2.1.P.3.2 Batch formula

2.1.P.3.2.1 Batch size

Industrial batch size of Ivermectin MEDITOP 3 mg tablet is 100 000 tablets; 6 000 g material.

2.1.P.3.2.2 Manufacturing formula

Following compositions were used to produce batches of tablets.

Component	Quantity (mg/tablet)	Quantity (g/batch) 100 000 tablets	Quality
Ivermectin*	3.00	300.00	Ph.Eur.
Cellulose, Microcrystalline I.	10.00	1 000.00	Ph.Eur.
Cellulose, Microcrystalline II.*	43.44	4 344.00	Ph.Eur.
Corn Starch, pregelatinized	3.00	300.00	Ph.Eur.
Citric acid anhydrous	0.20	20.00	Ph.Eur.
Magnesium stearate	0.30	30.00	Ph.Eur.
Butilhydroxyanisole	0.06	6.00	Ph.Eur.
Nominal weight of tablets	**60.00**	**6 000.00**	

* The amount of ivermectin must be corrected for the “as is” (Ivermecin H2B1b+H2B1) of ivermectin and 3% overages is used. The nominal weight is corrected by reducing the weight of the Microcrystalline cellulose.

Amount of ivermectin:
$X = 300 / (Y / 100) \times 1.03$

where X is the actual amount of ivermectin to be measured, Y is the “as is” of ivermectin (%) (based on quality control measurements of MEDITOP).

Amount of MCC:
$Z = 4344 - (X-300)$
where Z is the amount of Microcrystalline cellulose to be measured and X is the actual amount of ivermectin to be measured.