

2.0 Other Information

The formulation of clopidogrel bisulfate tablets (75 mg) for use in this blinded trial is identical (with the exception of identity markings) to PLAVIX® Tablets (75 mg) currently marketed in Canada. Sanofi has provided a letter of confirmation (see Section 1.2.11).

A list of ingredients used in the preparation of placebo tablets is provided below:

2.1.P PLACEBO

2.1.P.1 Description and composition of the placebo

The placebo is available as pink round slightly biconvex not engraved film-coated tablets.

Table (2.1.P.1) 1 - Composition of the placebo tablets

Name of ingredients	Quantity (mg)	Reference to standards
Core :		
Calcium hydrogen phosphate	130.45	Ph. Eur.
Microcrystalline cellulose (low water content, 90 µm)	129.13	Ph. Eur. and in-house specifications
Maize starch	29.00	NF
Magnesium stearate ^a	1.42	NF
Core mass	290	
Coating :		
Powder for coating suspension (Opadry® 32K14834 type II) ^{b c d}	7.5	In-house monograph
Carnauba wax	Traces	Ph. Eur.
Coating solvent eliminated during manufacture : Purified water		Ph. Eur.
Film-coated tablet mass	297.5	

^a : Vegetable origin

^b : Opadry® 32K14834 type is the same coating agent as the one used in SR25990C tablets (Plavix® / Iscover®)

^c : Component is BSE free, see certificate in Section 2.1.A.2.

^d : Composition: lactose (Ph. Eur.), hypromellose (Ph. Eur.), titanium dioxide (Ph. Eur.), glycerol triacetate (Ph. Eur.), red iron oxide (NF)