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

FEBUXOSTAT

API MATERIAL BALANCE | SINGLE-BATCH TECHNICAL REVIEW

Based on five worksheets: Material Balance / Flow Chart / Raw Materials / CC / Moles

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TOTAL INPUT (MB)	TOTAL OUTPUT (MB)	FINAL API OUTPUT	CALCULATED CLOSURE	REPORTED YIELD
47.3125 kg	47.3100 kg	1.0000 kg	99.9947%	88.8%

MANUFACTURING PROCESS & MATERIAL MOVEMENT

From Flow Chart and Material Balance sheets

01	02	03	04	05	06	07	08
REACTION	FILTRATION	ISOLATION	FILTRATION	LEACHING	FILTRATION	DRYING	FINAL API
KSM, THF, MeOH, LiOH, PW	Hyflo, MeOH / solids	PW, conc. HCl	PW / filtrate	PW wash	PW / ETP filtrate	Volatiles removed	Febuxostat 1.000 kg

MATERIAL INPUTS - 12 CHARGE ENTRIES

MB worksheet | original quantities

NO.	INPUT MATERIAL / OPERATION	QTY (kg)
01	Ethyl-2(3-cyano)-4 Isobutoxyphenyl} 4-methyl-5-Thiazole carboxylate.	1.2500
02	Tetrahydrofuranz [source spelling]	5.5000
03	Methanol - Lot 01	7.3000
04	Lithium hydroxide	0.2625
05	Purified water - Lot 01	6.2500
06	Hyflo	1.0000
07	Methanol (filtration charge)	1.0000
08	Purified water (isolation)	6.5000
09	Concentrated HCl	0.7500
10	Purified water (filtration)	5.0000
11	Purified water (leaching)	7.5000
12	Purified water (final filtration)	5.0000
SOURCE TOTAL		**47.3125 kg**

OUTPUT STREAMS - 9 REPORTED ENTRIES

MB worksheet | source order preserved

NO.	OUTPUT STREAM / DISPOSITION	QTY (kg)
01	Evaporation loss - filtration	1.0833
02	Solid waste	1.0000
03	Aqueous filtrate for ETP	15.0000
04	Filtrate - disposition unspecified	16.0000
05	Evaporation loss - filtration	0.5900
06	Filtrate for ETP - final filtration	10.8333
07	Evaporation loss - final filtration	0.9700
08	Evaporation loss - drying	0.8333
09	Febuxostat final API	1.0000
SOURCE TOTAL (ROUNDED)		**47.3100 kg**

CHARGE COMPOSITION & MATERIAL REGISTER

CC + Raw Materials sheets

NO.	REGISTERED MATERIAL	CC (kg)
1	Starting material (KSM)	1.2500
2	Tetrahydrofuranz [as recorded]	5.5000
3	Lithium hydroxide	0.2625
4	Hyflo	1.0000
5	Methanol	8.3000
6	Conc. HCl	0.7500

CC charges = 17.0625 kg | MB purified water additions = 30.2500 kg

MOLAR & PROPOSED CONSUMPTION DATA

Moles sheet | figures as provided

NO.	COMPONENT	MW	MOLES	RATIO	MT/DAY*
1	Starting material	344.43	3.63	1.00	41.66
2	Tetrahydrofuran	-	-	-	183.33
3	Lithium hydroxide	23.95	10.85	2.99	8.66
4	Hyflo	-	-	-	33.33
5	Methanol	-	-	-	276.6666
6	Conc. HCl	-	-	-	24.9999

* Consumption-unit and production-rate basis require verification.

WASTE & ENVIRONMENTAL ACCOUNTING

Material Balance sheet - waste schedule

WASTE / DESTINATION	QTY / BATCH	REPORTED RATE
Liquid effluent - ETP	25.83 kg	0.861 MT/day
Solid waste - disposal	1.00 kg	0.033 MT/day
Fugitive emissions - scrubbing	3.47 kg	0.116 MT/day

TECHNICAL RECONCILIATION & SOURCE-REVIEW FINDINGS

Open items - not GMP approved

- Overall closure: 47.3100 / 47.3125 = 99.9947% (-0.0025 kg).
- Yield: 88.8% reported; 1.00 / 0.90 = 111.11% if theoretical figure is kg.
- THF is called "Tetrahydrofuranz" in MB/CC/RM but "Tetrahydrofuran" in FC/Moles.
- Generic filtrate (16.00 kg) has no stated disposal route; molar/day basis is unverified.

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ILLUSTRATIVE TECHNICAL REVIEW - CLIENT-SUPPLIED WORKBOOK DATA; RECONCILE ALL FLAGS BEFORE GMP APPROVAL.