TERBINAFINE API

STAGE-WISE MASS BALANCE | MANUFACTURING PROCESS

One-page technical illustration based on the uploaded workbook - quantities in kg

SOURCE-BASED | 2026

Summary + TERBINAFINE

Reference / review copy

SUMMARY BATCH REFERENCE	STAGE 1 MATERIAL CHARGES	STAGE 2 REPORTED TOTAL	FINAL API REPORTED
500 kg	2,743.36 kg	2,346.38 kg	100.00 kg
Summary sheet	Detail sheet / row sum	Detail sheet / recorded	Terbinafine Hydrochloride

PROCESS FLOW

STAGE 1 Reaction > Layer separation > Distillation → **STAGE 2** Reaction > Layer separation > Distillation → **STAGE 3** Reaction > Filtration > Drying

STAGE 01 Primary reaction & separation

Reaction / layer separation / distillation

INPUTS / MATERIAL CHARGES	kg
N-methyl-1-naphthalene methanamine	124.43
1,3-dichloro-1-propene	92.91
Potassium carbonate	120.29
Methyl ethyl ketone	414.78
Toluene	497.74
Water	1,493.21

RECOVERIES, LOSS, WASTE & PRODUCT	kg
Methyl ethyl ketone recovery	394.04
Methyl ethyl ketone loss	20.74
Effluent water with inorganic salt	1,652.07
Toluene recovery	472.85
Toluene loss	24.89
Organic residue / impurities	6.64
Stage 1 intermediate	172.13

Sheet total: 2,743.40 kg
Listed charges & outputs: 2,743.36 kg

STAGE 02 Intermediate conversion

Reaction / layer separation / distillation

INPUTS / MATERIAL CHARGES	kg
Stage 1 intermediate	172.13
1,1-dichloro-3,3-dimethylbutene	129.04
n-Butyllithium	625.82
Toluene	903.25
Tetrahydrofuran	258.07
Ammonia (30% solution in water)	258.07

RECOVERIES, LOSS, WASTE & PRODUCT	kg
Heptane recovery [verify charge]	443.88
Heptane loss [verify charge]	25.29
Tetrahydrofuran recovery	245.17
Tetrahydrofuran loss	12.90
Effluent water with inorganic salt	562.85
Toluene recovery	858.09
Toluene loss	45.16
Organic residue / impurities	33.04
Stage 2 intermediate	162.07

Reported total: 2,346.38 kg
Listed output lines: 2,388.45 kg (+42.07)

STAGE 03 Final API isolation

Reaction / filtration / drying

INPUTS / MATERIAL CHARGES	kg
Stage 2 intermediate	162.07
Methyl ethyl ketone	1,333.33
Concentrated HCl	44.83

RECOVERIES, LOSS, WASTE & PRODUCT	kg
Methyl ethyl ketone recovery	1,264.37
Methyl ethyl ketone loss	68.97
Effluent water with inorganic salt	44.82
Organic residue / impurities	62.07
Terbinafine Hydrochloride (final)	100.00

Reported total: 1,540.23 kg
Listed inputs & outputs: 1,540.23 kg

DATA RECONCILIATION & GMP REVIEW POINTS

ACTION REQUIRED

01 Stage 1 reported rounding difference

2,743.40 kg recorded total vs 2,743.36 kg itemised; 0.04 kg difference.

02 Stage 2 material imbalance - +42.07 kg

2,388.45 kg itemised outputs vs 2,346.38 kg recorded total.

03 Heptane recovery without matching charge

469.17 kg combined heptane recovery/loss is listed; no heptane input row.

04 Batch-size basis & API form

Summary: 500 kg "batch size"; detail: 100 kg Terbinafine Hydrochloride. Verify basis.

Basis: client-supplied Excel workbook (Summary and TERBINAFINE sheets). Intermediate transfers repeat across stages; do not sum stage totals.

This illustration is for technical review only. Confirm yield, batch basis and discrepancies before issuing approved GMP documentation.

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