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

OLMESARTAN

API MASS BALANCE | TECHNICAL ILLUSTRATION

Based on client-supplied Excel workbook · All 5 worksheets reviewed

DOCUMENT TYPE
REVIEW DRAFT
NOT A RELEASED GMP RECORD

TOTAL INPUT	TOTAL OUTPUT	FINAL API	BALANCE CLOSURE	REPORTED YIELD
154.380 kg	154.380 kg	1.000 kg	100.00%	79.36%

MANUFACTURING PROCESS | RECORDED FLOW CHART

01 REACTION
Trityl Olmesartan
Acetic acid + MDC

02 WORK-UP & DISTILLATION
DM water / charcoal / Hyflo

03 FILTRATION
Ethyl acetate charge

04 DRYING
Evaporation losses

05 FINAL API
Olmesartan solid: 1.000 kg

MATERIAL CHARGE | CC + MB

No.	Material / Reagent	Qty (kg)	Source
01	Trityl Olmesartan	1.810	CC / MB
02	Acetic acid	6.180	CC / MB
03	MDC (dichloromethane)	36.300	CC / MB
04	Activated charcoal	0.090	CC / MB
05	Ethyl acetate	54.500	CC / MB
06	Hyflo	1.000	CC / MB
07	Demineralised water	54.500	MB only
	TOTAL CHARGE	**154.380**	**kg**

OUTPUT STREAMS | MATERIAL BALANCE

No.	Output / Disposition	Qty (kg)
01	Distillate (MDC recovery stated)	30.000
02	Aqueous layer to ETP	60.000
03	Evaporation loss – operation 1	2.280
04	Solid waste	1.100
05	Filtrate – disposition unconfirmed	54.000
06	Evaporation loss – operation 2	4.000
07	Evaporation loss – drying	2.000
08	Olmesartan (solid API)	1.000
	TOTAL OUTPUT	**154.380**

MOLAR CALCULATIONS & PROPOSED CONSUMPTION | REPORTED VALUES FROM "MOLES" SHEET

No.	Input component	MW	Amount kg	Moles*	Ratio*	Prop. MT/day*	Remark
01	Trityl Olmesartan	800	1.810	226.25	1.00	7.54	Starting material
02	Acetic acid	60.05	6.180	102.91	0.46	25.75	Reagent
03	MDC	—	36.300	—	—	151.25	Solvent
04	Activated charcoal	—	0.090	—	—	0.38	Process aid
05	Ethyl acetate	—	54.500	—	—	227.08	Solvent
06	Hyflo	—	1.000	—	—	4.17	Process aid

WASTE & RECOVERY | MB SHEET

Liquid effluent to ETP	**60.000 kg**
Solid waste	**1.100 kg**
Fugitive emissions (2.28 + 4 + 2)	**8.280 kg**
MDC recovered (reported)	**30.000 kg**

GMP SOURCE REVIEW | TO VERIFY BEFORE APPROVAL

- Yield: 79.36% reported; 1.000 / 0.697 × 100 = 143.47% if theoretical yield is in kg.
- Moles: 226.25 reported for Trityl Olmesartan; 1.81 kg / (800 g/mol) = 2.2625 mol.
- Filtrate 54.000 kg: confirm recovery, reuse, disposal or internal-transfer disposition.
- Proposed MT/day values: verify production basis, scaling and units; CC omits 54.50 kg DM water.

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