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

API MASS BALANCE | TECHNICAL ILLUSTRATION

TOLPERISONE HYDROCHLORIDE

Five-sheet consolidated review | Source: 44-Tolperison.xlsx | All quantities as recorded

GROSS STAGE INPUT
13.610 kg

GROSS STAGE OUTPUT
13.610 kg

FINAL TOLPERISONE HCl
1.000 kg

RECORDED YIELD
44.05%

MANUFACTURING PROCESS FLOW | FC + MB

01 CHARGE & REACTION A → 02 DISTILLATION METHANOL → 03 ISOLATION & FILTRATION → 04 STAGE-A SOLID 0.770 kg → 05 REACTION B REAGENTS → 06 FILTRATION FILTRATE → 07 DRYING EVAP. LOSS → 08 FINAL API 1.000 kg

RAW MATERIAL CHARGES | CC + RAW MATERIALS

No.	Raw material / substance	Qty	Unit
01	Piperidine	0.690	kg
02	Concentrated HCl - Stage A	0.860	kg
03	Methanol	1.710	kg
04	Acetone	1.710	kg
05	4'-Methyl propiophenone	0.740	kg
06	Ethyl acetate (3.70 + 2.22)	5.920	kg
07	Concentrated HCl - Stage B	0.020	kg
08	1,3-Dioxolane	1.190	kg

Charge-sheet total (external inputs): 12.840 kg

Stage-A solid transfer (internal, counted in gross): 0.770 kg

Gross stage input on MB: 12.840 + 0.770 = 13.610 kg

OUTPUT STREAMS | MATERIAL BALANCE SHEET

Stage	Output stream	Quantity (kg)
A	Methanol distillate / recovery	1.600
A	Evaporation loss - distillation	0.210
A	Filtrate - isolation	1.800
A	Evaporation loss - isolation	0.310
A	Stage-A solid (internal transfer)	0.770
B	Filtrate - filtration	6.500
B	Evaporation loss - filtration	0.870
B	Evaporation loss - drying	0.550
B	**Final Tolperisone HCl**	**1.000**

Stage-A output: 4.690 kg | Stage-B output: 8.920 kg

Gross stage output (including intermediate): 13.610 kg

STAGE BALANCE CHECK

Stage	Input	Output	Delta
Stage A	4.970	4.690	-0.280
Stage B	8.640	8.920	+0.280
GROSS	**13.610**	**13.610**	**0.000**

Delta = output minus input (kg)

MOLES & PROPOSED CONSUMPTION | MOLES SHEET

Material	MW	Moles	Ratio	MT/day
Piperidine	85.15	8.10	1.00	2.88
Conc. HCl (A)	-	-	-	3.58
Methanol	-	-	-	7.13
Acetone	-	-	-	7.13
4'-Methyl propiophenone	148.20	4.99	0.62	3.08
Ethyl acetate	-	-	-	24.67
Conc. HCl (B)	-	-	-	0.08
1,3-Dioxolane	-	-	-	4.96

WASTE & RECOVERY

Methanol recovered	**1.600 kg**
Filtrates (1.8 + 6.5)	**8.300 kg**
Evaporation loss	**1.940 kg**
Liquid effluent (source)	**NIL**
Solid waste (source)	**NIL**
Fugitive emissions	**1.940 kg**

SOURCE RECONCILIATION & GMP REVIEW NOTES

01 Stage-level discrepancies offset: Stage A -0.280 kg; Stage B +0.280 kg. Gross closure is not stage closure.

02 Yield: reported 44.05%; calculated 30.30% if theoretical yield of 3.30 is kg (1.000 / 3.30 x 100).

03 Waste classification: 8.300 kg of filtrates recorded while liquid effluent is marked NIL. Confirm recovery / disposal.

04 The Moles sheet labels proposed consumption as MT/day; verify production scale, batch basis and units.

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