World Journal of Pharmacy and Biotechnology
ISSN: 2349-9087 | www.pharmaresearchlibrary.com/wjpbt
W. J. Pharm. Biotech., 2017, 4(1): 08-12
DOI: https://doi.org/10.30904/j.wjpbt.2017.3506

Design and *In-Vitro* Characterization of Oxymorphone Tablets for Controlled Release Drug Delivery System

Amareshwar Shabada*[1], Yellanki Prashanthi[2]

[1]Assistant Professor, Department of Pharmaceutics, St. Mary's Pharmacy College, Deshmukhi, Pochampally, Yadadri, Telangana-508284
[2]Assistant Professor, Department of Pharmaceutical Analysis and Quality Assurance, Nizam Institute of Pharmacy, Deshmukhi, Pochampally, Yadadri, Telangana-508284

A B S T R A C T
Attempt has been made to develop controlled release tablets of Oxymorphone by using xanthan gum, karaya gum, guar gum as polymers. Nine formulations were prepared by taking different concentrations of polymers. All the formulations were prepared by direct compression method using 6mm punch on 8 station rotary tablet punching machine. The blend of all the formulations showed good flow properties such as angle of repose, bulk density, tapped density. The prepared tablets were shown good post compression parameters and they passed all the quality control evaluation parameters as per I.P limits Compared to all formulations F3 formulation showed maximum % drug release i.e., 98.56 % in 12 hours hence it is considered as optimized formulation.

Keywords: Oxymorphone, xanthan gum, karaya gum, guar gum.

A R T I C L E I N F O

Corresponding Author
Amareshwar Shabada
Assistant Professor, Department of Pharmaceutics,
St. Mary's Pharmacy College,
Pochampally, Yadadri, Telangana.

Article History
Received : 29 Mar 2017
Revised : 27 April 2017
Accepted : 25 May 2017
Published : 29 June 2017

Citation: Amareshwar Shabada. Design and *In-Vitro* Characterization of Oxymorphone Tablets for Controlled Release Drug Delivery System. *W. J. Pharm. Biotech.*, 2017, 4(1): 08-12.

Contents

1. Introduction

Controlled release drug delivery system

The US FDA defines sustained release dosage form as one that allows a reduction in dosing frequency from that necessitated by a conventional dosage form, such as solution or an immediate release dosage form. An opioid analgesic with actions and uses similar to those of morphine, apart from an absence of cough suppressant activity. It is used in the treatment of moderate to severe pain, including pain in obstetrics. The half-life of the drug is about 1.3 (+/-0.7) hours indicating its promising candidature for the controlled-release formulation Hence, the purpose of present investigation was to develop controlled-release tablet of oxymorphone by using various natural polymers which would release the drug for prolonged period of time in view to maximize therapeutic effect of the drug.

2. Materials and Methods

Oxymorphone, Xanthan gum, Karaya gum, Guar gum, Magnesium Stearate, Talc, MCC pH 102chemicals were Laboratory grade made of SD Fine chemicals Pvt Ltd

Formulation of Oxymorphone controlled release Tablet by Direct- Compression:

Composition of preliminary trials for Oxymorphone Controlled release Tablet by direct compression is shown in table 6.1. All the ingredients were weighed. Required quantity of drug and excipient mixed thoroughly in a polybag. The blend is compressed using rotary tablet machine-8 station with 9mm flat punch, B tooling. Each tablet contains 40mg of Oxymorphone and other pharmaceutical ingredients.

Evaluation of prepared tablets

The designed formulation tablets were studied for their physicochemical properties like weight variation, hardness, thickness, friability, *In-vitro* release and drug content.

3. Results and Discussion

Table 2: Concentration and absorbance obtained for calibration curve of Oxymorphone in 0.1 N hydrochloric acid buffer (pH 1.2)

S. No.	Concentration (µg/ml)	Absorbance* (at 298 nm)
1	2	0.193
2	4	0.34
3	6	0.461
4	8	0.579
5	10	0.709
Correlation Coefficient = 0.9985 y = 0.0636x + 0.0751		

It was found that the estimation of Oxymorphone by UV spectrophotometric method at λ_{max}298 nm in 0.1N Hydrochloric acid had good reproducibility and this method was used in the study. The correlation coefficient for the standard curve was found to be closer to 1, at the concentration range, 2-10µg/ml. The regression equation generated was y = 0.0636x + 0.0751.

Table 3: Concentration and absorbance obtained for calibration curve of Oxymorphone in pH 6.8 Phosphate buffer.

S. No.	Concentration (µg/ml)	Absorbance* (at 299nm)
1	2	0.193
2	4	0.331
3	6	0.446
4	8	0.553
5	10	0.677
Correlation Coefficient = 0.9982 y = 0.0595x + 0.083		

It was found that the estimation of Oxymorphone by UV spectrophotometric method at λ_{max}299 nm in pH 6.8 Phosphate buffer had good reproducibility and this method was used in the study. The correlation coefficient for the standard curve was found to be closer to 1, at the concentration range, 2-10µg/ml. The regression equation generated was y = 0.0595x + 0.083.

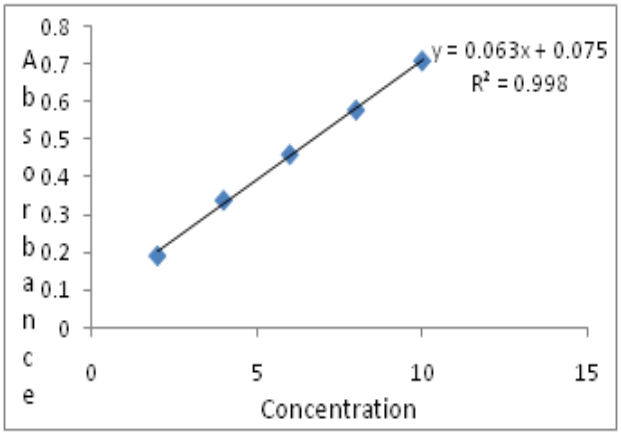

Figure 1: Standard graph of Oxymorphone in 0.1 N HCl

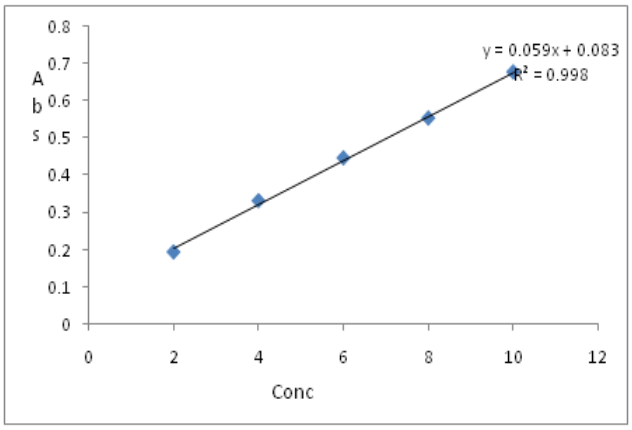

Figure 2: Standard graph of Oxymorphone in pH 6.8 Phosphate buffer

In-vitro Dissolution studies:

In-vitro dissolution studies were carried out by using 900ml of 0.1 N HCl in USP dissolution apparatus by using paddle method for about 2 hours. After 2 hours the dissolution medium was withdrawn keeping the tablet in the dissolution basket. Then pH 6.8 phosphate buffer was added to the dissolution medium (900ml) and the dissolution was carried out for about 6 hours. The samples were withdrawn at regular time intervals of 30 min,1 hour,2 hr,3,5,5,6,7 & 8 hours respectively. The results were displayed in table 7.5.

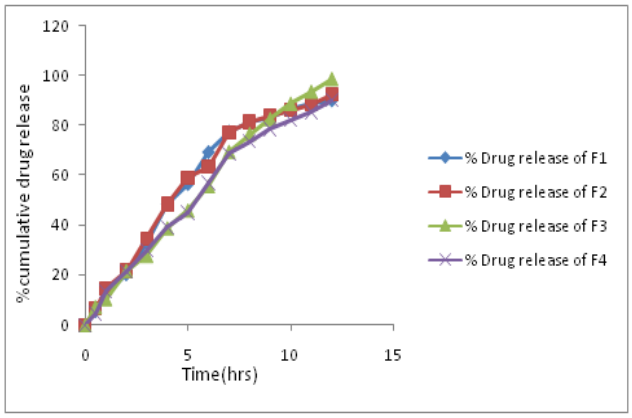

Figure 3: Dissolution profile of formulations prepared with Xanthan gum

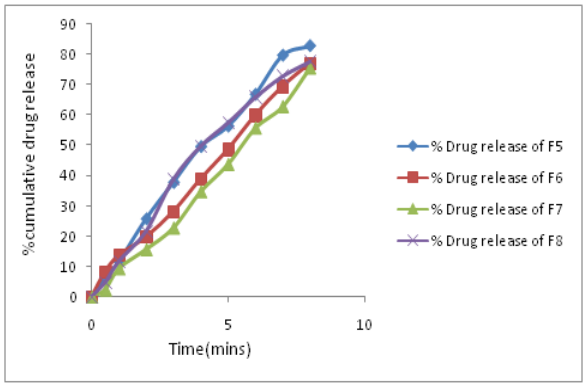

Figure 4: Dissolution profile of formulations prepared with Karaya gum

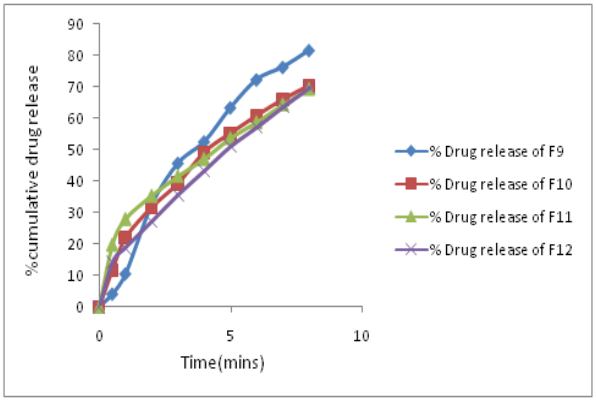

Figure 5: Dissolution profile of formulations prepared with Guar gum

From the above results it was evident that the formulation F3 is best formulation with desired drug release pattern extended up to 12 hours.

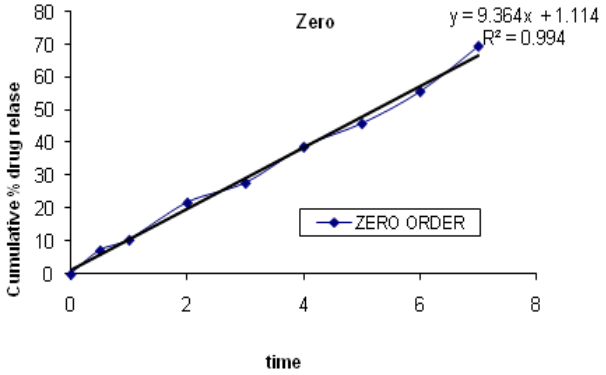

Figure 6: Zero order release kinetics

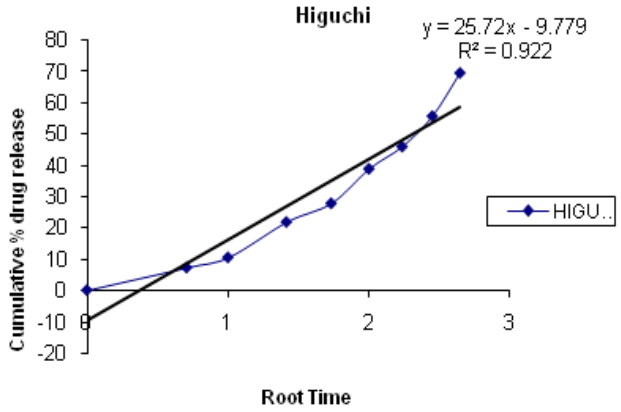

Figure 7: Higuchi release kinetics

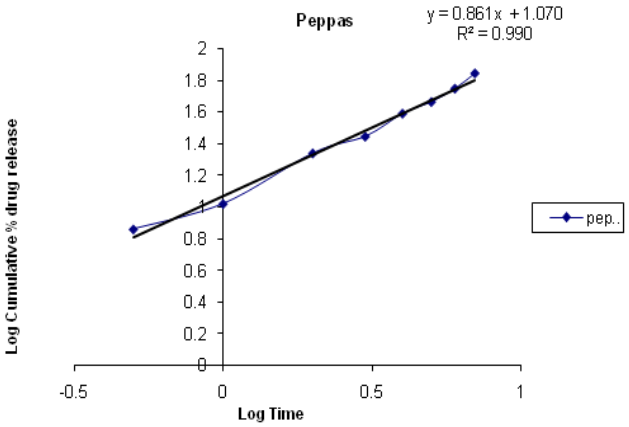

Figure 8: Kars mayerpeppas

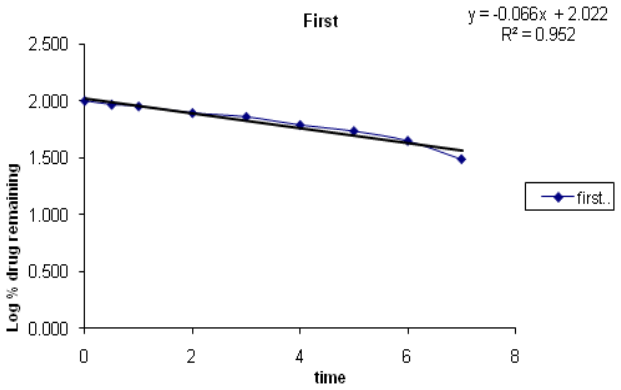

Figure 9: First order release kinetics

From the above graphs it was evident that the formulation F3 was followed Zero order release mechanism.

Table1: Formulation of Oxymorphone Controlled release tablets

INGREDIENT	F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8	F_9	F10	F11	F12
Oxymorphone	40	40	40	40	40	40	40	40	40	40	40	40
Xanthan gum	30	60	90	120	-	-	-	-	-	-	-	-
Karaya gum	-	-	-	-	30	60	90	120	-	-	-	-
Guar gum	-	-	-	-	-	-	-	-	30	60	90	120
Talc	5	5	5	5	5	5	5	5	5	5	5	5
Mg. Stearate	5	5	5	5	5	5	5	5	5	5	5	5
MCC pH102	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Total	250	250	250	250	250	250	250	250	250	250	250	250

Table 4: Pre-compression parameters

Formulations	Bulk Density (gm/cm^2)	Tap Density (gm/cm^2)	Carr's Index (%)	Hausner ratio	Angle of Repose(Ɵ)
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
F10	0.42	0.51	18.24	1.20	26.68
F11	0.48	0.56	18.12	1.21	26.70
F12	0.41	0.54	18.11	1.22	26.71

Table 5: Post compression Parameters

FD	Weight variation (mg)	Hardness (kg/cm^2)	Thickness (mm)	Friability (%)	Assay (%)
F_1	244	4.5	5.5	0.43	97.23
F_2	254	4.3	5.5	0.34	98.55
F_3	260	4.2	5.5	0.49	98.16
F_4	245	4.2	5.4	0.47	99.34
F_5	252	4.3	5.5	0.49	98.16
F_6	258	4.3	5.5	0.34	98.55
F_7	260	4.4	5.4	0.49	98.16
F_8	244	4.5	5.5	0.34	99.25
F_9	256	4.4	5.5	0.34	99.25
F10	251	4.4	5.5	0.43	98.6
F11	252	4.3	5.5	0.54	98.7
F12	254	4.5	5.5	0.43	98.5

All the pre and post compression parameters were found to be within the limits

Table 6: In-vitro dissolution data

Time(Hrs)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
0.5	5.68	6.54	7.23	4.71	6.32	8.29	2.34	4.79	4.09	11.81	19.89	14.21
1	12.45	14.56	10.45	13.54	11.56	13.65	9.31	11.71	10.53	22.02	28.04	18.87
2	20.46	21.67	21.78	21.56	25.75	19.78	15.67	21.65	32.53	31.70	35.43	27.19
3	32.65	34.62	27.76	29.87	37.74	28.18	22.78	38.76	45.71	39.32	41.65	35.66
4	48.71	48.43	38.76	39.1	49.54	38.89	34.76	49.71	52.56	49.25	47.18	43.32
5	56.62	58.92	45.87	44.98	56.27	48.67	43.78	57.41	63.43	55.28	53.81	51.06
6	69.35	63.43	55.63	56.92	66.75	59.91	55.76	65.81	72.31	60.92	58.89	57.13
7	77.51	77.13	69.43	68.77	79.63	69.41	62.87	72.76	76.31	66.08	64.53	63.63
8	81.54	81.34	76.56	73.65	82.75	76.98	75.61	77.61	81.67	70.44	69.43	69.71
9	83.45	83.76	82.56	78.56	84.17	81.65	81.76	82.45	85.91	77.22	72.83	73.34
10	86.59	85.98	88.67	82.19	89.32	85.71	89.94	85.52	87.31	80.90	79.98	79.27
11	88.82	88.42	93.46	85.35	91.85	89.75	88.83	88.65	88.86	87.83	83.52	82.86
12	90.13	92.18	98.56	90.12	92.89	92.57	93.9	90.53	89.97	91.90	88.65	85.97

Table 7: Release kinetics data for optimised formulation

Cumulative (%) Release Q	TIME (T)	ROOT (T)	LOG (%) Release	LOG (T)	LOG (%) REMAIN
0	0	0			2.000
7.23	0.5	0.707	0.859	-0.301	1.967
10.45	1	1.000	1.019	0.000	1.952
21.78	2	1.414	1.338	0.301	1.893
27.76	3	1.732	1.443	0.477	1.859
38.76	4	2.000	1.588	0.602	1.787
45.87	5	2.236	1.662	0.699	1.733

55.63	6	2.449	1.745	0.778	1.647
69.43	7	2.646	1.842	0.845	1.485
76.56	8	2.828	1.884	0.903	1.370
82.56	9	3.000	1.917	0.954	1.242
88.67	10	3.162	1.948	1.000	1.054
93.46	11	3.317	1.971	1.041	0.816
98.56	12	3.464	1.994	1.079	0.158

4. Conclusion

In the present work, an attempt has been made to develop controlled release tablets of Oxymorphone by selecting xanthan gum, karaya" gum, guar gum as retarding polymers. Compared to all the formulations F3 formulation showed maximum % drug release i.e., 98.56 % in 12 hours hence it is considered as optimized formulation.

5. References

[1] Robinson J.R., Lee V.H.L.: Controlled Drug Delivery (Edition 3), Marcel Dekker Inc, New York, 1987, 29-30

[2] Debjit Bhowmik , Harish Gopinath , B. Pragati Kumar, S. Duraivel, K.P. Sampath Kumar Controlled Release Drug Delivery Systems The Pharma Innovation Vol. 1 No. 10 2012

[3] M. A. Bayomi, S. A. Al-Suwayeh, and A. R. M. El-Helw, "Excipient-Excipient Interaction in the Design of Sustained release Theophylline Tablets: In Vitro and In Vivo Evaluation," Drug Development and Industrial Pharmacy, Vol. 27, No. 6, pp. 499–506, 2001.

[4] K.P. Sampath Kumar, Debjit bhowmik Amit sankardutta, Shravan paswan , Lokesh Deb Recent Trends In Scope And Opportunities Of Control Release Oral Drug Delivery Systems Critical Review In Pharmaceutical Sciences Issue 1 : 2012

[5] Atyabi F, Sharma HL, Mohammad HAH, Fell JT. Invivo Evaluation of a Novel Gastro retentive Formulation Based On Ion Exchange Resins. J. Control. Rel. 1996; 42: 105-13.

[6] Klausner EA, Lavy E, Friedman M, Hoffman A. Expandable Gastro retentive Dosage Form. J. Control. Rel. 2003, 90: 143-62.

[7] Singh BN, Kim HK. Floating Drug Delivery Systems: An Approach to Oral Controlled Drug Delivery via Gastric Retention. J. Control. Rel. 2000; 63: 235-59.

[8] Timmermans J, Moes AJ. Factors Controlling the Buoyancy and Gastric Retention Capabilities of Floating Matrix Capsules: New Data for Reconsidering the Controversy. J. Pharm. Sci. 1994; 83: 18-24.

[9] Clarke GM, Newton JM, Short MD. Comparative Gastrointestinal Transit Of Pellet Systems Of Varying Density. Int. J. Pharm. 1995; 114: 1-11.

[10] J. Hamdani, A. J. Moes, And K. Amighi, "Development And Evaluation Of Prolonged Release Pellets Obtained By The Melt Pelletization Process," International Journal Of Pharmaceutics, Vol. 245, No. 1-2, Pp. 167–177, 2002.