

Vivo Drug Delivery GmbH

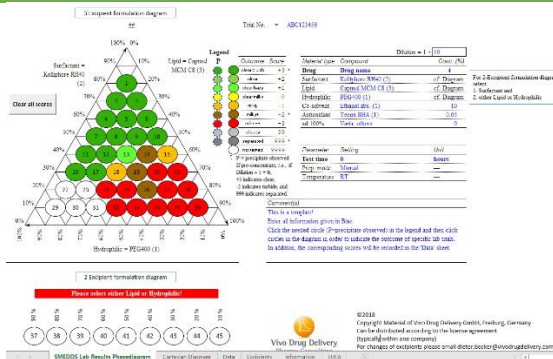
Dr Dieter Becker (founder)

Excel software for efficient & less risky oral SMEDDS development

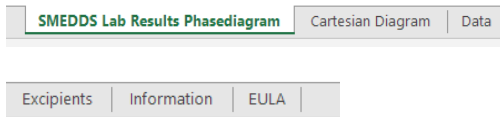
Licensed software

Plan, document and find your lab work results at your fingertip

Example Screen Phase Diagram



Tabs in the Excel Sheet



Who made the software

Dr. Dieter Becker has developed oral solid dosage forms for 25 years at Ciba-Geigy and Novartis. He is having led the SMEDDS formulation group for 3 years at Novartis. Novartis (Sandoz) launched the first SMEDDS formulation (Neoral®) in the Pharma market.

Benefits

- ✓ Easy and fast graphical documentation of SMEDDS formulation lab results (phase diagram)
- ✓ SMEDDS formulation lab results using 3 or 2 excipients can be documented
- ✓ 68 typical excipients used in SMEDDS formulations are classified for risk of registration by Health Authorities in USA, Europe and Japan (FDA, EMA; PMDA)
- ✓ Know-how preservation on all SMEDDS formulations by automatically listing all lab results in a clearly arranged Excel list (different Excel sheet – available on request)
- ✓ Efficient planning of lab-trials e.g. if only mg quantities of drug substance available, ...

How does it work?

SMEDDS Lab Results Phasediagram

- 1) Fill in the drug name and concentration & dilution ratio

$$\text{Dilution} = 1 + \boxed{10}$$

- 2) Select the excipients from the drop-down list – add concentration

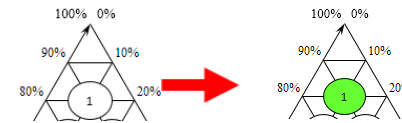
$$\text{Dilution} = 1 + \boxed{10}$$

Material type	Compound	Conc. (%)
Drug	Drug name	4
Surfactant	Kolliphore RH40 (2)	cf. Diagram
Lipid	Capmul MCM C8 (3)	cf. Diagram
Hydrophilic	PEG400 (1)	cf. Diagram
Co-solvent	Ethanol abs. (1)	10
Antioxidant	Tenox BHA (1)	0.05
ad 100%	Varia, others	0

- 3) Add settings e.g. testing time


Parameter	Setting	Unit
Test time	0	hours
Prep. mode	Manual	—
Temperature	RT	—

- 4) Add the lab results
 - Click e.g. on the light green circle (clear hazy) in the legend
 - Click on the corresponding composition(s) in the phase diagram



Legend → Use if precipitate is observed

P	Outcome	Score
	clear bluish	+3
	clear	+2
	clear hazy	+1
	clear milky	0
	milky	-1
	milky+	-2
	milky++	-3
	cloudy	99
	separated	999
	not tested	9999



Lab work procedure: For 3 excipients SMEDDS formulation a surfactant, a lipid and a hydrophilic non-aqueous excipient are mixed together with drug substance. Dilution with water e.g. 1:10 mimics the oral ingestion. The turbidity of the dilution allows the estimation of the droplet size – the lower the better. Different levels of turbidity are classified with colors.

Cartesian Diagram

This is just another representation of the triangle phase diagram.

Data

During the graphical filling of the lab results into the phase diagram

automatically the scores (+1 for clear hazy) are transferred to the data section. Also, the trial number, composition and test settings are collected.

TRIALNO	DRUG ID	DILUTION	TIME	PREP MODE	TEMP	SURFACTANT	LIPID	HYDRO	COSOL	ANTIOXID	OTHEREXCP	DRUGCONC	COCONC	ANTIOXCONC	OTHERCONC	SCORE01	SCORE02	SCORE03	SCORE04		
Trial number	entry	Drug name	#N/A	10	0	hours	Manual	RT	#N/A	Capmul MCM C8 (3)	PEG400 (1)	Ethanol abs. (1)	Tenox BHA (1)	Varia, others	4	10	0,05	0	3	3	3
Material Type																					

With a separate special Excel Macro sheet these data taps in many different files can be automatically read out and combined into a long list. This list represents all results from your lab work. With the Excel sort and filter functions you can easily find past experiments.

Excipients

The excipients that can be selected by drop down lists in the phase diagram are stored in this tap.

ID LIPID	LIPID	ID SURFACT	SURFACT	ID HYDRO	HYDRO
0	---	1	Octocore 4414 (5)	0	---
1	Capmul MCM (3)	CapM	2	Octocore 4816 (5)	Oct
				1	Ardisolve DM (5)
					DM1

ID COSOL	COSOL	ID ANTIOXID	ANTIOXID	ID OTHEREXCP	OTHEREXCP
0	None	0	None	1	None
1	Benzylalcohol (1)	1	EDTA (3)	2	Varia, others
	BnzA		EdA		Var_

Currently 68 excipients are listed. All excipients are ranked by the author due to their risk of being approved by health authorities.

Priority definition for excipient foreseen for oral use in SMEDDS formulations covering the main pharmaceutical markets USA, EU, Japan.

Priority	Description
0	do not use
1	Monography in USP/NF and PhEur and (JP or JPE) and ADI assigned by WHO/FAO
2	Monography in USP/NF and PhEur and ADI assigned by WHO/FAO and allowed in
3	Monography in USP/NF or PhEur or JP and ADI assigned by WHO/FAO and allowed
4	no Monography but allowed in Food in USA, EU, J and ADI assigned by WHO/FAO
5	no Monography but allowed in Food in USA, EU, J

Information

Content of this sheet

- Priority definition SMEDDS excipients
- Disclaimer
- ADI and health authority requirements
- List of excipients (general name, trade name, priority, manufacturer, HLB [not complete])
- Pictures SMEDDS diluted with water - turbidity versus droplet size

EULA

This is the **End User License Agreement**

Contact

Licensed software -
Request a quotation

Dr. Dieter Becker
Vivo Drug Delivery GmbH
Erwinstrasse 21
D-79102 Freiburg, Germany
Phone +49 761 42 99 29 73

dieter.becker@vividrugdelivery.com
Web: <http://www.vividrugdelivey.com>



Vivo Drug Delivery
Pharma Consulting

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