Clomid 50 mg tablets are beige, round, flat faced bevelled edge tablet, approximately 10 mm in diameter. "M" in double circle is embossed on one side and the tablet is scored on the other side.

The qualitative and quantitative composition of one tablet is reported in the following table.

Name of ingredients	Quantity (mg/tablet)	Function	References
Drug substance			
Clomifene citrate	50,0	Drug substance	Ph. Eur. current edition
Excipients			
Yellow iron oxide (E 172)	0,248	Colouring agent	French Ph.
Lactose monohydrate	67,50	Filler	Ph. Eur. current edition
Maize starch	106,752	Disaggregant	Ph. Eur. current edition
Pre-gelatinised starch	25,0	Disaggregant	Ph. Eur. current edition
Sucrose	67,50	Sweetener	Ph. Eur. current edition
Magnesium stearate	3,00	Lubricant	Ph. Eur. current edition

The tablets are packed in conventional blisters made of transparent PVC welded on an aluminium foil (PVC 250 micron/Al 20 micron).

2.3.P.2 Pharmaceutical Development

Components of the Drug Product

The product is an oral formulation which contains Clomiphene citrate as the drug substances.
The drug substance is described in European Pharmacopoeia and the main information is reported in *Module 3.2.S.*
No incompatibilities between the active components and any of the excipients were encountered during development studies or stability testing.

Excipients

Name of excipient	Function	Reference
Yellow iron oxide (E 172)	Colouring agent	French Ph. curr.ed.
Lactose monohydrate	Filler	Ph. Eur. curr.ed.
Maize starch	Disaggregate	Ph. Eur. curr.ed.
Pre-gelatinised starch	Disaggregate	Ph. Eur. curr.ed.
Sucrose	Sweetener	Ph. Eur. curr.ed.
Magnesium Stearate	Lubricant	Ph. Eur. curr.ed.
Purified water	Solvent	Ph. Eur. curr.ed.

Drug Product

Clomid tablets has been marketed from many years.
The aim of the formulation development program was to create a formulation meeting the requirements for tablets described in the corresponding monographs of the European Pharmacopoeia as well as corresponding to generally accepted quality determining characteristics for drug products.

Container Closure System

The tablets are packaged in blister consisting of an aluminium foil and a transparent foil of PVC. Further details are provided in *Section 3.2.P.7 Container Closure System.*

This primary packaging material is a standard type of container-closure system for solid dosage forms.

The stability data confirmed that the primary packaging material chosen was adequate for the good conservation for the validity period (See *Section 3.2.P.8.3 Stability Data*).