

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

1 Products description

The product is presented as follows:

Hydroxychloroquine MEDITOP 200 mg film-coated tablets are white or almost white, round, biconvex tablets with plain surfaces on both sides. The dimensions: diameter 9.0 ± 0.2 mm and height 4.0 - 4.7 mm.

Composition

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

Component	Quantity (mg/tablet)	Percentage (%)	Function	Quality
Hydroxychloroquine sulfate	200.0	63.5	active ingredient	Ph. Eur.
Lactose monohydrate	30.0	9.5	diluent, binder	Ph. Eur.
Maize starch	69.5	22.1	disintegrant	Ph. Eur.
Povidone	3.5	1.1	binder	Ph. Eur.
Magnesium stearate	3.0	0.9	lubricant	Ph. Eur.
Purified water*	14.0	-	solvent	Ph. Eur.
Opadry OY-L-28900	9.0	2.9	film-coating	Colorcon Ltd. in Haus
Purified water*	51.0	-	solvent	Ph. Eur.
Nominal weight of a film-coated tablet	315.0			

*Purified water is eliminated during the manufacturing and film-coating process

Quantitative formula of Opadry OY-L-28900:

Ingredient	Quantity % w/w	Grade	E Number	Quality
Lactose monohydrate	36.0	-	-	Ph. Eur.
HPMC 2910/ Hypromellose	28.0	15 mPas	E464	Ph. Eur.
Titanium dioxide	26.0	-	E171	Ph. Eur.
Macrogol	10.0	MW 4000	E1521	Ph. Eur.

2 Description of Accompanying Reconstitution Diluent(s)

Not applicable.

3 Container Closure System

HDPE flacon + PP cap

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