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

CLOPIDOGREL BISULFATE

API MASS BALANCE | SOURCE-BASED TECHNICAL POSTER

All five workbook sheets: MB • FC • CC • RM • Moles

1.00 kg
FINAL API OUTPUT

MB TOTAL INPUT
4.350 kg
MB!C24

MB TOTAL OUTPUT
4.350 kg
MB!I24

REPORTED YIELD
82.64%
MB!C28

THEORETICAL YIELD
1.210 kg
MB!C26

MANUFACTURING PROCESS FLOW

FC + MB | source terminology

01 **REACTION 1** — Couple amine HCl, paraformaldehyde, water
02 **REACTION 2** — Methanol and sulfuric acid
03 **FILTRATION** — Methanol charge; filtrate to ETP
04 **DRYING** — Evaporation loss
05 **MILLING & SIFTING** — Final processing
06 **FINAL API** — Clopidogrel Bisulfate 1.00 kg

MB | INPUT MATERIALS

Mass-balance sheet — kg

SR.	MATERIAL / CHARGE	QTY (kg)	SOURCE
1	Couple amine HCl	1.000	MB row 2
2	Paraformaldehyde	0.100	MB row 3
3	Water	2.000	MB row 4
4	Methanol	1.000	MB row 6
5	Sulfuric acid	0.150	MB row 7
6	Methanol	0.100	MB row 10

SUM OF INDIVIDUAL CHARGES **4.350 kg**

MB | RECORDED OUTPUT STREAMS

Product, effluent and evaporation

SR.	OUTPUT	QUANTITY
01	Filtration evaporation loss	0.250 kg
02	Filtrate to ETP (liquid)	2.100 kg
03	Drying evaporation loss	1.000 kg
04	Clopidogrel Bisulfate (final)	1.000 kg

CC + RM | RAW-MATERIAL MASTER

Recorded CC charges (not full MB basis)

SR.	RAW MATERIAL	CC QTY
1	Couple amine HCl	1.000 kg
2	Sulfuric acid	0.150 kg
3	Paraformaldehyde	0.100 kg
4	Methanol	0.100 kg

CC recorded charge total: **1.350 kg** RM names match CC (4 entries)

MOLES | MOLECULAR / DAILY CONSUMPTION SCHEDULE

As recorded in Moles sheet

No.	MATERIAL	MW	kg	MOLES	RATIO	ROLE	EXIST	PROP. MT/d	TOTAL MT/d
1	Couple amine HCl	346.27	1.000	2.888	1	Starting material	o	33.3333	33.3333
2	Sulfuric acid	98.079	0.150	1.53	0.53	Reagent	o	4.9999	4.9999
3	Paraformaldehyde	—	0.100	3.33	1.15	Reagent	o	3.3333	3.3333
4	Methanol	—	0.100	—	—	Solvent	o	3.3333	3.3333

SOURCE RECONCILIATION / VERIFICATION BEFORE GMP APPROVAL

MB inputs = outputs = 4.350 kg, yield = (1.000 / 1.210) × 100 = 82.64%. CC sum = 1.350 kg versus MB charges 4.350 kg: CC omits 2.000 kg water and 1.000 kg methanol. Moles “existing consumption” cells contain letter “o”; proposed MT/day units and batch basis require confirmation. MB waste: effluent 2.100 kg (ETP), solid Nil, fugitive emissions 1.250 kg (source treatment “Scrubbing”).

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+91 8667589984 • info@ishasgmp.com • www.ishasgmp.com