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

R-SALBUTAMOL SULPHATE

API MATERIAL BALANCE | SOURCE-WORKBOOK ILLUSTRATION

All 2 worksheets reviewed • 3 manufacturing stages • Source quantities are not adjusted

SUMMARY BATCH REFERENCE	GROSS STAGE INPUT SUM	FINAL PRODUCT	STAGE 2 OUTPUT EXCESS
500.00 kg	2,407.30 kg	20.00 kg	+20.00 kg

PROCESS FLOW | EACH STAGE: REACTION → LAYER SEPARATION → DISTILLATION

STAGE 1 Bhoj + reagents / solvents → XY-I
21.50 kg intermediate

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STAGE 2 XY-I + reagents / water → XY-II
20.00 kg intermediate

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STAGE 3 XY-II + reagents / solvents → product
20.00 kg R-Salbutamol Sulphate

STAGE 1 — Intermediate XY-I: 21.50 kg

MATERIAL CHARGES / INPUTS		kg
01	Bhoj	32.30
02	L+ Tartaric Acid	16.00
03	Retarder	105.00
04	IPA	180.00
05	Ethyl Acetate	105.00
ITEMISED INPUT TOTAL		**438.30 kg**

RECOVERED / WASTE / PRODUCT OUTPUTS		kg
01	EA + Retarder distilled from MLR	195.00
02	IPA distilled from MLR	178.00
03	Distillation residue	18.00
04	Vent & handling losses	25.80
05	Final Product	21.50

STAGE 2 — Intermediate XY-II: 20.00 kg

MATERIAL CHARGES / INPUTS		kg
01	XY-I	21.50
02	Activated Charcoal	1.20
03	Sodium Hydroxide	12.00
04	Toluene	12.00
05	Purified Water	900.00
ITEMISED INPUT TOTAL		**946.70 kg**

RECOVERED / WASTE / PRODUCT OUTPUTS		kg
01	Charcoal after filtration (Wet condition)	4.00
02	Water MLR	860.00
03	Water + Toluene MLR	60.00
04	Vent & handling losses	22.70
05	Final Product	20.00

STAGE 3 — Final API: 20.00 kg

MATERIAL CHARGES / INPUTS		kg
01	XY-II	20.00
02	5%Palladium Catalyst	2.00
03	Activated Charcoal	2.00
04	Conc. Sulphuric Acid	2.00
05	Methanol	696.00
06	Acetone	300.00
07	Hydrogen gas	0.30
ITEMISED INPUT TOTAL		**1,022.30 kg**

RECOVERED / WASTE / PRODUCT OUTPUTS		kg
01	CAT-B after filtration (Wet Condition)	5.00
02	Charcoal after filtration (Wet Condition)	5.00
03	Methanol distilled from MLR	650.00
04	Acetone distilled from MLR	270.00
05	Methanol + Acetone MLR	40.00
06	Distillation residue	25.00
07	Vent & handling losses	7.30
08	Final Product	20.00

TECHNICAL RECONCILIATION / SOURCE-DATA REVIEW

STAGE 1: 438.30 in = 438.30 out • STAGE 2: 946.70 in vs 966.70 itemised out (+20.00 kg) • STAGE 3: 1,022.30 in = 1,022.30 out

Stage 2 displays a total of 946.70 kg despite 966.70 kg in listed outputs. Per-kg and Summary distillation formulas contain #REF! errors.

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