Polymer based wafer

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PHARMACEUTICS

- Wafer drug delivery is an advancing field which represents highly versatile polymeric devices consisting of porous matrices that allow for rapid delivery of drugs.
- Most wafers are produced via lyophilization, a process key to its rapidly disintegrating properties. The removal of unbound moisture from the wafer during the lyophilization process creates voids within the matrix resulting in the formation of a porous network which facilitates disintegration when exposed to the hydrophilic, saliva-rich oral cavity.

Wafer – an innovative oral dosage form

- New oral thin films, so-called wafers, thus creating new possibilities for action profiles and patient compliance. Wafers are paper-thin polymer films used as carriers for pharmaceutical agents. The innovative dosage form is taken orally but does not require water or swallowing.
- Effective absorption of active ingredient**:** The wafer quickly dissolves in the oral cavity, and the active ingredient can be absorbed into the blood - stream via the oral mucosa. The active ingredient, once absorbed by the oral mucosa, thus bypasses the liver's first-pass effect, which improves bioavailability. Depending on the selected wafer type, the active ingredient's release may also be delayed. In this case, it is absorbed after swallowing via the gastrointestinal tract.

- Lyophilized wafers can be prepared by freeze-drying aqueous gels of polymer(s) to form a porous polymeric inter-connecting network .
- During drug dissolution, swelling and diffusion compete, with swelling dominating initially, by increasing the gel layer thickness and subsequently reaches a plateau due to synchronization of swelling, drug diffusion and dissolution .
- To obtain optimum bioavailability, swelling, mucoadhesion and dissolution characteristics must be optimized as they affect residence time and eventual drug release .

Advantages of wafers

- No first – pass effect
- Controlled release
- Improved bio-availability, translates to lower doses
- Reduction of side-effects
- Discrete and easy application (no additional intake of liquids required)
- Excellent compliance, especially in children and seniors

Type of wafers

- Flash dissolved wafers
- Melt away wafers
- Sustained release wafers
- Flash dispersed wafers

Sustained-release Wafer

Long-acting release formulation

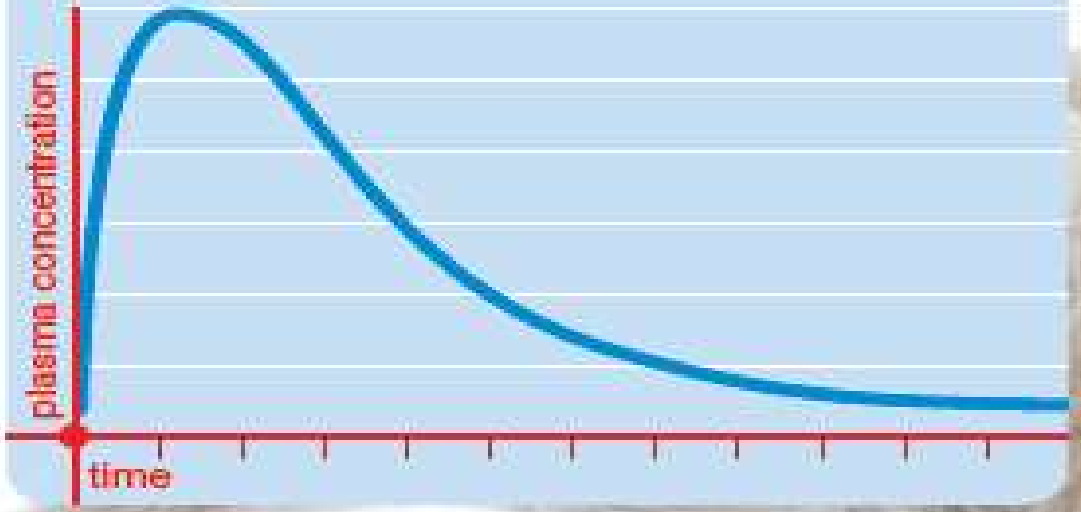
Dissolution/release:
several hours

Resorption site:
gums

Effect:
systemic

Flash-dispersal Wafer

Rapid release formulation, absorption into the gastrointestinal tract



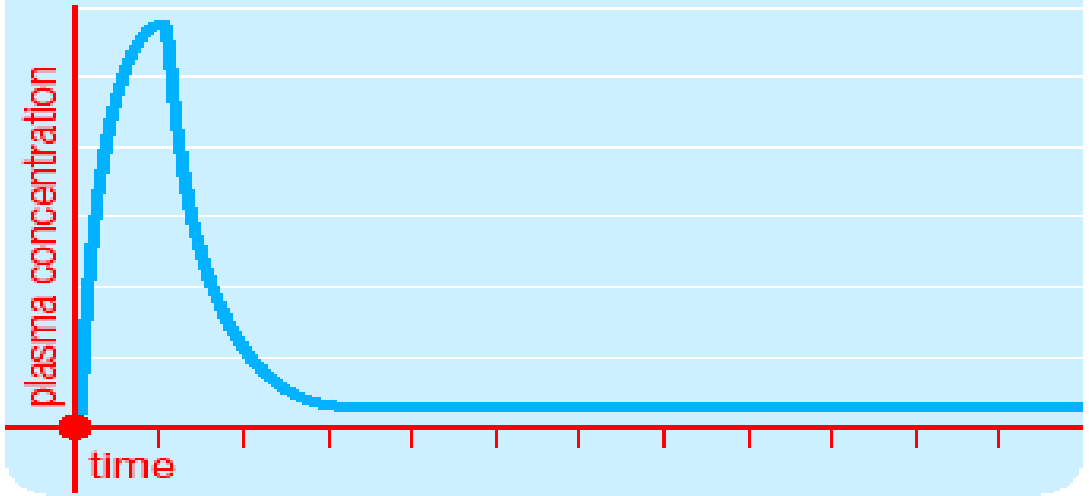
Dissolution/release:
maximum of 30 seconds until complete dissolution

Resorption site:
gastrointestinal tract

Effect:
systemic or local

Flash-dissolve wafer

Rapid release formulation, fast onset of action



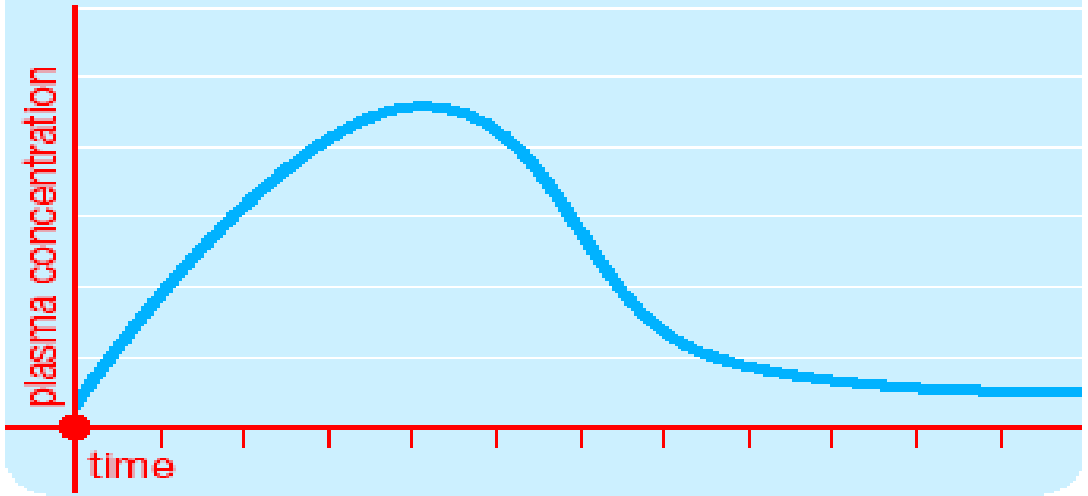
Dissolution/release:
maximum of 30 seconds until complete dissolution

Resorption site:
oral mucosa

Effect:
systemic or local

Melt-away Wafer

Intermediate dissolution at application site, high local drug concentration



Dissolution/release:
5-30 minutes, formation of gel-like depot

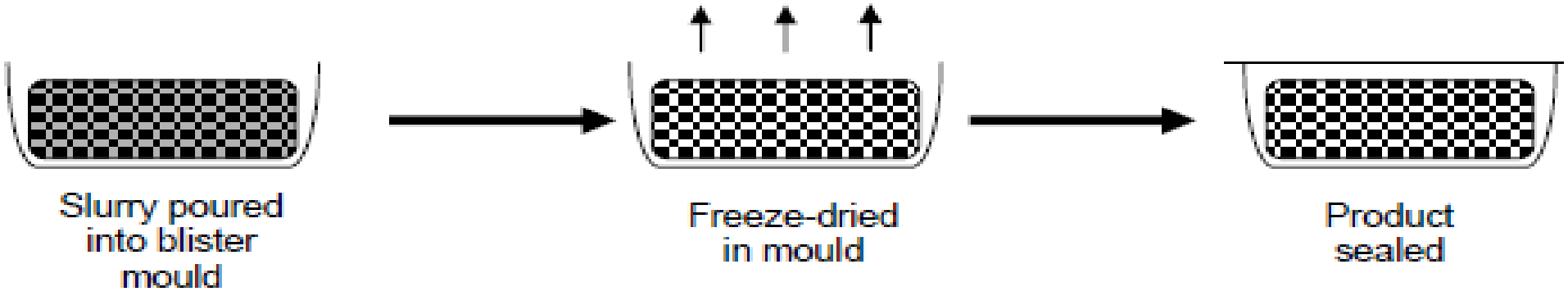
Resorption site:
oral mucosa

Effect:
systemic or local

Type /Property	Flash Release Wafer	MucoadhesiveMelt-away wafer	Mucoadhesive release Wafer	Sustained
Area (cm2)	2 – 8	2 – 7	2 – 4	
Thickness (µm)	20 – 70	50 – 500	50 – 250	
Structure	Film: single layer	Single or multilayer system	Multilayer System	
Excipients	Hydrophilic polymers	Hydrophilic polymers	Low / Non-soluble Polymers	
Drug phase	Solid solution	Solid solution or suspension	Suspension or solid Solution	
Application	Tongue (upper palate)	Gingival or buccal region	Gingival or other region in oral cavity	
Dissolution	Maximum 60 seconds	Disintegration in a few minutes, forming gel	Maximum 8 – 10 hr.	

Manufacturing of wafers

- The active ingredient in wafer is integrated into a polymer matrix. The typical size of an oral film is between 2cm2 to 10cm2 , with a thickness of 20 micrometer to 500 micrometer. Oral thin films can be composed of a single-layered system. The active ingredient may be presented within the wafer matrix in either a dissolved an emulsified or a dispersed state. If required, it can also be bound in a complex form ,for example ,to enable taste masking .



Wafers in protein drug delivery

- Lyophilised wafers from chitosan have been developed as potential protein drug delivery systems via the buccal mucosa.
- Wafers provide a potential means of delivering pharmacological agents such as proteins to mucosal surfaces for both local and systemic applications.
- They offer advantages over other delivery systems such as semi solid polymer gels and solvent cast, films. Unlike semi solid polymer gels which flow easily after application, wafers can maintain their swollen gel structure for a longer period and therefore longer residence time to allow for effective drug absorption. Due to their porous nature and higher surface area, wafers have a higher drug loading capacity compared to the thin and continuous solvent cast equivalent

.

Wafers in protein drug delivery

- Lyophilization is a preferred drying method as it overcomes most limitations associated with the formulation of protein products.
- Lyophilized formulations offer stable products, extend shelf life and allow storage of products at room temperature instead of −20 ◦C. They also avoid the complications of cold chain supply management; facilitate transportation of products and increases patient compliance .

(a) SA:Ch 1g SA:Ch 2g SA:Ch 3g SA:Ch 5g

(b) SA:Ch 4:1, 3g, 0.25% w/w BSA SA:Ch 4:1, 3g, 0.50% w/w BSA

Figure 2 : (a) Freeze-dried wafers obtained by pouring different weights of composite (SA:Ch 4:1) gels showing differences in thickness (b) BSA loaded wafers obtained from pouring 3g of SA:Ch 4:1 gels.

Wafer in wound healing

- Lyophilized wafers are good candidates as a novel dressing for mucosal wound healing. They are prepared by freeze-drying gels, and could be medicated and applied to the mucosal surfaces.
- When applied to wound sites, they absorb wound exudates and are converted into a gel, thereby maintaining a moist environment and providing sustained release of the drugs
- The major advantage of using wafers is their porosity that permits gaseous exchanges to allow water evaporation from wound exudates.
- It prevents the accumulation of fluids under the dressing and ultimately inhibits maceration and infection.

Wafer in wound healing

- Both sodium carboxymethyl cellulose (CMC) and methylcellulose (MC) wafers have previously shown desirable characteristics, such as sponginess, flexibility, acceptable color, odor, and a uniform texture, to be used as a wound dressing.
- CMC has good film forming characteristics with high drug-loading capacity and can deliver drugs to mucosal surfaces in the form of wafers.
- Furthermore, MC was employed as a viscosity modifier in wafer formulation containing sodium alginate and xanthan gum (XG).