About OMICS Group

OMICS Group is an amalgamation of Open Access Publications and worldwide international science conferences and events. Established in the year 2007 with the sole aim of making the information on Sciences and technology 'Open Access', OMICS Group publishes 500 online open access scholarly journals in all aspects of Science, Engineering, Management and Technology journals. OMICS Group has been instrumental in taking the knowledge on Science & technology to the doorsteps of ordinary men and women. Research Scholars, Students, Libraries, Educational Institutions, Research centers and the industry are main stakeholders that benefitted greatly from this knowledge dissemination. OMICS Group also organizes 500 International conferences annually across the globe, where knowledge transfer takes place through debates, round table discussions, poster presentations, workshops, symposia and exhibitions.

Sanovel

OMICS International

OMICS International is a pioneer and leading science event organizer, which publishes around 500 open access journals and conducts over 500 Medical, Clinical, Engineering, Life Sciences, Pharma scientific conferences all over the globe annually with the support of more than 1000 scientific associations and 30,000 editorial board members and 3.5 million followers to its credit.

OMICS Group has organized 500 conferences, workshops and national symposiums across the major cities including San Francisco, Las Vegas, San Antonio, Omaha, Orlando, Raleigh, Santa Clara, Chicago, Philadelphia, Baltimore, United Kingdom, Valencia, Dubai, Beijing, Hyderabad, Bengaluru and Mumbai.

Effect of Formulation Development and API Characteristics on Fast Dissolving Dosage Forms Bioequivalence Studies

Gülay YELKEN DEMIREL, MSc

Sanovel Pharmaceuticals

BA/BE Studies Summit, Chicago/USA

18.08.2015

Sanovel

Contents

- Introduction
  - Regulatory Definitions
  - What are Fast Dissolving Dosage Forms?
  - Advantages and Limitations of Fast Dissolving Drug Delivery Systems(FDDDS)
- Formulation and Technologies
  - Oral lyophilized dosage forms
  - Orally disintegrating tablets
  - Oral films
- In-vitro Evaluating Parameters of FDDDS
- Clinical Considerations: Bioequivalence Studies
- Case Study: Conventional Tablet vs Orally Disintegrating Tablet
- Conclusion

Introduction

FDDDS were developed in the late 1970s as an alternative to conventional dosage forms for pediatric and geriatric patients.*

This systems have better patient acceptance and compliance and may offer improved biopharmaceutical properties compared with conventional oral dosage forms.

FDDDS may disintegrate in the mouth and can be taken without water.

** Ashish Garg, M.M. Gupta, Mouth Dissolving Tablets: A Review, Journal of Drug Delivery&Therapeutics; 2013*

Regulatory Definitions

US Definition*

- A solid dosage form containing medicinal substances which disintegrates rapidly, usually within a matter of seconds when placed upon the tongue.
- Tablet weight <500mg. In-vitro USP disintegration test <30 seconds.

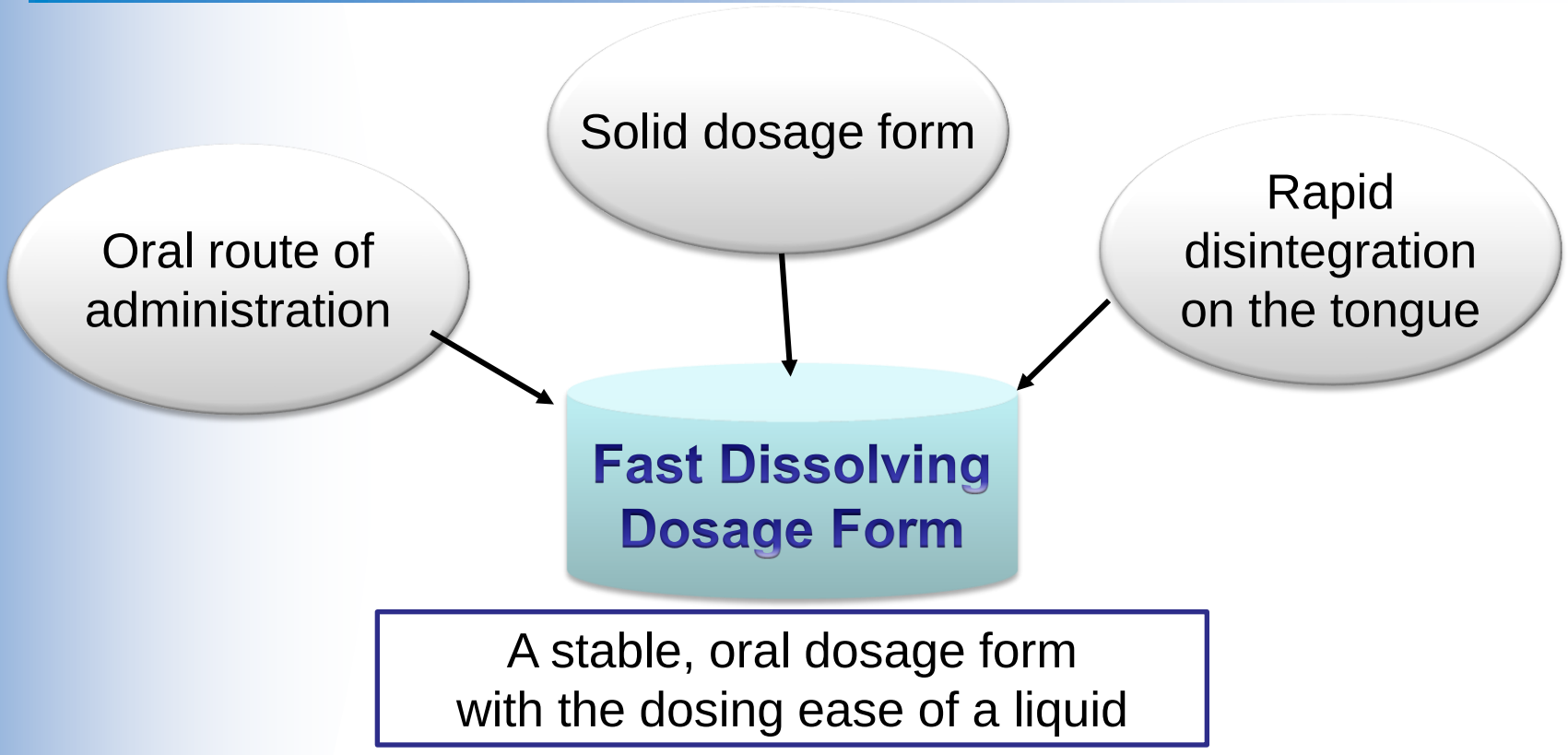
FDA Guidance for Industry -Orally Disintegrating Tablets***

EU Definition**

- **Orodispersible tablets** are uncoated tablets intended to be placed in the mouth where they disperse rapidly before being swallowed.
- Disintegration Test: Orodispersible tablets disintegrate *within 3 minutes* when examined by the test for disintegration...

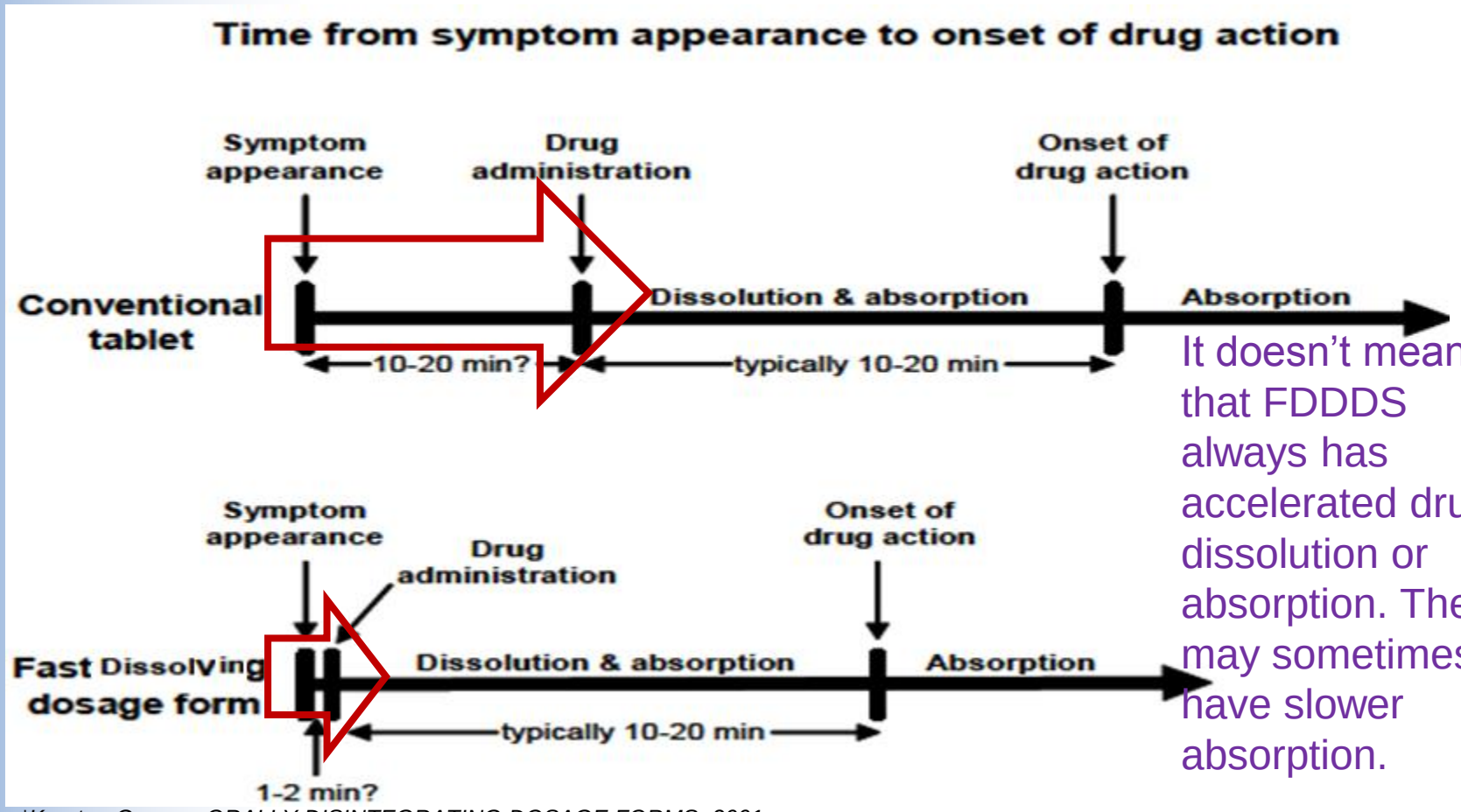
***European Pharmacopoeia (Ph.Eur.)*

What are Fast Dissolving Dosage Forms?



They are swallowed as easily as liquids, but at the same time they are stabl like tablets and capsules.

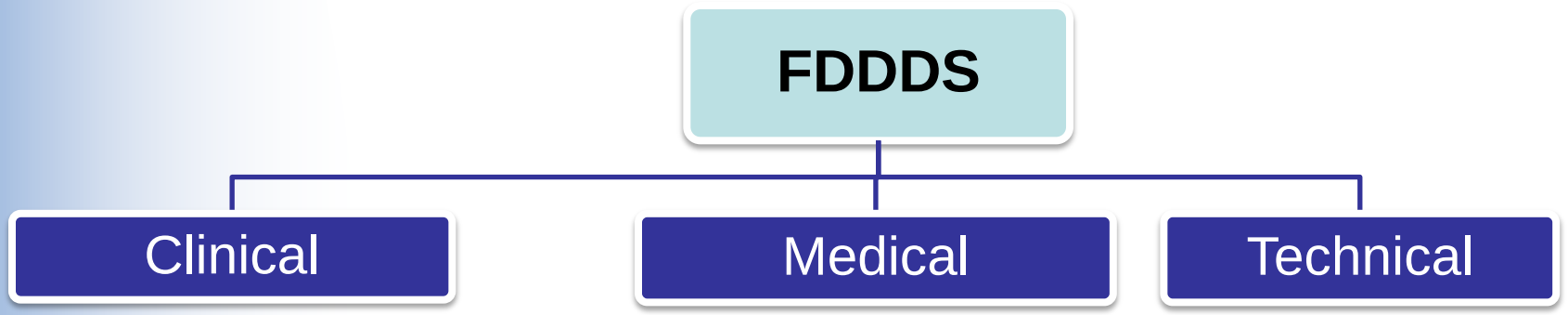
Advantages of FDDDS: Onset of drug action



It doesn't mean that FDDDS always has accelerated drug dissolution or absorption. They may sometimes have slower absorption.

**Karsten Cremer, ORALLY DISINTEGRATING DOSAGE FORMS, 2001*

Advantages of FDDDS



- ✓ Enhanced efficacy (quick onset of action, improved effectiveness)
- ✓ Enhanced oral absorption
- ✓ Minimized first-pass effect
- ✓ Faster onset of action

- ✓ Improved compliance
- ✓ Improved convenience
- ✓ Better taste
- ✓ Administration without water
- ✓ Ease of swallowing

- ✓ Accurate dosing
- ✓ Common process
- ✓ Conventional equipment

Advantages of FDDDS *(cont.)*

FDDDS

Business

- ✓ Unique product differentiation
- ✓ Value-added product line extension
- ✓ Provide exclusive marketing
- ✓ Extend patent protection
- ✓ Reduction of development costs

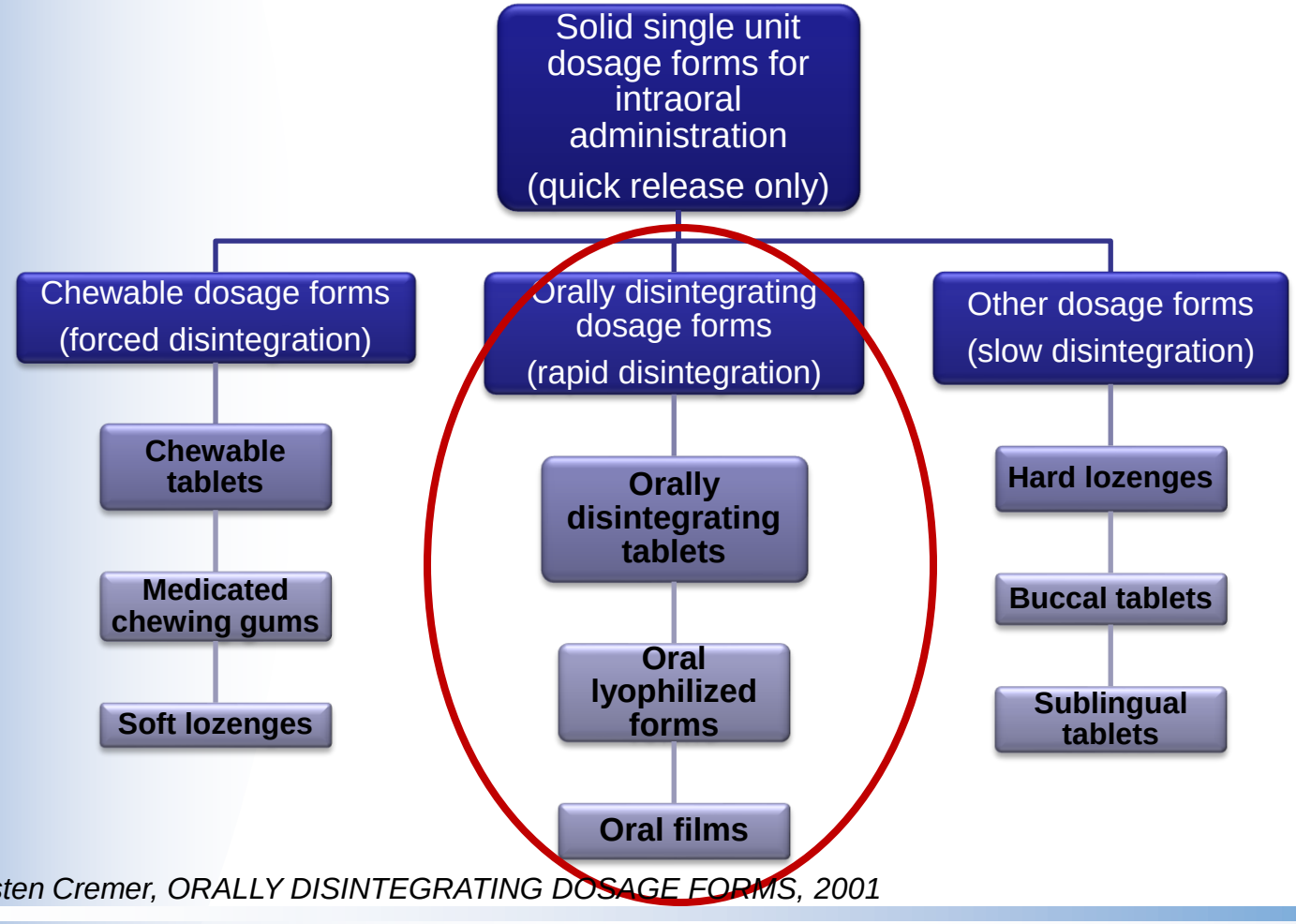
Formulation

- ✓ Rapid disintegration
- ✓ Stability
- ✓ Improve taste
- ✓ Aged-spesific formulations *(pediatric, geriatric and dysphagic patients)*

Limitations of FDDDS

- Limited drug load capacity
- Fragile products, special unit-dose packaging
- Hygroscopicity
- Unpleasant taste of a drug and poor organoleptic properties
- The lack of coated drug(API) particules may cause mucosal irritation.

What are Orally Disintegrating Dosage Forms?



*Karsten Cremer, ORALLY DISINTEGRATING DOSAGE FORMS, 2001

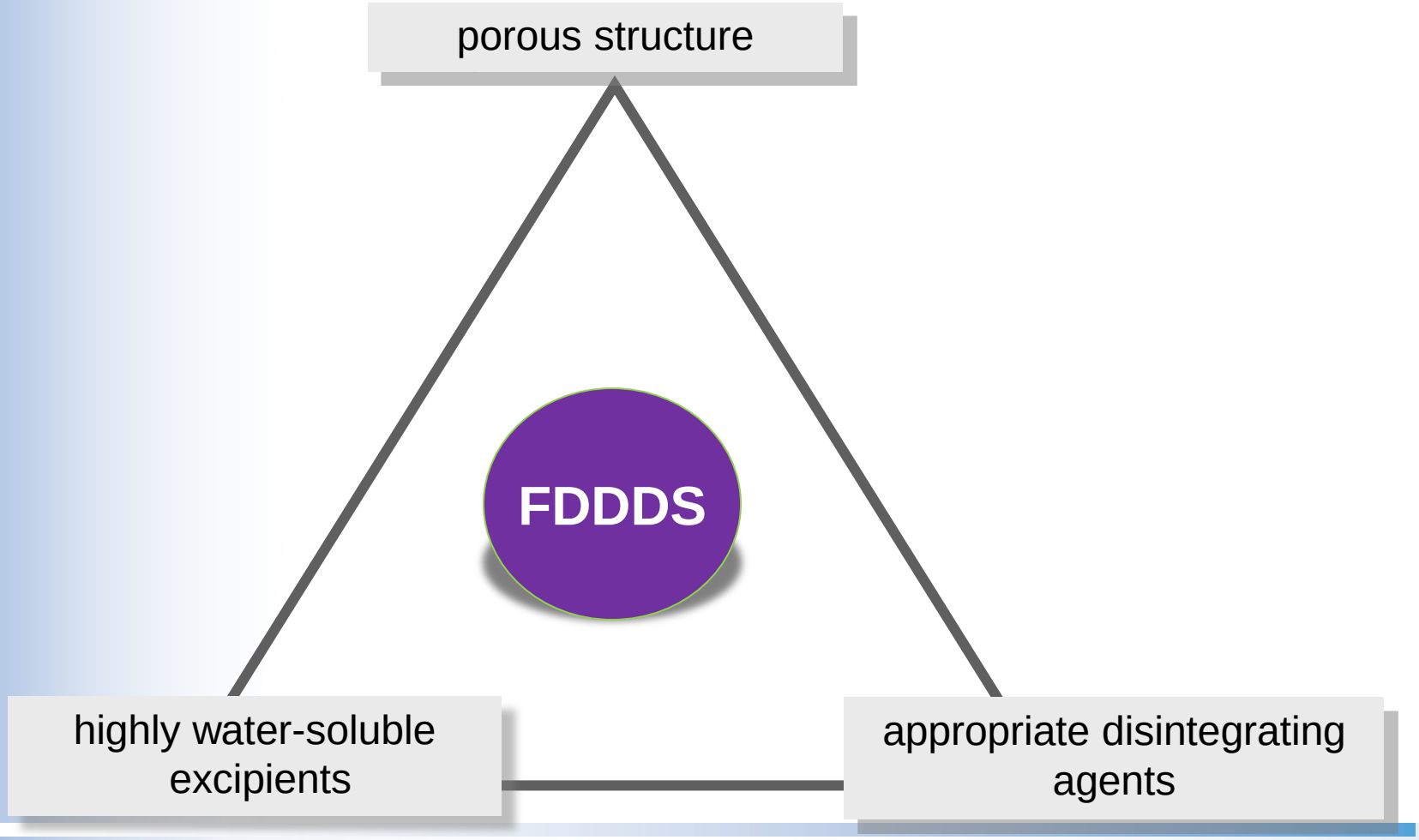
Contents

- Introduction
  - Regulatory Definitions
  - What are Fast Dissolving Dosage Forms?
  - Advantages and Limitations of Fast Dissolving Drug Delivery Systems(FDDDS)
- Formulation and Technologies
  - Oral lyophilized dosage forms
  - Orally disintegrating tablets
  - Oral films
- In-vitro Evaluating Parameters of FDDDS
- Clinical Considerations: Bioequivalence Studies
- Case Study: Conventional Tablet vs Orally Disintegrating Tablet
- Conclusion

Contents

- Introduction
  - Regulatory Definitions
  - What are Fast Dissolving Dosage Forms?
  - Advantages and Limitations of Fast Dissolving Drug Delivery Systems(FDDDS)
- **Formulation and Technologies**
  - **Oral lyophilized dosage forms**
  - **Orally disintegrating tablets**
  - **Oral films**
- In-vitro Evaluating Parameters of FDDDS
- Clinical Considerations: Bioequivalence Studies
- Case Study: Conventional Tablet vs Orally Disintegrating Tablet
- Conclusion

Formulation:Basic Approaches to Develop FDDDS



Technologies for Manufacturing FDDDS

- Oral lyophilized dosage forms
- Orally disintegrating tablets
- Oral films

Technologies for Manufacturing FDDDS

- **Oral lyophilized dosage forms**
- Orally disintegrating tablets
- Oral films

Oral Lyophilized Dosage Forms

- The most successful fast-dissolving oral dosage forms today
- Resulting solid material is a highly porous matrix network
- Disintegrates in less than 10s, typically less than 5s
- Their basic manufacturing process are freeze-drying or lyophilization.
- Expensive manufacturing technology
- Freeze dried ODT - **Zydis®,** RP Scherer in 1986

Formulation Composition
Matrix former
Structure former
Structure promoter
Sweeteners
Other

The critical point of the formulation is that particles are not larger than about 100 µm.

Technologies for Manufacturing FDDDS

- Oral lyophilized dosage forms
- **Orally disintegrating tablets**
- Oral films

Orally Disintegrating Tablets

ODTs are also called as;

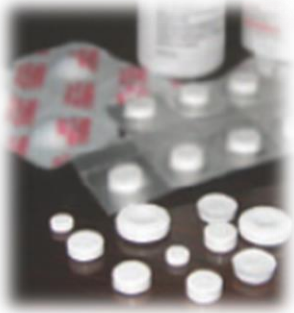
- ✓Orodispersible tablets
- ✓Fast disintegrating tablets,Quick disintegrating tablets
- ✓Fast dissolving tablets, Rapid dissolving tablets
- ✓Mouth dissolving tablets
- ✓Quick melt tablets

Orally Disintegrating Tablets

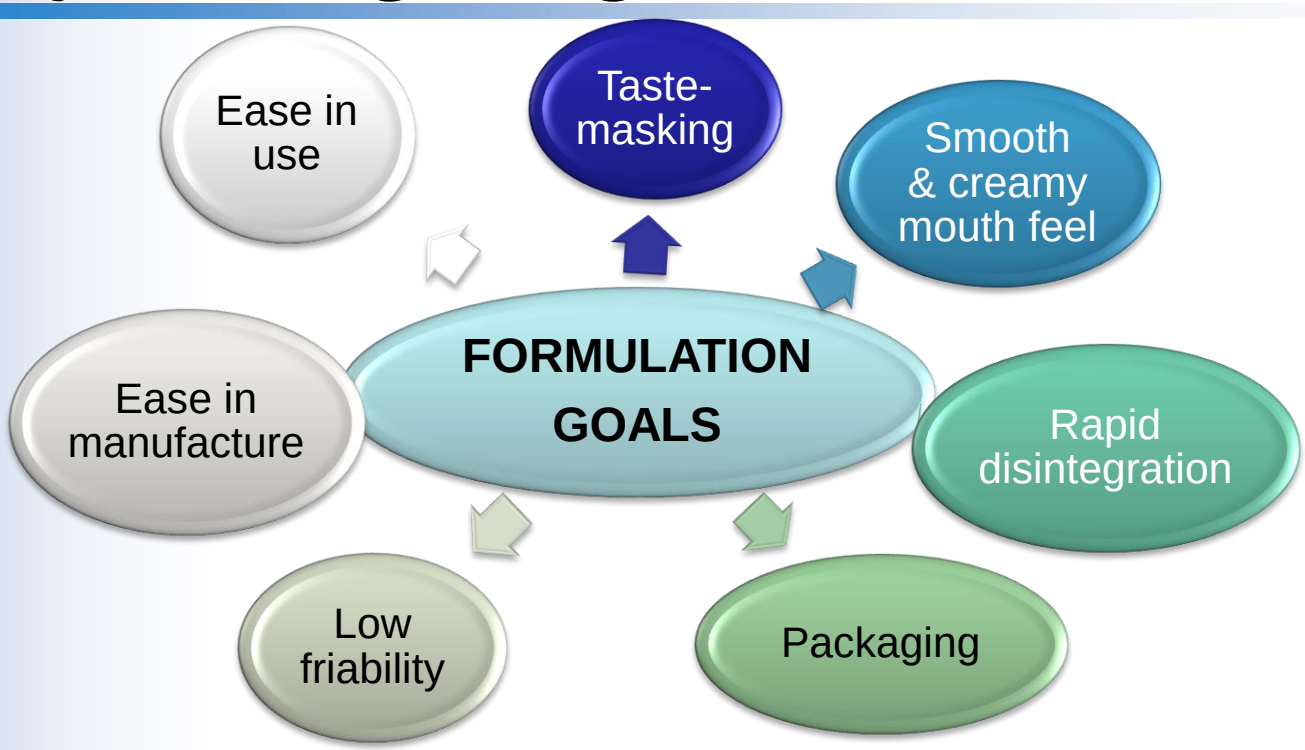
The majority of this technology involves compressed tablets.

Main product attributes;

- Easy to manufacture; lower cost
- Less breakable and friable *(less than 2%)* than lyophilized dosage forms
- Sufficient mechanical strength and good package design
- Disintegrate within 20-30 seconds
- May be moisture-sensitive
- Gritty of insoluble excipient residue may remain on the tongue
- Effervescent couples are used



Orally Disintegrating Tablets



One of the more important thing about formulation is mouthfeel and taste of ODTs.

If the drug has bitter taste, API taste-masking coating may be necessary (Microencapsulation, chelation, complexation, cyclodextrins...).

Orally Disintegrating Tablets

Tablet manufacturers and patented technologies characteristics				
Technology	**In-vitro disintegration time(s)**	**Tablet hardness and robustness**	**Packaging**	**Drug-loading dose(mg)**
AdvaTab(Eurand)	15-30	hard, robust	bottles or blister pack	<700
DuraSolv(Cima Labs)	<30	hard, robust	bottles or blister pack	<500
FlashDose(Biovail)	5-15	soft, friable	blister pack	<600
FlashTab(Ethypharm SA)	30-60	relatively durable	blister pack	<650
Lyoc(Cephalon)	<10	soft, friable	blister pack	<1000
OraQuick(KV Pharmaceuticals)	<20	relatively durable	bottles or blister pack	<500
OraSolv(Cima Labs)	<30	soft, friable	blister pack	<750
SATAB(Sato)	<10	relatively durable	blister pack	<600
WOWTAB(Yamanouchi)	<30	relatively durable	bottles or blister pack	<500

**K. Ostrander, "Advances in Fast Dispersing Technologies-Zydis", Oct. 29, 2003.*

Orally Disintegrating Tablets: OraSolv® &DuraSolv™

OraSolv® Technology, Cima Labs Inc.

- ❑Tasted-masked API
- ❑Contains effervescent agents
- ❑Direct compression technique at low compression force
- ❑Soft and fragile nature, packed in specially designed pick and place system(PackSolv™)

DuraSolv™ Technology, Cima Labs Inc.

- ❑Second generation technology
- ❑Used conventional tableting equipment, 15-50 Newton
- ❑Low friability(less than 2 %), packaging in conventional packaging systems

Orally Disintegrating Tablets: OraSolv®&DuraSolv™

Formulation Composition
Filler
Disintegrant
Flavor
Sweetener
Lubricant
Colorant, if required
Effervescent components

Technologies for Manufacturing FDDDS

- Oral lyophilized dosage forms
- Orally disintegrating tablets
- **Oral films**

Oral Films (Rapid Films)

- It is complying with the orodispersible tablet definition of the Ph.Eur.
- The delivery system based on a water soluble polymer and it is usually obtained by solvent casting, hot-melt extrusion, solid dispersion.

Advantages

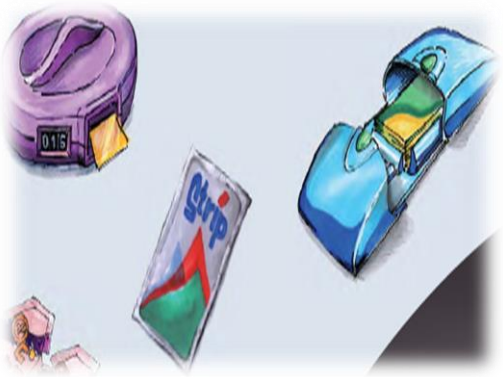
- Rapid disintegration
- Elegant presentation
- Improved portability
- Accurate dosing
- Discrete administration

Limitations

- Drug loading
- Unpleasant taste of API
- Manufacturing cost
- Stability
- Film integrity

Oral Films: Formulation

Formulation Composition
Water soluble polymer
Plasticizers
Surfactants
Sweetening agent
Saliva stimulating agent
Fillers, colours, flavors etc.



Contents

- Introduction
  - Regulatory Definitions
  - What are Fast Dissolving Dosage Forms?
  - Advantages and Limitations of Fast Dissolving Drug Delivery Systems(FDDDS)
- Formulation and Technologies
  - Oral lyophilized dosage forms
  - Orally disintegrating tablets
  - Oral films
- In-vitro Evaluating Parameters of FDDDS
- Clinical Considerations: Bioequivalence Studies
- Case Study: Conventional Tablet vs Orally Disintegrating Tablet
- Conclusion

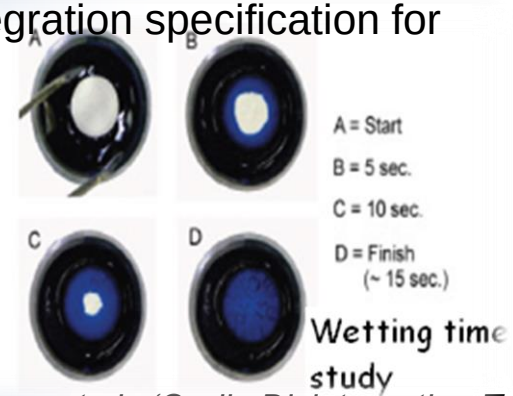
Contents

- Introduction
  - Regulatory Definitions
  - What are Fast Dissolving Dosage Forms?
  - Advantages and Limitations of Fast Dissolving Drug Delivery Systems(FDDDS)
- Formulation and Technologies
  - Oral lyophilized dosage forms
  - Orally disintegrating tablets
  - Oral films
- **In-vitro Evaluating Parameters of FDDDS**
- Clinical Considerations: Bioequivalence Studies
- Case Study: Conventional Tablet vs Orally Disintegrating Tablet
- Conclusion

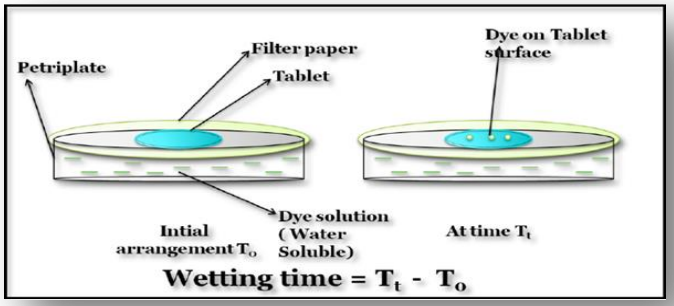
In-vitro Evaluating Parameters of FDDDS

- In-process control tests (thickness, hardness, uniformity of weight, friability, disintegration test...), dissolution, assay and impurity analyses
- Wetting time and water absorption ratio

FDA recommends using a disposable syringe,1 mL of water is delivered directly onto a tablet placed on a flat surface, completeness of disintegration of the tablet is checked and is set as the disintegration specification for ODTs.



10 cm diameter Petri dish is filled with 10 mL of water containing a water soluble dye and a 10 cm diameter tissue paper is placed in the petri dish. The tablet is placed in the center of the dish and the time for the tablet to completely disintegrate is noted as the disintegration time.

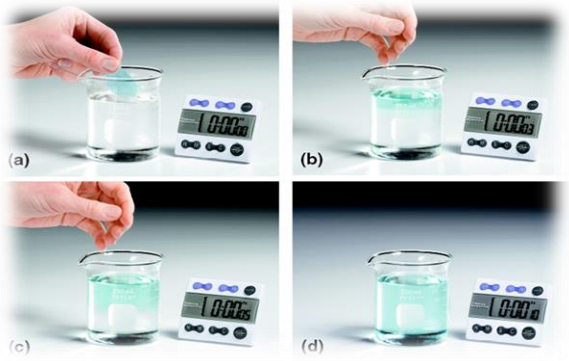


**J.Segado Ferran et al., 'Orally Disintegrating Tablets and Process for obtaining them', WO103629(2003)*

In-vitro Evaluating Parameters of FDDDS

Oral Films

- Thickness
- Dryness test
- Tensile strength
- Percent elongation
- Folding endurance
- Stickiness determination
- Contact angle measurement



Electronic Tongue is very helpful for taste comprasion*(organoleptic properities)* studies especially for the generic companies.

Contents

- Introduction
  - Regulatory Definitions
  - What are Fast Dissolving Dosage Forms?
  - Advantages and Limitations of Fast Dissolving Drug Delivery Systems(FDDDS)
- Formulation and Technologies
  - Oral lyophilized dosage forms
  - Orally disintegrating tablets
  - Oral films
- In-vitro Evaluating Parameters of FDDDS
- Clinical Considerations: Bioequivalence Studies
- Case Study: Conventional Tablet vs Orally Disintegrating Tablet
- Conclusion

Contents

- Introduction
  - Regulatory Definitions
  - What are Fast Dissolving Dosage Forms?
  - Advantages and Limitations of Fast Dissolving Drug Delivery Systems(FDDDS)
- Formulation and Technologies
  - Oral lyophilized dosage forms
  - Orally disintegrating tablets
  - Oral films
- In-vitro Evaluating Parameters of FDDDS

- **Clinical Considerations: Bioequivalence Studies**
- **Case Study: Conventional Tablet vs Orally Disintegrating Tablet**
- Conclusion

Clinical Considerations:Bioequivalence Studies

- Creating a Fast Dissolving Dosage Form version of an existing immediate release product means that the two formulations must be bioequivalent. Typically the results are similar.

- If the method of taste-masking retards the dissolution rate of active ingredients, it may cause failure of the bioequivalence study.

- Whenever a significant degree of buccal absorption of a drug with a high hepatic first-pass effect is achieved, the bioavailability may be increased considerably.

Clinical Considerations:Bioequivalence Studies

- If drug absorption of FDDF is faster than with the corresponding formulation*(conventional tablet or capsule)*, whether caused by some degree of buccal absorption or simply by faster disintegration and drug dissolution followed by rapid gastric or intestinal absorption, clinical studies for the establishment of product **efficacy** and **safety** should be established.

- If no significant degree of buccal or sublingual absorption occurs, the pharmacokinetic profile will typically be similar to that of a conventional tablet or capsule containing the same dose of the drug. In these cases, a bioequivalence status should be established.

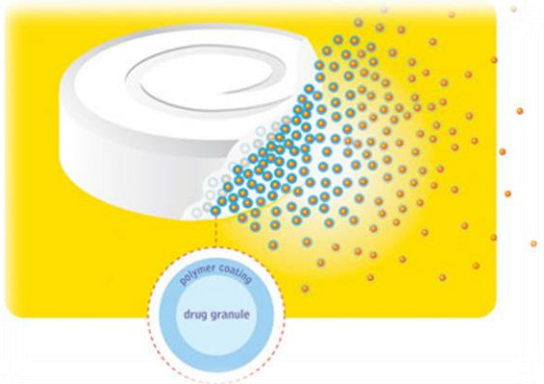
Clinical Considerations: API Characteristics

API Characteristics
▪ Buccal and sublingual absorption ▪ Water-solubility ▪ pKa value ▪ Molecular weight ▪ Lipophilicity

Buccal absorption takes place when a drug is water-soluble to a degree that allows the dose to dissolve in saliva, has a moderate pKa allowing a fraction of the dissolved drug to be unionized, has a relatively low molecular weight and a degree of lipophilicity leading to a high mucosal permeability relative to its dose.

Mucosal irritation of the oral cavity may be another factor to be considered.

Using taste-masking polymers may retard the dissolution rate of API and may cause problems.



Case Study: Conventional Tablet vs Orally Disintegrating Tablet

API Characteristics: BCS Class-II : High Permeability, Low Solubility
There is no buccal and sublingual absorption information is available.
There is no food effect.

Dissolution method development conditions

- FDA-Recommended Dissolution Methods**(0.5 % SLS in water, 1000 mL, 50 rpm, paddle)*
- Different SLS content*(0.25 %, 1.0 %, SLS-free)*
- Rotation speed*(50, 75 rpm)*
- Dissolution volume*(1000,500 mL)*
- 3 different pH media with and without different amount of SLS content
- Fassif*(Fasted State Simulated Intestinal Fluid-biorelevant dissolution media)*

Fasted State Simulated Intestinal Fluid (FaSSIF)

Sodium taurocholate	3mM
Lecithin	0.75 mM
NaOH (pellets)	0.174 g
$NaH_2PO_4.H_2O$	1.977 g
NaCl	3.093 g
Purified water qs.	500 mL

Media has a pH of 6.50 and an osmolality of about 270 mOsmol/kg.

**http://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm*

Case Study: Conventional Tablet vs Orally Disintegrating Tablet

Developed Formulation Unit Formula*	Reference Listed Drug Unit Formula**
API	API
Mannitol	Lactose monohydrate
Crospovidone	Croscarmellose sodium
Polyvinylpyrrolidone	Hydroxypropylcellulose
Sucralose	Microcrystalline cellulose
Sodium lauryl sulfate	Sodium lauryl sulfate
Flavor	Magnesium stearate
Colouring agent	Film coating material*(Opadry II Yellow)*
Sodium stearyl fumarate	

**Appearance : blue-coloured, round tablets*
***Appearance : yellow-coloured round tablets*

Case Study: Conventional Tablet vs Orally Disintegrating Tablet: In-vitro Dissolution Studies

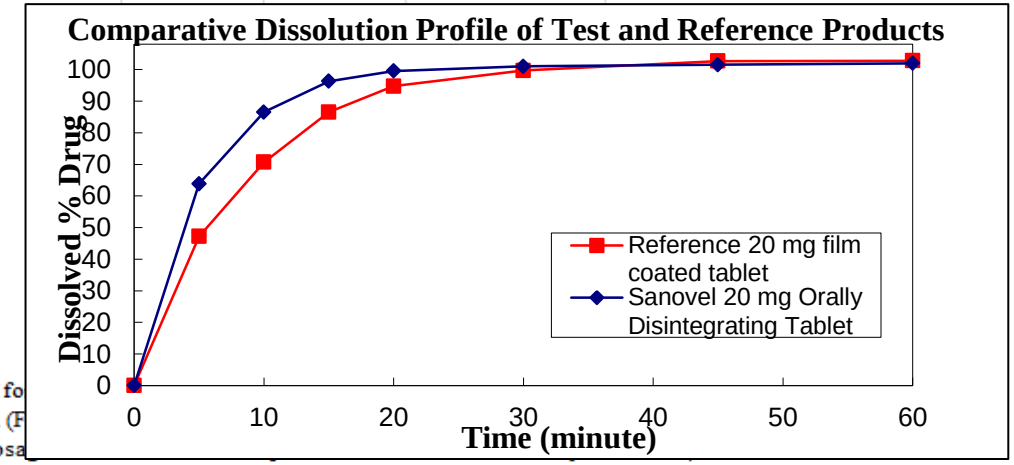
Time (minute)	DISSOLVED %							
	Reference 20 mg film coated tablet				Sanovel 20 mg Orally Disintegrating Tablet			
	Average (%)	Standart Deviation	Relative Standart Deviation (%)	Confidence Interval (95 %)	Average (%)	Standart Deviation	Relative Standart Deviation (%	Confidence
0	**0**	0.0	0.0	0.0	**0**	0.0	0.0	
5	**47**	6.6	13.9	3.7	**64**	2.8	4.4	
10	**71**	5.3	7.5	3.0	**87**	1.5	1.8	
15	**87**	3.5	4.0	2.0	**96**	1.8	1.9	
20	**95**	1.7	1.8	1.0	**100**	1.9	2.0	
30	**100**	1.3	1.3	0.7	**101**	1.4	1.4	
45	**103**	1.1	1.1	0.6	**102**	1.8	1.8	
60	**103**	1.3	1.2	0.7	**102**	1.6	1.5	0.9

Dissolution Conditions:
0.5 % SLS in water , 1000 mL, 50 rpm, paddle

Reference / Test Product:

Time (minute)	(R-T)	SR :	604.3
0	0.0	S(R-T) :	50.2
5	16.6		
10	15.8		
15	9.8		
20	4.8		
30	1.3		
45	1.1		
60	0.8		

Conclusion: Where more than 85% of the drug is dissolved fo
accepted as similar without further mathematical evaluation. (F
Bioequivalence Studies for Immediate-Release Solid Oral Dosa



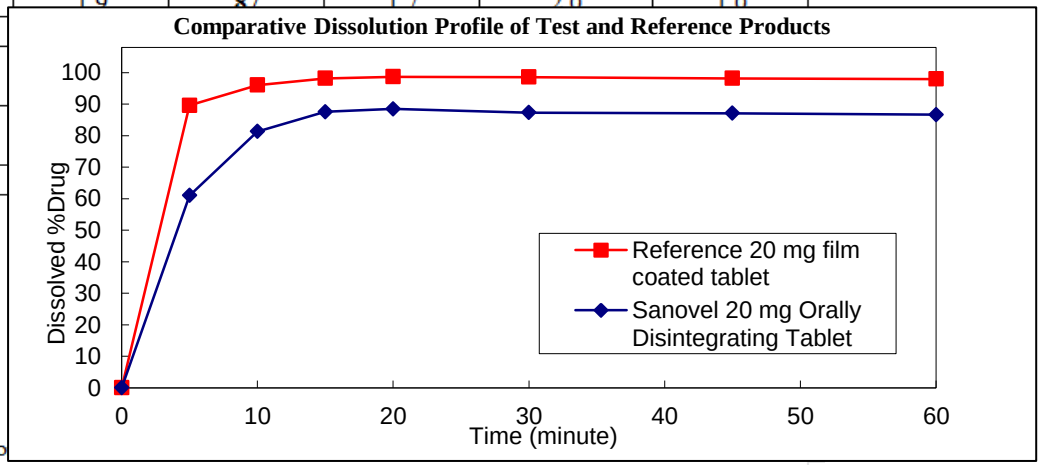
Case Study: Conventional Tablet vs Orally Disintegrating Tablet: In-vitro Dissolution Studies

Time (minute)	DISSOLVED %							
	Reference 20 mg film coated tablet				Sanovel 20 mg Orally Disintegrating Tablet			
	Average (%)	Standart Deviation	Relative Standart Deviation (%)	Confidence Interval (95 %)	Average (%)	Standart Deviation	Relative Standart Deviation (%)	Confidence Interval (95 %)
0	**0**	0.0	0.0	0.0	**0**	0.0		
5	**90**	3.1	3.4	1.7	**61**	6.9		
10	**96**	2.1	2.2	1.2	**81**	2.8		
15	**98**	2.8	2.8	1.6	**88**	1.5		
20	**99**	3.1	3.1	1.7	**88**	1.7		
30	**99**	3.2	3.2	1.8	**87**	1.8	2.0	1.0
45	**98**	3.3	3.4	1.9	**87**	1.7	2.0	1.0
60	**98**	3.6	3.7					

Dissolution Conditions:
0.1 N HCl with 0.5 % SLS, 1000 mL, 50 rpm, paddle

Reference / Test Product:

Time (minute)	(R-T)		
0	0.0	SR :	677.1
5	28.6	S(R-T) :	97.8
10	14.7		
15	10.6		
20	10.2		
30	11.3		
45	11.1		
60	11.3		



Conclusion: Where more than 85% of the drug is dissolved fo
similar without further mathematical evaluation. (FDA, Guidance for industry, Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System, 2000.)

Case Study: Conventional Tablet vs Orally Disintegrating Tablet: In-vitro Dissolution Studies

Time (minute)	DISSOLVED %							
	Reference 20 mg film coated tablet				Sanovel 20 mg Orally Disintegrating Tablet			
	Average (%)	Standart Deviation	Relative Standart Deviation (%)	Confidence Interval (95 %)	Average (%)	Standart Deviation	Relative Standart Deviation (%)	Confidence Interval
0	**0**	0.0	0.0	0.0	**0**	0.0		
5	**90**	3.1	3.4	1.8	**69**	2.9		
10	**96**	2.1	2.2	1.2	**88**	2.1		
15	**98**	2.8	2.8	1.6	**92**	1.3		
20	**99**	3.1	3.1	1.7	**93**	1.3		
30	**98**	3.2	3.3	1.8	**95**	1.1		
45	**98**	3.3	3.3	1.8	**97**	1.6	1.7	0.9
60	**98**	3.3	3.4	1.9	**95**	1.3	1.4	0.7

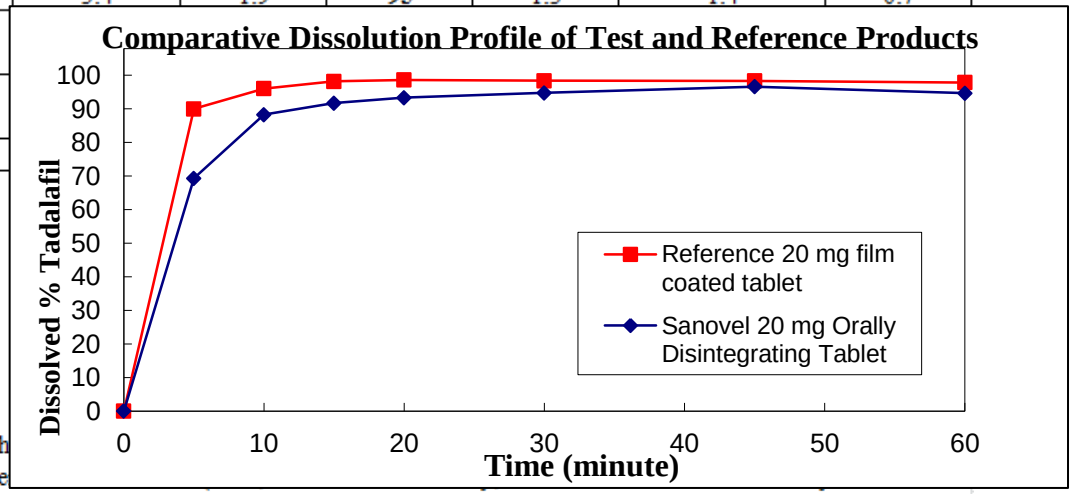
Dissolution Conditions: pH=4.5 acetate buffer with 0.5 % SLS, 1000 mL, 50 rpm, paddle

Reference / Test Product:

Time (minute)	(R-T)
0	0.0
5	20.7
10	7.8
15	6.5
20	5.3
30	3.6
45	1.7
60	3.2

SR :

S(R-T) :



Conclusion: Where more than 85% of th
accepted as similar without further mathe
Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System, 2000.)

Case Study: Conventional Tablet vs Orally Disintegrating Tablet: In-vitro Dissolution Studies

Time (minute)	DISSOLVED %							
	Reference 20 mg film coated tablet				Sanovel 20 mg Orally Disintegrating Tablet			
	Average (%)	Standart Deviation	Relative Standart Deviation (%)	Confidence Interval (95 %)	Average (%)	Standart Deviation	Relative Standart	Confidence Interval
0	**0**	0.0	0.0	0.0	**0**	0.0		
5	**90**	3.2	3.6	1.8	**68**	4.5		
10	**97**	1.1	1.2	0.6	**91**	3.0		
15	**99**	0.9	0.9	0.5	**96**	3.2		
20	**99**	0.9	0.9	0.5	**96**	1.9		
30	**99**	0.6	0.6	0.4	**97**	2.2		
45	**99**	0.7	0.7	0.4	**98**	2.3	2.4	1.3
60	**99**	0.7	0.7	0.4	**99**	2.2	2.2	1.2

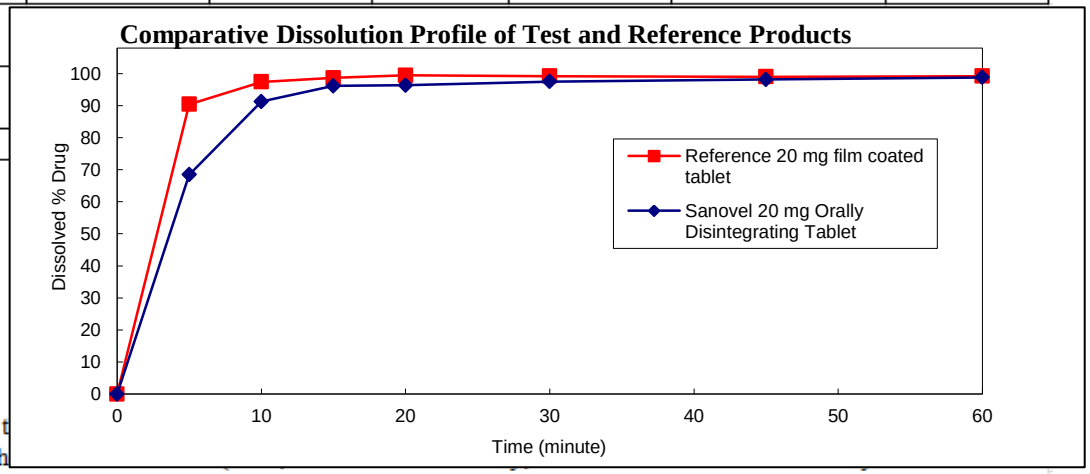
Dissolution Conditions: pH=6.8 phosphate buffer with 0.5 % SLS, 1000 mL, 50 rpm, paddle

Reference / Test Product:

Time (minute)	(R-T)
0	0.0
5	22.0
10	6.2
15	2.5
20	3.1
30	1.7
45	0.9
60	0.4

SR :

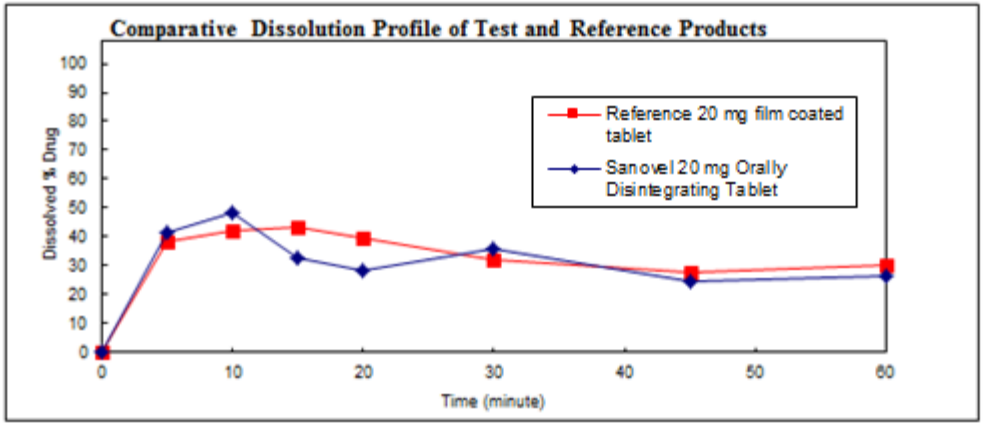
S(R-T) :



Conclusion: Where more than 85% of t
accepted as similar without further math
Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System, 2000.)

Case Study: Conventional Tablet vs Orally Disintegrating Tablet

Time (minute)	DISSOLVED %							
	Reference 20 mg film coated tablet				Sanovel 20 mg Orally Disintegrating Tablet			
	Average (%)	Standart Deviation	Relative Standart Deviation (%)	Confidence Interval (95 %)	Average (%)	Standart Deviation	Relative Standart Deviation (%)	Confidence Interval (95 %)
0	**0**	0.0	0.0	0.0	**0**	0.0	0.0	0.0
5	**38**	3.2	3.6	1.8	**42**	4.5	6.5	2.5
10	**42**	1.1	1.2	0.6	**48**	3.0	3.3	1.7
15	**43**	0.9	0.9	0.5	**33**	3.2	3.3	1.8
20	**40**	0.9	0.9	0.5	**28**	1.9	2.0	1.1
30	**32**	0.6	0.6	0.4	**36**	2.2	2.3	1.3
45	**28**	0.7	0.7	0.4	**25**	2.3	2.4	1.3
60	**30**	0.7	0.7	0.4	**26**	2.2	2.2	1.2



FASSIF CONDITIONS

Case Study: Conventional Tablet vs Orally Disintegrating Tablet

Comparative Pharmacokinetic Results		
Parameters	Test*	Reference**
Cmax(µg/mL)	369.631±59.185	353.056±87.772
Tmax(h)	2.926±1.177	3.280±1.295
$t_{1/2}$(h)	21.903±7.558	21.569±6.212
$AUC_{0-tlast}$(µg/mL/h)	9160.425±2426.795	8990.354±2045.818
$AUC_{0-\infty}$(µg/mL/h)	10494.620±3200.168	10094.698±2728.826

The mean plasma concentration-time profiles were similar for ODT and Conventional Tablet.

The test and reference formulations met the regulatory requirements for bioequivalence*(80–125%, 90% CI).*

**Sanovel 20 mg Orally Disintegrating Tablet*
***Conventional 20 mg Film Coated Tablet*

Conclusion

- FDDDS can be used for improving patient compliance, extending patent life, product life cycle and product differentiation.

- Because of increased patient demand, these dosage forms are expected to become more popular.

- The pharmacokinetic profile will typically be similar to that of a conventional tablet or capsule containing the same dose of the drug with FDDDS.

- Some clinical studies should be concern if API has significant degree of buccal or sublingual absorption.

Thank you for your attention…

Let us meet again..

We welcome you all to our future conferences of

OMICS International

7th World Congress on

Bioavailability & Bioequivalence: BA/BE Studies Summit

On

August 29 - 31, 2016 at **Atlanta, USA**

http://bioavailability-bioequivalence.pharmaceuticalconferences.com/

Sanovel