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

NEPAFENAC API

MASS BALANCE | TECHNICAL REVIEW MODEL

Source worksheets: Material Balance Sheet • FC • CC • RM • M0LES

SOURCE: 26-NEPAFENAC(1).xlsx | REVIEW COPY

GROSS INPUT | MB	GROSS OUTPUT | MB	FINAL API	REPORTED YIELD
726.880 kg	726.880 kg	1.000 kg	35.46%

SOURCE PROCESS ROUTE | Flow Chart (FC) & Material Balance Sheet

STAGE A

REACTION › FILTRATION › WORK-UP

Distillation • Purification • Filtration • Drying

Stage-A solid: 2.500 kg

→

STAGE B

REACTION › FILTRATION › DISTILLATION

Purification • Filtration • Drying

Stage-B solid: 1.500 kg

→

STAGE C

PURIFICATION › FILTRATION › DRYING

Final isolation

Nepafenac final API: 1.000 kg

MATERIAL INPUTS | All MB entries (including internal transfers)

No.	Stg	Material / internal transfer	Quantity	Unit
01	A	Amino benzophenone	2.190	kg
02	A	N-Chlorophthalimide	2.240	kg
03	A	2-(Methylthio)acetamide	1.750	kg
04	A	Triethylamine	1.690	kg
05	A	Methylene dichloride	72.240	kg
06	A	Sodium hydroxide	0.880	kg
07	A	Water	20.000	kg
08	A	Ethyl Acetate	35.000	kg
09	B	Stage-A	2.500	kg
10	B	Raney-Nickel	21.890	kg
11	B	Tetrahydrofuran	324.000	kg
12	B	Hyflow	1.000	kg
13	B	Isopropyl alcohol	96.000	kg
14	C	Stage-B	1.500	kg
15	C	Isopropyl alcohol	144.000	kg

MB GROSS INPUT (incl. 4.00 kg transfers) **726.880 kg**

STAGE-LEVEL CHECK | Output − Input

A: -1.490 kg B: -0.010 kg C: +1.500 kg

REPORTED OUTPUT STREAMS | All MB entries

No.	Stg	Output / recovery / waste stream	Quantity	Unit
01	A	Evaporation loss	5.000	kg
02	A	Aqueous layer-To ETP	20.000	kg
03	A	Evaporation loss	5.000	kg
04	A	Distillate	63.000	kg
05	A	Evaporation loss	5.000	kg
06	A	Filtrate	31.000	kg
07	A	Evaporation loss	2.000	kg
08	A	Evaporation loss	1.000	kg
09	A	Solid	2.500	kg
10	B	Insolubles solid waste	22.000	kg
11	B	Evaporation loss	9.000	kg
12	B	Distillate-THF	250.000	kg
13	B	Evaporation loss	66.000	kg
14	B	Filtrate	90.000	kg
15	B	Evaporation loss	5.000	kg
16	B	Evaporation loss	1.880	kg
17	B	Solid	1.500	kg
18	C	Filtrate	140.000	kg
19	C	Evaporation loss	2.000	kg
20	C	Evaporation loss	4.000	kg
21	C	Out put	1.000	kg

MB GROSS OUTPUT (incl. 4.00 kg transfers) **726.880 kg**

CHARGE COMPOSITION | 11 source materials (CC / RM)

No.	Raw material	Charge	Unit
01	Amino benzophenone	2.19	Kg
02	N-Chlorophthalimide	2.24	Kg
03	2-(Methylthio)acetamide	1.75	Kg
04	Triethylamine	1.69	Kg
05	Methylene dichloride	72.24	Kg
06	Sodium hydroxide	0.88	Kg
07	Ethyl Acetate	35	Kg
08	Raney-Nickel	21.89	Kg
09	Tetrahydrofuran	324	Kg
10	Hyflow	1	Kg
11	Isopropyl alcohol	240	Kg

CC total: 702.880 kg | MB additionally includes 20.000 kg water

MOLAR & PROPOSED CONSUMPTION | M0LES sheet

No.	Input component	MW	Moles	Ratio	MT/day*
01	Amino benzophenone	197.23	11.1	1	0.292
02	N-Chlorophthalimide	181.575	12.34	1.11	0.299
03	2-(Methylthio)acetamide	—	—	—	0.233
04	Triethylamine	101.19	16.7	1.51	0.225
05	Methylene dichloride	—	—	—	9.632
06	Sodium hydroxide	39.997	22	1.98	0.117
07	Ethyl Acetate	—	—	—	4.667
08	Raney-Nickel	—	—	—	2.919
09	Tetrahydrofuran	—	—	—	43.199
10	Hyflow	—	—	—	0.1333
11	Isopropyl alcohol	—	—	—	31.999

*** Proposed consumption as recorded; production basis to be verified.**

SOURCE WASTE SUMMARY | MB rows 74–79

Liquid effluent	Solid waste	Fugitive emissions
20.00 kg	22.00 kg	55.88 kg

TECHNICAL RECONCILIATION | NOT AN APPROVED GMP RECORD

- Stage A −1.490 kg; B −0.010 kg; C +1.500 kg (offset overall).
- Yield: reported 35.46%; 1.00 / 1.28 × 100 = 78.13% (if 1.28 kg).
- Evaporation rows total 105.88 kg vs source fugitive figure 55.88 kg.

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