SIF media : FaSSIF, FeSSIF, FaSSGF  
(previously known as SIF Powder Original)

for dissolution of drugs and other solubility studies, make simply and quickly FaSSIF, FeSSIF, FaSSGF !

Product Description

Catalog : 1A7101, 2.5L (5.6g)  
1A7102, 25L (56g)  
1A7103, 250L (560g)  
1A7104, 4x25L

Name: FaSSIF, FeSSIF, FaSSGF  
(previously known as SIF Powder Original)

Complex of taurocholate and lecithin buffer. Make 3 different media  
(FaSSIF/FeSSIF/FaSSGF) from 1 powder for biorelevant dissolution methods

Note: 56g (1A7102) makes 25 litres of FaSSIF or 5 litres of FeSSIF  
or 938 litres of FaSSGF

Storage: Room temperature (Z)

For Research Use Only

What is SIF Powder ?

SIF Powder Original makes high quality FaSSIF, FeSSIF and FaSSGF buffers in seconds.

FaSSIF: Fasted State Simulated Intestinal Fluid  
FeSSIF: Fed State Simulated Intestinal Fluid  
FaSSGF: Fasted State Simulated Gastric Fluid

These media are incredibly useful tools when developing an oral drug because simple laboratory experiments in them can help predict how the drug is likely to perform in the gut. Based on Professor Jennifer Dressman’s original formulation (Pharm Res, 1998, 15(5), pages 698-705), they contain natural surfactants (bile salts and phospholipids) present in the gut to simulate gastrointestinal fluids much more accurately than conventional dissolution media. Importantly they also take food into account: drugs in Fasted State media (before a meal) often behave very differently from those in the Fed State (after a meal).

Conventional methods of preparing these biorelevant media are very slow, complicated and expensive. The SIF powder was invented to solve these problems. It is a patented complex of taurocholate and lecithin in a 4:1 molar ratio.

- **Super Fast**
  Conventional preparation methods required you to source multiple ingredients and could take several hours to prepare even a small amount of media.
  With SIF Powder, **add powder to buffer and you’re ready to go, in seconds!**

- **Great Value**
  Whether your media requirements are very small (e.g. for solubility tests) or extremely large (e.g. for multiple dissolution tests), SIF Powder is the most cost-effective way of making FaSSIF, FeSSIF or FaSSGF. SIF Powder is even cheaper than buying taurocholate alone!
InterBioTech

FT-1A7101

- **High Quality Fast**
  - SIF Powder is made from high quality taurocholate and lecithin and is manufactured in a carefully monitored production environment. The product is quality controlled and every bottle comes with a Certificate of Analysis.

- **Trusted**
  - The top 12 Big Pharma companies have all bought SIF Powder to make FaSSIF, FeSSIF or FaSSGF.
  - referenced in hundreds of publications

Directions for use

How to make FaSSIF, FeSSIF and FaSSGF with SIF Powder Original

**Protocol 1:**
The desired biorelevant medium is made by dissolving the appropriate amount of SIF Powder Original in the recommended blank buffer (for FaSSIF and FeSSIF) or NaCl/HCl solution (for FaSSGF).

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**To make 1 L of FaSSIF**

**STEP 1**
- Prepare buffer
  - Weigh 41.65 g (or 35.00 mL) of FaSSIF Buffer
  - Concentrate into suitable container
  - Adjust the pH to 6.5 with either 1 M NaOH or 1 M HCl.
  - Make up to volume (1 L) with purified water at room temperature.

**STEP 2**
- Add SIF Powder
  - Add 2.24 g of FaSSIF/FeSSIF/FaSSGF powder into suitable container
  - Stir until powder is completely dissolved

✔ it's Ready to use
Let stand for 2 hours. It will become slightly opalescent.
Your FaSSIF is ready to use. Use within 48 hours at room temperature and 24 hours at 37°C.

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**To make 1 L of FeSSIF**

**STEP 1**
- Prepare buffer
  - Weigh 81.41 g (or 70.00 mL) of FeSSIF Buffer
  - Concentrate into suitable container
  - Adjust the pH to 5 with either 1 M NaOH or 1 M HCl.
  - Make up to volume (1 L) with purified water at room temperature.

**STEP 2**
- Add SIF Powder
  - Add 11.20 g of of FaSSIF/FeSSIF/FaSSGF powder into suitable container
  - Stir until powder is completely dissolved.

Make up to volume (1 L) with buffer at room temperature.

✔ it's Ready to use
Let stand for 2 hours. It will become slightly opalescent.
Your FeSSIF is ready to use. Use within 48 hours at room temperature and 24 hours at 37°C.
**To make 1 L of FaSSGF**

**STEP 1** ● Prepare buffer

Weigh 36.78 g (or 35.00 mL) of FaSSGF Buffer

Concentrate into suitable container

● Adjust the pH to 1.6 with HCl.

● Make up to volume (1 L) with purified water at room temperature.

**STEP 2** ● Add Powder

Weigh 0.0597 g of FaSSIF/FeSSIF/FaSSGF powder into suitable container

Make up to volume (1 L) with buffer solution at room temperature.

✓ it's Ready to use

We recommend using the medium at room temperature or at 37°C. It can be used for up to 48 hours at these temperatures

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**Technical and Scientific Information**

**Dissolution and solubility test**

Dissolution of five drugs was tested in FaSSIF, FeSSIF and FaSSGF made from SIF Powder. These were compared to profiles of the same drugs tested in biorelevant media prepared using methylene chloride (dichloromethane) (figures 1 to 15 below). The dissolution profiles in biorelevant media made by either method were found to be equivalent.

Table 2 f2 values for comparing the dissolution profiles of the five drug products in FaSSIF, FeSSIF and FaSSGF made from SIF Powder and prepared using methylene chloride

<table>
<thead>
<tr>
<th>Drug Product</th>
<th>f2 values FaSSIF</th>
<th>f2 values FeSSIF</th>
<th>f2 values FaSSGF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Danazol 100mg capsules</td>
<td>94.4</td>
<td>93.3</td>
<td>100.0</td>
</tr>
<tr>
<td>Ketoconazole 200mg tablets</td>
<td>98.3</td>
<td>76.4</td>
<td>60.8</td>
</tr>
<tr>
<td>Mefanamic acid 250mg capsules</td>
<td>94.6</td>
<td>98.2</td>
<td>100.0</td>
</tr>
<tr>
<td>Metoprolol tartrate 100mg tablets</td>
<td>97.4</td>
<td>92.2</td>
<td>72.1</td>
</tr>
<tr>
<td>Paracetamol 500mg tablets</td>
<td>89.0</td>
<td>87.2</td>
<td>82.7</td>
</tr>
</tbody>
</table>

**Conclusion:**

From the below Figures 1 to 15, it can be seen that the method of making the biorelevant media FaSSIF, FeSSIF and FaSSGF does not significantly affect the dissolution of the five drug products tested. SIF Powder Original gave equivalent solubility results compared to the same type of media prepared using methylene chloride. The f2 values comparing the two different methods were always greater than 50 indicating that there was less than 10% difference between the two methods.

**Detail: methods and results**

<table>
<thead>
<tr>
<th>Component</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lecithin (phospholipid)</td>
<td>397460</td>
</tr>
<tr>
<td>Sodium taurocholate</td>
<td>15284</td>
</tr>
<tr>
<td>Methylene chloride (dichloromethane)</td>
<td>IEV63</td>
</tr>
<tr>
<td>Sodium dihydrogen phosphate dihydrate</td>
<td>14172A</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>141814</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>89678A</td>
</tr>
<tr>
<td>Acetic acid glacial</td>
<td>BV572</td>
</tr>
<tr>
<td>HCl 1N</td>
<td></td>
</tr>
<tr>
<td>HCl &gt;37%</td>
<td></td>
</tr>
<tr>
<td>Water (deionized)</td>
<td>45742A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug</th>
<th>Manufacturer/Supplier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Danazol</td>
<td>Mylan, UK</td>
</tr>
</tbody>
</table>

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**Component**

- Metoprolol tartrate
- Daiichi-Sankyo, Switzerland
- Mefanamic acid
- Pfizer, Switzerland
- Ketoconazole
- Janssen-Cilag, UK
- Paracetamol
- Boots Pharmaceuticals, UK
Results of Dissolution profile in FaSSIF made from SIF Powder and in FaSSIG prepared using methylene chloride

**Figure 1, 2, 3 - Paracetamol**

**Figure 4, 5, 6 - Metoprolol**

**Figure 7, 8, 9 - Danazol**

**Figure 10, 11, 12 - Mefenamic acid**
Figure 13, 14, 15 - Ketoconazole

References:

Ask for the full study "biorelevant dissolution tests with SIF Powder Original."
Solubility test

Equilibrium solubilities of 5 drugs were measured, in FaSSIF, FeSSIF and FaSSGF made from SIF Powder Original, and in biorelevant media prepared using methylene chloride (dichloromethane) (results below: figures 1 to 5).

The equilibrium solubility of each drug was determined after incubating an excess of the individual drug in biorelevant media in a sealed 5ml glass vial for 24hours at 37°C while stirring the suspension using a magnetic stirrer at 600rpm . The 24hours time point was taken as the equilibrium solubility, after which the suspension was filtered through a 0.22 μm PVDF filter and drug content determined by HPLC. To reduce any potential adsorption effects on the filter, the first 200 microliters were discarded. The equilibrium solubility of each drug was determined in triplicate (n=3)

Conclusion:
From Figure 1 to 5, it can be seen that the method of making the biorelevant media FaSSIF, FeSSIF and FaSSGF does not significantly affect the equilibrium solubility of the five drugs tested . SIF Powder Original gave equivalent solubility results compared to the same type of media prepared using methylene chloride.

References:
Ask for the full study: biorelevant solubility tests with SIF Powder .

Other technical data - references
Comparison of the Solubility and Dissolution of Drugs in Fasted-State Biorelevant Media (FaSSIF and FaSSIF-V2) Mathew Leigh*, Bastian Kloefner, and Michael Schaich Dissolution Technologies | August 2013, pp.44-50 Article 1
## FT-1A7101 Composition

<table>
<thead>
<tr>
<th>Component</th>
<th>FaSSIG</th>
<th>FeSSIG</th>
<th>FaSSGF</th>
<th>FaSSIG-V2</th>
<th>FeSSIG-V2</th>
<th>FaSSCoF</th>
<th>FeSSCoF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taurocholate</td>
<td>3mM</td>
<td>15mM</td>
<td>0.08mM</td>
<td>3mM</td>
<td>10mM</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Phospholipids</td>
<td>0.75mM</td>
<td>3.75mM</td>
<td>0.02mM</td>
<td>0.2mM</td>
<td>2mM</td>
<td>0.3mM</td>
<td>0.5mM</td>
</tr>
<tr>
<td>Sodium</td>
<td>148mM</td>
<td>319mM</td>
<td>34mM</td>
<td>106mM</td>
<td>218mM</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Chloride</td>
<td>106mM</td>
<td>203mM</td>
<td>59mM</td>
<td>69mM</td>
<td>125mM</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Phosphate</td>
<td>29mM</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Acetic acid</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Maleic acid</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>19mM</td>
<td>55mM</td>
<td>76mM</td>
<td>30mM</td>
</tr>
<tr>
<td>Oleate</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0.8mM</td>
<td>0.1mM</td>
<td>0.2mM</td>
</tr>
<tr>
<td>Glycerol monoleate</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>5mM</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sodium Cholate</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0.15mM</td>
<td>0.6mM</td>
</tr>
<tr>
<td>Sodium OH</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>120mM</td>
<td>34mM</td>
</tr>
<tr>
<td>Tris</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>45mM</td>
<td>31mM</td>
</tr>
</tbody>
</table>

## Quality

- Manufactured from a dedicated factory in London and apply strict production protocols and analytical procedures, with considerable capacity (not been out of stock for even one week for 10 years!).
- All raw ingredients are sourced from quality certified companies and chemically tested by a 3rd party laboratory before manufacturing even begins. Every batch is analysed by a GLP certified and FDA approved independent laboratory, as reflected in the Certificates of Analysis supplied with each bottle. Tested in biorelevant facility to ensure they are working perfectly.

## Associated products:

- **Other biorelevant media:**
  - FaSSIF-V2 (Fasted State Simulated Intestinal Fluid) #1D1011-V2FAS01-2.5L-25L [Technical sheet](#)
  - FeSSIF-V2 (Fed State Simulated Intestinal Fluid) #1Q7710-V2FES01-0.5L-5L-50L
  - FaSSCoF Buffer (Fasted State Simulated Colonic Fluid) #BFUJ0-COFAS01-10L
  - FeSSCoF Buffer (Fed State Simulated Colonic Fluid) #BFUK0-COFES01-10L
  - FEDGAS pH6 (early), pH4.5 (Intermediate), pH3 (late)
    - To test oral drug in dissolution media simulating stomach fluids after a high-fat FDA meal
    - 3 different fluids (early/intermediate/late stages after dosing) give new insights into food effects on drug absorption
    - Designed for dissolution tests with USP Apparatus 1 or 2
    - Straightforward HPLC analysis with no need for extraction
    - Buffer and syringe filters included so you can start testing immediately
    - Dog FaSSIF/FaSSGF #ANF1H0-DOGFAS01-1L-10L-4x1L
      - To test Dog FaSSIF (makes 1L) or Dog FaSSGF (makes 50L)

- **Buffers:** simply dilute the concentrate to the amount of buffer you require and combine with SIF powder #1A710 to make in seconds ready-to-use high quality FaSSIF/FeSSIF/FaSSGF media:
  - FaSSIF Buffer Concentrate #B49I00-FASBUF01-6L-10X6L
  - FeSSIF Buffer Concentrate #B49I00-FESBUF01-3L-10X3L
  - FaSSGF Buffer Concentrate #B49IP0-FASGBUF01-6L-10X6L

- **Consumables:** Syringe Filters

## Related products

SIF Powder Original #1A7101 - [Technical sheet](#)
- Allows to prepare easily dissolution buffers FaSSIF, FeSSIF, FaSSGF
- FaSSIF Buffer Concentrate, B49I00
- FeSSIF Buffer Concentrate, B49I00
- FaSSGF Buffer Concentrate, B49I00
Ordering information

Catalog size quantities and prices may be found at http://www.interchim.com.
Please inquire for higher quantities (availability, shipment conditions).
Please contact InterBioTech – Interchim for any other information
Hotline : +33(0)4 70 03 73 06 – Interbiotech@interchim.com

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