

3.2.P.1 Composition of the Drug Product

3.2.P.1.1 Quantitative Composition and Function of Each Component

The following table provides the quantitative composition of each component in the generic drug product, including solvents, processing aids, and auxiliary substances used during the manufacture:

Component	Function	Amount per Tablet (mg)	Percentage (%) w/w
Active Ingredient	Active pharmaceutical	50	10
Lactose Monohydrate	Diluent	150	30
Microcrystalline Cellulose	Binder	100	20
Croscarmellose Sodium	Disintegrant	20	4
Magnesium Stearate	Lubricant	10	2
Hypromellose	Coating Agent	70	14
Polyethylene Glycol	Plasticizer (in coating)	5	1
Colloidal Silicon Dioxide	Glidant	1	0.2
Purified Water (removed completely during process)	Solvent	100	0
Ethanol (removed completely during the process)	Solvent	100	0
Sodium Lauryl Sulfate	Surfactant	4	0.8
<i>Total</i>		<i>410</i>	<i>100</i>

3.2.P.1.2 Physical Description and Comparison to RLD

The generic drug product is a white, round, biconvex tablet with a diameter of 8 mm and a thickness of 3 mm. The tablet is scored on one side to facilitate breaking into equal halves. This description matches the reference listed drug (RLD) in size, shape, color, and scoring.

3.2.P.1.3 Quality Standards of Components

All components comply with the following quality standards:

- **Active Ingredient:** USP
- **Lactose Monohydrate:** NF
- **Microcrystalline Cellulose:** NF
- **Croscarmellose Sodium:** USP
- **Magnesium Stearate:** NF
- **Hypromellose:** NF
- **Purified Water:** USP

- **Ethanol:** USP
- **Polyethylene Glycol:** NF
- **Colloidal Silicon Dioxide:** NF
- **Sodium Lauryl Sulfate:** NF

No colors, flavors, or imprinting ink are used in this product.