

FT-1A7101



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 : 1A7107, 3L (7g) 1A7108, 4 x3L (4x7g) 1A7109, 30L (70g)
1A710A, 4x30L (4x70g)

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: 70g makes
30 litres of FaSSIF or 6 litres of FeSSIF or >1000 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!**

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➤ 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

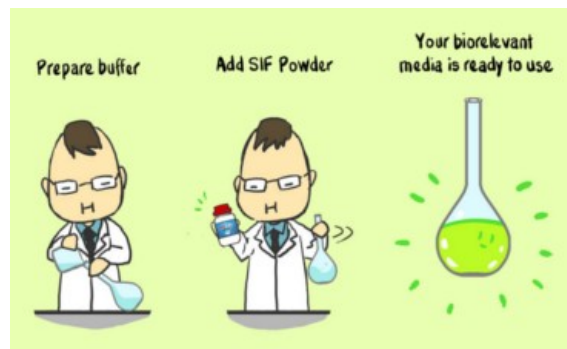
- **The top 12 Big Pharma companies have all bought SIF Powder** to make FaSSIF, FeSSIF or FaSSGF.
- **referenced in hundreds of publications**

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).



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 1M NaOH or 1M 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

Add buffer to volume (1 L)

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.

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 1M NaOH or 1M HCl.
- Make up to volume (1 L) with purified water at room temperature.

STEP 2 • Add SIF Powder

Add **11.20 g 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.

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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

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

Drug Product	f2 values FaSSIF	f2 values FeSSIF	f2 values FaSSGF
Danazol 100mg capsules	94.4	93.3	100.0
Ketoconazole 200mg tablets	98.3	76.4	60.8
Mefenamic acid 250mg capsules	94.6	98.2	100.0
Metopropolol tartrate 100mg tablets	97.4	92.2	72.1
Paracetamol 500mg tablets	89.0	87.2	82.7

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

Component	
Lecithin (phospholipid)	397460
Sodium taurocholate	15284
Methylene chloride (dichloromethane)	IEV63
Sodium dihydrogen phosphate dihydrate	14172A
Sodium hydroxide	141814
Sodium chloride	89678A
Acetic acid glacial	BV572
HCl 1N	
HCl >37%	
Water (deionized)	45742A

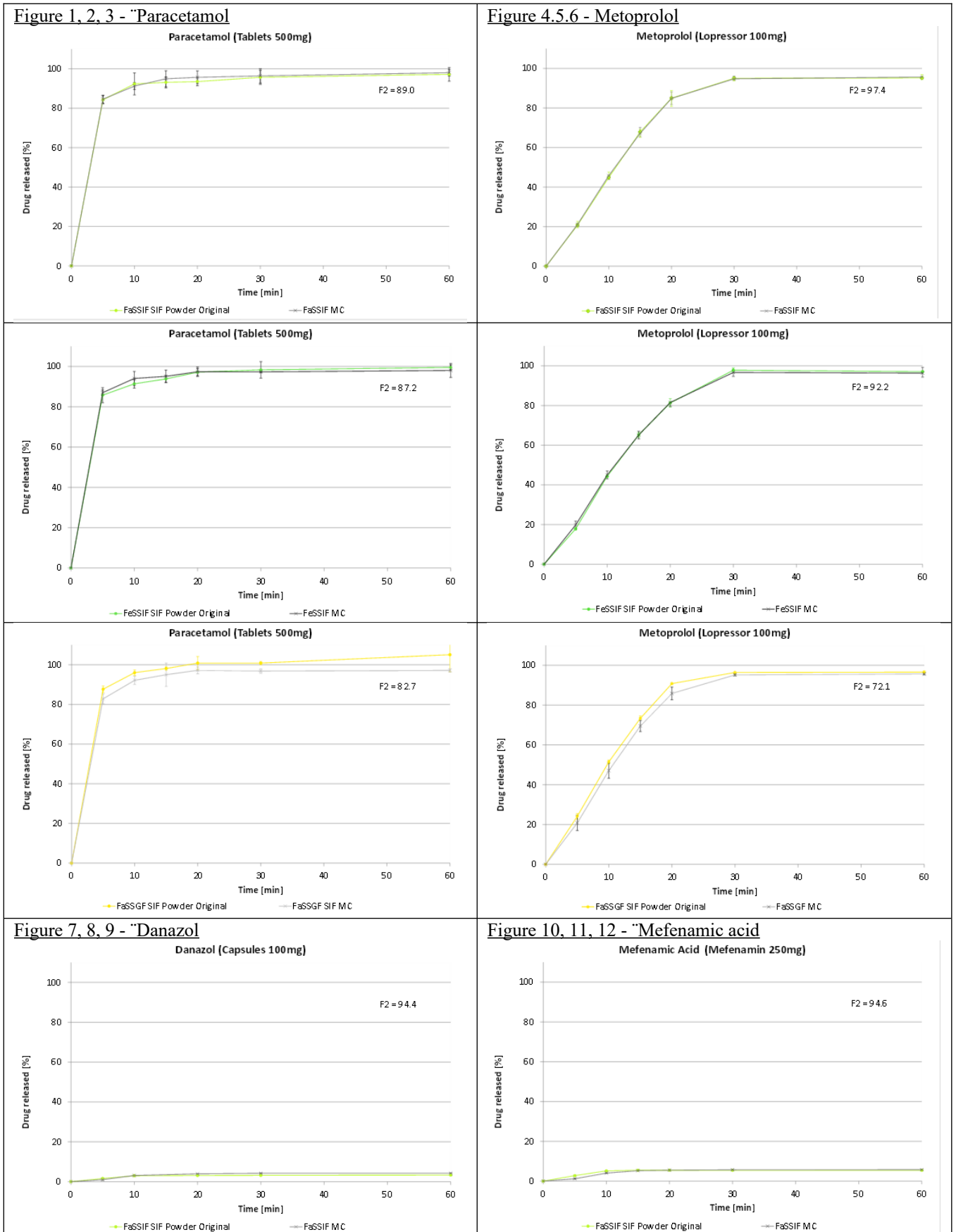
Metopropolol tartrate	Daiichi-Sankyo, Switzerland
Mefenamic acid	Pfizer, Switzerland
Ketoconazole	Janssen-Cilag, UK
Paracetamol	Boots Pharmaceuticals, UK

Tested drugs

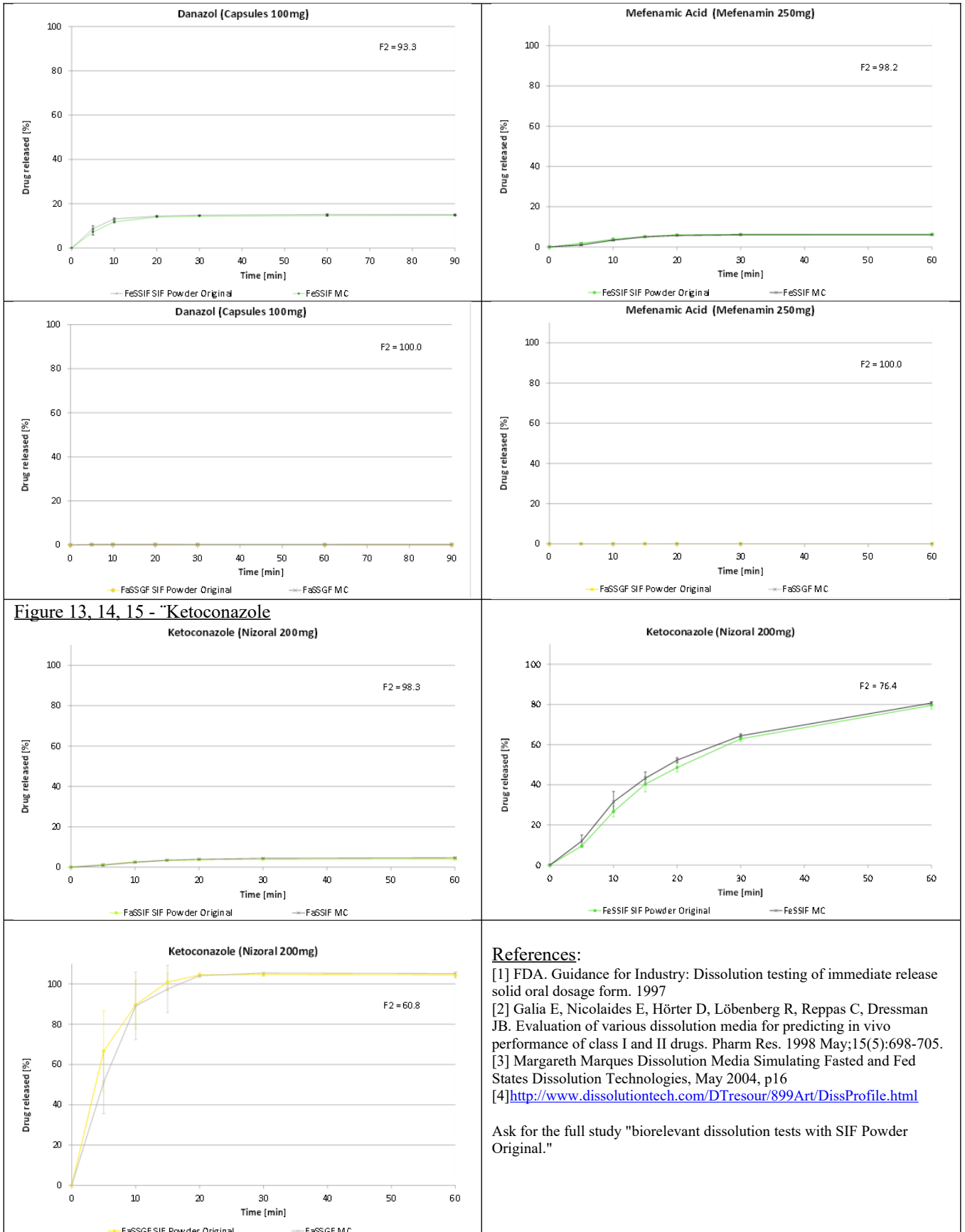
Drug	Manufacturer/Supplier
Danazol	Mylan, UK

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Results of Dissolution profile in FaSSIF made from SIF Powder and in FaSSIG prepared using methylene chloride



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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).

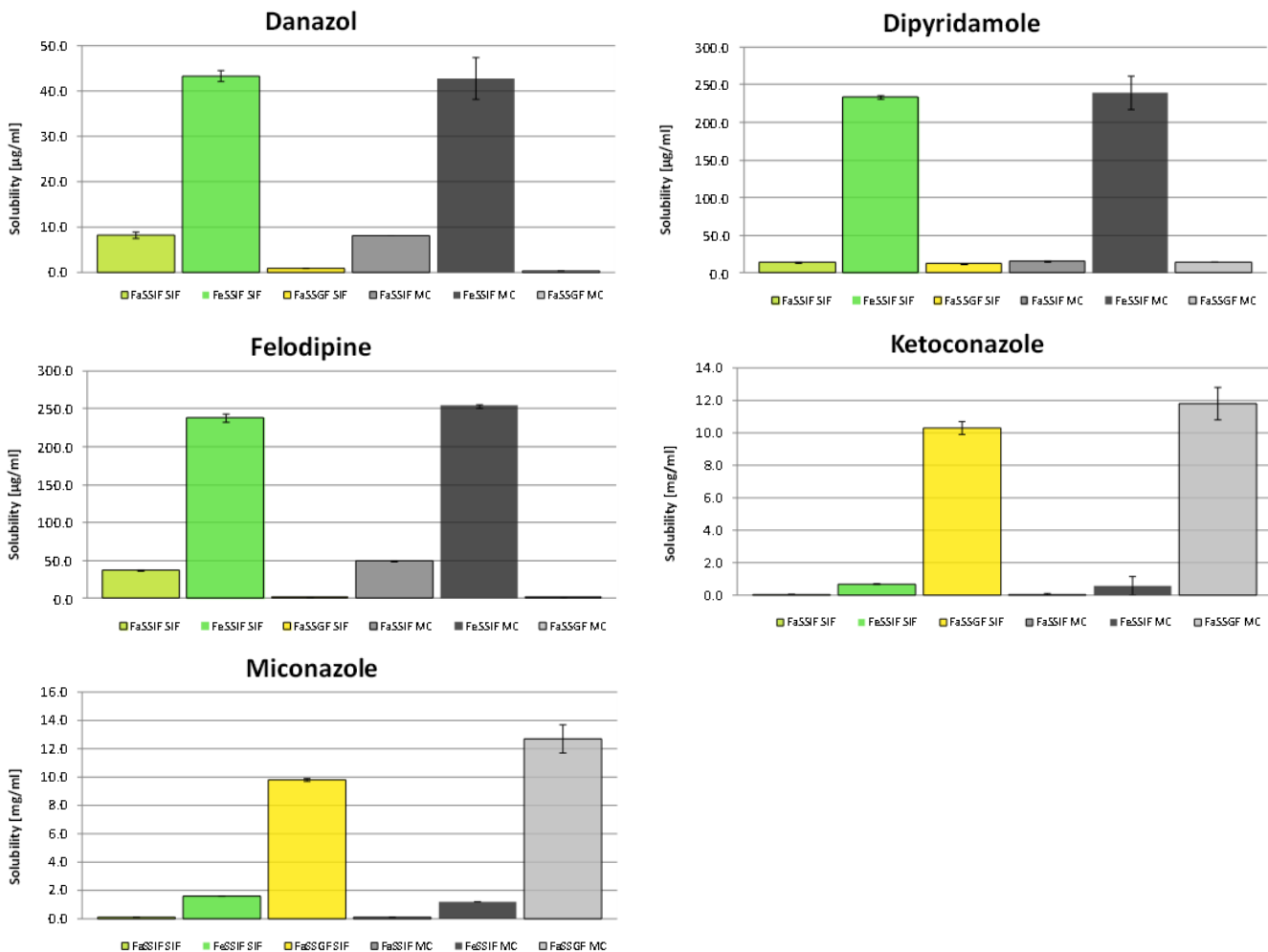
The equilibrium solubility of each drug was determined after incubating an excess of the individual drug in biorelevant media in a sealed 5ml glass vial for 24hours at 37°C while stirring the suspension using a magnetic stirrer at 600rpm . The 24hours time point was taken as the equilibrium solubility, 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:

[1] Margareth Marques - Dissolution Media Simulating Fasted and Fed States Dissolution Technologies, May 2004, p16
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 Kloefer, and Michael Schaich
Dissolution Technologies | August 2013, pp.44-50 [Article](#) ¹.

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Composition

Component	FaSSIG	FeSSIG	FaSSGF	FaSSIG-V2	FeSSIG-V2	FaSSCoF	FeSSCoF
Taurocholate	3mM	15mM	0.08mM	3mM	10mM	-	
Phospholipids	0.75mM	3.75mM	0.02mM	0.2mM	2mM	0.3mM	0.5mM
Sodium	148mM	319mM	34mM	106mM	218mM	-	
Chloride	106mM	203mM	59mM	69mM	125mM	-	
Phosphate	29mM	-	-	-	-	-	-
Acetic acid	-	144mM	-	-	-	-	-
Maleic acid	-	-	-	19mM	55mM	76mM	30mM
Oleate	-	-	-	-	0.8mM	0.1mM	0.2mM
Glycerol monoleate	-	-	-	-	5mM	-	-
Sodium Cholate	-	-	-	-	-	0.15mM	0.6mM
Sodium OH	-	-	-	-	-	120mM	34mM
Tris	-	-	-	-	-	45mM	31mM

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](#)

To test Fasted prandial state of **small intestinal** fluid (pH6.5)

FeSSIF-V2 (Fed State Simulated Intestinal Fluid) #1Q7710-V2FES01-0.5L-5L-50L

To test Fed prandial state of small intestinal fluid (pH5.8)

FaSSCoF Buffer (Fasted State Simulated Colonic Fluid) #BFWUJ0-COFAS01-10L

To test fasted prandial state of **colon** dissolution (pH7.8)

FeSSCoF Buffer (Fed State Simulated Colonic Fluid) #BFWUK0-COFES01-10L

To test fed prandial state of colon dissolution (pH6.0)

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 #B49IQ0-FASBUF01-6L-10X6L

FeSSIF Buffer Concentrate #B49IQ0-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, FaSSG

FaSSIF Buffer Concentrate, B49IQ0

FeSSIF Buffer Concentrate, B49IQ0

FaSSGF Buffer Concentrate, B49IP0

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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