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

DIMETHYL FUMARATE

API MASS BALANCE | ALL WORKSHEETS

MODEL TECHNICAL POSTER • Client-supplied Excel data • Review before GMP approval

TOTAL INPUT	TOTAL OUTPUT	FINAL API	REPORTED YIELD
8.220 kg	8.220 kg	1.000 kg	80.64%

MANUFACTURING ROUTE | MB + Flow chart

1. **REACTION** — Fumaric acid 1.00 kg + sulphuric acid 0.22 kg + methanol 5.00 kg
2. **ISOLATION** — Intermediate isolation; no stage quantity given
3. **FILTRATION** — Methanol 2.00 kg; filtrate 6.50 kg; loss 0.50 kg
4. **DRYING** — Evaporation loss 0.22 kg
5. **DIMETHYL FUMARATE** — Final API 1.00 kg

Sheets checked: material balance sheet • Flow chart • CC • Raw materials • Moles

MATERIAL CHARGES | MB + CC + RM

No.	Material / operation	kg
01	Fumaric acid - reaction	1.000
02	Sulphuric acid - reaction	0.220
03	Methanol - reaction	5.000
04	Methanol - filtration	2.000
	TOTAL MATERIAL INPUT	**8.220**

CC lists consolidated methanol 7.000 kg; the MB sheet separates this as 5.000 + 2.000 kg.

OUTPUT STREAMS | MB

No.	Recovered stream / product	kg
01	Filtrate (disposition unspecified)	6.500
02	Filtration evaporation loss	0.500
03	Drying evaporation loss	0.220
04	Dimethyl Fumarate API	1.000
	TOTAL MATERIAL OUTPUT	**8.220**

Mass-balance closure = 8.220 / 8.220 × 100 = 100.00%. Stream disposition requires verification.

MOLAR & CONSUMPTION DATA | Moles

Component	MW	Moles	Ratio	MT/day
Fumaric acid	116.07	8.62	1.00	0.833
Sulphuric acid	98.00	2.24	0.26	0.183
Methanol	—	—	—	5.833

YIELD & CLOSURE | MB

Theoretical yield (reported)	**1.24 [unit unspecified]**
Actual final output	**1.000 kg**
Reported yield	**80.64%**

1 / 1.24 × 100 = 80.65% (rounding)

WASTE & GMP REVIEW

- Liquid effluent: NIL (waste table)
- Solid waste: NIL (waste table)
- Fugitive emissions: 0.72 kg; source says "Scrubhing"

Verify: 6.50 kg filtrate disposition vs. "NIL" effluent; waste rates (0.007 MT/month, 0.00023 MT/day) and unit/batch basis.

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