

2.1.P.1 Description and Composition of the Drug Product

1 Products description

The product is presented as follows:

White or almost white, round flat-faced tablet of bevelled edge on both sides with marked “I” on one side and without sign on the other side. The dimensions: diameter 6.0 ± 0.2 mm and height 1.5 - 2.2 mm.

2 Composition

The composition of tablets, the quality standard and the role of ingredients are shown in the following tables:

Material	Quantity (mg)	Function	Quality
<i>Excipients of tablet</i>			
Ivermectin	3.00*	Active substance	Ph.Eur.
Cellulose, microcrystalline I.	10.00	diluent	Ph.Eur.
Cellulose, microcrystalline II.	43.44**	diluent	Ph.Eur.
Corn Starch, pregelatinized	3.00	disintegrant	Ph.Eur.
Magnesium-stearate	0.30	lubricant	Ph.Eur.
Citric acid (anhydrous)	0.20	antioxidant, buffering agent	Ph.Eur.
Butyl hydroxy anisole	0.06	antioxidant	Ph.Eur.
<i>Nominal weight of tablet</i>	<i>60.00</i>		

* calculated on measured “as is” of active substance (based on quality control measurements of MEDITOP), +3% overages

** amount of microcrystalline cellulose is reduced by the amount of ivermectin overages

3 Description of Accompanying Reconstitution Diluent(s)

Not applicable.

4 Container Closure System

- Alu//Alu blister

For detailed information, see in part *2.1.P.7 Container Closure System*.