Different substrates for orodispersible films: You have the choice!

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ATC Code –

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Background

Orodispersible films (ODFs) are thin layers of a polymer that can be loaded with an active ingredient (API). This could be realized during the film forming process or afterwards. Different polymers lead to different film properties e.g. dissolution behaviour. So, you have the choice!

Objectives

Films of different compositions and heights were produced and investigated. It should be estimated whether the resulting films are appropriate candidates for further processing.

Materials and methods

Four formulations were chosen based on PVA, HPMC, HPMC with MCC and starch. The ODF based on starch was a commercial product, an “edible paper”. ODF were produced with solvent casting and different heights.

After drying pieces are cut in pieces of 35 cm² and investigated for appearance, residual moisture and dissolution time.

Fig. 1: Height

Fig. 2: Residual moisture

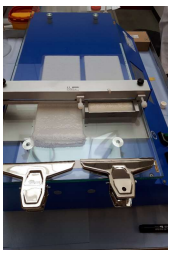

Fig. 3: Preparation of the films

Results

The dried films differ in resulting thickness. Edible paper is thicker than HPMC MCC > PVA > HPMC. The very thin films of HPMC are difficult to handle.

All films look different: PVA is white and very flexible. HPMC is colourless and flexible, too. It becomes sticky in contact with water. When MCC is mixed with HPMC films are white and too brittle to handle. Edible paper is rose (colorant added) and also brittle, but good to handle.

Residual moisture depends especially on the formulation. PVA has about 1-2%, HPMC MCC about 5%, starch about 7% and HPMC about 7-10%.

Basis	Height wet film [µm]	Height dried film [µm]	Residual moisture [%]	Dissolution time [s]	Mechanical resistance	Appearance
PVA	1000	281	1,0	147	Very flexible	
	800	182	1,1	78		
	600	151	2,0	37		
	500	122	2,1	30		
	400	107	2,2	21		
HPMC	1000	83	7,9	184	Very flexible	
	800	44	10,7	110		
	600	30	10,8	123		
	500	26	9,7	96		
	400	19	11,7	70		
HPMC MCC	800	381	-	-	Brittle	
	600	322	5,0	38		
	500	173	5,2	18		
	400	142	4,7	11		
Starch (edible paper)	-	839	7,3	>15 min	Brittle	

Table 1: Four formulations and appearances, heights, dissolution times and residual moistures

Dissolution time depends on both the formulation and the height of the films. Starch takes more than 15 minutes, HPMC up to 3 minutes. Both formulations become sticky in contact with water. The others show predominant times under one minute.

Conclusion

Investigations reveal different characteristics of the resulting films.

The stickiness and prolonged dissolution time could be useful for mucoadhesial formulations. Mixture with MCC shortens the dissolution times but increases the brittleness. This formulation could be optimized.

PVA and starch shows the easiest handling.

Incorporation of API should be possible for all formulations. Therefore the API has to be dissolved before the film forming process starts.

If API should be loaded after film production - e.g. via inkjet printing - PVA and starch are promising candidates.