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

PANTOPRAZOLE API

MASS BALANCE | SOURCE-DERIVED TECHNICAL POSTER

2 SHEETS • 1 DETAILED STAGE

ITEMISED INPUT	ITEMISED OUTPUT	SHEET OUTPUT TOTAL	"PRODUCT" STREAM	SUMMARY BATCH REF.
5,591.01 kg	5,591.01 kg	5,591.00 kg	150.00 kg	500.00 kg

RECORDED PROCESS SEQUENCE | Summary worksheet, Stage 1

Reaction mass maintaining shown in PANTOPRAZOLE

01 MATERIAL CHARGES → 02 REACTION → 03 LAYER SEPARATION → 04 DISTILLATION → 05 OUTPUT STREAMS

MATERIAL INPUTS | PANTOPRAZOLE!C48:E55

8 recorded material rows

ROW	SOURCE MATERIAL / STREAM	kg	kg/kg*
48	2-Chloromethyl-3,4-dimethoxy pyridine HCl	**100.00**	0.2
49	5-Difluoromethoxy-2- Mercapto Benzimidazole	**96.50**	0.193
50	Sodium Hydroxide	**52.35**	0.1047
51	Acetone	**400.00**	0.8
52	Water	**4,003.66**	8.00732
53	Hydrogen Peroxide	**32.00**	0.064
54	Pantoprazole	**156.50**	0.313
55	IPA	**750.00**	1.5

* Source "quantity per kg of output" values are calculated on a 500 kg denominator.

ITEMISED TOTAL **5,591.01 kg**

MATERIAL OUTPUTS | PANTOPRAZOLE!H48:J53

6 recorded disposition rows

ROW	SOURCE MATERIAL / STREAM	kg	kg/kg*
48	Acetone (Recovered)	**392.00**	0.784
49	Wastewater (To ETP)	**4,104.09**	8.20818
50	IPA (Recovered)	**735.00**	1.47
51	Evaporation Loss	**156.48**	0.31296
52	Product	**150.00**	0.3
53	Process Residue	**53.44**	0.10688

* Source-normalised values also use 500 kg, not the 150 kg "Product" stream.

ITEMISED TOTAL **5,591.01 kg**

MATERIAL DISPOSITION | kg



Wastewater (ETP)	**4,104.09 kg**
Recovered solvents	**1,127.00 kg**
Evaporation + residue	**209.92 kg**
Product	**150.00 kg**

WORKBOOK CROSS-CHECK

Source sheets	**Summary; PANTOPRAZOLE**
Summary batch reference	**500 kg (basis not linked)**
Stage-1 Total Volume	**5,591 (unit not specified)**
Input total shown	**5,591.01 kg**
Output total shown	**5,591 kg (rounded)**
Itemised closure	**100.000% (5,591.01 / 5,591.01)**

TECHNICAL REVIEW / EXCEPTIONS

- **BROKEN FORMULA**
  Summary!F6 displays #REF! for Distillation.
- **BATCH / PRODUCT BASIS**
  500 kg summary batch reference vs. 150 kg "Product" output; link not established.
- **MATERIAL CLASSIFICATION**
  Pantoprazole is also listed as an input (156.50 kg); confirm meaning and disposition.
- **STAGE & NORMALISATION**
  Detailed balance covers Stage 1; Stage-4 shows 500 without explanation. Per-kg values use 500 as denominator.

ISHA'S GMP CONSULTANCY PVT. LTD. | INDIA
+91 86675 89984 • info@ishasgmp.com • www.ishasgmp.com
© 2026 ISHA'S GMP Consultancy Pvt. Ltd. All rights reserved. Unauthorised reproduction prohibited.

CLIENT-SUPPLIED DATA • TECHNICAL REVIEW ONLY
Reconcile recorded figures and source labels before GMP approval.