3.2.P.7. CONTAINER CLOSURE SYSTEM(S)

3.2.P.7.1. Description(s) of Container Closure System(s)

DMPA-SC-Pre-Filled Injection System

Depot-Medroxyprogesterone Acetate-SC (DMPA-SC) 104 mg/ 0.65 mL is packaged in an all in one, pre-fillable single use drug delivery system (manufactured and sterilized by Becton Dickinson) designed for subcutaneous injections. This delivery system features with a 1 mL multilayered thermoformed plastic film reservoir with linear low-density polyethylene (LLDPE) product contact layer. Each DMPA-SC 104 mg/ 0.65 mL pre-filled single use injection system is packaged in a foil laminate pouch.

Prior to use the injection system is activated by the piercing of the membrane barrier by the double pointed cannula. The dose is then delivered by depressing the unit reservoir. After the dose is expressed, the collapsed reservoir and a one-way valve inhibit refill, preventing reuse.

Table 3.2.P.7-1. Container Closure System Description: Single Use Injection System

Component Description: Injection System	
SIZE	1 mL (reservoir)
COLOR	Natural (clear to translucent)
MATERIALS OF CONSTRUCTION	Reservoir: multilayered thermoformed plastic film with a linear low density polyethylene innermost layer Port: low density polyethylene Needle hub: polystyrene Needle shield: polypropylene Cannula: stainless steel grade 304 (siliconized)
SIZE (NEEDLE)	23-gauge thin walled
DRAWING	Provided for illustrative purposes only

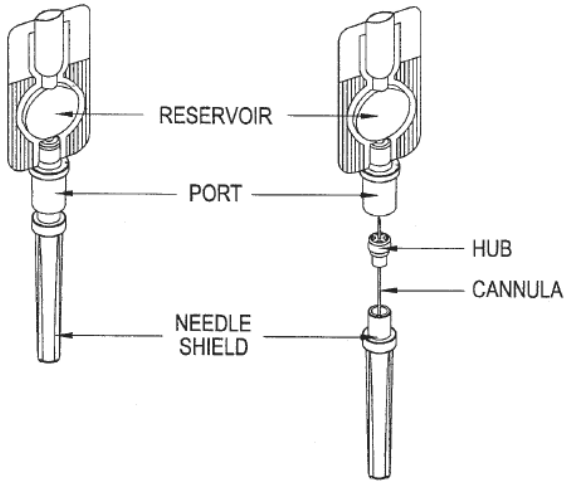

Table 3.2.P.7-2. Critical Secondary Packaging Description: Pouch

Component Description: Foil Pouch	
MATERIALS OF CONSTRUCTION	PET / adhesive / aluminum / PE (product contact side)
COLOR	Silver, printed overall white
DRAWING	Provided for illustrative purposes only

Product Side

3.2.P.7.2. Specifications

Each packaging component is identified with a unique code number. This number is used to order and track components and corresponds to a descriptive document that provides all relevant information pertaining to the component, such as materials of construction, dimensions, and supplier's drawings.

Each incoming shipment of packaging materials is assigned a unique receiving number and is withheld from use until it has been sampled, tested, and examined for conformance using internal plant standard operating procedures (SOPs) and standard test procedures.

Pre-fillable injection system components are visually inspected. Their physical dimensions and style are verified against supplier drawings or approved packaging specifications.

3.2.P.7.3. Analytical Procedures for Packaging Components

Test methods that comprise the Incoming Testing Specifications and are not described in a compendium are listed in this section. Method summaries are provided below.

Identity Check

Pre-fillable injection system components are visually inspected. Their physical dimensions and style are verified against supplier drawings or approved packaging specifications.

Appearance and Cleanliness

Inspect for the presence of biological foreign material, loose particulate matter or fibers within the fluid path of the device, wrinkles or cuts in the filling channel (compared to limit samples; causing leakage), foreign material on the needle, curved or bent needle or needle shield, and loose needle shield.

Sterility Check

Confirm sterilization of components indicated on Certificate of Compliance received from manufacturer.

Particles per Container

Particulate matter is determined by the supplier and conformance to the criteria is stated on the Certificate of Compliance for each batch.

Acceptance Criteria: max. 5 particles/unit > 25 µm; max. 35 particles/unit > 10µm.

Standard IR Spectra, Representative Certificates of Compliance

Standard IR spectra and certificates of compliance are used during incoming inspection of primary packaging components. The standard IR spectra are used for comparative purposes to identify the material of construction (Figure 3.2.P.7-1). A certificate of compliance (Figure 3.2.P.7-2) is used to ensure each lot of packaging components meets or exceeds specifications.

Figure 3.2.P.7-1. Representative IR Spectrum for Product Contact Surface of Injection System Cavity

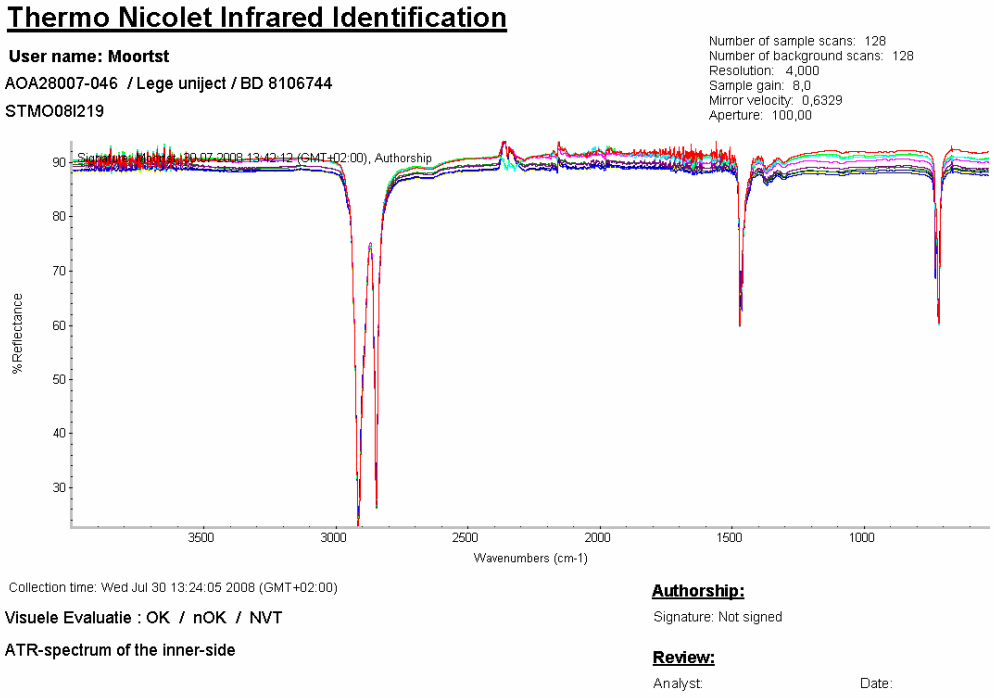

Figure 3.2.P.7-2. Representative Supplier Certificate of Compliance for Pre-Fillable Drug Delivery System

30 Tuas Avenue 2
Singapore 639461
tel: 68610633
fax: 68601592
www.bd.com

BD
Helping all people live healthy lives

CERTIFICATE OF COMPLIANCE

CUSTOMER : **Pfizer Manufacturing Belgium N.V.**

B.D. REF NO. : **8010334934**

This is to certify that the Uniject Injection Device were manufactured in accordance with Becton Dickinson Medical (Singapore) Pte Ltd Customer Specification No. SC47.

PURCHASE ORDER NO.	PRODUCT CATALOG NO. DESCRIPTION	PRODUCT LOT NO.	PRODUCT LOT QTY
4502371210	UNIJECT 1 ML 23G X 3/8IN TW 47290187	2017957	199,266

Quality control steps were carried out accordingly to established quality system at the manufacturing site. All products which are labeled as sterile and released for sale by Becton Dickinson are certified to be sterile as long as the package is unopened and undamaged.
All products which are labeled as non-pyrogenic and released for sale by Becton Dickinson have been originally tested and found to be non-pyrogenic. All materials which are labeled non-toxic and released for sale by Becton Dickinson have passed animal toxicity and/or cytotoxicity tests.

All products meet the foreign matter flush test specification defined as >10µm of 35 particles and >25µm of 5 particles as tested per BD test procedure 80005644.

Date : 09 April 2012

Name : Florence Kuan

Sign : 9 Apr 12

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(SINGAPORE) PTE LTD
QA Engineer/~~QA Manager~~

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