

## FRONT

600 mm

NO TEXT AREA

NO TEXT AREA

NO TEXT AREA

NO TEXT AREA

NO TEXT AREA

40 mm

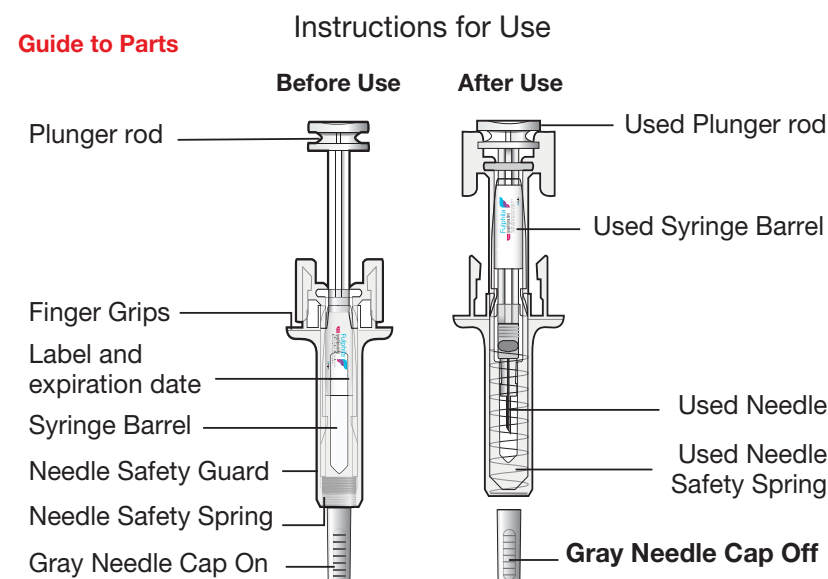
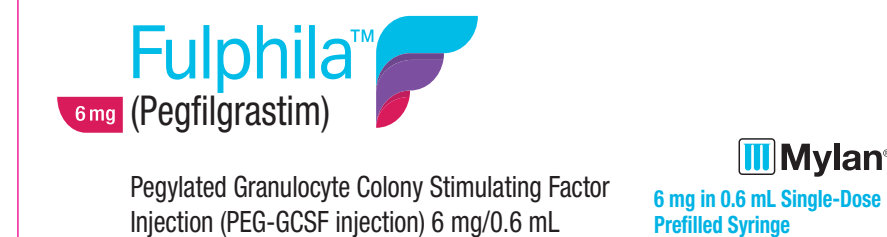
40 mm

NO TEXT AREA

NO TEXT AREA

NO TEXT AREA

5 mm



**Important:** The needle is covered by the gray needle cap before use.

#### Important Information

Read the Patient Information for important information you need to know about Fulphila™ before using these Instructions for Use.

**Before you use a Fulphila™ prefilled syringe with needle safety guard, read this important information:**

- It is important that you do not try to give yourself the injection unless you have received training from your doctor or healthcare provider.
- Fulphila™ is given as an injection into the tissue just under the skin (subcutaneous injection).
- Call your doctor or healthcare provider if you have any questions.
- Keep prefilled syringes out of the reach of children.**
- Do not** shake the prefilled syringe. If the prefilled syringe has been shaken vigorously, the solution may appear foamy and it should not be used.
- Do not** use the prefilled syringe if the carton is open or damaged.
- Do not** remove the gray needle cap from the prefilled syringe until you are ready to inject.
- Do not** use the prefilled syringe if it has been dropped on a hard surface. The syringe may be broken even if you cannot see the break. Use a new prefilled syringe.
- Do not** attempt to activate the prefilled syringe prior to injection.
- Do not** attempt to remove the needle safety guard from the prefilled syringe.
- Do not** attempt to remove the label from the prefilled syringe barrel before administering your injection.

#### Storage

Store Fulphila™ in the refrigerator between 36°F to 46°F (2°C to 8°C). **Do not** freeze. Keep the prefilled syringe in the original carton to protect from light or physical damage. If Fulphila™ is accidentally frozen, allow it to thaw in the refrigerator before injecting. **Do not** try to warm it by using a heat source such as hot water or a microwave. However, if it is frozen a second time, **do not** use. Throw away (dispose of) any Fulphila™ that has been left at room temperature, 68°F to 77°F (not above 30°C), for more than 24 hours. **Do not** leave Fulphila™ in direct sunlight. For all questions about storage, contact your doctor, nurse, or pharmacist.

#### Step 1: Gather supplies

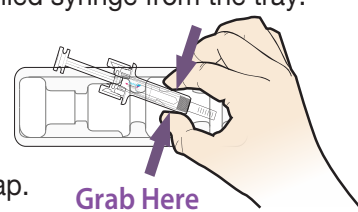
- A** - Find a clean, well-lit and flat working surface, such as a table.
- B** - Take the prefilled syringe out of the refrigerator 30 minutes before use and allow it to reach room temperature before giving an injection. put any remaining prefilled syringe back in the refrigerator.
- C** - Make sure the name Fulphila™ appears on the carton and prefilled syringe label and that the dose strength is 6 mg.
- D** - Remove the prefilled syringe tray from the carton.
- E** - Gather the supplies for the injection: alcohol wipes, a cotton ball or gauze pad and sharps disposal container.
- F** - Wash hands thoroughly with soap and water.

#### Step 2: Prepare for injection

- A** - Open the tray by peeling away the cover. Grab the needle safety guard to remove the prefilled syringe from the tray.

For safety reasons:

- Do not** grab the plunger rod.
- Do not** grasp the gray needle cap.

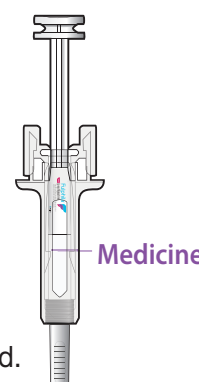


- B** - Inspect the medicine and prefilled syringe. **It must be a clear and colorless liquid.**

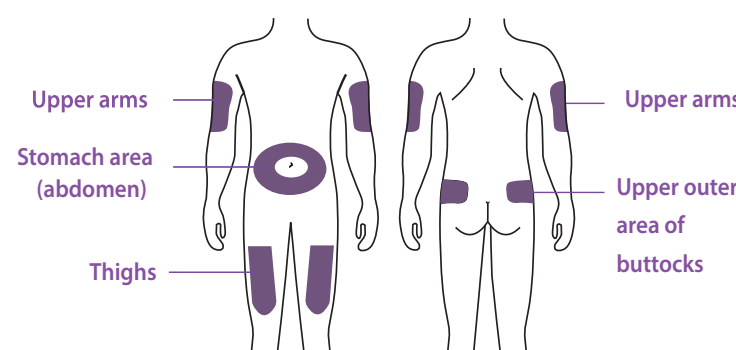
**Do not** use the prefilled syringe if:

- The medicine is cloudy or discolored, or contains flakes or particles.
- The prefilled syringe has been dropped.
- Any part appears cracked or broken.
- The gray needle cap is missing or not securely attached.
- The expiration date printed on the label has passed.

In all cases, use a new prefilled syringe and call your healthcare provider.



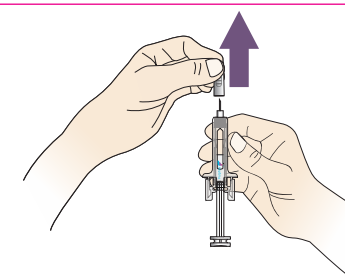
- C** - Clean the injection site with an alcohol wipe. Let the skin dry. There are four recommended injection sites: The thigh; the stomach area (abdomen), except for a 2-inch area right around the navel (belly button); the upper outer area of the buttocks (only if someone else is giving you the injection); and the outer area of the upper arm (only if someone else is giving you the injection).



- Do not** touch this area again before injecting.
- Do not** inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.
- If you want to use the same injection site, make sure it is not the same spot on the injection site you used for a previous injection.

- D** - Hold the prefilled syringe by the needle safety guard. When ready, carefully pull the gray needle cap straight off and away from the body.

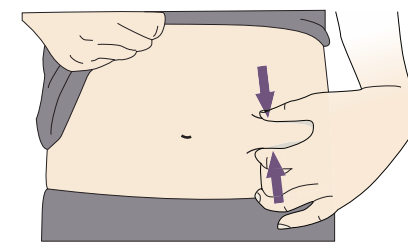
- Do not** twist or bend the gray needle cap.
- Do not** hold the prefilled syringe by the plunger rod.
- Do not** put the gray needle cap back onto the prefilled syringe.



#### Step 3: Inject the dose

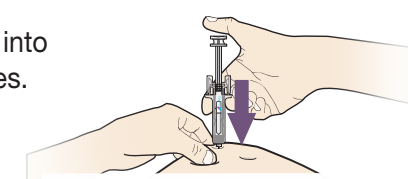
- A** - Pinch the cleaned injection site to create a firm surface.

- Keep skin pinched while injecting.**



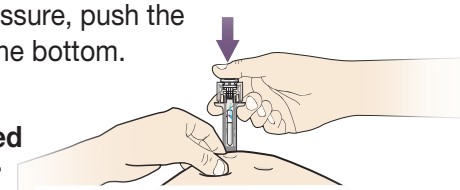
- B** - Hold the pinch. Insert the needle into the skin between 45 to 90 degrees.

- Do not** touch the cleaned area of the skin.



- C** - Using slow and constant pressure, push the plunger rod until it reaches the bottom.

- The plunger must be pushed fully in order to administer the full dose.**

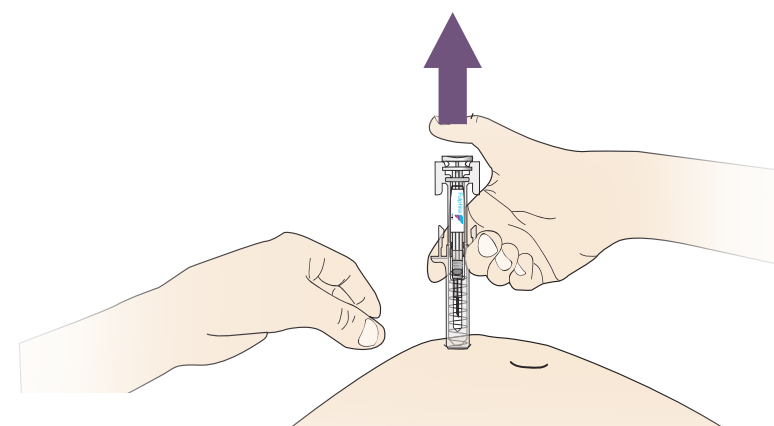


- D** - Once the entire dose has been delivered, the needle safety guard will be triggered and either of the following actions can be followed:

- Release the plunger until the entire needle is covered and then remove the needle from the injection site.

**Or**

- Gently remove the needle from the injection site and release the plunger until the entire needle is covered by the needle safety guard.



After releasing the plunger, the needle safety guard will safely cover the injection needle.

- Once the needle has been removed from the injection site dispose of the syringe as per Step 4.
- If the needle safety guard is not activated or only partially activated, discard the product (without replacing the needle cap) as in Step 4.**
- If your injection is given by another person, he or she should also be careful when removing the needle from your skin in order to prevent accidental needlestick injury and possible infections.**
- When you remove the syringe, if it looks like the medicine is still in the syringe barrel, this means you have not received the full dose. Call your healthcare provider right away.**

- E** - Examine the injection site. If there is blood, press a cotton ball or gauze pad on the injection site. Do not rub the injection site. Apply an adhesive bandage if needed.

#### Step 4: Dispose of supplies

- A** - Put the used prefilled syringe and other supplies in sharps disposal container right away after use. **Do not** throw away the syringe in the household trash.
  - If you do not have sharps disposal container, you may use a household container that is:
    - Made of heavy-duty plastic
    - Can be closed with a tight-fitting, puncture-resistant lid without sharps being able to come out
    - Upright and stable during use
    - Leak-resistant
    - Properly labeled to warn of hazardous waste inside the container

- B** - When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal reference to local guidelines in the state that you live in.



**Important:** Keep the syringe and sharps disposal container out of the reach of children.

- Do not** reuse the prefilled syringe.
- Do not** recycle prefilled syringes or throw them into household waste.

**Manufactured By:**  
**Biocon Biologics India Limited,**  
Block No. B1, B2, Q13 of Q1 and W20,  
Unit S18, 1st Floor, Block B4,  
Special Economic Zone,  
Plot No; 2, 3, 4 & 5, Phase-IV,  
Bommasandra-Jigani Link Road,  
Bommasandra Post, Bengaluru - 560 099, India.

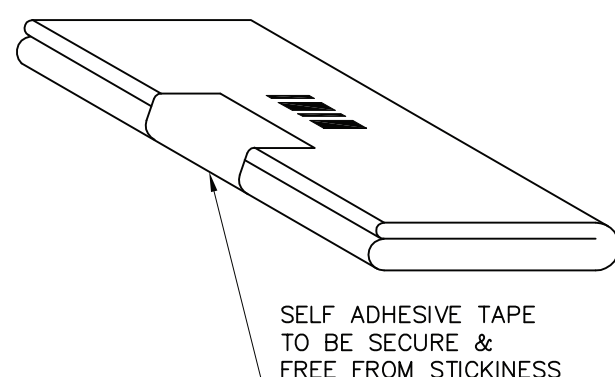
**Marketed by:**  
**Mylan**  
**Mylan Pharmaceuticals Private Limited.**  
Plot No. 1-A/2, MIDC Industrial Estate,  
Taloja, Panvel, Dist.-Raigad - 410208,  
Maharashtra, India.

Open Size : 390(W) x 600(H) mm ; Folded Size : 100(W) x 40(H) mm ; PAPER : 60gsm Maplitho Paper  
BOOKLET TO BE SEALED WITH SELF ADHESIVE TAPE  
SAP CODE : 650006091

Pharmacode Size: 10x10mm



6485



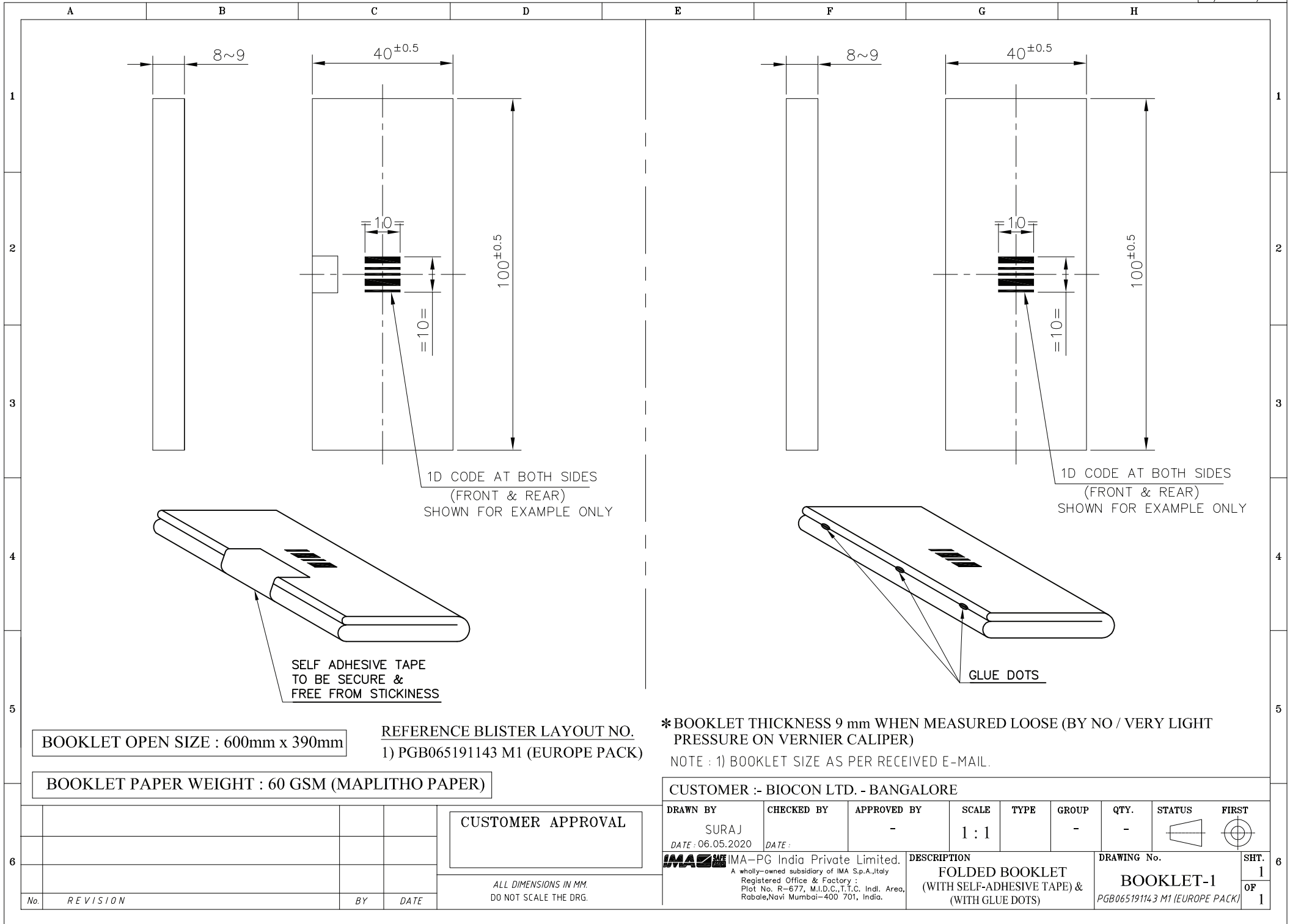
SELF ADHESIVE TAPE  
TO BE SECURE &  
FREE FROM STICKINESS

REFERENCE BLISTER LAYOUT NO.

1) PGB065191143 M1 (EUROPE PACK)

DRAWING No.  
**BOOKLET-1**  
PGB065191143 M1 (EUROPE PACK)

390 mm  
5 mm



Artwork Approval sheet				
Product Brand Name	Fulphila	Market	Singapore	
Product Generic Name	Pegfilgrastim	Sales / PS	Sales	
Strengths	6 mg	Pack Size	NA	
Type of Component	IFU	Component Size	390 x 600 mm	
Substrate	60 GSM Maplitho			
Design & Style	PRC			
Foil Width	NA	Blister size	NA	
Current Site material code	BF2750/01	Superseded Site material code	NA	
Pantone Numbers / Colour Scheme	CMYK			
Reason for Issuance	New Component / Revise Component			
Reason for Revision	NA			
Mylan Approvals				
Packaging Coordinator	Business Development	Marketing	Regulatory Affairs	Quality Assurance
Third Party Site Approvals				
Packaging Development	Production	Regulatory Affairs	Quality Assurance	