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

API MATERIAL BALANCE | TECHNICAL ILLUSTRATION

CLONIDINE HYDROCHLORIDE

Source-based model • All 7 Excel worksheets considered • Not an approved batch record

FINAL API PRODUCT
1.000 kg

GROSS INPUT • MB	GROSS OUTPUT • MB	MASS CLOSURE	THEORETICAL YIELD	YIELD • SOURCE / CALC.
296.807 kg	296.810 kg	100.001%	1.64 kg	17.85% / 60.98%

MANUFACTURING PROCESS ROUTE | FC + MB sheets

01 STAGE A
Reaction → distillation → aqueous work-up → filtration → drying
Stage-A solid: 4.000 kg

→

02 STAGE B
Reaction → distillation → filtration → extraction → isolation
Stage-B solid: 1.200 kg

→

03 FINAL STAGE
Reaction / acid treatment → filtration → drying → milling & sifting
Final API: 1.000 kg

RAW MATERIALS • CC + RM + MOLES (14 ENTRIES)

NO.	RAW MATERIAL	CHARGE (kg)	RATIO	PROP. MT/DAY
1	**1,4 dichlorobenzene**	3.400	1.00	0.238
2	**Benzoyl Chloride**	3.540	—	0.248
3	**Ammonium Thiocyanate**	2.393	1.50	0.167
4	**Acetone**	29.580	—	2.071
5	**Sodium hydroxide**	3.488	4.16	0.244
6	**Conc HCl**	10.010	—	0.701
7	**Methanol**	29.620	—	2.073
8	**Methyl Iodide**	3.600	1.21	0.252
9	**Isoamyl alcohol**	31.370	—	2.196
10	**Ethylene diamine**	1.886	1.50	0.132
11	**Ethyl acetate**	53.669	—	3.757
12	**Potassium carbonate**	3.741	1.29	0.262
13	**Activated charcoal**	0.112	—	0.008
14	**Hyflo**	0.560	—	0.039

CC total: 176.969 kg (excludes process-water charges). Moles total proposed: 12.388 MT/day.

OUTPUTS • MB (GROSS STREAMS)

Distillates / solvent streams	109.200
Aqueous layers to ETP	127.500
Filtrate to ETP	11.000
Other filtrates	31.530
Evaporation losses	10.580
Stage A / B intermediates	5.200
Solid waste	0.800
Final Clonidine HCl	**1.000**

GROSS OUTPUT TOTAL **296.810 kg**
Includes 4.0 + 1.2 kg internal transfers.

SOURCE REVIEW • RECONCILIATION

01 MB gross totals differ by +0.003 kg (output − input). Near-closure does not validate individual stages.

02 Yield reported as 17.85% vs 60.98% from 1.000 / 1.640 kg theoretical product.

03 Isoamyl alcohol: CC / Moles 31.370 kg; MB 16.886 kg. MB separately lists 14.841 kg isopropyl alcohol.

04 Separate “material balance sheet”: 56.375 kg input vs 56.380 kg output; different material-charge basis.

05 MB shows 0.800 kg “Solid Waste”; bottom waste schedule states solid waste “Nil”.

06 CC total excludes process water; source flow charts are not identical to MB stage details.

ADDITIONAL BALANCE SHEET • SEPARATE BASIS

Input **56.375 kg**
Output **56.380 kg**

“material balance sheet” + “Flow chart”: independent source presentation; includes final 1.000 kg API but is not merged into the main MB total.

WASTE / RECOVERY SCHEDULE • MB

Liquid effluent to ETP	**138.50 kg**
Fugitive emissions	**10.58 kg**
Methanol recovery	**28.50 kg**

Solid waste conflict: “Nil” in waste schedule / 0.80 kg in MB.

DOCUMENT STATUS & DATA PROVENANCE

Sheets reviewed: material balance sheet, Flow chart, MB, FC, CC, RM and Moles.

For technical illustration and client review only. Verify input charges, stage transfers, losses, yields and waste classifications before any GMP approval.

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