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

MOXIFLOXACIN HYDROCHLORIDE

API MASS BALANCE / TECHNICAL MODEL

One-page consolidation of MB • FC • CC • RM • Moles

SOURCE: 25-Moxifloxacin(1).xlsx | REVIEW COPY

GROSS INPUT • MB	GROSS OUTPUT • MB	FINAL API	REPORTED YIELD
69.67344 kg	69.67264 kg	1.000 kg	45.87%

SOURCE PROCESS ROUTE | Flow Chart + MB

STAGE A
Reaction · Work-up · Filtration · Leaching · Filtration
Wet solid transfer: 2.080 kg

→

STAGE B
Reaction · Work-up · Distillation · Filtration · Isolation · Drying
Stage-B solid transfer: 1.260 kg

→

FINAL STAGE
Reaction · Filtration · Product isolation
Moxifloxacin HCl: 1.000 kg

MATERIAL BALANCE | Charged inputs · MB sheet

No.	Stg	Material / Intermediate	Qty	Unit
01	A	Gati ester	1.552	kg
02	A	Zinc chloride	0.01552	kg
03	A	Boric acid powder	0.32592	kg
04	A	Acetic anhydride	3.104	Kg
05	A	Water	13.184	Kg
06	A	Water	3.104	Kg
07	A	Water	10.864	Kg
08	A	Water	3.104	Kg
09	B	Solid (Wet) Stage-A	2.08	Kg
10	B	Methylene dichloride	7.28	Kg
11	B	Triethyl amine	0.56	Kg
12	B	Nonane	0.56	Kg
13	B	Purified Water	2.8	Kg
14	B	Methylene dichloride	0.72	Kg
15	B	Water	2.8	Kg
16	B	MDC	1.44	Kg
17	B	Methanol	0.4424	Kg
18	B	Methanol	3.168	kg
19	B	Charcoal	0.144	kg
20	B	Hyflo	0.032	Kg
21	B	Water	2.8	Kg
22	B	Conc HCl	0.848	kg
23	B	IPA	0.8736	kg
24	C	Stage-B	1.26	Kg
25	C	Isopropyl alcohol	3.12	Kg
26	C	Purified Water	0.4	Kg
27	C	Isopropyl alcohol	1.392	Kg
28	C	Purified Water	0.2	L
29	C	Acetone	1.5	Kg

MB RECORD TOTAL (includes 3.340 kg internal transfers) **69.67344 kg**

MATERIAL BALANCE | Reported output streams · MB sheet

No.	Stg	Output stream	Qty	Unit
01	A	Evopration loss	1.6	kg
02	A	Filtrate to ETP	21.28	kg
03	A	Evopration loss	0.368	kg
04	A	Filtate to ETP	13.6	kg
05	A	Solid (Wet)	2.08	Kg
06	B	Water to ETP	0.64	Kg
07	B	Evopration loss	0.32	kg
08	B	Aq. Layer-to ETP	2.88	Kg
09	B	Evopration loss	0.48	kg
10	B	Distillate	8.8	Kg
11	B	Evopration loss	0.32	kg
12	B	Filtrate	3.2	kg
13	B	Solid waste	0.176	Kg
14	B	Evopration loss	0.16	kg
15	B	Filtrate	4.32	kg
16	B	Evopration loss	0.32	kg
17	B	Solid	1.26	kg
18	C	Evopration loss	0.62864	kg
19	C	Filtrate	6.24	Kg
20	C	Solid	1	Kg

MB RECORD TOTAL (includes intermediate outputs) **69.67264 kg**

WASTE SUMMARY | MB rows 67-72 • Source treatment

Liquid effluent	38.40 kg	ETP
Solid waste	0.18 kg	Waste management
Fugitive emissions	4.20 kg	Scrubbing

CHARGE COMPOSITION | 13 source materials (CC / RM)

No.	Charge material	Amount	Unit
01	Gati ester	1.552	kg
02	Nonane	0.56	kg
03	Methylene dichloride	9.44	kg
04	TEA	0.56	kg
05	Zinc chloride	0.02	kg
06	Methanol	3.61	kg
07	Charcoal	0.144	kg
08	Conc HCl	0.848	kg
09	Acetone	1.5	kg
10	Boric acid powder	0.32592	kg
11	Acetic anhydride	3.104	Kg
12	Hyflo	0.032	Kg
13	Isopropyl alcohol	5.38	Kg

TOTAL CC CHARGES (water additions excluded) **27.07592 kg**

MOLAR & CONSUMPTION SCHEDULE | Moles sheet

No.	Component	MW	kg	Moles	Ratio	Proposed MT/day*
01	Gati ester	323.290	1.55200	4.7950	1	155
02	Nonane	—	0.56000	—	—	56
03	Methylene dichloride	—	9.44000	—	—	944
04	TEA	101.190	0.56000	5.5300	1.1500	56
05	Zinc chloride	136.286	0.02000	0.1500	0.0300	2
06	Methanol	—	3.61000	—	—	361
07	Charcoal	—	0.14400	—	—	14
08	Conc HCl	—	0.84800	—	—	85
09	Acetone	—	1.50000	—	—	150
10	Boric acid powder	61.831	0.32592	5.3400	1.1100	33
11	Acetic anhydride	102.090	3.10400	30.3653	6.3327	310
12	Hyflo	—	0.03200	—	—	3
13	Isopropyl alcohol	—	5.38000	—	—	538

* Proposed consumption figures reproduced as labelled in source; production basis requires verification.

TECHNICAL REVIEW • NOT AN APPROVED GMP RECORD

Yield: source 45.87% vs 70.92% if theoretical 1.41 means kg | Stage differences (outputs - inputs): A +3.67456, B -3.67200, Final -0.00336 kg | MB mixes 0.20 L with kg in its numeric total; confirm unit conversion, internal transfers and proposed MT/day basis.

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