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

API MASS BALANCE / GMP TECHNICAL REVIEW

TROSPIUM CHLORIDE

Source: 46-Trospium Chloride.xlsx | Five sheets: Material Balance · Flow Chart · CC · Raw Materials · Sheet1

MATERIAL INPUT | MB
21.110 kg

MATERIAL OUTPUT | MB
21.110 kg

FINAL TROSPIUM CHLORIDE
1.000 kg

REPORTED YIELD
90%

SOURCE PROCESS ROUTE | FLOW CHART + MATERIAL BALANCE

01 **PURIFICATION** — MeOH / CHARCOAL
›
02 **FILTRATION** — HYFLO / MeOH
›
03 **DISTILLATION** — MeOH RECOVERY
›
04 **ISOLATION** — IPA CHARGE
›
05 **FILTRATION** — FILTRATE
›
06 **DRYING** — 1.00 kg LOSS
›
07 **FINAL API** — 1.000 kg

MATERIAL CHARGES | MATERIAL BALANCE SHEET

No.	Operation	Input material / chemical	Quantity
1	Purification	3-(2-hydroxy-2,2-diphenylacetoxy)spiro[bicycle 3,2,1]octane-8,1-pyrrolidin]-1-ionchloride	1.110 kg
2	Purification	Methanol	8.760 kg
3	Purification	Activated charcoal	1.000 kg
4	Filtration	Hyflo	2.000 kg
5	Filtration	Methanol	2.200 kg
6	Distillation	Isopropyl alcohol	0.860 kg
7	Isolation	Isopropyl alcohol	4.320 kg
8	Filtration	Isopropyl alcohol	0.860 kg

Recorded input total: 21.110 kg

Input names and quantities reproduced from the MB worksheet.

OUTPUT / RECOVERY / LOSS | MATERIAL BALANCE

No.	Output, recovered material or loss	Quantity
1	Solid waste	3.000 kg
2	Evaporation loss	0.900 kg
3	Distillate (Methanol)	9.000 kg
4	Evaporation loss	1.000 kg
5	Filtrate	5.000 kg
6	Evaporation loss	0.210 kg
7	Evaporation loss	1.000 kg
8	**Output**	**1.000 kg**

Recorded output total: 21.110 kg

Gross balance difference: 0.000 kg (100.00% closure)

CHARGE COMPOSITION | CC + RAW MATERIALS

No.	Raw material	Qty (kg)
1	KSM* (name in main table)	1.110
2	Methanol	10.960
3	Activated charcoal	1.000
4	Isopropyl alcohol	6.040
5	Hyflo	2.000

CC charge total: 21.110 kg | RM list: 5 materials

MOLES / PROPOSED CONSUMPTION | SHEET1

Material	MW	Moles	Ratio	MT/day (source)
KSM*	392.51	2.83	1	0.3699
Methanol	—	—	—	3.6533
Isopropyl alcohol	—	—	—	2.0133
Activated charcoal	—	—	—	0.3333
Hyflo	—	—	—	0.6666

KSM*: starting compound (full name in main table); proposed daily quantities are reproduced as stated and require capacity-basis confirmation.

WASTE / RECOVERY | MB

Recovered methanol	**9.000 kg**
Filtrate (unclassified)	**5.000 kg**
Liquid effluent	**NIL (source)**
Solid waste	**3.000 kg**
Fugitive emissions	**2.110 kg**
Evaporation entries	**3.110 kg**

RECONCILIATION / SOURCE-QUALITY REVIEW | VERIFY BEFORE GMP APPROVAL

01 Overall material balance: 21.110 kg input and 21.110 kg output; CC charges also total 21.110 kg.

02 Reported yield 90%; 1.000 kg actual / 1.000 stated theoretical = 100% if theoretical quantity is in kg.

03 MB evaporation losses total 3.110 kg (0.900 + 1.000 + 0.210 + 1.000); waste summary states 2.110 kg emissions.

04 The 5.000 kg filtrate has no documented final disposition; waste table reports liquid effluent as NIL. Confirm streams and units.

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