

2.1.P.3.2 Batch formula**2.1.P.3.2.1 Batch size**

Industrial batch size of Hydroxychloroquine MEDITOP 200 mg film-coated tablet is 100 000 tablets; 31 500 g material.

2.1.P.3.2.2 Manufacturing formula

Following compositions were used to produce batch of film-coated tablets.

Component	Quantity (mg/tablet)	Quantity (g/batch)	Function	Quality
Hydroxychloroquine sulfate	200.0	20 000	active ingredient	Ph. Eur.
Lactose monohydrate	30.0	3 000	diluent, binder	Ph. Eur.
Maize starch	69.5	6 950	disintegrant	Ph. Eur.
Povidone	3.5	350	binder	Ph. Eur.
Magnesium stearate	3.0	300	lubricant	Ph. Eur.
Purified water*	14.0	1 400	solvent	Ph. Eur.
Opadry OY-L-28900	9.0	900	film-coating	Colorcon Ltd. in Haus
Purified water*	51.0	5 100	solvent	Ph. Eur.
Nominal weight of a film-coated tablet	315.0	31 500		

*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.