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

FLAVOXATE HYDROCHLORIDE

API MASS BALANCE | ALL FIVE EXCEL WORKSHEETS

MATERIAL CHARGES • PROCESS FLOW • MOLAR DATA • WASTE • RECONCILIATION

MB: TOTAL INPUT	MB: TOTAL OUTPUT	FINAL FLAVOXATE HCl	YIELD REPORTED
38.533 kg	38.530 kg	1.000 kg	66%

PROCESS FLOW | MB + FLOW CHART

1 REACTION 1 — Carboxylic acid 1.05 kg; thionyl chloride 1.13 kg; toluene 1.80 kg; DMF 0.10 kg

→ **2 DISTILLATION** — Toluene distillate 2.80 kg; evaporation loss 0.25 kg

→ **3 REACTION 2** — 1-(2-hydroxyethyl)piperidine 0.483 kg; toluene 9.03 kg

→ **4 FILTRATION / DRYING** — Toluene wash 0.90 kg; filtrate 9.50 kg; evaporations 0.50 + 0.50 kg

→ **5 STAGE-A** — Stage-A intermediate 1.26 kg (internal transfer)

→ **6 PURIFICATION** — Stage-A 1.26 kg; IPA 19.65 kg; water 2.14 kg

→ **7 FILTRATION / DRYING** — IPA wash 0.99 kg; filtrate 21.62 kg; evaporations 0.50 + 0.60 kg

→ **8 FINAL API** — Flavoxate hydrochloride 1.00 kg

MATERIAL INPUTS | MB

No.	Recorded input component	kg
01	3-methylflavone-8-carboxylic acid	1.050
02	Thionyl chloride	1.130
03	Toluene — Reaction 1	1.800
04	DMF	0.100
05	1-(2-hydroxy ethyl)piperidine	0.483
06	Toluene — Reaction 2	9.030
07	Toluene — filtration wash	0.900
08	Stage-A intermediate (internal transfer)	1.260
09	Isopropyl alcohol — purification	19.650
10	Water	2.140
11	Isopropyl alcohol — filtration wash	0.990
	TOTAL REPORTED MB INPUT	**38.533**

MATERIAL OUTPUTS / DISPOSITION | MB

No.	Recovered / waste / product stream	kg
01	Toluene distillate	2.800
02	Evaporation loss — distillation	0.250
03	Filtrate — Stage-A filtration	9.500
04	Evaporation loss — Stage-A filtration	0.500
05	Evaporation loss — Stage-A drying	0.500
06	Stage-A intermediate (transfer)	1.260
07	Filtrate — final filtration	21.620
08	Evaporation loss — final filtration	0.500
09	Evaporation loss — final drying	0.600
10	Final Flavoxate hydrochloride API	1.000
	TOTAL REPORTED MB OUTPUT	**38.530**

MB DIFFERENCE −0.003 kg

TOTAL OUTPUT / INPUT = 99.992% | Gross totals contain an internal Stage-A transfer of 1.26 kg.

CC + RAW MATERIALS

01	Carboxylic acid	1.05 kg
02	Thionyl chloride	1.13 kg
03	DMF	0.10 kg
04	Hydroxyethyl piperidine	0.48 kg
05	Toluene (combined)	11.73 kg
06	Isopropyl alcohol (combined)	20.64 kg

CC total 35.13 kg | water not included; piperidine rounded.

MOLES + PROPOSED CONSUMPTION

Component	MW	Moles	Ratio	MT/day
Carboxylic acid	280.27	3.75	1.000	4.38
Thionyl chloride	118.97	9.50	2.533	4.71
DMF	—	—	—	0.42
Hydroxyethyl piperidine	129.20	3.72	0.992	1.99
Toluene	—	—	—	48.88
Isopropyl alcohol	—	—	—	85.99

TECHNICAL REVIEW FINDINGS

- Stage-A input 14.493 vs output 14.810 kg: +0.317 kg.
- Stage-B input 24.040 vs output 23.720 kg: −0.320 kg.
- Evaporations total 2.35 kg; reported fugitive 2.35 kg.
- Liquid effluent NIL; filtrate streams total 31.12 kg.
- Yield: 1.00 / 1.52 = 65.79%; reported as 66%.
- CC piperidine 0.48 vs MB 0.483 kg; consumption basis unverified.

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