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

API MASS BALANCE / GMP TECHNICAL REVIEW

TOPIRAMATE

Source: 45-Topiramate.xlsx | Five sheets: MB · FC · CC · RM · Moles | Values retained from workbook

MATERIAL INPUT – MB	MATERIAL OUTPUT – MB	FINAL TOPIRAMATE API	REPORTED YIELD
12.811 kg	12.810 kg	1.000 kg	53.8%

PROCESS ROUTE | FLOW CHART + MATERIAL BALANCE

01 RAW MATERIAL — CHARGING
02 REACTION — IPA / NH_3
03 FILTRATION — HYFLO / CHARCOAL
04 ISOLATION — WATER
05 FINAL — FILTRATION
06 DRYING — LOSS 0.500 kg
07 TOPIRAMATE — 1.000 kg

MATERIAL CHARGES | MB SHEET

No.	Operation	Material / chemical input	Source qty
1	Reaction	(3as,5aR,8bS)-2,2,7,7-Tetramethyl tetrahydro-3aH-bis[1,3]Dioxolo[4,5-b:4,5'-d]pyran [-3a-yl] methanol	1.430 kg
2	Reaction	Thionyl chloride	0.021 kg
3	Reaction	IPA	1.670 kg
4	Reaction	Aqueous ammonia	0.310 kg
5	Filtration	Hyflo	0.500 kg
6	Filtration	Activated charcoal	0.020 kg
7	Filtration	Isopropyl alcohol	0.280 kg
8	Isolation	Water	7.150 kg
9	Filtration	DM water	1.430 L

Recorded gross input: 12.811 kg | DM water is 1.430 L in the input entry.

Source total adds 1.430 to kg charges; confirm the volume-to-mass conversion before formal approval.

OUTPUT / LOSS STREAMS | MB SHEET

No.	Output / recovery / loss	Quantity
1	Filtrate – first filtration	3.910 kg
2	Evaporation loss – first filtration	0.250 kg
3	Solid waste	0.520 kg
4	Filtrate to ETP – final filtration	6.480 kg
5	Evaporation loss – final filtration	0.150 kg
6	Evaporation loss – drying	0.500 kg
7	**Final Topiramate API**	**1.000 kg**

Reported output total: 12.810 kg

Input – output difference: 0.001 kg

Calculated closure: 99.9922%

CHARGE COMPOSITION | CC + RM

No.	Raw material	Qty (kg)
1	Protected KSM (full name above)	1.430
2	Isopropyl alcohol	1.950
3	Thionyl chloride	0.024
4	Aqueous ammonia	0.310
5	Activated charcoal	0.020
6	Hyflo	0.500

CC total: 4.234 kg (excludes water additions)

MOLES / PROPOSED CONSUMPTION | MOLES SHEET

Material	MW	Moles	Ratio	MT/day
Protected KSM	260.284	5.49	1.00	23.833
Isopropyl alcohol	—	—	—	32.499
Thionyl chloride	118.970	0.17	0.03	3.333
Aqueous ammonia	—	—	—	5.167
Activated charcoal	—	—	—	3.333
Hyflo	—	—	—	8.333

Moles sheet lists 0.020 kg thionyl chloride, vs 0.021 kg (MB) and 0.024 kg (CC).

WASTE SUMMARY | MB

Liquid to ETP	**6.480 kg**
Solid waste	**0.520 kg**
Fugitive emissions	**0.900 kg**
Evaporation entries	**0.900 kg**
Liquid: MT/month	**3.240**
Liquid: MT/day	**0.00324**

RECONCILIATION / SOURCE-QUALITY REVIEW | VERIFY BEFORE GMP APPROVAL

01 Gross mass balance: 12.811 kg in versus 12.810 kg out (difference -0.001 kg; 99.992% closure).

02 Reported yield: 53.8%; calculated 76.92% if the theoretical quantity 1.30 is kg (1.000 / 1.300 × 100).

03 Thionyl chloride differs by sheet: MB 0.021 kg, CC 0.024 kg, Moles 0.020 kg; check charged quantity.

04 Moles sheet proposed-consumption figures for thionyl chloride/charcoal and liquid effluent daily/monthly units require checking.

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