DARIFENACINE HBr | API MASS BALANCE

PROCESS FLOW • MATERIAL CHARGES • MOLES • OUTPUTS • WASTE

One-page technical illustration based on five workbook sheets: MB / FC / RM / CC / Moles

SOURCE DATA ONLY • TECHNICAL REVIEW / NOT A GMP-APPROVED BATCH RECORD

82.560 kg	82.555 kg	1.000 kg	-0.005 kg	99.994%
MB GROSS INPUT	MB GROSS OUTPUT	FINAL API · MB	OUTPUT - INPUT	MB CLOSURE

PROCESS FLOW | FC + MB

Stage-A operations → final Darifenacin HBr

STAGE-A: Reaction → Filtration → Reaction → Distillation → Isolation → Filtration → Work-up / filtration → Reaction → Filtration → Drying → Stage-A · 1.30 kg

FINAL STAGE: Reaction / work-up → Filtration → Drying → Darifenacin HBr · 1.00 kg

RAW MATERIAL INPUTS | MB

18 stage-wise charge entries

ROW	INPUT MATERIAL	QTY (kg)	UNIT
2	3-(S)-(+)-(1-Carbamoyl-1,1- diphenylmethyl)pyrrolidine-L-(+)-tartrate	**1.500**	kg
3	5-(2-Bromoethyl)-2,3-dihydrobenzofuran	**1.000**	kg
4	Potassium crabonate	**2.385**	kg
5	Acetonitrile	**4.000**	kg
10	Aqueous Hydrobromic acid	**0.600**	kg
16	Ethyl Acetate	**20.000**	kg
22	Potassium Carbonate	**0.750**	kg
23	Water	**20.000**	kg
24	Ethyl Acetate	**13.000**	kg
31	Charcoal	**0.075**	kg
32	Hyflo	**1.000**	kg
40	Stage-A (internal transfer)	**1.300**	kg
41	Water	**7.500**	kg
42	Potassium carbonate	**0.250**	kg
43	Ethyl acetate	**7.800**	kg
44	Charcoal	**0.200**	kg
45	Hyflo	**1.000**	kg
46	Aq.HBr	**0.200**	kg
RECORDED MB INPUT TOTAL		**82.560 kg**	

OUTPUT STREAMS | MB

17 reported entries

ROW	OUTPUT / DISPOSITION	QTY (kg)	UNIT
7	Solid waste	**1.100**	kg
8	Evaporation loss	**0.200**	kg
13	Distillate	**3.500**	kg
14	Evaporation loss	**0.200**	kg
19	Filtrate	**19.000**	kg
20	Evaporation loss	**1.000**	kg
31	Filtrate to ETP	**30.000**	kg
32	Evaporation loss	**5.000**	kg
33	Solid waste	**1.075**	kg
35	Evaporation loss	**0.200**	kg
38	Stage-A (internal transfer)	**1.300**	kg
46	Water layer	**7.000**	kg
47	Solid waste	**1.200**	kg
48	Filtrate	**8.000**	kg
49	Evaporation loss	**2.280**	kg
52	Evaporation loss	**0.500**	kg
54	FINAL: Darifenacin HBr	**1.000**	kg
RECORDED MB OUTPUT TOTAL		**82.555 kg**	

CHARGE COMPOSITION | CC

8 materials

#	CC MATERIAL	kg
1	3-(S)-(+)-(1-Carbamoyl-1,1- diphenylmethyl)pyrrolidine-L-(+)-tartrate	**1.500**
2	5-(2-Bromoethyl)-2,3-dihydrobenzofuran	**1.000**
3	Potassium crabonate (source)	**3.385**
4	Acetonitrile	**4.000**
5	Aqueous Hydrobromic acid	**0.800**
6	Ethyl Acetate	**40.800**
7	Charcoal	**0.275**
8	Hyflo	**2.000**
CHARGE LIST TOTAL		**53.760 kg**

MOLES & DAILY CONSUMPTION | Moles

8 components

#	COMPONENT	kg	MW	Moles	Ratio	MT/day
1	3-(S)-(+)-(1-Carbamoyl-1,1-diphenylmethyl)pyrrolidine-L-(+)-tartrate	1.500	430.45	3.49	1.00	2.50
2	5-(2-Bromoethyl)-2,3-dihydrobenzofuran	1.000	227.10	4.40	1.00	1.67
3	Potassium crabonate	3.385	138.21	7.02	—	5.64
4	Acetonitrile	4.000	41.05	97.44	—	6.67
5	Aqueous Hydrobromic acid	0.800	—	—	—	1.33
6	Ethyl Acetate	40.800	—	—	—	68.00
7	Charcoal	0.275	—	—	—	0.46
8	Hyflo	2.000	—	—	—	3.33

Proposed MT/day figures are source values; batch / operating basis not verified.

RECONCILIATION / WASTE

Review required

- MB input 82.560 vs output 82.555 kg (−0.005 kg).
- Stage-A grouped: 64.310 in / 62.575 out; final group: 18.250 in / 19.980 out.
- CC 53.760 kg + MB water 27.500 kg + internal transfer 1.300 kg = 82.560 kg.
- Reported yields 84.74% and 57.14%; theoretical entries 1.09 / 1.17 kg. Confirm bases.
- Moles sheet: potassium carbonate lists 7.02 mol; 3.385 kg / 138.205 g/mol ≈ 24.49 mol.
- Waste table (kg) shows: liquid 4.6 / 37; solid 1.1 / 2.2; gas 1.7 / 9.3; headings unclear.
- MB itemised solid streams total 3.375 kg; evaporation streams total 9.380 kg.

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