

Sof' Bag[®]+

Metered dose airless pouch-in-bottle+ system for dermal and transdermal therapies

Manual Filling Kit Instructions



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1 Introduction to the filling

This section aims to introduce the general requirement to perform the correct filling.

It must be reminded that the manual filling kit is not intended to prepare samples:

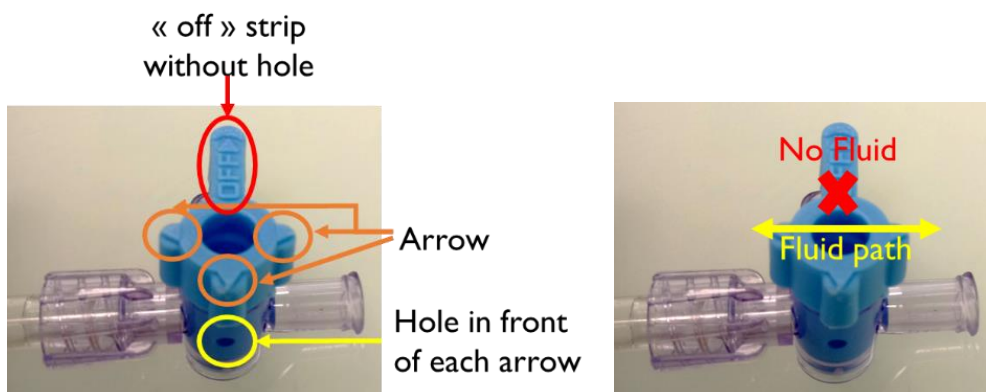
- for human use,
- for regulatory filling purpose.

1.1. Filling kit

Equipments provided with the filling kit are described as below:



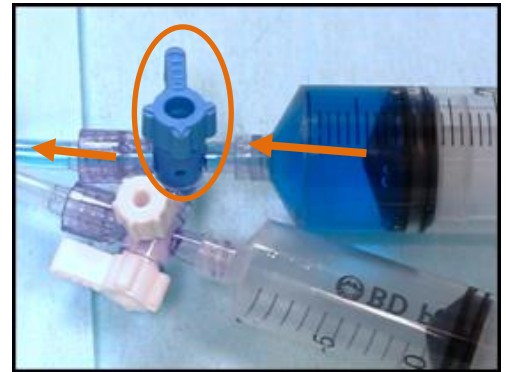
The vacuum cock function is detailed hereafter:



It is recommended to use safety glasses and gloves to perform the Sof'Bag+[®] filling. The whole safety protection linked to the formulation manipulation is under customer's responsibility.



Pathway 1



Pathway 2

1.2. Sof'Bag+® versions and filling targets

The filling method is applicable to all Sof'Bag+® Bottle-Pouch sub-assemblies versions. However, the the maximum targeted filling volume varies based on the Sof'Bag+® Bottle-Pouch sub-assemblies versions:

Sof'Bag+® Bottle-Pouch sub-assemblies versions	Maximum targeted filling volume allowed
100mL STD	109mL ± 3mL
50mL STD	61mL ± 3mL
100mL B-Design	98mL ± 3mL
50mL B-Design	51mL ± 3mL

Table 1 : Filling volume target / Sof'Bag+® Bottle-Pouch sub-assemblies versions

2 Filling Method

This section aims to describe the filling method defined in 6 main steps:

- Nozzle preparation
- Air removal from the pouch
- Formulation injection into the pouch
- Nozzle removal
- Filling level assessment
- Pump snapping

2.1. Nozzle preparation

2.1.1. Fill the syringe with the formulation (depending on the Sof'Bag+® Bottle-Pouch sub-assemblies version) according to table 1:

Sof'Bag+® Bottle-Pouch sub-assemblies version	Syringe filling
100mL STD	<p>Syringe way 1 / Filling Volume 65mL</p> <p>Additional volume to set filling level (5 mL)</p> <p>Purge (≈5mL)</p> <p>Syringe way 2 / Filling Volume 59mL</p>
50mL STD	<p>Syringe way 1 / Filling Volume 56mL</p> <p>Additional volume to set filling level (4 mL)</p> <p>Purge (≈5mL)</p> <p>Syringe way 2 / Filling Volume 19mL</p>
100mL B-Design	<p>Syringe way 1 / Filling Volume 65mL</p> <p>Additional volume to set filling level (5 mL)</p> <p>Purge (≈5mL)</p> <p>Syringe way 2 / Filling Volume 48mL</p>
50mL B-Design	<p>Syringe way 1 / Filling Volume 56mL</p> <p>Additional volume to set filling level (4 mL)</p> <p>Purge (≈5mL)</p> <p>Syringe way 2 / Filling Volume 9mL</p>

Table 2: Syringe filling / Sof'Bag+® Bottle-Pouch sub-assemblies versions

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2.1.2. Open the pathway 1 of the filling cock.

2.1.3. Plug the Syringe pathway 1 on the filling cock (as described on the below picture).



2.1.4. Inject 5mL of the formulation into the nozzle to remove the air from the fluid flow.

2.1.5. Plug the Syringe pathway 2 on the filling cock (as described on the below picture).



2.1.6. Open the pathway 2 of the filling cock.

2.1.7. Inject 5mL of the formulation into the nozzle to remove the air from the fluid flow.

2.1.8. Close the filling cock.

2.2. Removing of the air from the pouch

2.2.1. Plug the vacuum syringe on the vacuum cock.

2.2.2. Open the vacuum cock.

2.2.3. Insert the nozzle into the bottle and push it all the way to ensure the tightness with the pouch adaptor.



2.2.4. Pull the piston of the vacuum syringe at a full stroke, hold it in position and close the vacuum cock. The piston has a slight backward movement due to depression. **If it is not the case, the bottle must be discarded.**



2.3. Formulation injection into the pouch

2.3.1. Open the pathway 1 of the filling cock

2.3.2. Inject the entire content of the Syringe pathway 1.



2.3.3. Open the pathway 2 of the filling cock and remove the Syringe pathway 1.

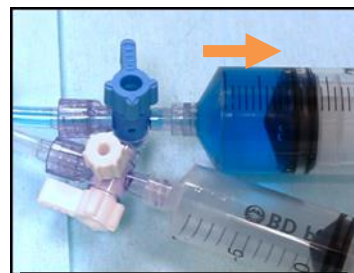
2.3.4. Complete the targeted filling volume by the Syringe pathway 2 (refer to the table 1 and table 2).

2.3.5. Inject an additional volume of 5mL for the 100mL bottle version or 4mL for the 50mL bottle version, then remove it to set the filling level.

This step is very important to set the filling level.



**+5mL (all versions)
+4 mL (50mL B-Design)**



**-5mL (all versions)
-4 mL (50mL B-Design)**

2.3.6. Close the the filling cock and remove the Syringe pathway 2.

2.4. Nozzle removal

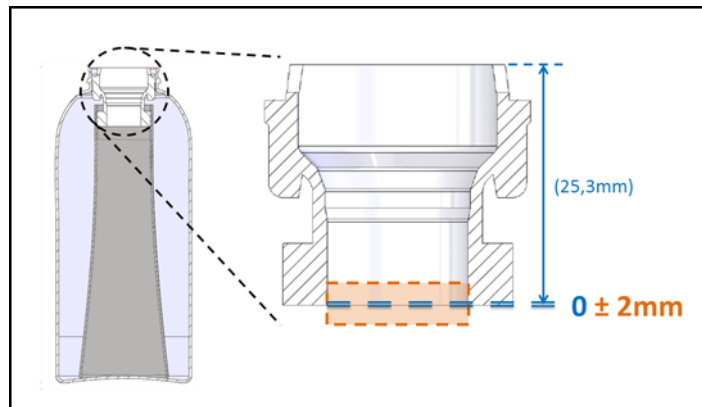
2.4.1. Put the bottle upright.

2.4.2. Remove the nozzle by turning it



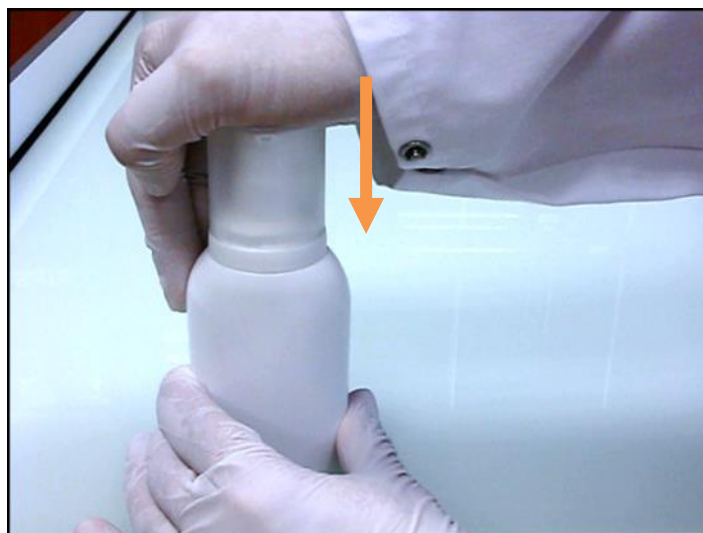
2.5. Filling level assessment

Check the filling level (as detailed below) and if required, add or remove some formulation to adjust the level.



2.6. Pump snapping

Snap the pump immediately after filling (to avoid filling level changes).



2.7. Maintenance

At the end of manual filling kit use:

- Verify that the plastic tubing is correctly fitted onto the nozzle.
- After use, rinse the inside of the syringes, stopcocks and plastic tubing.

3 Video

Find an explicative video of manual filling kit instructions by scanning this QR-code.

