

Calculation to show the content of ethanol in **BIOMOL 100MCG/DOSE HFA METERED DOSE INHALER**

Batch Formula

Name of Material	Specification	Function	Quantity/Dose(mg)	Quantity/Can (g)	Batch Quantity
Salbutamol Sulphate (Micronized)	BP/Ph. Eur	Active	0.12000	0.0300	0.30000
Oleic Acid (Vegetable Source)	USNF	Surfactant	0.00864	0.00216	0.0216
Dehydrated Alcohol	USP	Vehicle	4.32000	1.08000	10.8000
1,1,1,2-Tetrafluoroethane (HFA 134a)	Ph. Gr.	Propellant	53.15137	13.28784	132.87800

(Table No. 1: Ref_ MFR/BM/03-00 and MFR/BM/01-00)

Based on the above batch manufacturing formula, please note;

- The content of ethanol /dehydrated alcohol per actuation (dose) = 4.32000 mg
= **0.00432 g** (conversion of mg to g x1000 – 4.32000mg x 1000)
- Total quantity per dose of all material = 57.59 mg
- Percentage of Ethanol = (4.32mg/57.59mg) X 100
= **7.5 % w/w**

Hence, the total content of ethanol per actuation is 0.00432g based on the above calculation.