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

FLUVOXAMINE MALEATE | API MASS BALANCE

WORKBOOK-BASED PROCESS, MATERIAL FLOW, CONSUMPTION & RECONCILIATION • TECHNICAL REVIEW

FINAL API	GROSS INPUT	GROSS OUTPUT	GROSS CLOSURE	REPORTED YIELD	CALC. YIELD*
1.000 kg	56.430 kg	56.430 kg	100.00%	43.85%	66.67%

* Calculated from 1.000 / 1.500 × 100, assuming the source theoretical quantity is expressed in kg.

PROCESS FLOW | Based on the Flow chart and material balance sheets

STAGE A · Intermediate generation

Reaction › Work-up › Distillation

5-Methoxy starting material, hydroxylamine HCl, sodium acetate, methanol, ethyl acetate and water

STAGE-A SOLID 0.950 kg

STAGE B · Reaction and isolation

Reaction › Filtration › Wet material › Filtration › Drying

Stage-A, 2-chloroethylamine HCl, maleic acid, KOH, PEG-400, toluene and purified water

STAGE-B SOLID 1.050 kg

STAGE C · Final purification

Purification › Filtration › Drying

Stage-B solid and MTBE (11.000 kg + 1.000 kg)

FINAL FLUVOXAMINE MALEATE 1.000 kg

CC + Raw Materials | 11 unique charges

#	Material	kg
1	5-Methoxy-1-[4-(trifluoromethyl) phenyl]-1-pentanone	0.870
2	Hydroxylamine Hydrochloride	0.460
3	Sodium Acetate	0.550
4	Methanol	4.350
5	Ethyl Acetate	8.700
6	2-chloroethylamine Hydrochloride	0.620
7	Maleic Acid	0.380
8	Potassium Hydroxide	1.950
9	PEG-400	0.350
10	Toluene	11.000
11	MTBE (11 + 1 kg in MB)	12.000
	CC charge-sheet total	**41.230 kg**
	MB: Added water + purified water	**13.200 kg**
	MB: Internal Stage A + B transfers	**2.000 kg**

MB | Process outputs, losses & API

#	Output stream	kg
A	Aqueous layer to ETP	8.300
A	Evaporation loss	0.150
A	Distillate	12.500
A	Evaporation loss	0.160
A	Stage-A solid (internal)	0.950
B	Filtrate	14.200
B	Evaporation loss	0.200
B	Filtrate to ETP	5.220
B	Evaporation loss	0.300
B	Evaporation loss	0.800
B	Stage-B solid (internal)	1.050
C	Filtrate	11.200
C	Evaporation loss	0.200
C	Evaporation loss	0.200
C	**Final Fluvoxamine Maleate**	1.000

RECORDED MB GROSS OUTPUT **56.430 kg**

STAGE RECONCILIATION | Derived from MB

Stage	Input kg	Output kg	Difference kg
Stage A	23.630	22.060	−1.570
Stage B	19.750	21.770	+2.020
Stage C	13.050	12.600	−0.450

Differences cancel overall; stages remain unreconciled.

WASTE SUMMARY | Source reported

Liquid effluent to ETP	13.520 kg
Fugitive emissions / evaporation	2.010 kg
Solid waste	NIL

SOURCE VERIFICATION | Before GMP approval

- Reported yield 43.85% vs 66.67% from 1.00 / 1.50 (if kg).
- Stage A −1.57, Stage B +2.02 and Stage C −0.45 kg.
- Verify MT/day denominator and molar / material identifiers.

MOLES + PROPOSED CONSUMPTION | Source values transcribed from worksheet “Moles”

#	Input component	MW	Qty kg	Moles	Molar	Role	Existing MT/d	Proposed MT/d	Total MT/d
1	5-Methoxy-1-[4-(trifluoromethyl) phenyl]-1-pentanone	260.25	0.870	3.340	1.00	Starting material	0	3.63	3.63
2	Hydroxylamine Hydrochloride	69.49	0.460	6.619	1.98	Reagent	0	1.92	1.92
3	Sodium Acetate	82.0343	0.550	6.710	2.01	Reagent	0	2.29	2.29
4	Methanol	—	4.350	—	—	Solvent	0	18.13	18.13
5	Ethyl Acetate	—	8.700	—	—	Solvent	0	36.25	36.25
6	2-chloroethylamine Hydrochloride	116	0.620	5.340	1.60	Reagent	0	2.58	2.58
7	Maleic Acid	134.08	0.380	2.830	0.84	Reagent	0	1.58	1.58
8	Potassium Hydroxide	56.10	1.950	34.760	10.41	Reagent	0	8.13	8.13
9	PEG-400	—	0.350	—	—	Catalyst	0	1.46	1.46
10	Toluene	—	11.000	—	—	Solvent	0	45.83	45.83
11	MTBE	—	12.000	—	—	Reagent	0	49.99	49.99

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REFERENCE ILLUSTRATION • NOT AN APPROVED BATCH RECORD
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