

P.1 DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT

Description

Stelbatalol is formulated as an immediate-release, oral, solid dosage form in strengths of 20 mg of the free base equivalent. The 20 mg strength is presented as an orange, round, film coated tablet, debossed with “175” on one side.

Composition

Qualitative and Quantitative Composition

Components	Quantity (mg per unit)	Percentage (% w/w)	Function	Quality Standard
Active drug salt	15.2	97.9%	Active	In-house
Mannitol	145.0	1%	Diluent	NF / Ph Eur
Maize starch	13.8	0.5%	Disintegrant	NF / Ph Eur
Calcium carboxymethylcellulose	4.0	0.25%	Disintegrant	NF / Ph Eur
Magnesium stearate	2.0	0.35%	Lubricant	NF / Ph Eur
Nominal tablet Weight	180			

Container closure system

The commercial primary pack is a high-density polyethylene (HDPE) bottle with a child-resistant polypropylene (PP) screw cap. Inside the bottle is a desiccant, containing silica gel. Induction seal membranes provide additional tamper evidence.

For further details of the packaging components, see ‘P.7 Container Closure System for Drug Product’.