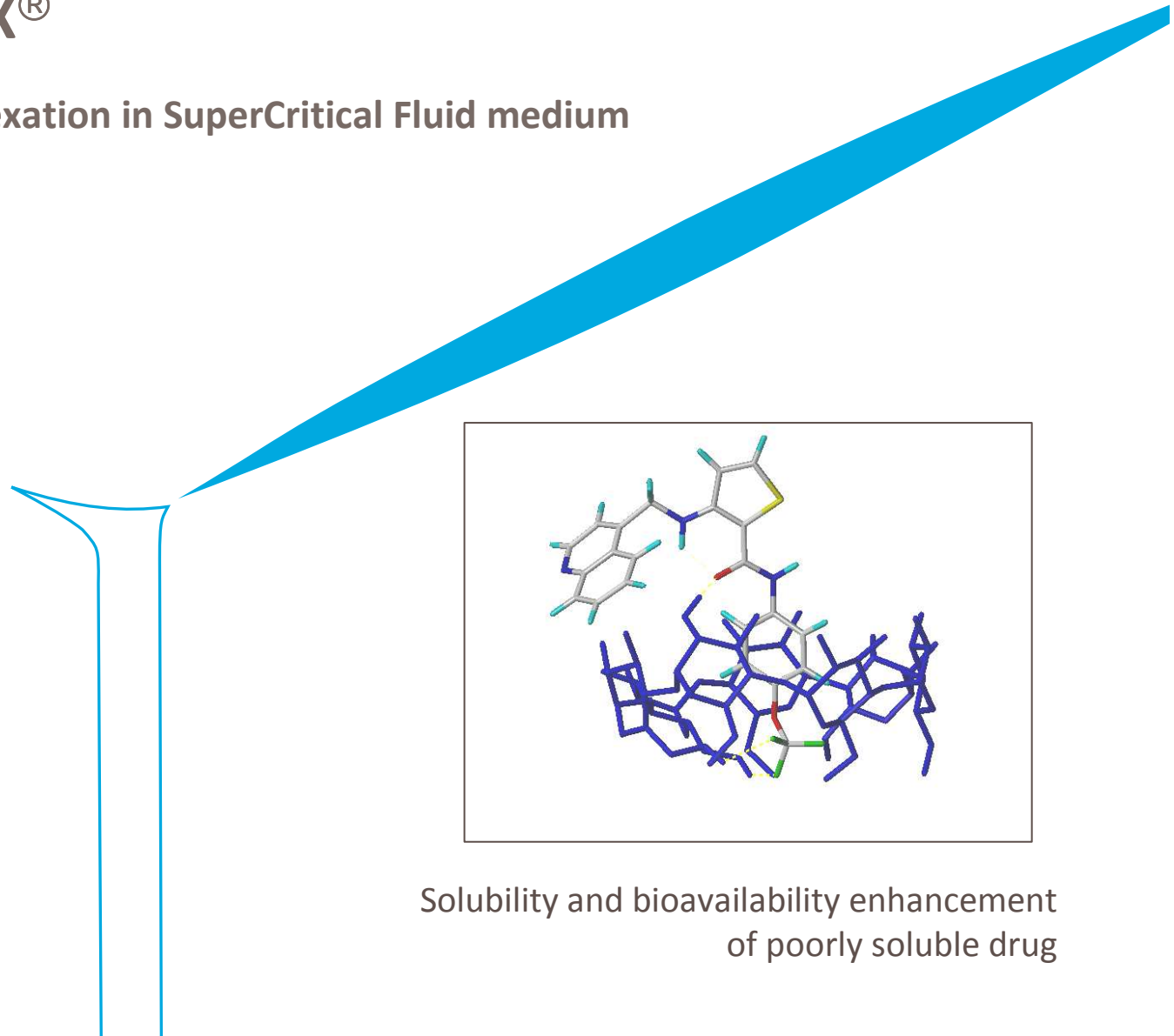


FORMULPLEX[®]

Cyclodextrin complexation in SuperCritical Fluid medium



Solubility and bioavailability enhancement
of poorly soluble drug

INNOVATION

by **Preformulation Contract Manufacturing**

FORMULPLEX[®]

FORMULPLEX[®] presents great advantages such as **mild and free-solvent** operating conditions, or energy-lower cost.

It is a batch process, without stirring, at mild temperature using only pressurized carbon dioxide and a small amount of water.

- **Single step**
- **Production yield 100%**
- **Solvent free**
- **Reduced costs and investments**
- **Simple and reproducible reaction**
- **Scaling-up mastered**

FORMULPLEX[®] is considered as a first step of formulation process.

(French Health Authority decision , November 2004)

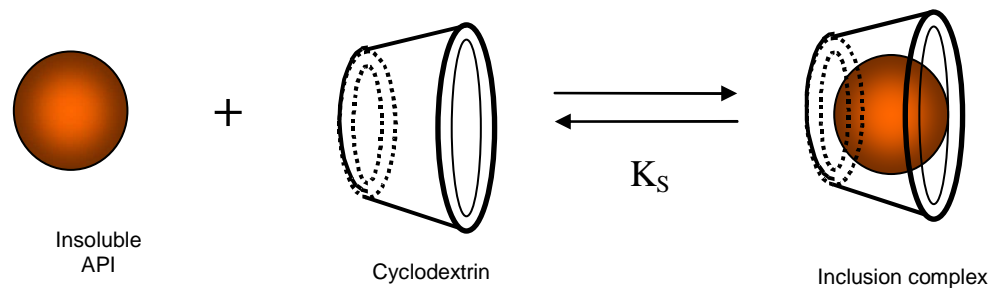


FORMULPLEX[®]

We have demonstrated the efficiency of the technology FORMULPLEX[®] for various types of poorly soluble drugs.

Cyclodextrins commonly used are

- Native cyclodextrins α , β and γ
- HP- β -cyclodextrins
- Methyl- β -cyclodextrins



FORMULPLEX[®]: In-Vitro Results

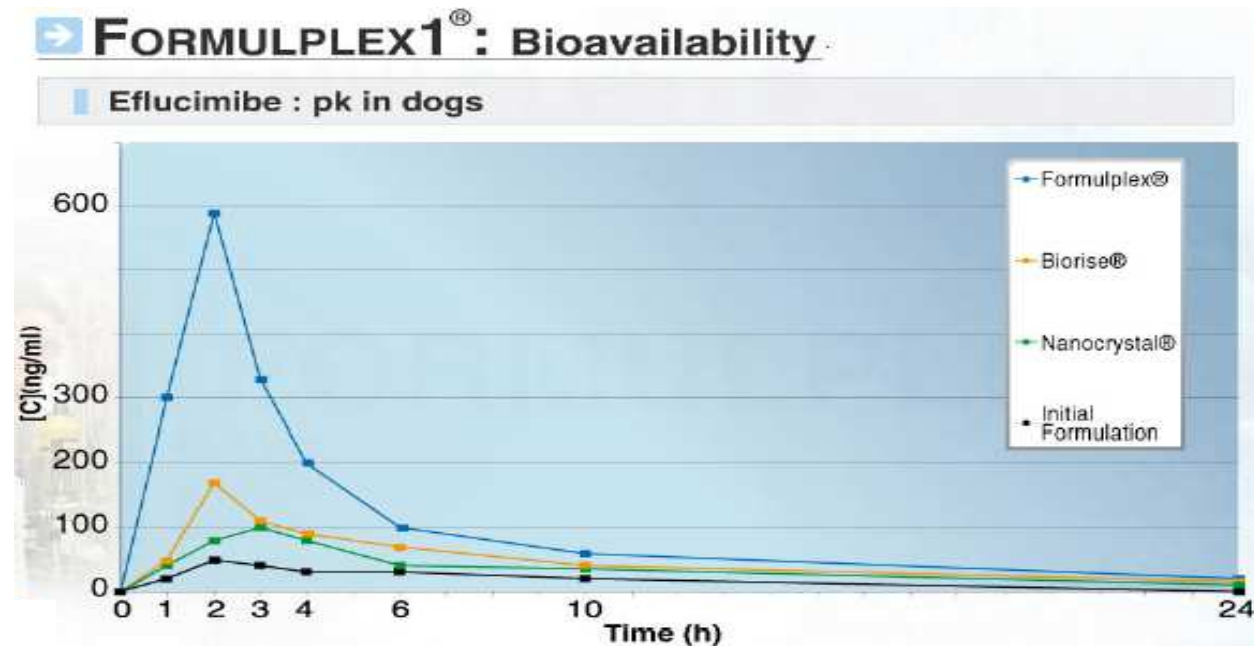
Class	API alone (µg/ml)	After Formulplex [®] (µg/ml)
NSAID	0,2	824
Anti-fungal	274	4628
Cholesterol treatment / dvt	1	156
Cicatrizant	0	318
Antiseptic	80	2500
Veinotonic	5	10
NSAID	25	3887
NSAID	3,23	110,12
Statin	0	40
Anticancerous	0	184
Anticancerous	31	70
Anftifungal	7700	17453

Cyclodextrin used : beta, gamma, Methyl-beta RAMEB, HP-beta

Dissolution test : Buffered Water, 37° C, Solubility after 15'

FORMULPLEX[®]: In-Vivo Results

FORMULPLEX[®] allows to increase dramatically the bioavailability of an oral drug formulation, especially BCS class II (low solubility, high permeability).



pK study (dog) on Eflucimibe:

FORMULPLEX[®] complex (γ -cyclodextrin) compared with initial formulation and other Drug Delivery Technologies.

FORMULPLEX[®]

FORMULPLEX[®] has been rewarded

by the **Silver CPhI Innovation Award** in 2008
and by the **Potier Award** in 2009 (Green Chemistry Price).



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