch No., Mfg. Date, Exp. Date)	Satisfactory Satisfactory		✓ 06-May-25	QP 06-May-25	
Ensure selection of correct format/recipe number as per SOP No. PAP-SM-022.	Satisfactory		✓ 06-May-25	QP 06-May-25	
*Take a sample of printed bag for each die and verified all details against the BMR and printing matter and approved for printing.	Satisfactory		✓ 06-May-25	QP 06-May-25	
* Attach the printed bag sample proof to BMR for reference.					

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CHALLENGE STUDY

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 80 of 133	

19.0	FILLING LINE PROCESS	
Approved Artwork: <div style="display: flex; align-items: center; justify-content: space-between;"> <div style="flex: 1;">  <p>Paracetamol Infusion I.P. (1% w/v)</p> <p>PARAUNIPORT® परायुनिपोर्ट</p> <p>1g/100 ml</p> <p>Each 100 ml contains: Paracetamol I.P. 1 g Water for Injection I.P. q.s. Dosage: As directed by the Physician. To be used with a pyrogen free I.V. administration set using aseptic technique. The solution must be used immediately after port is first broken. Do not use in series connection. Do not introduce additives to this solution. Storage: Do not store above 30°C. Do not Freeze. Protect from light. Do not use the bag if aluminium pouch is missing or tampered.</p> <p>Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only.</p> <p>Caution: Not to be used if container is found leaking or solution is not clear. Solution containing visible solid particles should not be used. Paracetamol overdose may be injurious to liver.</p> <p>Manufactured by: Amneal Pharmaceuticals Pvt. Ltd. Parenteral Unit Survey No. 168/1/1, Pipan, Sanand Dist. Ahmedabad-382110, Gujarat, INDIA Marketed by: Amneal Healthcare Pvt. Ltd. 9th Floor, 901 to 905, Iscon Elegance S. G. Highway, Ahmedabad 380015 Gujarat, INDIA R1023-02</p> <p style="text-align: center;"></p> </div> <div style="width: 10%; text-align: center;"> <p>For Intravenous Infusion Only. 100 ml Single-Dose Container. Discard Unused Portion. Sterile, Non-Pyrogenic.</p> <p>Mfg. Lic. No.: G/28D/LVP/20</p> <p>DETAILS TO BE PRINTED ONLINE</p> <p>Batch No.</p> <p>Mfg. Date 26 x 26 mm</p> <p>Expiry Date</p> <p>M.R.P. Rs. (incl. of all taxes)</p> </div> </div>		

CHALLENGE STUDY

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		BATCH MANUFACTURING RECORD
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
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19.0 FILLING LINE PROCESS			
Differential Pressure Monitoring of Filling LAF: Frequency: Take a reading of differential pressure gauges of LAF at start & End of filling.			
LAF IDs	DP gauge IDs	Date & Time	Date & Time
		06-May-25 22:55	08-May-25 04:31
		Start of filling.	End of filling.
		Observation (Limit: 25 to 130 Pa)	Observation (Limit: 25 to 130 Pa)
EQP/P1/PRD/043	P1/PRD/043/DMG/001/00	112	112
	P1/PRD/043/DMG/002/00	114	117
	P1/PRD/043/DMG/003/00	108	106
	P1/PRD/043/DMG/004/00	91	132
	P1/PRD/043/DMG/005/00	45	95
EQP/P1/PRD/043A	P1/PRD/043A/DMG/001/00	42	44
EQP/P1/PRD/043B	P1/PRD/043B/DMG/001/00	88	24
EQP/P1/PRD/043C	P1/PRD/043C/DMG/001/00	80	82
Checked by (SM)		✓ 06-May-25	✓ 08-May-25
Verified By (SM)		✓ 06-May-25	✓ 08-May-25

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 82 of 133	

19.0	FILLING LINE PROCESS							
Filled volume verification detail (by Weight method): Average weight of Empty Non PVC bag (with Twist off port) (Balance Id No: ECOP191) 102.00 gm								
1	2	3	4	5	6	7	8	Avg. Weight (W1) (g)= $\{[Bag(1+2+3+4+5+6+7+8)]/8\}$
7.9086 gm	7.9976 gm	7.9279 gm	7.8817 gm	7.8663 gm	7.8493 gm	7.9667 gm	7.9716 gm	7.9212 gm
								Done by. (SM)
								7-07-May-25
Checked by (SM): _____								
Reference filled volume calculation:								
Filled Volume				=	102.00 mL to 106.12 mL (Target volume= 104.04 mL= 104.0 mL*) =105.3 g			
Average density (Weight/ mL)				=	1.012 g/mL			
Avg. weight of Empty Non PVC bag (W1)				=	7.9212 g			
Lower control Limit (Min. Filled Volume x density) (W2)				=	102.00 x 1.012	=	103.224= 103.2 g	
Upper control Limit (Max. Filled Volume x density) (W3)				=	106.12 x 1.012	=	107.393 = 107.4 g	
Gross weight limit (W2 + W1 To W3 + W1)				=	111.1212 g to 115.3212 g			
Done By (SM) (Sign & Date): <u>7-07-May-25</u>					Checked By (SM) (Sign & Date): <u>7-07-May-25</u>			
*Actual target volume is 104.04 mL is rounded to 104.0 mL due to Filling machine HMI limitation to feed the fill volume value up to single decimal only.								
Note: <ol style="list-style-type: none"> Dose set up activity shall be performed as per SOP No. PAP-SM-022. Filling machine speed is 4000 bags/hours. 								
Final Filtration start Date: <u>07-May-25</u> & Time: <u>01:38</u> . Checked By (SM): <u>7-07-May-25</u>								
Air entrapment and rinsing of fill nozzles.								

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	BATCH MANUFACTURING RECORD		
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.	
BMR NO.	BMR-PA-063-05		AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)		
PAGE NO.	Page 83 of 133		

19.0	FILLING LINE PROCESS					
Approx. 8 Kg. solution use for Rinsing the fill nozzles.	Date	From	To	Qty. (Approx.)	Done By (SM) :	
	07-May-25	01:41	01:42	8 kg	F	07-May-25

Checked By (SM): Jar 07-May-25

Leftover solution in filtration vessel for hold time study N/A kg (From load cell of FV)

Done By (Sign/Date): N/A. Checked By (SM): N/A.

Filling start (Date & Time)	Done by (SM) (Sign/Date)
07-May-25 01:47	F 07-May-25

Volume setting rejection details:

No. of bags used for volume setting	=	Nos.	Done by. (SM)	Checked by (SM)
	=	20	F 07-May-25	Jar 07-May-25

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
PAGE NO.	Page 84 of 133	

19.0 FILLING LINE PROCESS	
Balance Id: <u>EAP/P1/PRD/142</u>	
FILL WEIGHT CHECKS, STOPPERING QUALITY, CLARITY, PRINTING QUALITY:	
In process quality check parameter	Frequency for SM
Stoppering quality, Clarity checks and Printing quality of filled bags	Startup, every 30 minutes ± 5 minutes and at the end of batch.
*Fill weight	Startup, every 30 minutes ± 5 minutes and at the end of batch.

Note: Take at least 5 Bags for printing quality checks.

Date	Time	Required Gross Wt. = <u>111.1212</u> g to <u>115.3212</u> g				Stoppering Quality (Ok/Not Ok)	Clarity (Ok/ Not Ok)	Printing Quality (Ok/ Not Ok)	Done by (SM)
		Nozzle A (g)	Nozzle B (g)	Nozzle C (g)	Nozzle D (g)				
07-May-25	02:08	N/A	N/A	N/A	N/A	OK	OK	OK	✓ 07-May-25
07-May-25	03:50	N/A	N/A	N/A	N/A	OK	Not OK	OK	✓ 07-May-25
07-May-25	04:20	N/A	N/A	N/A	N/A	not OK	OK	OK	✓ 07-May-25
07-May-25	05:04	N/A	N/A	N/A	N/A	OK	OK	OK	✓ 07-May-25
07-May-25	05:34	N/A	N/A	N/A	N/A	OK	OK	OK	✓ 07-May-25
07-May-25	06:10	N/A	N/A	N/A	N/A	Not OK	OK	OK	✓ 07-May-25
07-May-25	06:40	N/A	N/A	N/A	N/A	OK	OK	OK	✓ 07-May-25

*Note:

- 100 % fill weight checking shall be performed using online checkweigher at collection stage, attach the report in BMR and marking N/A in recording provision of in process fill weight in BMR.
- If Online Checkweigher is under breakdown then fill weight check shall be performed manually as per SOP: PAP-SM-022 as per defined frequency & record in-process data in BMR.

Checked By (SM): Jur 07-MAY-25

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		BATCH MANUFACTURING RECORD	
NAME OF PRODUCT		Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	
BMR NO.		BMR-PA-063-05	
BATCH SIZE		4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.		Page 85 of 133	

19.0	FILLING LINE PROCESS		
FILL WEIGHT CHECKS, STOPPERING QUALITY, CLARITY, PRINTING QUALITY:			

Date	Time	Required Gross Wt. = <u>111.1212</u> g to <u>115.3212</u> g				Stoppering Quality (Ok/Not Ok)	Clarity (Ok/ Not Ok)	Printing Quality (Ok/ Not Ok)	Done by (SM)
		Nozzle A (g)	Nozzle B (g)	Nozzle C (g)	Nozzle D (g)				
07-MAY-25	07:10	NA	NA	NA	NA	OK	OK	OK	✓ 07-May-25
07-MAY-25	07:40	NA	NA	NA	NA	OK	OK	OK	✓ 07-May-25
07-MAY-25	10:29	NA	NA	NA	NA	NOT OK	OK	OK	✓ 07-May-25
07-MAY-25	11:01	NA	NA	NA	NA	OK	OK	OK	✓ 07-May-25
07-MAY-25	11:30	NA	NA	NA	NA	OK	OK	OK	✓ 07-May-25
07-MAY-25	12:00	NA	NA	NA	NA	OK	OK	OK	✓ 07-May-25
07-MAY-25	13:23	NA	NA	NA	NA	OK	OK	OK	✓ 07-May-25
07-MAY-25	14:20	NA	NA	NA	NA	OK	OK	OK	✓ 07-May-25
07-MAY-25	14:50	NA	NA	NA	NA	OK	NOT OK	OK	✓ 07-May-25
07-MAY-25	15:20	NA	NA	NA	NA	OK	OK	OK	✓ 07-May-25
07-MAY-25	15:50	NA	NA	NA	NA	OK	OK	OK	✓ 07-May-25
07-MAY-25	16:20	NA	NA	NA	NA	OK	OK	OK	✓ 07-May-25

Checked By (SM): Jas 07-May-25.

QA AUTHORIZED COPY

CHALLENGE STUDY

MASTER COPY

		BATCH MANUFACTURING RECORD	
NAME OF PRODUCT		Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.		BMR-PA-063-05	AH250076
BATCH SIZE		4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.		Page 86 of 133	

19.0		FILL WEIGHT CHECKS, STOPPERING QUALITY, CLARITY, PRINTING QUALITY:							
Date	Time	Required Gross Wt. = <u>111.1212</u> g to <u>115.3212</u> g				Stoppering Quality (Ok/Not Ok)	Clarity (Ok/ Not Ok)	Printing Quality (Ok/ Not Ok)	Done by (SM)
		Nozzle A (g)	Nozzle B (g)	Nozzle C (g)	Nozzle D (g)				
07-MAY-25	16:38	114.3	114.7	114.1	114.1	OK	OK	OK	E 07-MAY-25
07-MAY-25	17:08	NA	NA	NA	NA	OK	OK	OK	E 07-May-25
07-MAY-25	17:44	NA	NA	NA	NA	OK	OK	OK	E 09-May-25
07-MAY-25	18:34	NA	NA	NA	NA	OK	OK	OK	E 07-May-25
07-MAY-25	19:04	NA	NA	NA	NA	OK	OK	OK	E 07-May-25
07-MAY-25	19:34	NA	NA	NA	NA	OK	OK	OK	E 07-May-25
07-MAY-25	21:00	NA	NA	NA	NA	OK	OK	OK	E 07-May-25
07-MAY-25	21:30	NA	NA	NA	NA	OK	OK	OK	E 07-May-25
07-MAY-25	22:10	NA	NA	NA	NA	OK	not OK	OK	E 07-May-25
07-MAY-25	22:38	NA	NA	NA	NA	OK	OK	OK	E 07-May-25
07-MAY-25	23:13	NA	NA	NA	NA	OK	OK	OK	E 07-May-25
07-MAY-25	23:49	NA	NA	NA	NA	OK	OK	OK	E 07-May-25

Checked By (SM): Jar 07-MAY-25.

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CHALLENGE STUDY

MASTER COPY

 amneal		BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.	
BMR NO.	BMR-PA-063-05		
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)		AH250076
PAGE NO.	Page 87 of 133		

		FILL WEIGHT CHECKS, STOPPERING QUALITY, CLARITY, PRINTING QUALITY:							
Date	Time	Required Gross Wt. = <u>111.1212</u> g to <u>115.3212</u> g				Stoppering Quality (Ok/Not Ok)	Clarity (Ok/ Not Ok)	Printing Quality (Ok/ Not Ok)	Done by (SM)
		Nozzle A (g)	Nozzle B (g)	Nozzle C (g)	Nozzle D (g)				
08-May-25	00:25	NA	NA	NA	NA	OK	OK	OK	✓ 08-May-25
08-May-25	00:56	NA	NA	NA	NA	OK	OK	OK	✓ 08-May-25
08-May-25	01:25	NA	NA	NA	NA	OK	OK	OK	✓ 08-May-25
08-May-25	01:55	NA	NA	NA	NA	OK	OK	OK	✓ 08-May-25
08-May-25	02:25	NA	NA	NA	NA	OK	OK	OK	✓ 08-May-25
08-May-25	03:52	NA	NA	NA	NA	OK	OK	OK	✓ 08-May-25
<hr/>									
N/A									
<hr/> 08-May-25									
Checked By (SM): <u>JUL</u> <u>08-May-25</u> .									

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CHALLENGE STUDY

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 88 of 133	

19.0	FILL WEIGHT CHECKS, STOPPERING QUALITY, CLARITY, PRINTING QUALITY:								
Date	Time	Required Gross Wt. = <i>~10</i> g to <i>~10</i> g				Stoppering Quality (Ok/Not Ok)	Clarity (Ok/ Not Ok)	Printing Quality (Ok/ Not Ok)	Done by (SM)
		Nozzle A (g)	Nozzle B (g)	Nozzle C (g)	Nozzle D (g)				
<i>WIA</i>									
<i>08-May-25</i>									
Checked By (SM): <i>WIA</i>									

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CHALLENGE STUDY

MASTER COPY

		BATCH MANUFACTURING RECORD
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 89 of 133	

19.0 FILLING LINE PROCESS	
STOPPERING QUALITY, CLARITY AND PRINTING QUALITY: QA CHECKS	
(Startup, Every 2 hours ± 10 min. & towards the end of batch or twice in a batch whichever is more)	
Date	Time
Stoppering Quality (Ok/Not Ok)	Clarity (Ok/ Not Ok)
Printing Quality (Ok/ Not Ok)	Done by (QA)
07-May-25	02:31
OK	OK
07-May-25	10:30
OK	OK
NOT OK	CD
07-May-25	13:25
OK	OK
OK	OK
07-May-25	15:26
OK	OK
OK	OK
07-May-25	17:55
OK	OK
OK	OK
07-May-25	19:29
OK	OK
OK	OK
07-May-25	21:25
OK	OK
OK	OK
07-May-25	23:23
OK	OK
OK	OK
07-May-25	01:24
OK	OK
OK	OK
08-May-25	03:55
OK	OK
OK	OK
Reviewed By : <u>PL 12-May-25</u>	

UNAUTHORIZED COPY

CHALLENGE STUDY

ADDITIONAL COPY
QA-SIGN/DATE *MRC24-DEF-24*

MASTER COPY

		BATCH MANUFACTURING RECORD
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 89 of 133	

19.0	FILLING LINE PROCESS				
STOPPERING QUALITY, CLARITY AND PRINTING QUALITY: QA CHECKS (Startup, Every 2 hours ± 10 min. & towards the end of batch or twice in a batch whichever is more)					
Date	Time	Stoppering Quality (Ok/Not Ok)	Clarity (Ok/ Not Ok)	Printing Quality (Ok/ Not Ok)	Done by (QA)
08-MAY-25	04:23	OK	OK	OK	<i>(P) 08-MAY-25</i>
<i>N/A</i>					
<i>(P) 08-MAY-25</i>					
Reviewed By : <i>(P) 12-MAY-25</i> .					

QA AUTHORIZED COPY

CHALLENGE STUDY

MASTER COPY

		BATCH MANUFACTURING RECORD
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 90 of 133	

19.0		FILLING LINE PROCESS										
Filling stoppage details:												
Note: During any breakdown or stoppage of filling machine record the details in below table. Take action as per respective procedure (if required). Machine restart as per SOP No.: PAP-SM-022												
Sr. No.	Filling Stoppage Start (Date & Time)	Reason	Done by. (SM)	Checked By (SM)	Filling Stoppage End (Date & Time)	Done by. (SM)	Checked By (SM)					
01	07-May-25 01:52	Film roll change	E 07-May-25	Jar 07-May-25	07-May-25 02:06	E 07-May-25	Jar 07-May-25					
02	07-May-25 02:19	Online Check after pre SQRs Challenge test	E 07-May-25	Jar 07-May-25	07-May-25 02:30	E 07-May-25	Jar 07-May-25					
03	07-May-25 02:33	Initial visual Inspection	E 07-May-25	Jar 07-May-25	07-May-25 03:09	E 07-May-25	Jar 07-May-25					
04	07-May-25 04:05	Micro activity	E 07-May	Jar 07-May-25	07-May-25 04:14	E 07-May-25	Jar 07-May-25					
05	07-May-25 04:37	Hot printing roll change & micro activity	E 07-May-25	Jar 07-May-25	07-May-25 05:03	E 07-May-25	Jar 07-May-25					
06	07-May-25 05:27	Micro activity	E 07-May-25	Jar 07-May-25	07-May-25 05:06	E 07-May-25	Jar 07-May-25					
07	07-May-25 06:01		E 07-May-25	06-May-25 05:33	07-May-25 05:33	E 07-May-25	Jar 07-May-25					
08	07-May-25 06:29	Tube roll change	E 07-May-25	Jar 07-May-25	07-May-25 06:09	E 07-May-25	Jar 07-May-25					
09	07-May-25 07:42	Shift change & micro activity	E 07-May-25	Jar 07-May-25	07-May-25 06:34	E 07-May-25	Jar 07-May-25					
10	07-May-25 10:43	Film roll change	E 07-May-25	Jar 07-May-25	07-May-25 10:28	E 07-May-25	Jar 07-May-25					
11	07-May-25 11:49	Tube roll change	E 07-May-25	Jar 07-May-25	07-May-25 10:51	E 07-May-25	Jar 07-May-25					
12	07-May-25 12:08	Lunch break	E 07-May-25	Jar 07-May-25	07-May-25 11:55	E 07-May-25	Jar 07-May-25					
13	07-May-25 13:50	Film roll change & micro activity	E 07-May-25	Jar 07-May-25	07-May-25 14:19	E 07-May-25	Jar 07-May-25					

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CHALLENGE STUDY

MASTER COPY

		BATCH MANUFACTURING RECORD
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
PAGE NO.	Page 91 of 133	

19.0		FILLING LINE PROCESS						
Sr. No.	Filling Stoppage Start (Date & Time)	Reason	Done by. (SM)	Checked By (SM)	Filling Stoppage End (Date & Time)	Done by. (SM)	Checked By (SM)	
14	07-May-25 15:10	Hot Stamping foil Roll Change	AS 07-May-25 07-May-25	Acty 07-May-25 07-May-25	07-May-25 15:16	AS 07-May-25	Acty 07-May-25 07-May-25	
15	07-May-25 15:38	Printing Setting	AS 07-May-25 07-May-25	Acty 07-May-25 07-May-25	07-May-25 15:49	AS 07-May-25	Acty 07-May-25 07-May-25	
16	07-May-25 16:07	Shift Change	AS 07-May-25 07-May-25	Acty 07-May-25 07-May-25	07-May-25 16:17	AS 07-May-25	Acty 07-May-25 07-May-25	
17	07-May-25 16:49	Film roll change	AS 07-May-25	Acty 07-May-25	07-May-25 16:57	AS 07-May-25	Acty 07-May-25 07-May-25	
18	07-May-25 17:00	Micro activity	AS 07-May-25	Acty 07-May-25	07-May-25 17:06	AS 07-May-25	Acty 07-May-25 07-May-25	
19	07-May-25 17:42	Tube roll change & Micro activity	AS 07-May-25	Acty 07-May-25	07-May-25 17:48	AS 07-May-25	Acty 07-May-25 07-May-25	
20	07-May-25 18:07	Micro activity	AS 07-May-25	Acty 07-May-25	07-May-25 06:33	AS 07-May-25	Acty 07-May-25 07-May-25	
21	07-May-25 18:54	Micro activity	AS 07-May-25	Acty 07-May-25	07-May-25 19:01	AS 07-May-25	Acty 07-May-25 07-May-25	
22	07-May-25 19:14	Film roll change & Hot stamping foil roll change	AS 07-May-25	Acty 07-May-25	07-May-25 19:22	AS 07-May-25	Acty 07-May-25 07-May-25	
23	07-May-25 19:51	Dinner break	AS 07-May-25	Acty 07-May-25	07-May-25 20:54	AS 07-May-25	Acty 07-May-25 07-May-25	
24	07-May-25 22:03	Film roll change	AS 07-May-25	Acty 07-May-25	07-May-25 22:08	AS 07-May-25	Acty 07-May-25 07-May-25	
25	07-May-25 22:12	Micro activity	AS 07-May-25	Acty 07-May-25	07-May-25 22:37	AS 07-May-25	Acty 07-May-25 07-May-25	
26	07-May-25 23:07	Tube roll change	AS 07-May-25	Acty 07-May-25	07-May-25 23:12	AS 07-May-25	Acty 07-May-25 07-May-25	
27	07-May-25 23:43	Hot stamping foil roll change	AS 07-May-25	Acty 07-May-25	07-May-25 23:48	AS 07-May-25	Acty 07-May-25 07-May-25	

MASTER COPY

CHALLENGE STUDY

MASTER COPY

		BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.	
BMR NO.	BMR-PA-063-05	AH250076	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)		
PAGE NO.	Page 93 of 133		

19.0 FILLING LINE PROCESS							
Air volume of Bag analysis:							
Frequency: Initial, Middle and end of the batch (Refer SOP No. PAP-SM-056). Take continuous 2 bags for each nozzle for in process checks.							
Frequency	Module number	Date	Time	No. of sample	Observation	Performed By	Checked By (SM)
				Limit: 10-20 mL			
				Bag 01	Bag 02		
Initial		Nozzle A	07-May-25	02:10	17	16	Jar 07-May-25
		Nozzle B	07-May-25	02:12	35	17	Jar 07-May-25
		Nozzle C	07-May-25	02:14	17	16	Jar 07-May-25
		Nozzle D	07-May-25	02:16	18	17	Gety 07-May-25
Middle		Nozzle A	07-May-25	17:16	17	18	Jar 07-May-25
		Nozzle B	07-May-25	17:17	18	18	Jar 07-May-25
		Nozzle C	07-May-25	17:18	18	17	Jar 07-May-25
		Nozzle D	07-May-25	17:19	16	17	Jar 07-May-25
End		Nozzle A	07-May-25	04:30	17	16	Gety 07-May-25
		Nozzle B	07-May-25	04:32	05	18	Gety 07-May-25
		Nozzle C	07-May-25	04:33	18	18	Gety 07-May-25
		Nozzle D	07-May-25	04:34	18	17	Gety 07-May-25
Total bags used for Air volume checks (I):		24	Nos.				
Recorded by Sign/Date (SM):		<u>Gety 07-May-25</u>					

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CHALLENGE STUDY

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amneal		BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.	
BMR NO.	BMR-PA-063-05		
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)		AH250076
PAGE NO.	Page 94 of 133		

19.0 FILLING LINE PROCESS						
Perform the Air volume of Bags, if filling machine stoppage occurs for more than 30 min. / if machine stops due to power failure/ Machine breakdown as per SOP No. PAP-SM-022.						
Note: Take 01 bag from each filling module.						
Module number	Date					
	Time	No. of sample	Observation (Limit: 10-20 mL)	Performed By	Checked By (SM)	
Nozzle A	07-May-25	03:52	01	17	JAR 07-May-25	JAR 07-May-25
Nozzle B	07-May-25	03:53	01	16	JAR 07-May-25	JAR 07-May-25
Nozzle C	07-May-25	03:54	01	18	JAR 07-May-25	JAR 07-May-25
Nozzle D	07-May-25	03:55	01	17	JAR 07-May-25	JAR 07-May-25
Nozzle A	07-May-25	10:31	01	16	JAR 07-May-25	JAR 07-May-25
Nozzle B	07-May-25	10:32	01	18	JAR 07-May-25	JAR 07-May-25
Nozzle C	07-May-25	10:33	01	17	JAR 07-May-25	JAR 07-May-25
Nozzle D	07-May-25	10:34	02	15	JAR 07-May-25	JAR 07-May-25
Nozzle A	07-May-25	13:24	01	17	JAR 07-May-25	JAR 07-May-25
Nozzle B	07-May-25	13:25	01	16	JAR 07-May-25	JAR 07-May-25
Nozzle C	07-May-25	13:26	01	17	JAR 07-May-25	JAR 07-May-25
Nozzle D	07-May-25	13:27	01	17	JAR 07-May-25	JAR 07-May-25
Nozzle A	07-May-25	21:01	02	15	JAR 07-May-25	JAR 07-May-25
Nozzle B	07-May-25	21:02	01	18	JAR 07-May-25	JAR 07-May-25
Nozzle C	07-May-25	21:03	01	17	JAR 07-May-25	JAR 07-May-25
Nozzle D	07-May-25	21:04	01	17	JAR 07-May-25	JAR 07-May-25

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CHALLENGE STUDY

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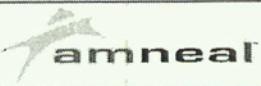
		BATCH MANUFACTURING RECORD
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 95 of 133	

19.0 FILLING LINE PROCESS	
Perform the Air volume of Bags, if filling machine stoppage occurs for more than 30 min. / if machine stops due to power failure/ Machine breakdown as per SOP No. PAP-SM-022.	
Note: Take 01 bag from each filling module.	
Module number	Date
Nozzle A	08-May-25
Nozzle B	08-May-25
Nozzle C	08-May-25
Nozzle D	08-May-25
Nozzle A	
Nozzle B	
Nozzle C	
Nozzle D	
Nozzle A	
Nozzle B	
Nozzle C	
Nozzle D	
Nozzle A	
Nozzle B	
Nozzle C	
Nozzle D	
Nozzle A	
Nozzle B	
Nozzle C	
Nozzle D	
Nozzle A	
Nozzle B	
Nozzle C	
Nozzle D	

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 96 of 133	

19.0 FILLING LINE PROCESS	
Perform the Air volume of Bags, if filling machine stoppage occurs for more than 30 min. / if machine stops due to power failure/ Machine breakdown as per SOP No. PAP-SM-022.	
Note: Take 01 bag from each filling module.	
Module number	Date
Nozzle A	
Nozzle B	
Nozzle C	
Nozzle D	
Nozzle A	
Nozzle B	
Nozzle C	
Nozzle D	
Nozzle A	
Nozzle B	
Nozzle C	
Nozzle D	
Nozzle A	
Nozzle B	
Nozzle C	
Nozzle D	
Nozzle A	
Nozzle B	
Nozzle C	
Nozzle D	

N/A

E
08-may-25

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
PAGE NO.	Page 97 of 133	

19.0 FILLING LINE PROCESS						
Perform the Air volume of Bags, if filling machine stoppage occurs for more than 30 min. / if machine stops due to power failure/ Machine breakdown as per SOP No. PAP-SM-022.						
Note: Take 01 bag from each filling module.						
Module number	Date	Time	No. of sample	Observation (Limit: 10-20 mL)	Performed By	Checked By (SM)
Nozzle A						
Nozzle B						
Nozzle C						
Nozzle D						
Nozzle A						
Nozzle B						
Nozzle C						
Nozzle D						
Nozzle A						
Nozzle B						
Nozzle C						
Nozzle D						
Total Sample (II): <u>18</u> .						
Total III= (I+II) <u>44</u> . Calculated By: <u>08-May-25</u> .						

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MASTER COPY

	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 98 of 133	

19.0	FILLING LINE PROCESS														
Filling activities: <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;">Sr. No.</th> <th style="width: 50%;">Steps</th> <th style="width: 20%;">Done by (SM) (Sign/Date)</th> <th style="width: 30%;">Checked by (SM) (Sign/Date)</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Filling Operation End Date & time: <u>08-MAY-25 04:26</u></td> <td style="text-align: center;"><u>F</u> 08-MAY-25</td> <td style="text-align: center;">JAR 08-MAY-25</td> </tr> <tr> <td>2</td> <td>Delete variable data for Bag Printing (If Applicable).</td> <td style="text-align: center;">N/A</td> <td style="text-align: center;">N/A</td> </tr> </tbody> </table>				Sr. No.	Steps	Done by (SM) (Sign/Date)	Checked by (SM) (Sign/Date)	1	Filling Operation End Date & time: <u>08-MAY-25 04:26</u>	<u>F</u> 08-MAY-25	JAR 08-MAY-25	2	Delete variable data for Bag Printing (If Applicable).	N/A	N/A
Sr. No.	Steps	Done by (SM) (Sign/Date)	Checked by (SM) (Sign/Date)												
1	Filling Operation End Date & time: <u>08-MAY-25 04:26</u>	<u>F</u> 08-MAY-25	JAR 08-MAY-25												
2	Delete variable data for Bag Printing (If Applicable).	N/A	N/A												

QA AUTHORIZED CCPY

CHALLENGE STUDY

MASTER COPY

amneal	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 99 of 133	

19.0	FILLING LINE PROCESS																																		
Perform Post integrity testing of 0.2 μ product filter as per respective SOP: PAP-SM-015.																																			
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 40%;">Description</th> <th style="width: 60%;">Filter Integrity Detail</th> </tr> </thead> <tbody> <tr> <td>Filter integrity testing machine ID No.</td> <td><input type="checkbox"/> EQP/P1/PRD/045 / <input type="checkbox"/> EQP/P1/PRD/322/ <input checked="" type="checkbox"/> EQP/P1/PRD/046 <input type="checkbox"/> If any other Id No. ~NIA~</td> </tr> <tr> <td>Date of test</td> <td>08-May-25</td> </tr> <tr> <td>Make</td> <td>Sartorius</td> </tr> <tr> <td>Catalogue No.</td> <td>5442507H1(Sartopore 2)</td> </tr> <tr> <td>Lot No.</td> <td></td> </tr> <tr> <td>Serial No.</td> <td>501120688 2747</td> </tr> <tr> <td>Limit</td> <td>NLT 3000 mbar</td> </tr> <tr> <td>Wetting medium</td> <td>Product</td> </tr> <tr> <td>Observed Bubble point value (mbar)</td> <td>3650 mbar</td> </tr> <tr> <td>Test Result</td> <td>Pass <input checked="" type="checkbox"/> Fail <input type="checkbox"/></td> </tr> <tr> <td>Done by (SM)</td> <td>08-May-25</td> </tr> <tr> <td>Checked by (SM)</td> <td>08-May-25</td> </tr> <tr> <td colspan="2">Put "✓" <input type="checkbox"/> mark on applicable filter integrity testing result of filter integrity.</td> </tr> <tr> <td colspan="2">Discard filter after passing in post integrity as per SOP No.: PAP-SM-015.</td> </tr> <tr> <td>Discarded By (SM):</td> <td>08-May-25</td> </tr> <tr> <td>Checked By (SM):</td> <td>08-May-25</td> </tr> </tbody> </table>		Description	Filter Integrity Detail	Filter integrity testing machine ID No.	<input type="checkbox"/> EQP/P1/PRD/045 / <input type="checkbox"/> EQP/P1/PRD/322/ <input checked="" type="checkbox"/> EQP/P1/PRD/046 <input type="checkbox"/> If any other Id No. ~NIA~	Date of test	08-May-25	Make	Sartorius	Catalogue No.	5442507H1(Sartopore 2)	Lot No.		Serial No.	501120688 2747	Limit	NLT 3000 mbar	Wetting medium	Product	Observed Bubble point value (mbar)	3650 mbar	Test Result	Pass <input checked="" type="checkbox"/> Fail <input type="checkbox"/>	Done by (SM)	08-May-25	Checked by (SM)	08-May-25	Put "✓" <input type="checkbox"/> mark on applicable filter integrity testing result of filter integrity.		Discard filter after passing in post integrity as per SOP No.: PAP-SM-015.		Discarded By (SM):	08-May-25	Checked By (SM):	08-May-25
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Checked By (SM):	08-May-25																																		

QA AUTHORIZED COPY

CHALLENGE STUDY

MASTER COPY

T amneal	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
PAGE NO.	Page 100 of 133	

19.0	FILLING LINE PROCESS		
Filling Details from Machine report:			
	Details	Done By (SM)	Checked By (SM)
Filling Start Date & Time	07-May-25 04:26	✓ 08-May-25	Jar 08-May-25
Filling End Date & Time	08-May-25 01:47	✓ 08-May-25	Jar 08-May-25
Total no. of bags (A)	38992	✓ 08-May-25	Jar 08-May-25
No. of Good Quantities(B)	37524	✓ 08-May-25	Jar 08-May-25
No. of Rejected Quantities (empty bag + filled bags) = (C=A-B)	1468	✓ 08-May-25	Jar 08-May-25

CHALLENGE STUDY

MASTER COPY

	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 101 of 133	

20.0 SIGNATURE LOG (BAG COLLECTION ACTIVITY)				
Record the name of persons who are involved in Bag Collection activity.				
#Declaration: I undersigned, hereby declare that I am trained on all relevant procedure and activity(s) that I am performing in this batch.				
Sr. No.	Name	Employee Code	Department	#Signature
1	Darshuninu Vaghela	343804	SM	(P) 03-May-25
2	Harshit Patel	341238	SM	(P) 07-May-25
3	Renuka Patel	315799	QA	(P) 10-May-25
4				
5				
6				
7				
8				
9				
10				
11				
12			W/A	
13				
14				
15				
16				(P) 10-May-25

CHALLENGE STUDY

MASTER COPY

	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 102 of 133	

20.0 SIGNATURE LOG (BAG COLLECTION ACTIVITY)				
Record the name of persons who are involved in Bag Collection activity.				
#Declaration: I undersigned, hereby declare that I am trained on all relevant procedure and activity(s) that I am performing in this batch.				
Sr. No.	Name	Employee Code	Department	#Signature
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				<i>W/A</i>
28				
29				
30				
31				
32				<i>NP 10-MAY-28</i>

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CHALLENGE STUDY

MASTER COPY

amneal	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 103 of 133	

21.0 BAG COLLECTION ACTIVITY				
<p>Perform Load cell verification for Online Checkweigher with Conveyor belt & Dropout Rejector unit (Eq. Id No. PA-SM-209) as per SOP form No.: PAP-SM-022-F008.</p> <p>Perform line clearance activity as per SOP No. PAP-QA-002 and attach the respective format with BMR.</p> <p>Perform the challenge test for Online Checkweigher with Conveyor belt & Dropout Rejector unit (Eq. Id No. PA-SM-209) as per SOP form No.: PAP-SM-022-F007 and record the Nos. bag used in the table below:</p>				
Bags used for Pre-Challenge test (A)	02	Done by. (SM): <i>JRD</i> 07-May-25	Checked by (SM): <i>②</i> 07-May-25	
Bags used for Post Challenge test (B)	02	Done by. (SM):	Checked by (SM):	
Bags used for challenge test (if any Break down/Power Failure) (C)	00	Done by. (SM): <i>JRD</i>	Checked by (SM): <i>②</i> 08-May-25	
Total No. of Bags used for Challenge test (D) = A+B+C	04	Done by. (SM): <i>JRD</i> 08-May-25	Checked by (SM): <i>②</i> 08-May-25	
<p>Ensure the selection of correct recipe format and verify the respective recipe parameters for online checkweigher as per SOP No.: PAP-SM-022.</p> <p>Recipe Name (Format Name): 100 ml NPVC bag Verified by: <i>②</i> 07-May-25</p> <p>Record the details of Online Check weigher with conveyor belt with drop out rejector in below table:</p>				
Date	Start Time	End Time	Done by (SM)	Checked by (SM)
07 - May - 25	02:31		<i>JRD</i> 07-May-25	<i>②</i> 07-May-25
08 - May - 25		04:30	<i>JRD</i> 08-May-25	<i>②</i> 08-May-25
From Checkweigher Report Printout				
Total Number of Bags from Filling Machine (A)	No of Bag rejected (B)		No. of Good/Ok Bag (C)	
37423	2043		35380	
Recorded By (SM): <i>JRD</i> 08-May-25	Verified By (SM): <i>②</i> 08-May-25			

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CHALLENGE STUDY

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 104 of 133	

21.0 BAG COLLECTION ACTIVITY				
After completion of online checkweigher operation, collect all the rejected units from rejection bin and re-pass the rejected units again from the checkweigher system.				
Record the details of Online Check weigher with conveyor belt with drop out rejector (Re-pass the rejected units) in below table:				
Date	Start Time	End Time	Done by (SM)	Checked by (SM)
08-May-25	04:46		<i>JRD</i> 08-May-25	② 08-May-25
08-May-25		05:47	<i>JRD</i> 08-May-25	② 08-May-25

From Checkweigher Report Printout (repass)			
No. of Rejected Bags for Repass (D)	No of Bag rejected after repassing (E)	No. of Good/Ok Bag after repassing (F)	Total good/ok bags G = C+F
2043	108	1935	37315
Recorded By (SM): <i>JRD</i> 08-May-25		Verified By (SM):	

Total good/ok bags (G)	Bags used Post challenge test + Bag used for challenge test during breakdown/Power Failure (if any) (H)	No. of Good/Ok bag after online check weighing activity (I = G - H)
37314	02	37313
Recorded By (SM): <i>JRD</i> 08-May-25	Verified By (SM):	② 08-May-25

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CHALLENGE STUDY

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		BATCH MANUFACTURING RECORD
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 105 of 133	

21.0 BAG COLLECTION ACTIVITY				
Perform line clearance for collection area as per SOP No.: PAP-QA-002.				
Fill line closure checklist as per SOP No.: PAP-QA-002 for filling area and attach to BMR.				
Record the details of Bag collection (Collection stage) in the table below:				
Date	Start Time	End Time	Done by (SM)	Checked by (SM)
07-May-25	02:31		<i>FDP</i> 07-May-25	② 07-May-25
07-May-25		05:47	<i>FDP</i> 07-May-25	② 07-May-25
Total Bags available for TS.				
Number of bags per tray	36 Bags			
No of trays per trolley	40 Trays (1440 Bags)			
Minimum load (One trolley)	360 bags			
Maximum load	5760 bags			
Lot No.	Trolley	Quantity Nos. Bags	Calculated By (SM)	
LOT-A	Trolley 1	1440	<i>FDP</i>	07-May-25
	Trolley 2	1440	<i>FDP</i>	07-May-25
	Trolley 3	1440	<i>FDP</i>	07-May-25
	Trolley 4	1440	<i>FDP</i>	07-May-25
	Bags for Sensor placement	04	<i>FDP</i>	07-May-25
LOT-B	Trolley 1	1440	<i>FDP</i>	07-May-25
	Trolley 2	1440	<i>FDP</i>	07-May-25
	Trolley 3	1440	<i>FDP</i>	07-May-25
	Trolley 4	1440	<i>FDP</i>	07-May-25
	Bags for Sensor placement	04	<i>FDP</i>	07-May-25
LOT-C	Trolley 1	1440	<i>FDP</i>	07-May-25
	Trolley 2	1440	<i>FDP</i>	07-May-25
	Trolley 3	1440	<i>FDP</i>	07-May-25
	Trolley 4	1440	<i>FDP</i>	07-May-25
	Bags for Sensor placement	04	<i>FDP</i>	07-May-25

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		BATCH MANUFACTURING RECORD	
NAME OF PRODUCT		Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	
BMR NO.		BMR-PA-063-05	
BATCH SIZE		4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.		Page 106 of 133	

21.0 BAG COLLECTION ACTIVITY			
Lot No.	Trolley	Quantity Nos. Bags	Calculated By (SM)
LOT-D	Trolley 1	1440	<i>TPD</i> 07-MU23-25
	Trolley 2	1440	<i>TPD</i> 07-MU23-25
	Trolley 3	1440	<i>TPD</i> 07-MU23-25
	Trolley 4	1440	<i>TPD</i> 07-MU23-25
	Bags for Sensor placement	04	<i>TPD</i> 07-MU23-25
LOT-E	Trolley 1	1440	<i>TPD</i> 07-MU23-25
	Trolley 2	1440	<i>TPD</i> 07-MU23-25
	Trolley 3	1440	<i>TPD</i> 07-MU23-25
	Trolley 4	1440	<i>TPD</i> 07-MU23-25
	Bags for Sensor placement	04	<i>TPD</i> 07-MU23-25
LOT-F	Trolley 1	1440	<i>TPD</i> 08-MU23-25
	Trolley 2	1440	<i>TPD</i> 08-MU23-25
	Trolley 3	1440	<i>TPD</i> 08-MU23-25
	Trolley 4	1440	<i>TPD</i> 08-MU23-25
	Bags for Sensor placement	04	<i>TPD</i> 08-MU23-25
LOT-G	Trolley 1	1440	<i>TPD</i> 08-MU23-25
	Trolley 2	1274	<i>TPD</i> 08-MU23-25
	Trolley 3	NIA	<i>TPD</i> 08-MU23-25
	Trolley 4	NIA	<i>TPD</i> 08-MU23-25
	Bags for Sensor placement	04	<i>TPD</i> 08-MU23-25
Total		37302	<i>TPD</i> 08-MU23-25

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 107 of 133	

21.0 BAG COLLECTION ACTIVITY			
At Filling and Collection stage Rejection details			
Sr. No.	Type of Rejection	Quantity Nos. Bags	Calculated By (SM)
1.	Damaged / Defective Bag	00	<i>Chp</i> 08-May-25
2.	Apparent printing rejection	00	<i>Chp</i> 08-May-25
3.	Without twist-off	00	<i>Chp</i> 08-May-25
4.	Leak bag		<i>Chp</i> 08-May-25
5.	Empty container	00	<i>Chp</i> 08-May-25
6.	De-shaped bags	00	<i>Chp</i> 08-May-25
7.	Improper Printing	00	<i>Chp</i> 08-May-25
8.	Hanger intactness	00	<i>Chp</i> 08-May-25
9.	Shrinkage on bag	00	<i>Chp</i>
10.	Others	00	<i>Chp</i> 08-May-25
11.	Online Visual inspection rejection*	07	<i>Chp</i> 08-May-25
Total Rejection(A)		07	<i>Chp</i> 08-May-25

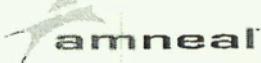
* Record the total number of Bags rejected during online Visual inspection as per SOP No.: PAP-SM-061.

Checked By (SM) *Chp* 08-May-25

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 108 of 133	

21.0 | BAG COLLECTION ACTIVITY

SAMPLING: Mention sampling details of filled Bags before TS in the table below as per SOP No.: PAP-QA-004.

Note: After completion activity fill line closure checklist for collection area as per SOP No.: PAP-QA-002

Sample Details	Sampled Qty. (Nos.)	Sample		Sampling done By (QA)
		Date	Time	
End of filling	04	08-May-25	04:27	PP 08-May-25
Total Samples	04	Verified By (SM): <u>PP 08-May-25</u>		

CHALLENGE STUDY

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		BATCH MANUFACTURING RECORD	
NAME OF PRODUCT		Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	
BMR NO.		BMR-PA-063-05	
BATCH SIZE		4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.		Page 109 of 133	

21.0 BAG COLLECTION ACTIVITY			
Collection stage reconciliation:			
Page No.	Stage	Qty.	Remarks
103	Total No. of Bags received from filling machine (A) (From Check weigher printout + Bags used for pre challenge test bags)	37425	NA
104	No. of bag rejected after repassing (From online check weigher) (B)	108	NA
103	Total No. of bags utilized for the challenge test of online check weigher (C)	04	NA
104	No. of Good/Ok bag after online check weighing activity (D)	37313	NA
107	Total number of Rejection at collection stage with online visual inspection (E)	07	NA
108,	Total Sample quantity (F)	04	NA
	Total rejection of online checkweigher and collection stage with online visual inspection (G) = B + C+ E	118	NA
	Total collected good quantity for TS (H) = D - (E+F)	37302	NA
Recorded by (SM): <i>[Signature]</i> 08-MAY-25		Verified By (SM): <i>[Signature]</i> 08-MAY-25	

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Tamneal		BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.	
BMR NO.	BMR-PA-063-05		
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)		AH250076
PAGE NO.	Page 110 of 133		

22.0 RECONCILIATION OF FILLED UNITS			
Filling Stage Reconciliation:			
Page No.	Stage	Quantity Nos. Bags	Remark
75	Actual filtered Bulk available for filling (A)	38043	NA
83	Left over solution in filtration vessel for hold time study (If any) (As per load cell after filtration) (B)	00	NA
	Total filled bags from machine Report (C)	37524	NA
83	Solution used for rinsing (D)	75	NA
83	Volume setting rejection (E)	20	NA
97	Bag used for air volume analysis (F)	44	NA
109	Total collected good Quantity (G)	37302	NA
108	Samples before TS (H)	03	NA
	Other Sample (If Any) (I)	00	NA
	Total Sample (J) = F+H+I	48	NA
109	Rejection at online checkweigher, collection stage & Visual Inspection Stage (Fillling stage) (K)	119	NA
	Manually rejected bags after filling in prior to online checkweigher process (L)	35	NA
	Other Rejection(M)	00	NA
	Total Process Loss (FV to FM) A - (B + C)	519	NA
	Total Rejection (N)= D+E+K+L+M	249	NA
	% Yield (At filling stage) (O) = (G+J/A) X100 (Limit: NLT 70%)	98.05 %	NA
Reconciliation Done By (SM)		Reconciliation Checked By (SM)	
<i>J.P. 08-May-25</i>		<i>C. 08-May-25</i>	
Filling part reviewed by QA: <i>RP</i> <i>10-May-25</i>			

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CHALLENGE STUDY

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amneal	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 111 of 133	

23.0 PRIMARY PACKAGING MATERIAL RETURN					
Balance ID: FOP1811PRD1156.					
POLYPROPYLENE FILM APP114-S-135-200-F (PMI-0998):					
1 Meter (A) = 0.049 Kg			Weight of Cone (B) = 0.515 Kg		
CONVERSION CALCULATION FOR RETURNED PRIMARY PACKING MATERIAL			CALCULATION FOR VARIANCE OF CONE WEIGHT:		
Roll No.	Actual Returned gross quantity in Kg	Actual Returned net quantity in Kg = Actual Returned gross Qty in Kg - Weight of cone	Actual Returned quantity in meter = (Actual Returned net quantity in Kg) / (A)	Weight of Cone after completion of Roll (C)=	Variance (To be established) = [(B-C)/B X 100] = %
1	Kg	= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.	0.510 Kg	= [(0.515 - 0.510) / 0.515 X 100] = 0.97 %
2	Kg	= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.	0.505 Kg	= [(0.515 - 0.505) / 0.515 X 100] = 1.94 %
3	Kg	= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.	0.505 Kg	= [(0.515 - 0.505) / 0.515 X 100] = 1.94 %
4	Kg	= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.	0.510 Kg	= [(0.515 - 0.510) / 0.515 X 100] = 0.97 %
5	Kg	= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.	0.510 Kg	= [(0.515 - 0.510) / 0.515 X 100] = 0.97 %
6	Kg	= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.	0.510 Kg	= [(0.515 - 0.510) / 0.515 X 100] = 0.97 %
7	Kg	= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.	0.515 Kg	= [(0.515 - 0.505) / 0.515 X 100] = 1.94 %

CHALLENGE STUDY

MASTER COPY

		BATCH MANUFACTURING RECORD
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 112 of 133	

23.0 PRIMARY PACKAGING MATERIAL RETURN					
POLYPROPYLENE FILM APP114-S-135-200-F (PMI-0998):					
1 Meter (A) = 0.049 Kg			Weight of Cone (B) = 0.515 Kg		
CONVERSION CALCULATION FOR RETURNED PRIMARY PACKING MATERIAL			CALCULATION FOR VARIANCE OF CONE WEIGHT:		
Roll No.	Actual Returned gross quantity in Kg	Actual Returned net quantity in Kg = Actual Returned gross Qty in Kg - Weight of cone	Actual Returned quantity in meter = (Actual Returned net quantity in Kg) / (A)	Weight of Cone after completion of Roll (C)=	Variance (To be established) = [(B-C)/B X 100] = %
8	= <u>NA</u> Kg	= <u>NA</u> - <u>NA</u> <u>NA</u> Kg.	= <u>NA</u> / <u>NA</u> <u>NA</u> meter.	<u>0.500</u> Kg	= [(0.515 - 0.500) / 0.515 X 100] = 2.91 %
9	= <u>NA</u> Kg	= <u>NA</u> - <u>NA</u> <u>NA</u> Kg.	= <u>NA</u> / <u>NA</u> <u>NA</u> meter.	<u>0.495</u> Kg	= [(0.515 - 0.495) / 0.515 X 100] = 3.88 %
10	= <u>26.505</u> Kg	= <u>26.505</u> - <u>0.515</u> <u>25.990</u> Kg.	= <u>25.990</u> / <u>0.049</u> <u>530.408</u> meter.	<u>NA</u> Kg	= [(<u>NA</u> - <u>NA</u>) / <u>NA</u> X 100] = <u>NA</u> %
11	= <u>24.850</u> Kg	= <u>27.850</u> - <u>0.515</u> <u>27.335</u> Kg.	= <u>27.335</u> / <u>0.049</u> <u>557.852</u> meter.	<u>NA</u> Kg	= [(<u>NA</u> - <u>NA</u>) / <u>NA</u> X 100] = <u>NA</u> %
12	= <u> </u> Kg	= <u> </u> - <u> </u> <u> </u> Kg.	= <u> </u> / <u> </u> <u> </u> meter.	<u> </u> Kg	= [(<u> </u> - <u> </u>) / <u> </u> X 100] = <u> </u> %
13	= <u> </u> Kg	= <u> </u> - <u> </u> <u> </u> Kg.	= <u> </u> / <u> </u> <u> </u> meter.	<u> </u> Kg	= [(<u> </u> - <u> </u>) / <u> </u> X 100] = <u> </u> %
14	= <u> </u> Kg	= <u> </u> - <u> </u> <u> </u> Kg.	= <u> </u> / <u> </u> <u> </u> meter.	<u>08-may-25</u> Kg	= [(<u> </u> - <u> </u>) / <u> </u> X 100] = <u> </u> %
Done By (SM/MM): <u> </u> 08-May-25			Checked By : <u> </u> 08-May-25		

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CHALLENGE STUDY

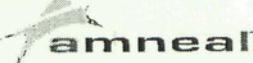
MASTER COPY

 amneal	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 113 of 133	

23.0 PRIMARY PACKAGING MATERIAL RETURN					
Balance ID: <u>60010119901156</u>					
POLYPROPYLENE TUBE APP 107-S 8.20 X 6.20 (PMI-0996):					
CONVERSION CALCULATION FOR RETURNED PRIMARY PACKING MATERIAL			CALCULATION FOR VARIANCE OF CONE WEIGHT:		
Roll No.	Actual Returned gross quantity in Kg	Actual Returned net quantity in Kg = Actual Returned gross Qty in Kg - Weight of cone	Actual Returned quantity in meter = (Actual Returned net quantity in Kg) / (A)	Weight of Cone after completion of Roll (C)=	Variance (To be established) = [(B-C)/B X 100] %
1	= <u>Kg</u>	= <u>-</u> <u>Kg.</u>	= <u>/</u> <u>meter.</u>	<u>0.330</u> Kg	= <u>[0.325 - 0.330]</u> / <u>0.325</u> X 100] = <u>-1.54</u> %
2	= <u>Kg</u>	= <u>-</u> <u>Kg.</u>	= <u>/</u> <u>meter.</u>	<u>0.325</u> Kg	= <u>[0.325 - 0.325]</u> / <u>0.325</u> X 100] = <u>0.0</u> %
3	= <u>Kg</u>	= <u>-</u> <u>Kg.</u>	= <u>/</u> <u>meter.</u>	<u>0.330</u> Kg	= <u>[0.325 - 0.330]</u> / <u>0.325</u> X 100] = <u>-1.54</u> %
4	= <u>Kg</u>	= <u>-</u> <u>Kg.</u>	= <u>/</u> <u>meter.</u>	<u>0.330</u> Kg	= <u>[0.325 - 0.330]</u> / <u>0.325</u> X 100] = <u>-1.54</u> %
5	= <u>Kg</u>	= <u>-</u> <u>Kg.</u>	= <u>/</u> <u>meter.</u>	<u>0.335</u> Kg	= <u>[0.325 - 0.335]</u> / <u>0.325</u> X 100] = <u>-3.08</u> %
6	= <u>0.680</u> Kg	= <u>0.680 - 0.325</u> = <u>0.355</u> Kg.	= <u>0.355 / 0.021</u> = <u>16.905</u> meter.	<u>NA</u> Kg	= <u>[0.325 - NA]</u> / <u>0.325</u> X 100] = <u>%</u>
7	= <u>6.855</u> Kg	= <u>6.855 - 0.325</u> = <u>6.530</u> Kg.	= <u>6.530 / 0.021</u> = <u>310.952</u> meter.	<u>NA</u> Kg	= <u>[0.325 - NA]</u> / <u>0.325</u> X 100] = <u>NA</u> %

CHALLENGE STUDY

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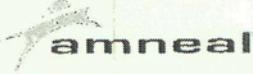
	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 114 of 133	

23.0		PRIMARY PACKAGING MATERIAL RETURN			
POLYPROPYLENE TUBE APP 107-S 8.20 X 6.20 (PMI-0996):					
1 Meter (A) = 0.021 Kg CONVERSION CALCULATION FOR RETURNED PRIMARY PACKING MATERIAL			Weight of Cone (B) = 0.325 Kg CALCULATION FOR VARIANCE OF CONE WEIGHT:		
Roll No.	Actual Returned gross quantity in Kg	Actual Returned net quantity in Kg = Actual Returned gross Qty in Kg - Weight of cone	Actual Returned quantity in meter = (Actual Returned net quantity in Kg) / (A)	Weight of Cone after completion of Roll (C)=	Variance (To be established) = [(B-C)/B X 100] = %
8	= 9.290 Kg	= 9.290 - 0.325 = 8.965 Kg.	= 8.965 / 0.021 = 426.905 meter.	N/A Kg	= [(-) / () X 100] = %
9	= Kg	= - = Kg.	= / = meter.	Kg	= [(-) / () X 100] = %
10	= Kg	= - = Kg.	= / = meter.	Kg	= [(-) / () X 100] = %
11	= Kg	= - = Kg.	= / = meter.	Kg	= [(-) / () X 100] = %
12	= Kg	= - = Kg.	= / = meter.	N/A Kg	= [(-) / () X 100] = %
13	= Kg	= - = Kg.	= / = meter.	08.425 Kg 13-25	= [(-) / () X 100] = %
14	= Kg	= - = Kg.	= / = meter.	Kg	= [(-) / () X 100] = %
Done By (SM/MM): <i>TD</i> 08-May-25			Checked By : <i>TD</i> 08-May-25		

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		BATCH MANUFACTURING RECORD
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 115 of 133	

23.0		PRIMARY PACKAGING MATERIAL RETURN			
Balance ID: <u>SCOP/91/PRD/156</u> HOT STAMPING FOIL, COLORIT 34973 BLACK, 220 MM (MMI-0358): 1 Meter (A) = 0.004 Kg Weight of Cone (B) = 0.435 Kg					
CONVERSION CALCULATION FOR RETURNED PRIMARY PACKING MATERIAL			CALCULATION FOR VARIANCE OF CONE WEIGHT:		
Roll No.	Actual Returned gross quantity in Kg	Actual Returned net quantity in Kg = Actual Returned gross Qty in Kg - Weight of cone	Actual Returned quantity in meter = (Actual Returned net quantity in Kg) / (A)	Weight of Cone after completion of Roll (C)=	Variance (To be established) = $\frac{[(B-C)/B \times 100]}{}$ %
1	<u>Kg</u>	<u>-</u> <u>Kg.</u>	<u>/</u> <u>meter.</u>	<u>0.430</u> Kg	$= \frac{(0.435 - 0.430)}{0.435} \times 100$ <u>= 1.15 %</u>
2	<u>Kg</u>	<u>-</u> <u>Kg.</u>	<u>/</u> <u>meter.</u>	<u>0.430</u> Kg	$= \frac{(0.435 - 0.430)}{0.435} \times 100$ <u>= 1.15 %</u>
3	<u>Kg</u>	<u>-</u> <u>Kg. NA</u>	<u>/</u> <u>meter.</u>	<u>0.445</u> Kg	$= \frac{(0.435 - 0.445)}{0.435} \times 100$ <u>= -2.30 %</u>
4	<u>Kg</u>	<u>-</u> <u>Kg. 08-04-25</u>	<u>/</u> <u>meter.</u>	<u>0.425</u> Kg	$= \frac{(0.435 - 0.425)}{0.435} \times 100$ <u>= 2.30 %</u>
5	<u>Kg</u>	<u>-</u> <u>Kg.</u>	<u>/</u> <u>meter.</u>	<u>0.425</u> Kg	$= \frac{(0.435 - 0.425)}{0.435} \times 100$ <u>= 2.30 %</u>
6	<u>0.690 Kg</u>	<u>$0.690 - 0.435$</u> <u>$= 0.255$ Kg.</u>	<u>$0.255 / 0.004$</u> <u>$= 63.75$ meter.</u>	<u>NA</u> Kg	$= \frac{(NA - NA)}{NA} \times 100$ <u>= NA %</u>
Done By (SM/MM): <u>208-May-25</u>			Checked By: <u>208-May-25</u>		

CHALLENGE STUDY

ADDITIONAL COPY
 QA-SIGN/DATE: *M28-24-Dec-25*

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 115 of 133	

23.0 PRIMARY PACKAGING MATERIAL RETURN					
Balance ID: <i>EOP1PI1PPD1156</i>					
HOT STAMPING FOIL, COLORIT 34973 BLACK, 220 MM (MMI-0358):					
1 Meter (A) = 0.004 Kg			Weight of Cone (B) = 0.435 Kg		
CONVERSION CALCULATION FOR RETURNED PRIMARY PACKING MATERIAL			CALCULATION FOR VARIANCE OF CONE WEIGHT:		
Roll No.	Actual Returned gross quantity in Kg	Actual Returned net quantity in Kg = Actual Returned gross Qty in Kg - Weight of cone	Actual Returned quantity in meter = (Actual Returned net quantity in Kg) / (A)	Weight of Cone after completion of Roll (C)=	Variance (To be established) = [(B-C)/B X 100] = _____ %
<i>* 1</i>	<i>= 1.990 Kg</i>	<i>= 1.990 - 0.435</i> <i>= 1.555 Kg.</i>	<i>= 1.555 / 0.004</i> <i>= 388.750 meter.</i>	<i>= NA Kg</i>	<i>= [(NA - NA) / NA X 100]</i> <i>= NA %</i>
<i>2</i>	<i>= _____ Kg</i>	<i>= _____ - _____</i> <i>= _____ Kg.</i>	<i>= _____ / _____</i> <i>= _____ meter.</i>	<i>= _____ Kg</i>	<i>= [(_____ - _____) / _____ X 100]</i> <i>= _____ %</i>
<i>3</i>	<i>= _____ Kg</i>	<i>= _____ - _____</i> <i>= _____ Kg.</i>	<i>= _____ / _____</i> <i>= _____ meter.</i>	<i>= _____ Kg</i>	<i>= [(_____ - _____) / _____ X 100]</i> <i>= _____ %</i>
<i>4</i>	<i>= _____ Kg</i>	<i>= _____ - _____</i> <i>= _____ Kg.</i>	<i>= _____ / _____</i> <i>= _____ meter.</i>	<i>= _____ Kg</i>	<i>= [(_____ - _____) / _____ X 100]</i> <i>= _____ %</i>
<i>5</i>	<i>= _____ Kg</i>	<i>= _____ - _____</i> <i>= _____ Kg.</i>	<i>= _____ / _____</i> <i>= _____ meter.</i>	<i>= _____ Kg</i>	<i>= [(_____ - _____) / _____ X 100]</i> <i>= _____ %</i>
<i>6</i>	<i>= _____ Kg</i>	<i>= _____ - _____</i> <i>= _____ Kg.</i>	<i>= _____ / _____</i> <i>= _____ meter.</i>	<i>= _____ Kg</i>	<i>= [(_____ - _____) / _____ X 100]</i> <i>= _____ %</i>
Done By (SM/MM): <i>✓ D. 08-may-25</i>			Checked By: <i>✓ 08-may-25</i>		

* Roll no. 01 consider as roll no. 07. *✓ D. 08-may-25*

CHALLENGE STUDY

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 116 of 133	

23.0 PRIMARY PACKAGING MATERIAL RETURN					
Balance ID: <i>NIA</i> Thermal Transfer Print Ribbon. 53 MM X 450 Mtr Black CFC (MMI-0368):					
1 Meter (A) = 0.0004 Kg			Weight of Cone = 0.0147 Kg (B)		
CONVERSION CALCULATION FOR RETURNED PRIMARY PACKING MATERIAL			CALCULATION FOR VARIANCE OF CONE WEIGHT:		
Roll No.	Actual Returned gross quantity in Kg	Actual Returned net quantity in Kg = Actual Returned gross Qty in Kg - Weight of cone	Actual Returned quantity in meter = (Actual Returned net quantity in Kg) / (A)	Weight of Cone after completion of Roll (C)=	Variance (To be established) = [(B-C)/B X 100] = _____ %
1	= _____ Kg	= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.	_____ Kg	= [(_____ - _____) / _____ X 100] = _____ %
2	= _____ Kg	= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.	_____ Kg	= [(_____ - _____) / _____ X 100] = _____ %
3	= _____ Kg	= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.	_____ Kg	= [(_____ - _____) / _____ X 100] = _____ %
4	= _____ Kg	= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.	_____ Kg	= [(_____ - _____) / _____ X 100] = _____ %
5	= _____ Kg	= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.	_____ Kg	= [(_____ - _____) / _____ X 100] = _____ %
6	= _____ Kg	= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.	_____ Kg	= [(_____ - _____) / _____ X 100] = _____ %
7	= _____ Kg	= _____ - _____ = _____ Kg.	= _____ / _____ = _____ meter.	_____ Kg	= [(_____ - _____) / _____ X 100] = _____ %
Done By (SM/MM): <i>JMP</i>			Checked By :		

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 117 of 133	

24.0 | PRIMARY PACKING MATERIAL RECONCILIATION

Twist off port Left over Quantity:

Calculate the left-over quantity of PPM (Twist off port) using weighing balance:

Balance ID: F001111PRD|139 & for 111PRD|147

PPM details	Left over quantity calculation		Leftover Qty. (B/A)	Done By (SM)	Checked By (SM)
Twist Off Port	A.	Wt. of single Twist Off Port: <u>1.4056</u> gm.	<u>1285</u> Nos.	<u>✓RD</u> 08-May-25	<u>②</u> 08-May-25
	B.	Total weight of leftover Twist Off Port: <u>1.8070</u> Kg = <u>1807</u> gm.			

PRIMARY PACKING MATERIAL RECONCILIATION PROCESS:

1. TWIST OFF PORT:

Page No.	Stage	Twist off port Nos.	Reconciled By
36	Dispensed quantity of Twist off port (A)	46135	<u>✓RD</u> 08-May-25
100	Total number of Twist off port (Good bags as per machine report) (B)	37524	<u>✓RD</u> 08-May-25
	Left over of Twist off port in Bowl (C)	1205	<u>✓RD</u> 08-May-25
	Total Twist off port rejected during filling (D)	120	<u>✓RD</u> 08-May-25
	Left over dispensed quantity of Twist off port (E)	7135	<u>✓RD</u> 08-May-25
	Total no of Twist off port used F = B+C+D+E	46064	<u>✓RD</u> 08-May-25
	% Variance ($\pm 2\%$) G = $[(A - F) / A] \times 100$	0.15%	<u>✓RD</u> 08-May-25

Checked By (SM): ② 08-May-25

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 amneal		BATCH MANUFACTURING RECORD					
NAME OF PRODUCT		Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL				BATCH NO.	
BMR NO.		BMR-PA-063-05				AH250076	
BATCH SIZE		4048.0 kg/ 4000 L (38446 Units)					
PAGE NO.		Page 118 of 133					

24.0 | PRIMARY PACKING MATERIAL RECONCILIATION

2. Other primary packing material:

Material Code	Material	Unit /Qty	Total Issued Qty (A) (Kg)	Empty Bag for machine setup (a) (Nos.)	Total no of bags (From Machine report) (b) (Nos.)	Total Bags (B) = a+b (Nos.)	Total Used Qty. (C)* (Kg)	Material to be unused D=A-C (Kg)
PMI-0998	Polypropylene Film APP114-S-135-200-F	115.0 mm	272.000 kg	188	38992	39180	220.449 kg	51.671 kg
PMI-0996	Polypropylene Tube APP107-S-8.20 X 6.20	48.00 mm	25.580 kg	188	38992	39180	19.747 kg	5.833 kg
PMI-0996	Polypropylene Tube APP107-S-8.20 X 6.20		28.840 kg				7.19.747 kg	9.093 kg
MMI-0358	Hot Stamping Foil, Colorit 34973 Black,220 Mm	45.00 mm	8.955 kg	188	38992	39180	7.052 kg	1.903 kg
MMI-0368	Thermal Transfer Print Ribbon. 53 MM X 450 Mtr Black CFC	NA	NA	NA	NA	NA	NA	NA

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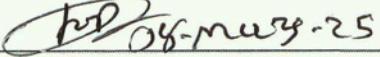
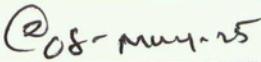
BATCH MANUFACTURING RECORD		
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 119 of 133	

24.0 | PRIMARY PACKING MATERIAL RECONCILIATION

* Quantity used: Total bags X Qty used for 1 Bag X Respective conversion factor

1000

For Tube roll, total used qty. = C/2

Reconciled By (SM)	Checked By (SM)
	

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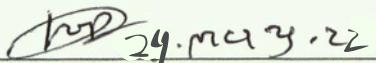
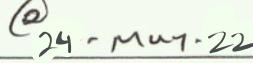
	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 119 of 133	

24.0 | PRIMARY PACKING MATERIAL RECONCILIATION

* Quantity used: Total bags X Qty used for 1 Bag X Respective conversion factor

1000

For Tube roll, total used qty. = C/2

Reconciled By (SM)	Checked By (SM)
 24-may-22	 24-may-22

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 119 of 133	

24.0 | PRIMARY PACKING MATERIAL RECONCILIATION

* Quantity used: Total bags X Qty used for 1 Bag X Respective conversion factor

1000

For Tube roll, total used qty. = C/2

Reconciled By (SM)	Checked By (SM)
<i>KD</i> 08-May-23	<i>Q</i> 08 - May - 23

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 120 of 133	

25.0 SIGNATURE LOG (STERILIZATION ACTIVITY)				
Record the name of persons who are involved in Terminal sterilization activity.				
#Declaration: I undersigned, hereby declare that I am trained on all relevant procedure and activity(s) that I am performing in this batch.				
Sr. No.	Name	Employee Code	Department	#Signature
1	Darshansing Vasham	343804	SM	(P) 07-May-25
2	Hukmjeet Patel	341238	SM	(HP) 07-May-25
3	Ronak Patel	315799	QA	(RP) 10-May-25
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				(P) 10-May-25

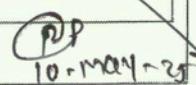
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NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 121 of 133	

25.0 SIGNATURE LOG (STERILIZATION ACTIVITY)				
Record the name of persons who are involved in Terminal sterilization activity.				
#Declaration: I undersigned, hereby declare that I am trained on all relevant procedure and activity(s) that I am performing in this batch.				
Sr. No.	Name	Employee Code	Department	#Signature
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				N/A
28				
29				
30				
31				
32				



 10-MAY-25

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 amneal		BATCH MANUFACTURING RECORD
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 122 of 133	

26.0 TERMINAL STERILIZATION PROCESS				
Perform line clearance as per SOP No.: PAP-QA-002 and attach respective copy to batch record.				
Transfer the collected Bags to TS loading area.				
Date	Lot No.	Total Number of Bags Transferred (Nos.)	Transferred By (SM)	Checked By (SM)
07-May-25	A	5760 + 04	<i>JRD</i> 08-May-25	(2) 08-May-25
07-May-25	B	5760 + 04	<i>JRD</i> 08-May-25	(2) 08-May-25
07-May-25	C	5760 + 04	<i>JRD</i> 08-May-25	(2) 08-May-25
07-May-25	D	5760 + 04	<i>JRD</i> 08-May-25	(2) 08-May-25
08-May-25	E	5760 + 04	<i>JRD</i> 08-May-25	(2) 08-May-25
08-May-25	F	5760 + 04	<i>JRD</i> 08-May-25	(2) 08-May-25
08-May-25	G	2714 + 04	<i>JRD</i> 08-May-25	(2) 08-May-25
		N/A	<i>JRD</i> 08-May-25	
Number of Bags taken for placement of in-built sensors: <u>28</u>				
Total No. of Bags available for TS = <u>37274</u> Nos.				
Done By (SM): <u>JRD 08-May-25</u>		Checked By (SM): <u>(2) 08-May-25</u>		

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CHALLENGE STUDY

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Amneal	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 123 of 133	

26.0 TERMINAL STERILIZATION PROCESS							
Verify the recipe parameters for the Terminal sterilization (EQP/P1/PRD/044) from SOP No.: PAP-SM-011 before start of TS load.							
Equipment No.	EQP/P1/PRD/044						
Recommended Maximum Load	5760 Nos.						
Recommended Minimum Load	360 Nos.						
Sterilization recipe Name:	Paracetamol Infusion IP 720 sec						
Lot Details	Lot - A	Lot - B	Lot - C	Lot - D	Lot - E	Lot - F	Lot - G
Recipe (Format) Name:	Paracetamol Inf. IP 720 sec						
Quantity of Bags loaded (Nos.)	5760	5760	5760	5760	5760	5760	2714
I/O Control Style:	Time						
Verified by (SM) (Sign/Date)	<i>[Signature]</i> 08-May-25	<i>[Signature]</i> 07-May-25	<i>[Signature]</i> 08-May-25	<i>[Signature]</i> 08-May-25	<i>[Signature]</i> 08-May-25	<i>[Signature]</i> 08-May-25	<i>[Signature]</i> 08-May-25
Total number of bags used for probe insertion	04	04	04	04	04	04	04
Cycle Start Time and Date	17:40 07-May-25	21:18 07-May-25	23:38 07-May-25	02:21 08-May-25	05:41 08-May-25	08:27 08-May-25	13:22 08-May-25
Sterilization Hold Start time & Date	18:04 07-May-25	21:39 07-May-25	23:59 07-May-25	02:44 08-May-25	06:03 08-May-25	08:49 08-May-25	13:41 08-May-25
Sterilization Hold End time & Date	18:17 07-May-25	21:52 07-May-25	00:12 08-May-25	02:57 08-May-25	06:16 08-May-25	09:02 08-May-25	13:54 08-May-25
Cycle End Time and Date	19:28 07-May-25	23:04 07-May-25	01:26 08-May-25	04:12 08-May-25	07:31 08-May-25	10:19 08-May-25	15:08 08-May-25
Complies/ Not Complies	Complies						
Done by (SM) (Sign/Date)	<i>[Signature]</i> 07-May-25	<i>[Signature]</i> 07-May-25	<i>[Signature]</i> 08-May-25	<i>[Signature]</i> 08-May-25	<i>[Signature]</i> 08-May-25	<i>[Signature]</i> 08-May-25	<i>[Signature]</i> 08-May-25

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CHALLENGE STUDY

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH50076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 124 of 133	

26.0	TERMINAL STERILIZATION PROCESS						
Verified by (SM) (Sign/Date)	(2) 07-May-15	(2) 07-May-15	(2) 08-May-15	(2) 08-May-15	(2) 08-May-15	(2) 08-May-15	(2) 08-May-15
Note: After completion of terminal sterilization, update the label on each trolley as per SOP No. AC-QM-007.							
Done by (SM): - <u>✓ 08-May-25</u>	Checked by (SM): <u>(2) 08-May-15</u>						
* Record type of rejection in below table:							
Type of rejection*	Qty. (Nos.)	Type of rejection*				Qty. (Nos.)	
Total Rejection: 00							

Recorded (SM): - ✓ 08-May-25 Checked By (SM): (2) 08-May-15

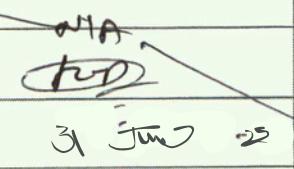
All the Bags used for placement of in-built sensors and rejected Bags shall be sent for destruction as per SOP No.: PAP-SM-014

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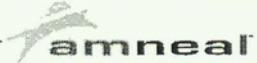
		BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.	
BMR NO.	BMR-PA-063-05		AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)		
PAGE NO.	Page 125 of 133		

26.0 TERMINAL STERILIZATION PROCESS				
FINISHED PRODUCT / OTHER SAMPLE DETAILS AFTER STERILIZATION PROCESS				
(Reference SOP No.: PAP-QA-004)				
Sr. No	Lot No.	Date of Sterilization	Sample Quantity (Nos.)	Sample collected by (QA)
01	A	31 -June -25	20 + 01 + 01 + 01	(P) 31 -Jun -25
02	B	31 -June -25	20 + 01	(P) 31 -Jun -25
03	C	31 -June -25	20 + 01 + 01	(P) 31 -Jun -25
04	D	31 -June -25	10 + 01 + 01	(P) 31 -Jun -25
05	E	31 -June -25	20 + 01	(P) 31 -Jun -25
06	F	31 -June -25	20 + 01 + 01 + 01	(P) 31 -Jun -25
07	G	31 -June -25	20 + 01	(P) 31 -Jun -25
 QA ✓ 31 Jun 25				
Total Sample		143 Nos.	(P) 31 -Jun -25	

CHALLENGE STUDY

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	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
PAGE NO.	Page 126 of 133	

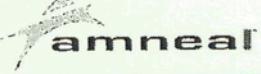
26.0 TERMINAL STERILIZATION PROCESS			
RECONCILIATION AT TERMINAL STERILIZATION STAGE			
Page No.	Stage	No. of Bags	Remark
122	Total Number of bags transferred for TS (A)	37302	N/A
122	Bags used for placement of in-built sensors (B)	28	N/A
124	Total Number of bags rejected at TS stage (C)	00	N/A
125	Finished product samples (D)	153	N/A
	Other Samples (E)	00	N/A
	Total sample (F)=D+E	153	N/A
	Total rejects (G)= B+C	28	N/A
	Total good units sent to online leak test & visual inspection (H) = A-(F+G)	37121	N/A
	% Yield (At terminal sterilization Stage) (I)= [(F+H) /A] X 100	99.92%	N/A
Reconciliation Done By (SM): <u>hpd 05-may-25</u>		Reconciliation Verified By (SM): <u>Qob-may-25</u>	

Terminal Sterilization Part Review By (QA) Sign/Date: (P)
10-may-25

QA AUTHORIZED COPY

CHALLENGE STUDY

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 amneal		BATCH MANUFACTURING RECORD		
NAME OF PRODUCT		Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL		
BMR NO.		BMR-PA-063-05		
BATCH SIZE		4048.0 kg/ 4000 L (38446 Units)		
PAGE NO.		Page 127 of 133		

27.0 HOLD TIME SUMMARY							
Calculate hold time and record in below table:							
Identified articles and bulk for hold	Hold time Start	Hold time end	Limit (NMT)	Start time	Valid/allowed hold time up to	Actual Time	Hold time is complying (Yes/No/NA)
				Time & Date	Time & Date	Time & Date	
CIP of Mixing Vessel (Loop - 2)	From End of Mixing vessel Loop-2 CIP (Page No.41)	Start of SIP Mixing vessel Loop-2 (Page No.43)	72 Hrs.	05:46 05-May-25	05:46 08-May-25	10:30 8 th May-25	Yes
				Sign/Date: <u>②</u> 05-May-25		Sign/Date: <u>②</u> 05-May-25	
CIP of filtration vessel (Loop - 3)	From End of Filtration vessel Loop- 3 CIP (Page No.64)	Start of SIP Filtration vessel Loop-3 (Page No.67)	72 Hrs.	12:06 06-May-25	12:06 09-May-25	15:20 06-May-25	Yes
				Sign/Date: <u>②</u> 06-May-25		Sign/Date: <u>②</u> 06-May-25	
CIP of filling Machine (Loop - 4)	From End of Filling Machine Loop- 4 CIP (Page No.76)	Start of SIP Filling Machine Loop-4 (Page No.76)	72 Hrs.	13:20 06-May-25	13:20 09-May-25	17:19 06-May-25	Yes
				Sign/Date: <u>②</u> 06-May-25		Sign/Date: <u>②</u> 06-May-25	
CIP of block valve (Loop - 5)	From End of Block valve Loop- 5 CIP (Page No.77)	Start of SIP Block valve Loop- 5 (Page No.77)	72 Hrs.	06:43 06-May-25	06:43 09-May-25	21:56 06-May-25	Yes
				Sign/Date: <u>②</u> 06-May-25		Sign/Date: <u>②</u> 06-May-25	

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CHALLENGE STUDY

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		BATCH MANUFACTURING RECORD		
NAME OF PRODUCT		Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL		
BMR NO.		BMR-PA-063-05		
BATCH SIZE		4048.0 kg/ 4000 L (38446 Units)		
PAGE NO.		Page 128 of 133		

27.0 HOLD TIME SUMMARY							
Identified articles and bulk for hold	Hold Start Time	Hold End Time	Limit (NMT)	Start time	Valid/allowed hold time up to	Actual Time	Hold time is complying (Yes/No)
				Time & Date	Time & Date	Time & Date	
SIP of Mixing Vessel (Loop-2)	From End of Mixing vessel Loop-2 SIP (Page No.43)	Start of Manufacturing (Page No.47)	72 Hrs.	13:05 05-May-25	13:05 08-May-25	07:43 06-May-25	Yes
				Sign/Date: <i>[Signature]</i> 05-May-25	Sign/Date: <i>[Signature]</i> 05-May-25	Sign/Date: <i>[Signature]</i> 06-May-25	
SIP of filtration vessel (Loop-3)	From End of Filtration vessel Loop-3 SIP (Page No.67)	Start of First Filtration (Page No.70)	72 Hrs.	18:54 06-May-25	18:54 09-May-25	25:66 09-May-25	Yes
				Sign/Date: <i>[Signature]</i> 06-May-25	Sign/Date: <i>[Signature]</i> 06-May-25	Sign/Date: <i>[Signature]</i> 09-May-25	
SIP of filling Machine (Loop-4)	From End of Filling Machine Loop- 4 SIP (Page No.76)	Start of Final Filtration (Page No.82)	72 Hrs.	20:02 06-May-25	20:02 09-May-25	01:38 07-May-25	Yes
				Sign/Date: <i>[Signature]</i> 06-May-25	Sign/Date: <i>[Signature]</i> 06-May-25	Sign/Date: <i>[Signature]</i> 07-May-25	
SIP of block valve (Loop- 5)	From End of Block valve Loop- 5 SIP (Page No.77)	Start of Final Filtration (Page No.82)	72 Hrs.	22:42 06-May-25	22:42 09-May-25	01:38 07-May-25	Yes
				Sign/Date: <i>[Signature]</i> 06-May-25	Sign/Date: <i>[Signature]</i> 06-May-25	Sign/Date: <i>[Signature]</i> 07-May-25	

CHALLENGE STUDY

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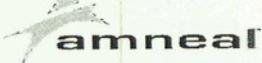
	BATCH MANUFACTURING RECORD		
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.	
BMR NO.	BMR-PA-063-05		
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)		AH250076
PAGE NO.	Page 128 of 133		

27.0 HOLD TIME SUMMARY							
Identified articles and bulk for hold	Hold Start Time	Hold End Time	Limit (NMT)	Start time	Valid/allowed hold time up to	Actual Time	Hold time is complying (Yes/No)
				Time & Date	Time & Date	Time & Date	
SIP of Mixing Vessel (Loop-2)	From End of Mixing vessel Loop-2 SIP (Page No.43)	Start of Manufacturing (Page No.47)	72 Hrs.	14:44 12-MAY-25	13:44 12-MAY-25	00:34 07-MAY-25	✓
				Sign/Date: <i>[Signature]</i> 06-MAY-25	Sign/Date: <i>[Signature]</i> 06-MAY-25	Sign/Date: <i>[Signature]</i> 07-MAY-25	
SIP of filtration vessel (Loop-3)	From End of Filtration vessel Loop-3 SIP (Page No.67)	Start of First Filtration (Page No.70)	72 Hrs.				
				Sign/Date:	Sign/Date:	Sign/Date:	
SIP of filling Machine (Loop-4)	From End of Filling Machine Loop-4 SIP (Page No.76)	Start of Final Filtration (Page No.82)	72 Hrs.				
				Sign/Date: <i>[Signature]</i>	Sign/Date: <i>[Signature]</i>	Sign/Date: <i>[Signature]</i>	
SIP of block valve (Loop- 5)	From End of Block valve Loop- 5 SIP (Page No.77)	Start of Final Filtration (Page No.82)	72 Hrs.				
				Sign/Date:	Sign/Date:	Sign/Date:	

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		BATCH MANUFACTURING RECORD		
NAME OF PRODUCT		Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL		BATCH NO.
BMR NO.		BMR-PA-063-05		AH250076
BATCH SIZE		4048.0 kg/ 4000 L (38446 Units)		
PAGE NO.		Page 129 of 133		

27.0 HOLD TIME SUMMARY							
Identified articles and bulk for hold	Hold time Start	Hold time end	Limit (NMT)	Start time	Valid/ allowed hold time up to	Actual Time	Hold time is complying. (Yes/No)
				Time & Date	Time & Date	Time & Date	
Un- filtered Bulk	Start time of API addition (Page No.50)	End time of first filtration (Page No.70)	48 Hrs.	14:44 06-May-25	14:44 08-May-25	00:34 07-May-25	Yes
Filtered bulk	End time of first filtration (Page No.70)	End time of filling process (Page No.98)	48 Hrs.	00:34 07-May-25	00:34 09-May-25	04:26 08-May-25	Yes
Filled Bag Hold time before TS	Start time of filling (Page No.83)	Start time of Terminal Sterilization cycle (Last Lot)	72 Hrs.	01:47 07-May-25	01:47 10-May-25	13:22 08-May-25	Yes
WFI Hold in Mixing Vessel	Start time of WFI collection in mixing vessel (Page No.47)	Start time of first raw material addition (Page No.49)	24 Hrs.	07:43 06-May-25	07:43 07-May-25	14:11 06-May-25	Yes

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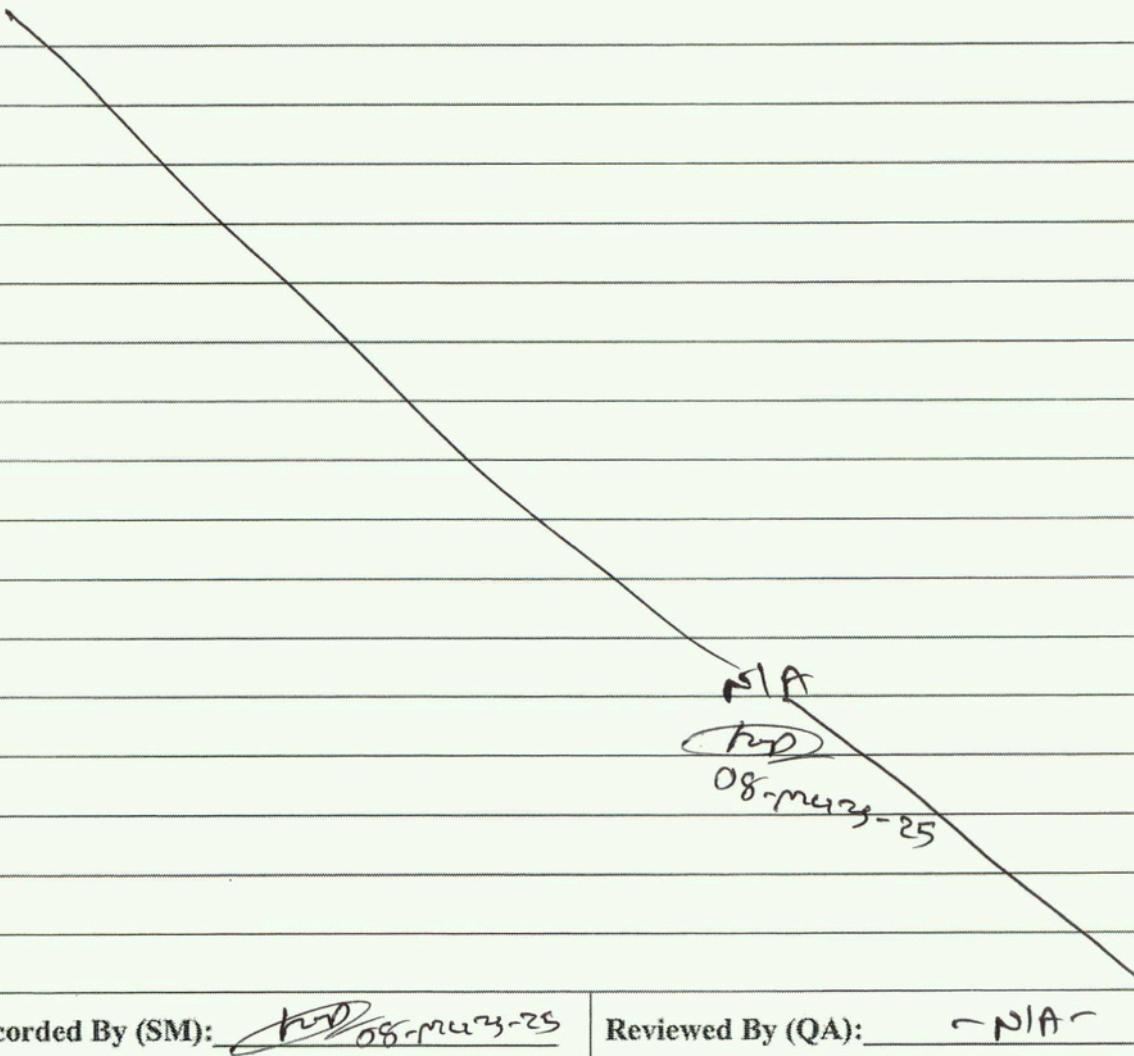
CHALLENGE STUDY

MASTER COPY

	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
PAGE NO.	Page 130 of 133	

28.0 DEVIATION DETAILS

During processing of batch if any deviation observed at any stage, initiate the deviation as per SOP No. IR-QA-005, "Deviation Management" Deviation details if any,

 <i>(Signature)</i> <i>08-MAY-25</i>	
Recorded By (SM):	Reviewed By (QA):
<i>08-MAY-25</i> <i>NIA</i>	

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CHALLENGE STUDY

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		BATCH MANUFACTURING RECORD
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 131 of 133	

29.0 | LIST OF ATTACHMENTS

Attachment No	Title / Details	No. of pages	Attached	Verified By
1.	Line clearance checklist of dispensing area	15	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	11/07-May-25
2.	COA of API	12	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	11/07-May-25
3.	Dispensing label	44	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	11/07-May-25
4.	CIP printouts of manufacturing vessel	45	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	11/07-May-25
5.	CIP printouts of manufacturing vessel	05	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	getd 12-May-25
6.	PHT printouts of manufacturing vessel	07	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	getd 12-May-25
7.	SIP printouts of manufacturing vessel	16	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	getd 12-May-25
8.	Line clearance checklist of manufacturing area	04	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	getd 12-May-25
9.	COA of WFI	03	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	11/08-May-25
10.	CIP printout of filtration vessel	05	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	11/08-May-25
11.	PHT printout of filtration vessel	07	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	11/08-May-25
12.	SIP printout of filtration vessel	20	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	getd 12-May-25
13.	Line clearance checklist of filtration area	03	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	getd 12-May-25
14.	COA of Filters & Pre-integrity test record of product filter	06	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	getd 12-May-25
15.	CIP printout of filling machine	05	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	11/09-May-25
16.	SIP printout of filling machine	10	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	11/09-May-25
17.	CIP printout of Block Valve	04	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	11/09-May-25
18.	SIP printout of Block Valve	10	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	11/09-May-25
19.	Line clearance checklist of filling area (Bag line)	03	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	11/09-May-25
20.	Post integrity test record of final filter	04	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	getd 12-May-25
21.	Filling Report of Filling machine	132	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	getd 12-May-25
22.	Page for pasting labels/ Printouts	04	<input checked="" type="checkbox"/> YES	getd 12-May-25

Put a tick mark “√” in “□” which is applicable.

CHALLENGE STUDY

MASTER COPY

P amneal	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 132 of 133	

29.0 LIST OF ATTACHMENTS				
Attachment No	Title / Details	No. of pages	Attached	Verified By
23.	Line clearance checklist of collection area	03	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Actd 12-May-25
24.	Line clearance checklist of Terminal sterilizer	03	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Actd 12-May-25
25.	Terminal sterilization printouts LOT-A	08	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Actd 12-May-25
26.	Terminal sterilization printouts LOT-B	18	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Actd 12-May-25
27.	Terminal sterilization printouts LOT-C	08	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Actd 12-May-25
28.	Terminal sterilization printouts LOT-D	08	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Actd 12-May-25
29.	Terminal sterilization printouts LOT-E	08	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Actd 12-May-25
30.	Terminal sterilization printouts LOT-F	08	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Actd 12-May-25
31.	Terminal sterilization printouts LOT-G	07	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Actd 12-May-25
32.	Line closure of Manufacturing area	02	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Actd 12-May-25
33.	Line closure of Filtration and filling area	02	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Actd 10-May-25
34.	Line closure checklist of collection area	02	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Actd 10-May-25
35.	Work request form (If any)	NA	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	Actd 12-May-25
36.	EM Summary	01	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Actd 12-May-25
37.	Fill weight check print out	04	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Actd 12-May-25
38.	Audit Trail	69	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Actd 15-May-25
39.	Material return Note	02	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Actd 12-May-25
40.	Visual Inspection record for bag	04	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Actd 15-May-25
41.	Material requisition slip	05	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Actd 12-May-25
42.	Bag Sample Proof	02	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Actd 10-May-25
43.	Average weight of NVPC bag print out	01	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Actd 15-May-25
44.	Line clearance checklist of decontaminating arrest for bag	02	Yes	Actd 12-May-25
45.	Product independent with time recording form of bag line.	03	Yes	Actd 12-May-25
46.	Verification procedure for position of sensor & compressed air pressure	07	Yes	Actd 10-May-25
47.	Online check weigher report	04	Yes	Actd 12-May-25

Put a tick mark “√” in “□” which is applicable.

CHALLENGE STUDY

ADDITIONAL COPY
QA-SIGN/DATE: *M.R.Du-Del-25*

MASTER COPY

 amneal	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 132 of 133	

29.0 | LIST OF ATTACHMENTS

Attachment No	Title / Details	No. of pages	Attached	Verified By
23.	Line clearance checklist of collection area		<input type="checkbox"/> YES <input type="checkbox"/> NO	
24.	Line clearance checklist of Terminal sterilizer		<input type="checkbox"/> YES <input type="checkbox"/> NO	
25.	Terminal sterilization printouts LOT-A		<input type="checkbox"/> YES <input type="checkbox"/> NO	
26.	Terminal sterilization printouts LOT-B		<input type="checkbox"/> YES <input type="checkbox"/> NO	
27.	Terminal sterilization printouts LOT-C		<input type="checkbox"/> YES <input type="checkbox"/> NO	
28.	Terminal sterilization printouts LOT-D		<input type="checkbox"/> YES <input type="checkbox"/> NO	
29.	Terminal sterilization printouts LOT-E		<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	
30.	Terminal sterilization printouts LOT-F		<input type="checkbox"/> YES <input type="checkbox"/> NO	
31.	Terminal sterilization printouts LOT-G		<input type="checkbox"/> YES <input type="checkbox"/> NO	
32.	Line closure of Manufacturing area		<input type="checkbox"/> YES <input type="checkbox"/> NO	
33.	Line closure of Filtration and filling area		<input type="checkbox"/> YES <input type="checkbox"/> NO	
34.	Line closure checklist of collection area		<input type="checkbox"/> YES <input type="checkbox"/> NO	
35.	Work request form (If any)		<input type="checkbox"/> YES <input type="checkbox"/> NO	
36.	EM Summary		<input type="checkbox"/> YES <input type="checkbox"/> NO	
37.	Fill weight check print out		<input type="checkbox"/> YES <input type="checkbox"/> NO	<i>Set A</i>
38.	Audit Trail		<input type="checkbox"/> YES <input type="checkbox"/> NO	<i>Set B</i>
39.	Material return Note		<input type="checkbox"/> YES <input type="checkbox"/> NO	<i>Set C</i>
40.	Visual Inspection record for bag		<input type="checkbox"/> YES <input type="checkbox"/> NO	<i>Set D</i>
41.	Material requisition slip		<input type="checkbox"/> YES <input type="checkbox"/> NO	
42.	Bag Sample Proof		<input type="checkbox"/> YES <input type="checkbox"/> NO	
43.	Average weight of NVPC bag print out		<input type="checkbox"/> YES <input type="checkbox"/> NO	
44. 48	visual inspection record for bags	02	Yes	<i>Set E</i>
45. 49	visual inspection booth light lux measurement record	02	Yes	<i>Set F</i>
46. 50	Verification checklist Do's & Don't's	02	Yes	<i>Set G</i>
47. 51	Request to deviate FIFO/FIFO	01	Yes	<i>Set H</i>

Put a tick mark "✓" in "□" which is applicable.

CHALLENGE STUDY

ADDITIONAL COPY

QA-SIGN/DATE: *M B M - Del-25*

MASTER COPY



BATCH MANUFACTURING RECORD

NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	AH250076
PAGE NO.	Page 132 of 133	

29.0 | LIST OF ATTACHMENTS

Attachment No	Title / Details	No. of pages	Attached	Verified By
23.	Line clearance checklist of collection area		<input type="checkbox"/> YES <input type="checkbox"/> NO	
24.	Line clearance checklist of Terminal sterilizer	\	<input type="checkbox"/> YES <input type="checkbox"/> NO	
25.	Terminal sterilization printouts LOT-A		<input type="checkbox"/> YES <input type="checkbox"/> NO	
26.	Terminal sterilization printouts LOT-B		<input type="checkbox"/> YES <input type="checkbox"/> NO	
27.	Terminal sterilization printouts LOT-C		<input type="checkbox"/> YES <input type="checkbox"/> NO	
28.	Terminal sterilization printouts LOT-D		<input type="checkbox"/> YES <input type="checkbox"/> NO	
29.	Terminal sterilization printouts LOT-E		<input type="checkbox"/> YES <input type="checkbox"/> NO	
30.	Terminal sterilization printouts LOT-F		<input type="checkbox"/> YES <input type="checkbox"/> NO	
31.	Terminal sterilization printouts LOT-G		<input type="checkbox"/> YES <input type="checkbox"/> NO	
32.	Line closure of Manufacturing area		<input type="checkbox"/> YES <input type="checkbox"/> NO	
33.	Line closure of Filtration and filling area		<input type="checkbox"/> YES <input type="checkbox"/> NO	
34.	Line closure checklist of collection area		<input type="checkbox"/> YES <input type="checkbox"/> NO	
35.	Work request form (If any)		<input type="checkbox"/> YES <input type="checkbox"/> NO	
36.	EM Summary		<input type="checkbox"/> YES <input type="checkbox"/> NO	
37.	Fill weight check print out		<input type="checkbox"/> YES <input type="checkbox"/> NO	
38.	Audit Trail		<input type="checkbox"/> YES <input type="checkbox"/> NO	NIA
39.	Material return Note		<input type="checkbox"/> YES <input type="checkbox"/> NO	
40.	Visual Inspection record for bag		<input type="checkbox"/> YES <input type="checkbox"/> NO	
41.	Material requisition slip		<input type="checkbox"/> YES <input type="checkbox"/> NO	
42.	Bag Sample Proof		<input type="checkbox"/> YES <input type="checkbox"/> NO	
43.	Average weight of NVPC bag print out		<input type="checkbox"/> YES <input type="checkbox"/> NO	
44. 52	Verification Procedure of unloading trolley transfer of Sterilized bags in vials	26	Yes	Act 12-Nov-25
45. 53	Load cell verification record	01	Yes	Act 12-Nov-25
46. 54	challenge test in inline check weigher machine for bags.	04	Yes	Act 12-Nov-25
47.	-NIA-	-NIA-	-NIA-	-NIA-

Put a tick mark "✓" in "□" which is applicable.

CHALLENGE STUDY

MASTER COPY

 amneal	BATCH MANUFACTURING RECORD	
NAME OF PRODUCT	Paracetamol Infusion IP 1% W/V (PARAUNIPORT) 100 mL	BATCH NO.
BMR NO.	BMR-PA-063-05	AH250076
BATCH SIZE	4048.0 kg/ 4000 L (38446 Units)	
PAGE NO.	Page 133 of 133	

30.0	BMR COMPLETION CHECK LIST
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BMR Reviewed By (SM): Ranjit 25-Jun-25

Review the above-mentioned stages of executed batch and write status as Satisfactory / Not Satisfactory in below table:

Sr. No.	Stages	Status	Checked By (QA)
01	RM & PPM Dispensing	Satisfactory	(RP) 06-Jun-25
02	Manufacturing	Satisfactory	(RP) 06-Jun-25
03	Filtration	Satisfactory	(RP) 06-Jun-25
04	Filling	Satisfactory	(RP) 06-Jun-25
05	Terminal Sterilization	Satisfactory	(RP) 06-Jun-25

BMR Reviewed By (QA)	BMR Approved By (QA)
<u>(RP) 06-Jun-25</u> <u>(Ranjan Pathi)</u>	<u>(S) 06-Jun-25</u> <u>(Mehul Samadhi)</u>