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

DAPOXETINE HYDROCHLORIDE

API MASS BALANCE | PROCESS FLOW | MATERIAL CONSUMPTION

One-page engineering review incorporating all 5 attached workbook sheets

CLIENT DATA • TECHNICAL REVIEW ONLY

156.550 kg	156.550 kg	1.000 kg	31.25%	22.88%
GROSS STAGE INPUT • MB	GROSS STAGE OUTPUT • MB	FINAL API • MB	YIELD REPORTED • MB	1.00 / 4.37 kg • CALCULATED

PROCESS ROUTE | FC + MATERIAL BALANCE SHEET

All four manufacturing stages and final operation are source-derived

STAGE A
Reaction • Work-up • Filtration
1.22 kg intermediate

→

STAGE B
Reactions • Work-up • Isolation
1.34 kg intermediate

→

STAGE C
Reaction • Distillation • Isolation
0.94 kg intermediate

→

FINAL API
Decolorization • Salt formation • Drying
1.00 kg Dapoxetine HCl

CHARGE / MOLAR / CONSUMPTION REGISTER

CC + Raw materials + Moles | 28 line items

#	RAW MATERIAL / COMPONENT	CHARGE (kg)	MW	MOLES	RATIO	PROPOSED (MT/day)	ROLE (MOLES)
1	Benzene	**0.740**	78.11	9.47	1.00	0.620	Starting material
2	Aluminium chloride	**1.220**	133.34	9.15	—	1.020	Reagent
3	3-chloro propionyl chloride	**1.040**	126.97	8.19	—	0.870	Starting material
4	MDC	**17.290**	—	—	—	14.410	Solvent
5	Sodium bi carbonate	**0.370**	84.07	4.40	0.47	0.310	Reagent
6	Conc. HCl	**0.840**	—	—	—	0.700	Reagent
7	Pet Ether	**28.200**	—	—	—	23.500	Solvent
8	Sodium Sulfate	**1.790**	142.04	12.60	1.33	1.500	Reagent
9	S-methyl oxazaboralidine	**0.070**	—	—	—	0.060	Reagent
10	BDMS	**0.400**	—	—	—	0.330	Reagent
11	Methanol	**0.490**	—	—	—	0.490	Solvent
12	Hydrogen Peroxide	**0.240**	34.00	7.06	0.75	0.200	Reagent
13	Sulfuric acid	**0.140**	—	—	—	0.120	Reagent
14	α-naphthol	**0.860**	—	—	—	0.720	Reagent
15	Potassium carbonate	**1.050**	138.21	7.59	0.80	0.870	Reagent
16	DMSO	**5.900**	—	—	—	4.920	Solvent
17	DIPE	**17.700**	—	—	—	14.750	Solvent
18	Sodium hydroxide	**1.200**	40.00	30.00	3.17	0.990	Reagent
19	Tetrahydrofuran	**10.200**	—	—	—	8.500	Solvent
20	Triethylamine	**1.030**	101.10	10.18	1.07	0.860	Reagent
21	Di-methyl amino pyridine	**0.590**	122.17	4.82	0.50	0.500	Reagent
22	Methane sulfonyl chloride	**0.870**	—	—	—	0.730	Reagent
23	Di-methyl amine solution	**1.420**	—	—	—	1.180	Reagent
24	Acetonitrile	**6.500**	—	—	—	5.420	Reagent
25	Activated Charcoal	**0.630**	—	—	—	0.530	—
26	Hyflow	**0.380**	—	—	—	0.320	—
27	Ethyl Acetate HCl	**1.700**	—	—	—	1.420	Reagent
28	Ethyl Acetate	**14.250**	—	—	—	11.880	Solvent

CC TOTAL (28 CHARGES): 117.110 kg + WATER (MB): 35.940 kg + INTERNAL TRANSFERS: 3.500 kg = MB GROSS 156.550 kg

OUTPUT STREAMS & MATERIAL RECOVERY

Material balance sheet | itemised streams

STAGE / STREAM DESCRIPTION	QUANTITY (kg)
STAGE A	6 stream(s) | Itemised output 20.92 kg
Solid waste	**0.700**
Aqueous layer for ETP	**8.500**
Evaporation loss	**0.350**
Filtrate	**9.500**
Evaporation loss	**0.650**
Solid	**1.220**
STAGE B	13 stream(s) | Itemised output 49.64 kg
Solid waste	**0.700**
Aqueous layer to ETP	**3.500**
Evaporation loss	**0.350**
Distillate	**1.300**
Evaporation loss	**0.500**
Solid waste	**1.700**
Aqueous layer to ETP	**15.500**
Evaporation loss	**0.350**
Distillate	**19.500**
Evaporation loss	**0.500**
Filtrate	**4.200**
Evaporation loss	**0.200**
Solid	**1.340**
STAGE C	7 stream(s) | Itemised output 45.39 kg
Solid waste	**0.300**
Aqueous layer to ETP	**16.000**
Distillate	**21.300**
Evaporation loss	**0.350**
Filtrate	**6.300**
Evaporation loss	**0.200**
Solid	**0.940**
FINAL API	6 stream(s) | Itemised output 40.60 kg
Solid waste	**1.200**
Evaporation loss	**0.350**
Filtrate	**37.350**
Evaporation loss	**0.200**
Evaporation loss	**0.500**
DAPOXETINE HCl - FINAL API	**1.000**

STAGE RECONCILIATION

Computed from itemised MB entries

STAGE A	IN 19.91 kg	OUT 20.92 kg	**+1.01 kg**
STAGE B	IN 50.49 kg	OUT 49.64 kg	**-0.85 kg**
STAGE C	IN 46.75 kg	OUT 45.39 kg	**-1.36 kg**
FINAL API	IN 39.40 kg	OUT 40.60 kg	**+1.20 kg**

WASTE / RECOVERY

MB rows 115-120

Liquid effluent — **43.50 kg**
4.350 MT/month | 0.145 MT/day

Solid waste — **4.60 kg**
0.460 MT/month | 0.0153 MT/day

Fugitive emissions — **4.50 kg**
0.450 MT/month | 0.015 MT/day

SOURCE REVIEW / GMP VERIFICATION

Source values are not silently changed

- Reported yield: 31.25%; 1.00 / 4.37 kg theoretical = 22.88%. Reconcile yield basis.
- Stages do not balance individually: +1.01 / -0.85 / -1.36 / +1.20 kg.
- Filename says "Dapoxatin HCl"; MB identifies final product as "Dapoxetine HCl".
- MB gross totals include Stage A/B/C internal transfers (3.50 kg); not fresh charges.

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