


DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT
S 6490
Light-green film-coated tablet containing 5 mg of drug substance

1. DESCRIPTION OF THE DRUG PRODUCT

The drug product is a breakable light-green rod-shaped film-coated tablet, 8 mm long and 4 mm wide with a curvature radius of 3.5 mm, scored on both edges and engraved with  on one face, containing 5 mg of drug substance and finished to a mass of 92 mg.
Standard Term: FILM-COATED TABLET

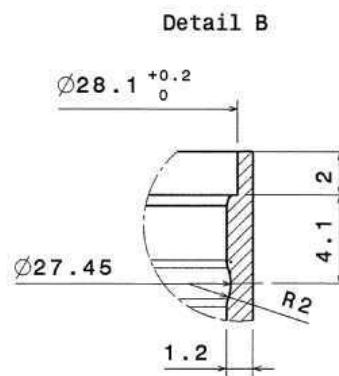
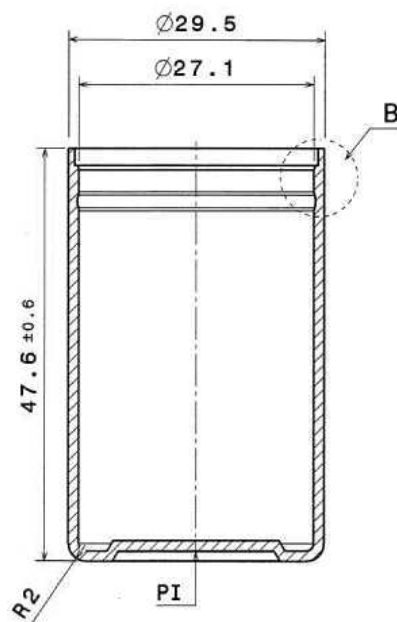
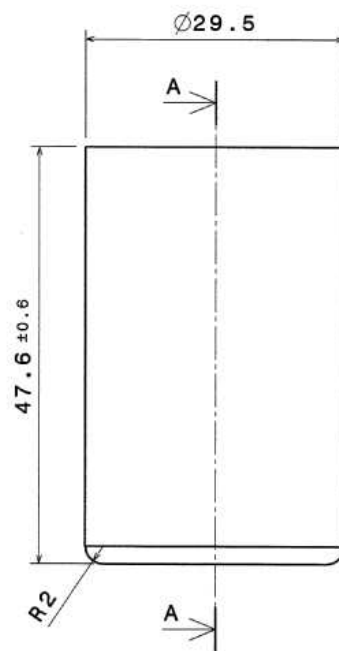
2. COMPOSITION

Ingredients	Amount (mg)	Role	Specification
TABLET			
S 9490-6 corresponding to 3.395 mg of Perindopril	5	Drug substance	In House monograph
Lactose monohydrate	72.58	Diluent	European Pharmacopoeia
Magnesium stearate	0.45	Lubricant	European Pharmacopoeia
Maltodextrin	9	Binding agent	European Pharmacopoeia
Silica, colloidal hydrophobic	0.27	Flow agent	In House monograph
Sodium starch glycolate (type A)	2.7	Disintegrant	European Pharmacopoeia
FILM-COATING			
Premix for light-green colour coating ¹	1.931	Film-coating agent	In House monograph
Macrogol 6000	0.069	Smoothing agent	European Pharmacopoeia
For a film-coated tablet with a finished mass of	92		

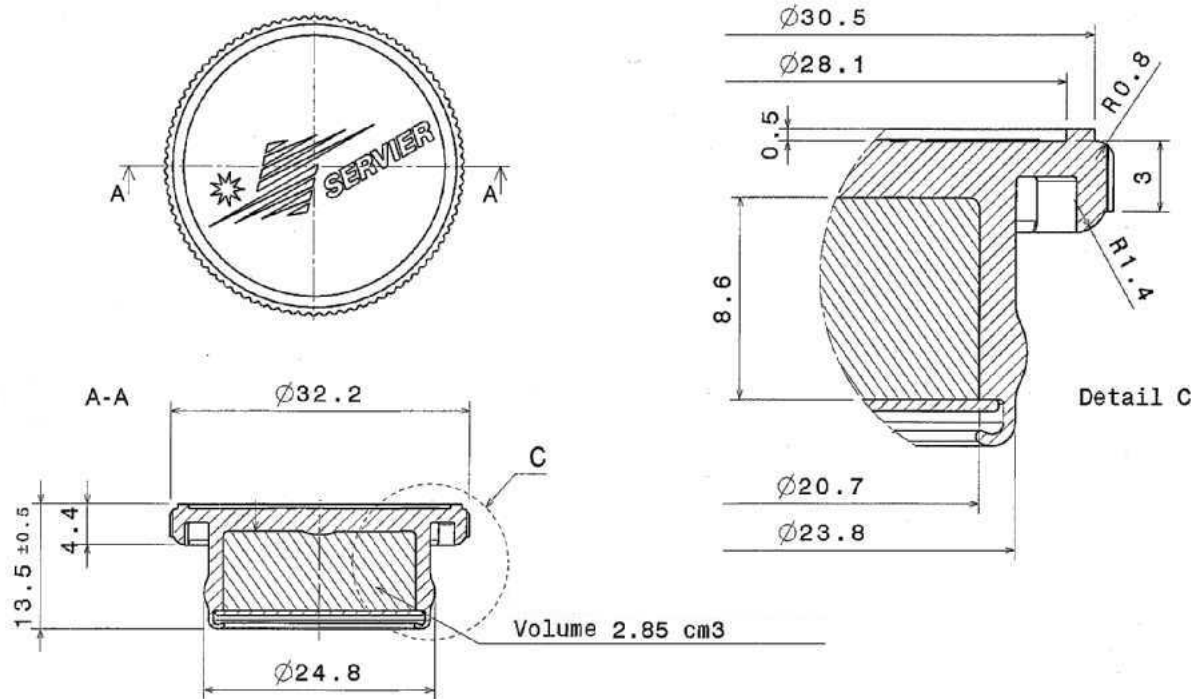
3. TYPE OF CONTAINER

The film-coated tablets are packed in a polypropylene white tube equipped with a low density polyethylene flow reducer and a low density polyethylene green opaque stopper containing 2.0 g of white desiccant gel. Each tablet container contains 30 film-coated tablets.
The dimensions are given in millimetres in the following diagrams.

¹ Ingredients of dry premix for light-green colour coating SEPIFILM 4193 (glycerol 4.5 %, hypromellose 74.8 %, copper chlorophyllin (E141 ii) 0.072 %, macrogol 6000 1.8 %, magnesium stearate 4.5 %, titanium dioxide (E171) 14.328 %)

Polypropylene tube - Face

Low density polyethylene stopper – Face and upper view



Low density polyethylene flow reducer - Face and upper view

