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

API MATERIAL BALANCE | TECHNICAL REVIEW

TERIFLUNOMIDE

Single-product consolidated poster • Source workbook: 41-Teriflunomide.xlsx

API

TOTAL INPUT
37.790 kg
11 detailed MB charges

TOTAL OUTPUT
37.790 kg
8 material/output streams

FINAL API
1.000 kg
Recorded Teriflunomide

GROSS CLOSURE
100.00%
37.790 / 37.790

MANUFACTURING PROCESS FLOW • MB + FC WORKSHEETS

01 Reaction › 02 Filtration › 03 Isolation › 04 Water filtration › 05 Leaching › 06 Methanol filtration › 07 Drying › 08 Milling & sifting › 09 Final Teriflunomide

DETAILED MATERIAL INPUTS • MB

NO.	MATERIAL / PROCESS CHARGE	KG
01	Starting material: 5-methyl-N-(4-(trifluoromethyl) phenyl) isoxazole-4-carboxamide	1.120
02	Methanol - Reaction	3.270
03	Sodium hydroxide	0.250
04	Water - Reaction	4.140
05	Hyflo - Filtration	0.500
06	Water - Filtration	2.240
07	Water - Isolation	0.660
08	Concentrated HCl - Isolation	1.120
09	Water - Second filtration	13.440
10	Methanol - Leaching	10.610
11	Methanol - Final filtration	0.440

TOTAL INPUT 37.790 kg | Includes 20.480 kg process water

DETAILED OUTPUT STREAMS • MB

NO.	RECORDED OUTPUT STREAM	KG
01	Solid waste - Filtration	0.500
02	Aqueous filtrate	20.000
03	Filtrate - Water filtration	4.930
04	Evaporation loss - Filtration	0.230
05	Filtrate - Methanol filtration	10.400
06	Evaporation loss - Filtration	0.230
07	Evaporation loss - Drying	0.500
08	Teriflunomide API (final)	1.000

TOTAL OUTPUT 37.790 kg | Final API = 1.000 kg

RAW-MATERIAL CHARGE + MOLAR SCHEDULE • CC / RM / MOLES

NO.	CC CHARGE MATERIAL	KG
01	Starting material	1.120
02	Methanol	14.320
03	Sodium hydroxide	0.250
04	Concentrated HCl	1.120
05	Hyflo	0.500

CC / RM: 5 listed materials | CC total = 17.310 kg

MATERIAL	MW	MOLES	RATIO	MT/D
Starting material	270.21	4.15	1.00	0.062
Methanol	—	—	—	0.795
Sodium hydroxide	39.9971	6.25	1.51	0.014
Conc. HCl	—	—	—	0.062
Hyflo	—	—	—	0.028

MT/D = source "Proposed consumption MT/Day".
Existing consumption: 0 for all 5 entries.

WASTE / DISPOSITION + RECONCILIATION

SOURCE WASTE	KG	MT/MO	MT/D	TREATMENT
Liquid effluent	20.000	0.200	0.00660	ETP
Solid waste	0.500	0.005	0.00016	Rounky W.M.*
Fugitive emissions	0.960	0.0096	0.00032	Scrubbing

REQUIRES TECHNICAL RECONCILIATION

20 kg aqueous filtrate is in the waste summary; 4.93 + 10.40 kg other filtrates need confirmed recovery / disposal classification.

REVIEW FINDINGS | SOURCE VALUES NOT ALTERED

Yield: 90% reported, vs. 100% if the stated theoretical 1.00 and final 1.00 are both kg. • CC 17.310 kg excludes 20.480 kg water included in MB 37.790 kg. • Confirm MT/day planning basis and waste treatment agency name. • No independent step-wise mass balances are supplied.

© 2026 ISHA'S GMP CONSULTANCY PVT. LTD. | All rights reserved
info@ishasgmp.com • www.ishasgmp.com • +91 86675 89984