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

MILRINONE API

MASS BALANCE | MODEL TECHNICAL ILLUSTRATION

Source: 23-Milrinone(1).xlsx

5 WORKSHEETS • MB / FC / CC / RM / Moles

TOTAL INPUT	TOTAL OUTPUT	FINAL MILRINONE API	MASS BALANCE CLOSURE
34.080 kg	**34.080 kg**	**1.000 kg**	**100.00%**
MB · recorded	MB · recorded	MB · product	Calculated from MB

MANUFACTURING PROCESS FLOW • from FC and MB

Reaction
Starting material + Malononitrile + Methanol

→

Work-up / Distillation
Methylene chloride + Water

→

Isolation
Acetone charged

→

Filtration
Filtrate / Evaporation loss

→

Drying
Evaporation loss

→

Milrinone API
Final product 1.000 kg

MATERIAL CHARGES • MB / CC / RM

Sr.	Material / input component	kg
1	1-ethoxy-2-(4-pyridinyl)ethenyl methyl ketone	1.200
2	Malononitrile	8.280
3	Methanol	4.740
4	Methylene Chloride	7.920
5	Water	9.600
6	Acetone	2.340

Source comparison: CC charges = 24.480 kg (five entries). MB also includes Water 9.600 kg; total MB inputs = 34.080 kg.

OUTPUT / RECOVERED STREAMS • MB

Sr.	Output stream / stream status	kg
1	Distillate	20.000
2	Aqueous layer-to ETP	9.500
3	Evaporation loss	1.040
4	Filtrate	2.000
5	Evaporation loss	0.200
6	Evaporation loss	0.340
7	Milrinone API (final)	1.000

MOLES / CONSUMPTION • Moles

Input component	kg	MT/day
1-Ethoxy-2-(4-pyridinyl)ethenyl methyl ketone	1.200	0.0199
Malononitrile	8.280	0.1380
Methanol	4.740	0.0789
Methylene Chloride	7.920	0.1320
Acetone	2.340	0.0389

Molar details (as reported)
Starting material: MW 191.23; 6.2752 mol; ratio 1.000.
Malononitrile: MW 66.06; 125.3406 mol; ratio 19.974.

WASTE SUMMARY • MB

Liquid effluent	Solid waste	Fugitive emissions
9.500 kg	**NIL**	**1.580 kg**
ETP	as reported	Scrubbing

Fugitive = 1.040 + 0.200 + 0.340 kg evaporation losses

MASS BALANCE & YIELD CALCULATIONS

Total inputs (MB)	**34.080 kg**
Total outputs (MB)	**34.080 kg**
Difference (outputs − inputs)	**0.000 kg**
Mass-balance closure	**100.00%**
Reported theoretical yield	**1.100 [unit not shown]**
Reported yield / calculated*	**75.75% / 90.91%**

SOURCE & VERIFICATION NOTES

- Reported yield 75.75% differs from 90.91% if 1.10 is kg theoretical yield.
- CC excludes 9.60 kg water listed in MB; consumption basis must be confirmed.
- 20.00 kg distillate and 2.00 kg filtrate require disposition / identity confirmation.

SOURCE WORKBOOK / TRACEABILITY

MB: material flows, yield & waste • FC: process route • CC: charges • RM: material list • Moles: MW, molar ratios & proposed MT/day

**Calculated yield = final 1.000 kg ÷ stated theoretical 1.100 × 100. Illustrative technical review only; not an approved GMP batch record.*

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