

**P. Drug Product (Placebo for Sildenafil Citrate Comparator, Tablets)****P.1. Description and Composition of the Drug Product (Placebo for Sildenafil Citrate Comparator, Tablets)**

The placebo tablet for the study is a blue rounded, diamond shaped film coated tablet with “Pfizer” debossed on one side. The components and quantitative composition of the placebo are given in Table PL.1-1.

**Table PL.1-1. Complete Composition for Placebo for Sildenafil Citrate 100 mg Film-coated Tablets**

| Component                                 | Function  | Compendial Grade | Unit Composition mg/tablet |
|-------------------------------------------|-----------|------------------|----------------------------|
| Lactose, hydrous, spray dried             | Diluent   |                  |                            |
| Microcrystalline cellulose                | Diluent   |                  |                            |
| Magnesium Stearate                        | Lubricant |                  |                            |
| Blue Opadry® (OY-LS-20921) <sup>a</sup>   | Colorant  |                  |                            |
| Clear Opadry® (YS-2-19114-A) <sup>a</sup> | Colorant  |                  |                            |
| Purified Water <sup>b</sup>               | Vehicle   | USP              |                            |
| Total                                     |           | N/A              |                            |

<sup>a</sup> For list of components, refer to the active comparator section, P.4 Control of Excipients, Table CP.4.1-4 and Table CP.4.1-6.

<sup>b</sup> Not present in final dosage form.

**P.2. Pharmaceutical Development**

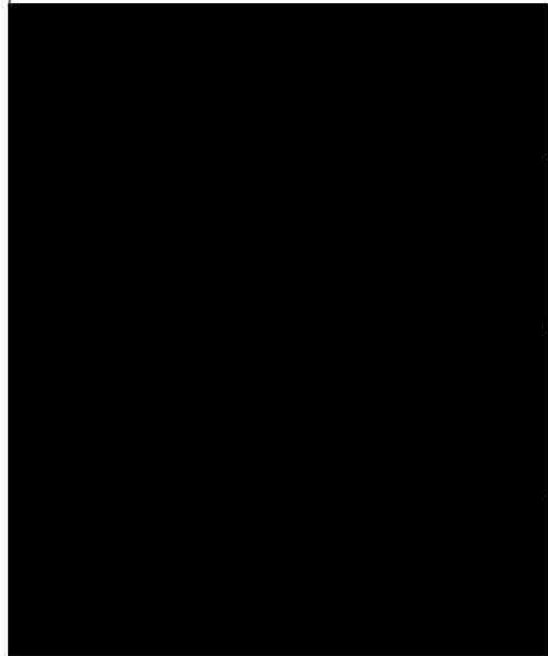
All excipients used in manufacturing the placebo for sildenafil citrate are well precededented pharmaceutical excipients for use in tablets.

### P.3. Manufacture

#### P.3.1. Manufacturer

Placebo clinical supplies were manufactured and released at the following locations identified in Table PL.3.1-2.

**Table PL.3.1-2. Site and Responsibilities for Release of Components of Placebo for Sildenafil Citrate Tablets**

| Site                                                                               | Site Responsibilities           |
|------------------------------------------------------------------------------------|---------------------------------|
|  | Manufacture and release testing |
|                                                                                    | Packaging and final release     |
|                                                                                    | Packaging and final release     |
|                                                                                    | Packaging and final release     |

#### Method of Manufacture

Microcrystalline cellulose, lactose (hydrous, spray dried) and magnesium stearate are blended. The blend is then compressed using diamond-shaped tooling with an upper punch debossed with “Pfizer” and a plain faced lower punch. The placebo tablet core is then aqueous film coated with blue Opadry® (OY-LS-20921) followed with clear Opadry® (YS-2-19114-A).

#### P.4. Control of Excipients

The information on compendial and noncompendial excipients used in the manufacture of placebos for sildenafil tablets are described in [Section P.4 Control of Excipients](#) for the active comparator.

#### P.5. Control of Drug Product (Placebo for Sildenafil Citrate Comparator, Tablets)

The release specification for sildenafil citrate placebo tablets is provided in Table PL.5-3.

**Table PL.5-3. Specification for the Placebo for Sildenafil Citrate Tablets**

| Test                 | Acceptance Criteria |
|----------------------|---------------------|
| Appearance           |                     |
|                      |                     |
| Identification (IR)  |                     |
|                      |                     |
| Identification (TLC) |                     |

**P.6. Reference Standards or Materials**

Not applicable for placebo.

**P.7. Container Closure System**

Placebo for sildenafil citrate tablets is packaged in HDPE bottles with heat induction seal and child-resistant closures.

**P.8. Stability**

Sildenafil citrate tablets packaged in HDPE bottles with heat induction seal and child resistant closures have been assigned a shelf life of five years.