BAMBUTEROL HYDROCHLORIDE

API MASS BALANCE | SOURCE-BASED TECHNICAL ILLUSTRATION

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

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QUALITY • COMPLIANCE
TECHNICAL REVIEW

STAGE 1 • CHARGES / OUTPUT	STAGE 2 • CHARGES / OUTPUT	STAGE 3 • CHARGES / OUTPUT	FINAL PRODUCT • STAGE 3	SUMMARY BATCH REFERENCE
2,500.30 kg	1,067.92 kg	3,092.50 kg	43.00 kg	500 kg

MANUFACTURING SEQUENCE | SUMMARY WORKSHEET

01 STAGE 1 Reaction • Layer separation • Distillation
Dry product noted: 60 kg

→

02 STAGE 2 Reaction • Layer separation • Distillation
Intermediate filtrate: 1,050 kg

→

03 STAGE 3 Reaction • Layer separation • Distillation
Final dry product: 43 kg

STAGE 1 — MATERIAL BALANCE

BAMBUTEROL HCL • rows 23–39

MATERIAL INPUTS	kg
1-4 Dioxin	176
DB	32.5
Selenium Metal	13
DX	3
L+Tartaric Acid	7.3
Activated Charcoal	1.5
TBA	23
IPA	330
Liquor Ammonia	39
Purified Water	1,875
TOTAL	**2,500.30 kg**

MATERIAL OUTPUTS / DISPOSITION	kg
Selenium metal after Filtration (Wet condition)	11
(Water+1-4 Dioxin) MLR	1,200
Charcoal after filtration (Wet Condition)	2.5
IPA MLR	315
(Water+Ammonia) MLR	550
Water MLR	330
Vent & handling losses	31.8
Final Product After drying	60
TOTAL	**2,500.30 kg**

ITEMISED BALANCE • 2,500.30 = 2,500.30 kg

STAGE 2 — MATERIAL BALANCE

BAMBUTEROL HCL • rows 66–73

MATERIAL INPUTS	kg
ABA I	60
CAT B	6.3
Acetone	1,000
Hydrogen gas	1.62
TOTAL	**1,067.92 kg**

MATERIAL OUTPUTS / DISPOSITION	kg
CAT B after filtration (Wet Condition)	15
ABA II A (Filtrate)	1,050
Handling loss	2.92
TOTAL	**1,067.92 kg**

Reported rounded Stage 2 total: 1,067.90 kg.
Itemised rows sum: 1,067.92 kg (+0.02 kg).

SUMMARY: Stage 1–3 process volume references

Stage 1: 2,500.3 Stage 2: 1,067.9
Stage 3: 3,092.5 Batch reference: 500 kg

Stage 1 & 2 transfers are counted in later stages.

ITEMISED BALANCE • 1,067.92 = 1,067.92 kg

STAGE 3 — MATERIAL BALANCE

BAMBUTEROL HCL • rows 100–112

MATERIAL INPUTS	kg
ABA IIA	1,050
DMCC	48.75
Potassium Carbonate	93
Neutral Alumina	5.25
Activated Charcoal	3
Methanol	360
Acetone	610
MDC	735
IPA+HCl	37.5
Purified Water	150
TOTAL	**3,092.50 kg**

MATERIAL OUTPUTS / DISPOSITION	kg
Acetone Distilled	750
(IPA	800
HCl+Water+Acetone) MLR	105
Potassium carbonate after filtration (Wet Condition)	15
Alumina after filtration (Wet Condition)	12
Charcoal after filtration (Wet Condition)	728
MDC distilled	356
Methanol distilled	170
Acetone MLR	113.5
Final Product After drying	43
TOTAL	**3,092.50 kg**

ITEMISED BALANCE • 3,092.50 = 3,092.50 kg

SOURCE REVIEW | DO NOT TREAT AS APPROVED GMP BATCH DATA

- Summary worksheet uses 500 kg batch reference; detailed Stage 3 reports 43 kg final product.
- Several “per kg of output” cells and Summary volume formulas show #REF! errors.
- Clarify split/ambiguous Stage 3 MLR labels and 728 kg wet-charcoal output.

BASIS, TRACEABILITY & INTERPRETATION

- 2 source sheets: Summary; BAMBUTEROL HCL. Quantities displayed in kg.
- Sum of stage inputs: 6,660.72 kg. This is a GROSS multi-stage sum, not net fresh charge.
- Intermediate transfer streams (60 kg and 1,050 kg) must not be double-counted.

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