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Formulation and *In-Vitro* Evaluation of Fentanyl Citrate Sublingual Tablets

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A B S T R A C T
In the present work, an attempt has been made to develop Sublingual tablets of Fentanyl Citrate. Among all the formulations F4 formulation showed maximum % drug release i.e., 99.16 % in 8 min hence it is considered as optimized formulation. "The F4 formulation contains Cross povidone as super disintegrate in the concentration of 4 mg".
Keywords: Fentanyl Citrate, Cross povidone, Cross carmellose sodium, Sodium starch, glycollate

A R T I C L E I N F O

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Contents

1. Introduction

Sublingual, meaning literally 'under the tongue' refers to a method of administering substances via the mouth in such a way that the substances are rapidly absorbed via the blood vessels under the tongue rather than via the digestive tract. There is considerable evidence that most sublingual substances are absorbed by simple diffusion. Systemic delivery of drugs through the mucosal membranes lining the floor of the mouth to the systemic circulation. Fentanyl is used as an adjunct to general anesthetics, and as an anesthetic for induction and maintenance. The purpose of the present study is to prepare sublingual tablets containing an fentanyl citrate to improve the relatively rapid onset of action compared to oral route and improve therapeutic response.

2. Materials and Methods

Fentanyl Citrate, Microcrystalline cellulose, Sodium starch glycollate, Cross povidone, Crooscarmellose sodium, Magnesium stearate, Talcchemicals were Laboratory grade made of SD Fine chemicals Pvt Ltd

Formulation of Sublingual tablets of Fentanyl Citrate:

Preparation of tablets: Composition of Fentanyl Citrate Sublingual Tablet by direct compression. All the ingredients were weighed. Required quantity of drug and excipient mixed thoroughly in a poly bag. The blend is compressed using rotary tablet machine-8 station with 4mm flat punch, B tooling. Each tablet contains 1 mg Fentanyl Citrate and other pharmaceutical ingredients. Total weight of tablet was found to be 60 mg.

3. Results and Discussion

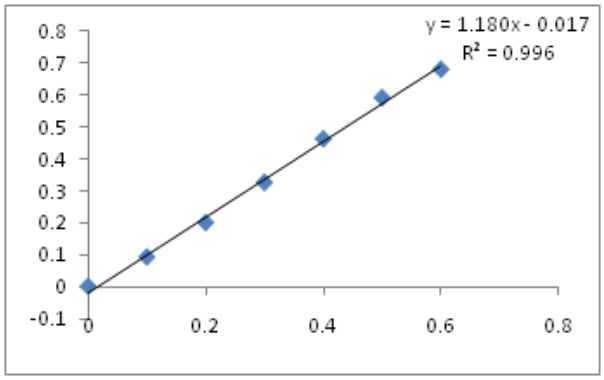

Figure 1: Standard graph of Fentanyl Citrate

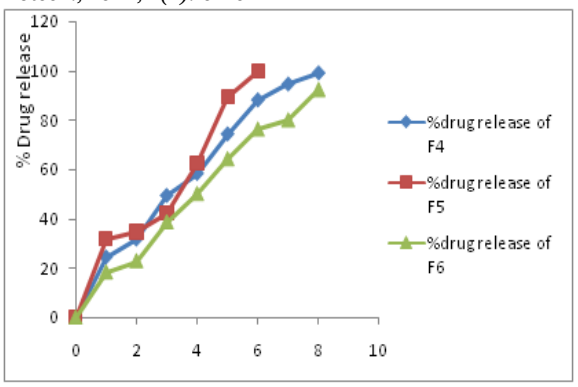

Figure 3: Dissolution profile of formulations prepared with Cross Povidone

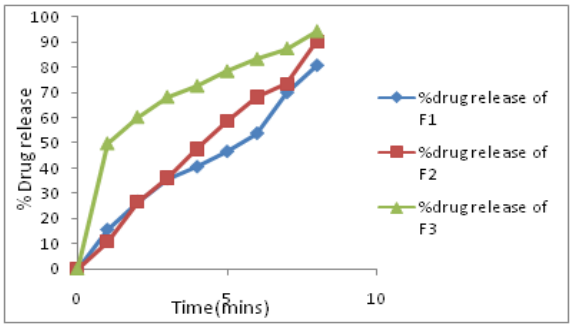

Figure 2: Dissolution profile of formulations prepared with Sodium starch Glycollate

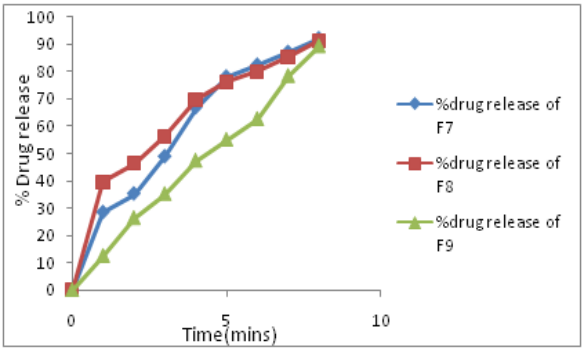

Figure 4: Dissolution profile of formulations prepared with Cross carmellose sodium

Table 1: Composition of various tablet formulations

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Fentanyl Citrate (mg)	1	1	1	1	1	1	1	1	1
Sodium Starch Glycollate (mg)	3	6	9	-	-	-	-	-	-
Cross Povidone(mg)	-	-	-	3	6	9	-	-	-
Cross Carmellose Sodium (mg)	-	-	-	-	-	-	3	6	9
Magnesium Stearate(mg)	2	2	2	2	2	2	2	2	2
Talc(mg)	2	2	2	2	2	2	2	2	2
MCC(mg)	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs
Total wt(mg)	60	60	60	60	60	60	60	60	60

Table 2: Concentration and absorbance obtained for calibration curve of Fentanyl Citrate

S. No.	Conc. (µg/ml)	Absorbance* (at 259 nm)
1	0	0
2	0.1	0.038
3	0.2	0.14
4	0.3	0.199
5	0.4	0.289
6	0.5	0.385
7	0.6	0.459

Table 3: Pre-compression parameters

Formulations	Bulk Density (gm/cm^2)	Tap Density (gm/cm^2)	Carr's Index (%)	Hausner ratio	Angle of Repose(Θ)
F_1	0.45	0.55	18.18	1.22	27.91
F_2	0.47	0.55	14.54	1.17	28.23
F_3	0.50	0.58	13.79	1.16	29.34
F_4	0.46	0.55	16.36	1.19	26.71
F_5	0.50	0.58	13.79	1.16	29.34
F_6	0.47	0.55	14.54	1.17	28.23

F_7	0.50	0.58	13.79	1.16	29.34
F_8	0.41	0.50	18	1.21	26.78
F_9	0.41	0.50	18	1.21	26.78

Table 4: Post compression Parameters

Formulation code	Weight variation (mg)	Hardness (kg/cm^2)	Thickness (mm)	Disintegration Time (sec)	Friability (%)	Assay (%)
F1	60	2.5	2.34	60	0.43	97.23
F2	62	2.6	2.24	62	0.34	98.55
F3	59	2.5	2.29	72	0.49	98.16
F4	61	2.6	2.28	69	0.47	99.34
F5	62	2.3	2.39	70	0.49	98.16
F6	63	2.7	2.24	62	0.34	98.55
F7	62	2.5	2.29	70	0.49	98.16
F8	60	2.6	2.36	67	0.34	99.25
F9	62	2.5	2.26	67	0.34	99.25

Table 5: In-vitro dissolution studies of all formulations

Time	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	15.46	10.83	49.72	24.37	31.73	18.35	28.45	39.50	12.51
2	26.63	26.72	60.16	31.68	34.56	22.90	35.28	46.35	26.38
3	35.64	36.16	68.15	49.37	41.91	38.71	48.90	56.28	35.17
4	40.38	47.46	72.56	58.35	62.48	50.16	66.83	69.71	47.37
5	46.44	58.57	78.41	74.37	89.19	64.32	78.17	76.26	54.96
6	53.64	68.25	83.27	88.18	99.50	76.42	82.45	80.14	62.56
7	69.82	73.19	87.45	94.65		80.14	87.16	85.26	78.35
8	80.56	90.16	94.26	99.16		92.46	92.18	91.28	89.26

In-vitro dissolution studies:

In-vitro dissolution studies were carried out by using 500ml of pH 6.8 Phosphate buffer in USP dissolution apparatus by using paddle method. The dissolution studies were carried out for about 30 min.

From the tabular column 5 it was evident that the formulations prepared with super disintegrate Cross povidone showed maximum % drug release in 8 min i.e 99.16% (F4 formulations and the concentration of super disintegrate was 3 mg). "So the principle of super disintegrates was found to be useful to produce Sublingual tablets. "F4 formulation was considered as optimized formulation".

4. Conclusion

In the present work, an attempt has been made to develop" Sublingual tablets of Fentanyl Citrate. Among all the formulations F4 formulation showed maximum % drug release i.e., 99.16 % in 8 min hence it is considered as optimized formulation. "The F4 formulation contains Cross povidone as super disintegrate in the concentration of 3 mg".

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