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

GLIMEPIRIDE API

MASS BALANCE & PROCESS FLOW

Source-based technical illustration | All 5 Excel worksheets reviewed

GMP TECHNICAL REVIEW
NOT AN APPROVED BATCH RECORD

GROSS STAGE INPUT	GROSS STAGE OUTPUT	FINAL GLIMEPIRIDE	CLOSURE / DIFFERENCE
122.540 kg	122.480 kg	1.000 kg	99.951% / -0.060 kg

PROCESS ROUTE | FC + MB worksheets

Stage-A intermediate reused during purification

REACTION → QUENCHING → ISOLATION → FILTRATION → DRYING → STAGE-A → PURIFICATION → FILTRATION → DRYING → GLIMEPIRIDE

MATERIAL INPUTS | MB worksheet

Includes 1.60 kg internal Stage-A transfer

#	INPUT MATERIAL / CHARGE (kg)	kg
1	Starting material: N-(4-[2-(3-ethyl-4-methyl-2-oxo-3-pyrroline-1-carboxamide-ethyl]-benzene sulfonamide	1.330
2	Trans-4-methyl-cyclohexyl isocynate	0.700
3	Potassium carbonate	1.250
4	Acetone	11.300
5	Water	90.000
6	Ammonia solution	3.320
7	Con.Hydrochloric acid	6.640
8	Acetone	6.400
9	Solid	1.600
	GROSS TOTAL	122.540

MATERIAL OUTPUTS | MB worksheet

As recorded, including internal intermediate

#	OUTPUT / RECOVERY / LOSS (kg)	kg
1	Filtrate to ETP	110.900
2	Evaporation loss	2.600
3	Solid	1.600
4	Filtrate	5.150
5	Evaporation loss	1.100
6	Evaporation loss	0.130
7	Solid	1.000
	GROSS TOTAL	122.480

MOLAR / CONSUMPTION SCHEDULE | Moles

CC + RM: 6 listed materials (30.94 kg)

MATERIAL	MW	kg	MOLES	RATIO	MT/DAY*
Starting material (full identity listed in MB/CC)	351.420	1.330	3.790	1	9.220
Trans-4-methyl-cyclohexyl isocynate	139.190	0.700	5.030	1.330	4.850
Potassium carbonate	138.205	1.250	9.050	2.390	8.670
Acetone	–	17.700	–	–	122.720
Ammonia solution	–	3.320	–	–	23.020
Con.Hydrochloric acid	–	6.640	–	–	46.040

WASTE / ENVIRONMENTAL STREAMS | MB worksheet

As labelled by source; not independently validated

STREAM	kg	MT/day	MT/month
Liquid effluent / ETP	110.900	0.55450	16.6350
Solid waste	NIL	NIL	NIL
Fugitive emissions / scrubbing	3.830	0.01915	0.5745

ADDITIONAL OUTPUT: 5.15 kg "Filtrate" in purification; its destination is not specified in the waste summary.

TECHNICAL REVIEW / RECONCILIATION FINDINGS

Source figures preserved — verify before GMP approval

- **STAGE-A: 114.54 kg inputs vs 115.10 kg outputs (+0.56 kg).**
- PURIFICATION: 8.00 kg inputs vs 7.38 kg outputs (-0.62 kg).
- OVERALL: 122.54 kg input vs 122.48 kg output (shortfall 0.06 kg).
- **YIELD: 54.05% reported; 1.00 / 1.40 = 71.43% if theoretical quantity is kg.**
- CONSUMPTION: MT/day values and scale basis require independent verification.
- FILTRATE: 5.15 kg disposition and solvent/waste categorisation need confirmation.

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