ISHA'S GMP CONSULTANCY PVT. LTD.
Ensuring Global GMP Compliance™ ®

PHENYLEPHRINE HYDROCHLORIDE

API MASS BALANCE / PROCESS & MATERIAL RECONCILIATION

Technical illustration based on the uploaded two-sheet Excel workbook

ONE-PAGE
A2 • LANDSCAPE
DATA REVIEW COPY

500 kg	245.00 kg	3	100.00%	2
SUMMARY BATCH REFERENCE	FINAL PRODUCT STREAM	MANUFACTURING STAGES	ITEMISED STAGE CLOSURE	SOURCE WORKSHEETS

MANUFACTURING ROUTE | AS DESCRIBED IN THE WORKBOOK

STAGE 01 — Reaction • layer separation • distillation
Crude intermediate: 315 kg

→

STAGE 02 — Reaction • layer separation • distillation
Purified intermediate: 215 kg

→

STAGE 03 — Reaction • layer separation • distillation
Final dried product: 245 kg

STAGE 1
Crude intermediate generation

TOTAL CHARGED	ITEMISED RECOVERED
3,617.992 kg	3,617.992 kg

MATERIAL INPUT (kg)	
Di potassium hydrogen phosphate	22.8
MAP Sulphate	400.00
Naoh Pallets	12.24
CAT-I	2.8
CAT-II	0.312
IPA	1,280.00
Liq Ammonia	230.00
Ortho phosphoric acid	5.84
Purified water	1,664.00

MATERIAL OUTPUT (kg)	
(IPA+Water) Distilled	2,280.00
(Water+Ammonia) MLR	1,000.00
Vent & handling losses	22.992
Final product after drying	315.00

BALANCE: 100.00%
Internal stage entries are gross quantities

315 kg -> Stage 2

STAGE 2
Intermediate purification

TOTAL CHARGED	ITEMISED RECOVERED
1,927.250 kg	1,927.250 kg

MATERIAL INPUT (kg)	
PEP Base Crude	315.00
Activated Charcoal	31.5
Hyflo	15.75
Conc. HCl	150.00
Liq ammonia	320.00
Purified water	1,095.00

MATERIAL OUTPUT (kg)	
Hyflo after filtration (wet)	40.00
Charcoal after filtration (wet)	75.00
(Ammonia+Water+HCl) MLR	1,470.00
Undissolved Salts	45.00
Vent & handling losses	82.25
Final product after drying	215.00

BALANCE: 100.00%
Internal stage entries are gross quantities

215 kg -> Stage 3

STAGE 3
Final API preparation

TOTAL CHARGED	ITEMISED RECOVERED
2,543.500 kg	2,543.500 kg

MATERIAL INPUT (kg)	
PEP Basepure	215.00
Activated Charcoal	21.5
Anhydrous HCL	47.00
Methanol	970.00
Acetone	1,290.00

MATERIAL OUTPUT (kg)	
Charcoal after filtration (wet)	50.00
Methanol distilled	921.00
Acetone distilled	327.00
Acetone distilled of MLR	942.00
Distillation residue	55.00
Vent & handling losses	3.5
Final product after drying	245.00

BALANCE: 100.00%
Internal stage entries are gross quantities

FINAL API: 245 kg

TECHNICAL REVIEW / SOURCE-DATA NOTES

01 SUMMARY VS DETAIL
Summary: batch reference 500 kg; final detailed API stream: 245 kg. Basis to be confirmed.

02 ROUNDING / FORMULAS
Stage 1 display 3,618 and Stage 2 display 1,927.3; itemised totals are 3,617.992 and 1,927.250 kg. #REF! in per-kg and Summary formulas.

03 SOURCE PRODUCT NAME
Workbook spells product “Phenylpherine HCL”; title uses standard spelling “Phenylephrine Hydrochloride”.

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