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

RACECADOTRIL API

STAGE-WISE MASS BALANCE | MANUFACTURING PROCESS

Source-based one-page engineering and GMP technical illustration | Quantities in kg

WORKBOOK-BASED | 2026

Summary + RACECADOTRIL

Reference / technical review copy

SUMMARY BATCH REFERENCE	STAGE 01 INPUT	STAGE 02 INPUT	STAGE 03 INPUT	FINAL API PRODUCT
500 kg	337.24 kg	2,070.38 kg	917.26 kg	100.00 kg
Summary sheet	Detailed sheet	Detailed sheet	Detailed sheet	Stage 03 output

PROCESS FLOW

STAGE 1 Reaction > Layer separation > Distillation → **STAGE 2** Reaction > Separation > Distill. > Purify > Filter > Dry → **STAGE 3** Reaction > Isolation > Filtration > Drying

STAGE 01 Primary synthesis

Reaction / layer separation / distillation

INPUTS / MATERIAL CHARGES	kg
2-Benzyl acrylic acid	76.65
Thionyl chloride	68.67
Toluene	191.92

OUTPUTS / RECOVERY / WASTE	kg
Toluene recovery	182.27
Toluene loss	9.65
Thionyl chloride consumption loss	59.55
Organic residue impurities	7.40
Stage 1 intermediate	**77.96**

Sheet totals: 337.24 kg IN / 337.20 kg OUT
Itemised OUT: 336.83 kg | Review: 0.41 kg net gap

STAGE 02 Intermediate conversion

Reaction, extraction, distillation, purification and drying

INPUTS / MATERIAL CHARGES	kg
Stage 1 intermediate	77.96
(toluene-4-sulfonylamino)-acetic acid benzyl ester	160.10
Triethyl amine	95.96
Toluene	389.79
Water	637.85
Sodium bicarbonate (5% solution in water)	159.46
HCL	88.59
Isopropyl alcohol	460.67

OUTPUTS / RECOVERY / WASTE	kg
Effluent water with inorganic salt	1,086.32
Toluene recovery	372.08
Toluene loss	17.72
Isopropyl alcohol recovery	437.63
Isopropyl alcohol loss	23.03
Organic residue impurities	27.29
Stage 2 intermediate	**106.31**

Reported IN = OUT = 2,070.38 kg

STAGE 03 Final API isolation

Reaction, isolation, filtration and drying

INPUTS / MATERIAL CHARGES	kg
Stage 2 intermediate	106.31
Thioacetic acid	31.36
Isopropyl alcohol	779.59

OUTPUTS / RECOVERY / WASTE	kg
Isopropyl alcohol recovery	744.15
Isopropyl alcohol loss	35.44
Organic residue impurities	37.67
Racecadotril (final API)	**100.00**

SHARE OF STAGE 3 RECORDED OUTPUTS



IPA recovered 81.1% | API 10.9% | Other streams 8.0%

Reported IN = OUT = 917.26 kg

SOURCE RECONCILIATION & GMP REVIEW POINTS

ACTION REQUIRED

01 STAGE 1 ITEMISED OUTPUT GAP

The 5 output rows add to 336.83 kg; the recorded output total is 337.20 kg (0.37 kg gap).

02 STAGE 1 INPUT / OUTPUT GAP

337.24 kg input versus 336.83 kg itemised output: 0.41 kg short. Recorded totals differ by 0.04 kg.

03 BROKEN SUMMARY FORMULA

Summary!F10 contains #REF!; Stage 2 volume 2,070.00 differs from detailed 2,070.38 kg.

04 BATCH & CALCULATION BASIS

Summary batch size is 500 kg, but final API is 100 kg. Verify the per-kg-of-output basis and yield.

Workbook basis: client-uploaded Summary and RACECADOTRIL sheets. Internal Stage 1/2 intermediates are counted in subsequent stages; do not add stage totals as unique consumption.

ILLUSTRATIVE FOR TECHNICAL REVIEW ONLY | Validate calculations, discrepancies and yield basis before approval as a GMP batch record.

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Technical illustration | Not an approved manufacturing record