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Preparation and Evaluation of Oro Dispersible Tablet of Tramadol Hydrochloride

Madhuri Reddy Muppa[1], Bale Varshitha[2], Bangala Soubhagya Shree[2], Bathini Manish[2], Begari Sudarshan[2], Bhangi Veeresham[2]
Assistant Professor, Department of Pharmaceutics[1]
St Mary's Group of Institutions, Deshmukhi, Pochampally (Mandal), Yadadri Bhuvanagiri, Hyderabad
madhurireddy.62@gmail.com

Abstract: *The work is planned to design orally disintegrating tablets (ODT) also known as Mouth dissolving tablets (MDT) of tramadol hydrochloride for rapid dissolving in mouth within 60 seconds, by using a method called as Direct compression method, Since oral route is considered as one of the most convenient method of administration, it is being selected where, all 15 formulations have undergone numerous evaluation parameters by using various excipients. Among which F15 have confirmed rapid dissolving nature in mouth.*

Keywords: Tramadol hydrochloride, croscarmellose sodium, Aspartame, Mannitol

I. INTRODUCTION

Oral administration has been considered as one of the most convenient and widely accepted routes of delivery for most therapeutic agents, oral dosage forms refer to tablets, capsules and liquid preparations taken orally, swallowed and transiting the gastrointestinal tract (GIT) for post buccal absorption.U.S Food and Drug Administration (FDA) defined ODT as "A solid dosage form containing medicinal substance or active ingredient which disintegrates rapidly usually within a matter of seconds when placed upon the tongue." ODT's are particularly suitable for patients, who find it inconvenient to swallow traditional tablets and capsules with an 8-oz glass of water. As Saliva is mainly composed of 99.5% water & 0.5% of solutes like $Na^{+2}K$,ODT's dissolves rapidly within 60 sec in oral cavity.

II.MATERIALS AND METHOD

Tramadol Hydrochloride (API) from AUROBINDO pharma, ltd, Hyderabad and other excipients like Croscarmellose Sodium, Sodium Starch Glycolate, Crosspovidone are used. All other chemicals which were used are of analytical grade.

III. METHODOLOGY

Tablets of Tramadol hydrochloride were prepared by Direct compression method, total 15 formulations are prepared in which F_1,F_2,F_3 are prepared by adding crosspovidone in the conc of 2%,3.5%,5% F_4,F_5,F_6 were prepared by addition of croscarmellose in the concentration of 2%,3.5%,5%and F_7,F_8,F_9 with sodium starch glycolate in conc of 2%,3.5%,5%remaining $F_{10}-F_{15}$ by combination of crosspovidone & croscarmellose within the conc of 1:1,1:2,2:1
The method includes accurately weighing API of 50 mg along with other excipients are sieved through no.40 and mixed properly & compressed directly into the tablets, Pré compression parameters namely, tapped density, bulk density, Carr's index, angle of repose and post compression parameters like disintegration, weight variation, hardness, thickness, friability, water absorption tests are performed accordingly.

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IV. RESULTS AND DISCUSSION

Pre compression parameters of tramadol hydrochloride

Formulation	Angle of repose (θ)*	Bulk density (gm/cm^3)*	Tapped density (gm/cm^3)*	Hausner's ratio*	Carr's index* (%)
F_1	27.78±0.04	0.82±0.067	0.92±0.035	1.12	10.77
F_2	26.08±0.06	0.86±0.034	0.90±0.084	1.04	4.53
F_3	25.08±0.05	0.84±0.043	0.91±0.046	1.08	7.83
F_4	28.67±0.04	0.83±0.056	0.92±0.057	1.10	9.76
F_5	27.55±0.06	0.82±0.067	0.92±0.049	1.12	10.74
F_6	27.08±0.05	0.86±0.057	0.91±0.068	1.05	5.03
F_7	29.06±0.04	0.84±0.028	0.99±0.047	1.17	14.78
F_8	27.67±0.06	0.86±0.063	0.92±0.086	1.06	6.43
F_9	26.85±0.04	0.82±0.049	0.92±0.035	1.12	11.09
F_{10}	27.48±0.07	0.84±0.042	0.94±0.049	1.11	10.63
F_{11}	26.48±0.06	0.82±0.038	0.90±0.058	1.09	8.94
F_{12}	28.08±0.05	0.85±0.056	0.93±0.075	1.09	8.60
F_{13}	26.78±0.07	0.84±0.039	0.91±0.067	1.08	7.88
F_{14}	28.47±0.06	0.83±0.062	0.92±0.076	1.10	9.60
F_{15}	25.67±0.04	0.83±0.047	0.95±0.047	1.14	12.63

Post compression parameters of tramadol hydrochloride

Parameter	F_1	F_2	F_3	F_4	F_5
Weight variation(mg)*	250.31±1.61	250.19±1.32	250.32±1.47	249.92±1.46	250.89±2.11
Friability (%)*	0.65±0.02	0.76±0.01	0.58±0.04	0.63±0.02	0.56±0.03
Hardness (kg/cm^2)*	3.4±0.23	3.2±0.52	3.1±0.29	3.7±0.52	3.5±0.59
Thickness(mm)*	2.5±0.02	2.6±0.03	2.5±0.04	2.4±0.02	2.4±0.01
Disintegration time(sec)*	29±0.69	30±0.77	24±0.81	31±1.02	35±0.89
Water absorption ratio	76.05±	79.83±	81.42±	70.52±	74.99±
Wetting time(sec)*	19±0.51	21±0.47	16±0.52	23±0.94	26±0.47
Assay	100.04±1.02	101.06±1.21	99.440±0.85	98.41±0.62	97.53±1.08

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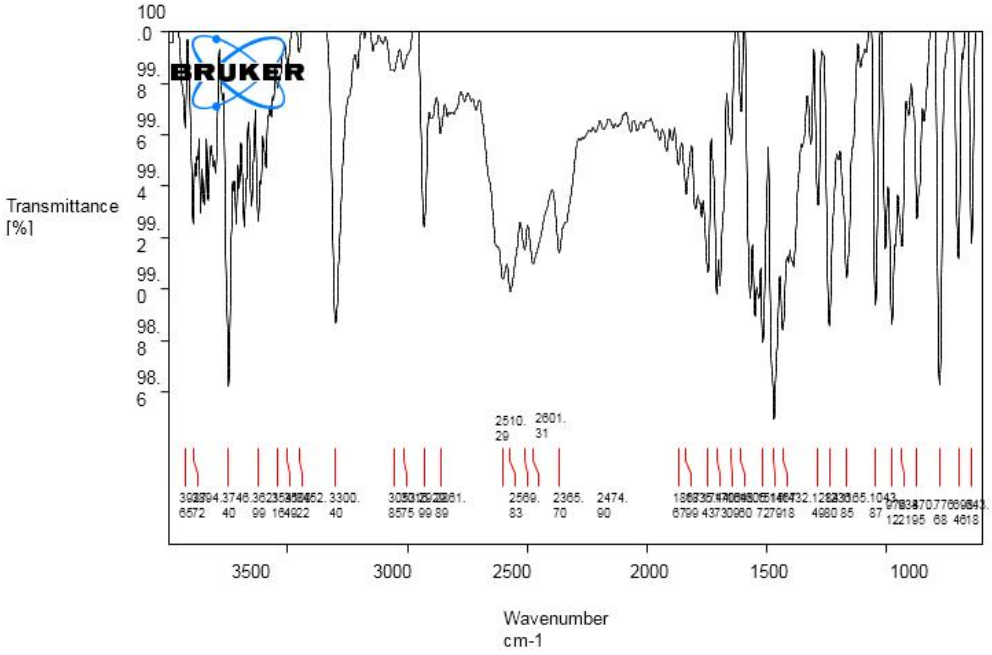
Parameter	F_6	F_7	F_8	F_9
Weight variation(mg)*	250.33±1.68	251.06±1.20	249.86±1.42	250.63±1.63
Friability(%)*	0.64±0.02	0.58±0.01	0.41±0.03	0.68±0.01
Hardness (kg/cm^2)*	3.3±0.76	3.9±0.72	3.8±0.53	3.6±0.28
Thickness (mm)*	2.6±0.02	2.4±0.05	2.3±0.03	2.6±0.04
Disintegration time(sec)*	40±1.21	48±0.67	41±0.96	33±0.82
Water absorption ratio	79.56±	67.41±	69.43±	72.56±
Wetting time(sec)*	31±0.81	31±0.68	29±0.59	21±0.74
Assay	98.92±0.96	98.93±1.21	99.78±1.05	98.23±0.85

FTIR Compatibility studies

FTIR Spectrum of the pure drug showed peaks at 3016.75 cm^{-1} and 1432.18cm^{-1} The IR Spectrum of Drug and super disintegrant exhibited peaks at 3017.07 cm^{-1} and 1465.33 cm^{-1}. Hence, the formula for preparing Tramadol Hydrochloride mouth dissolving tablets can be reproduced in the industrial scale without any possible drug-superdisintegrants interactions.

Functional Group	Frequency (cm^{-1})
C - H Aromatic (stretching)	3017.07
C = C Aromatic (stretching)	1402.79
C - N (stretching)	1165.85
C - H (stretching)	2861.89
CH_2 (bending)	1432.18
O-H (stretching)	3300.0



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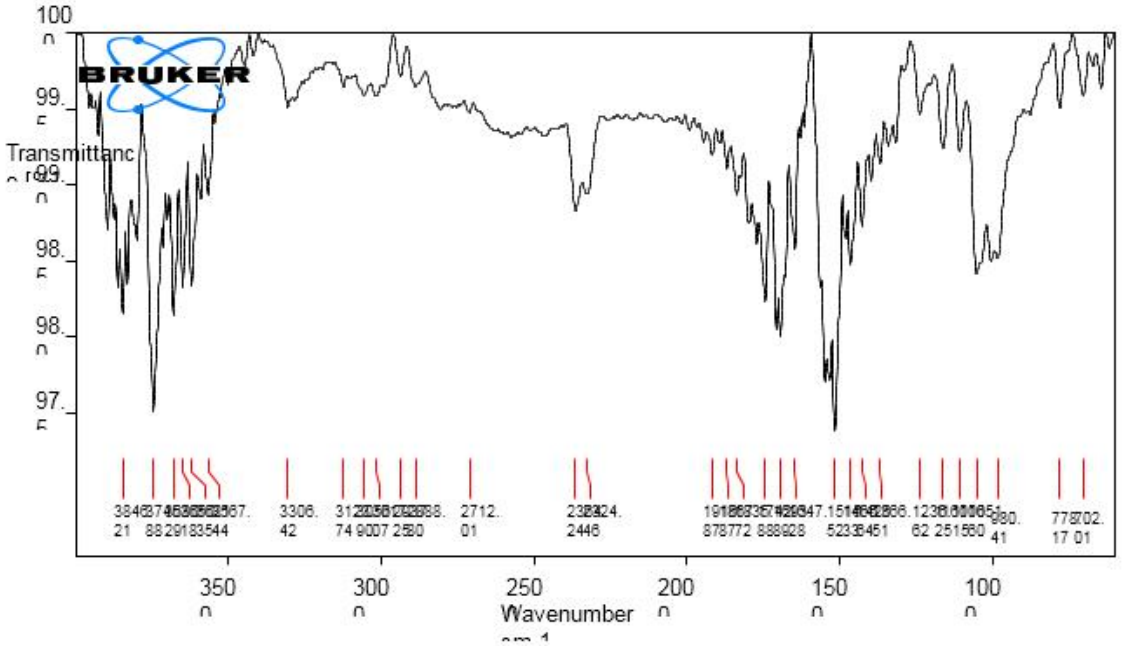

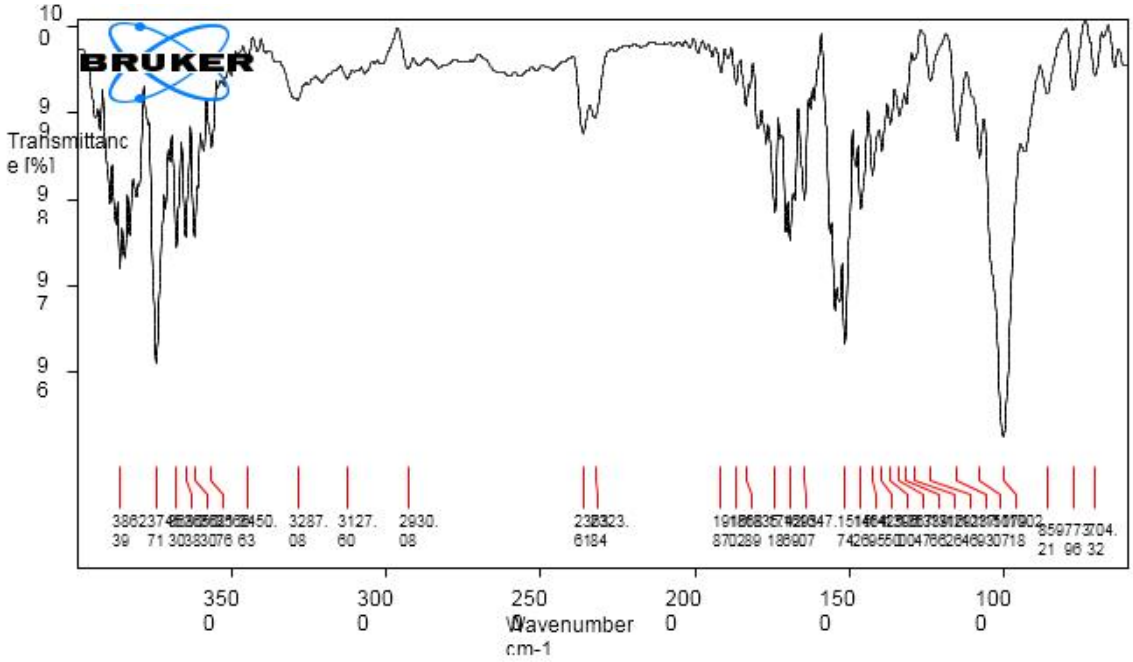

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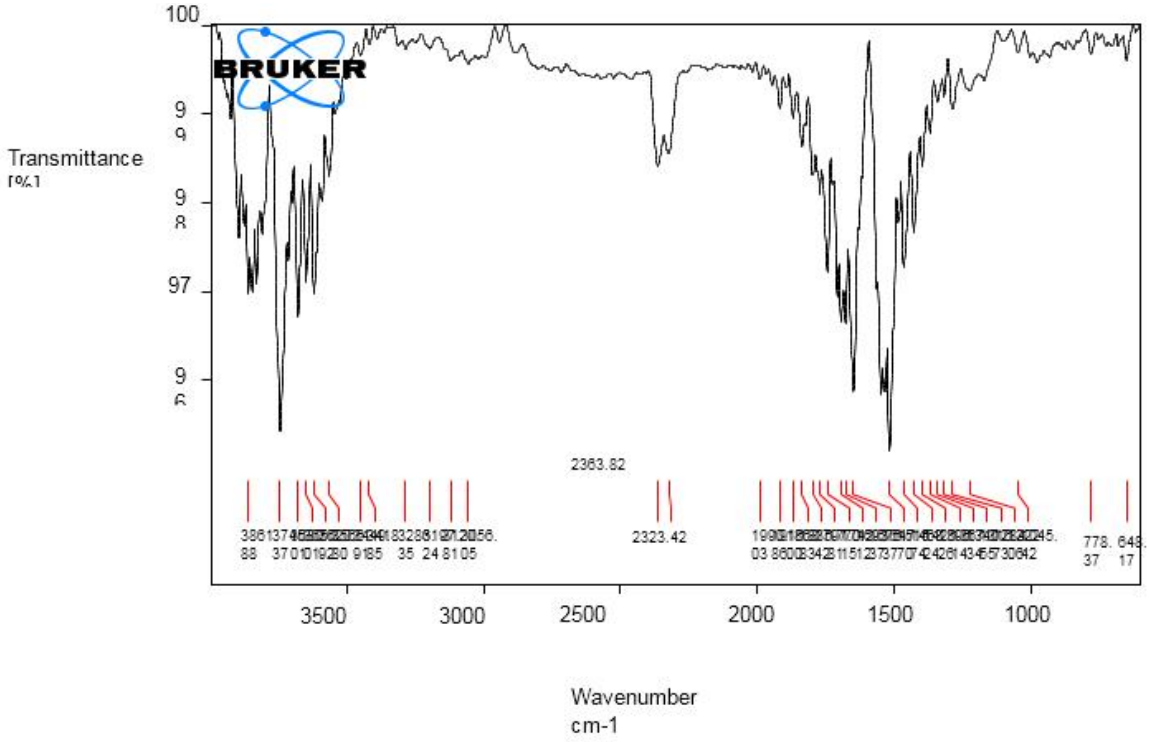

V. CONCLUSION

In the present work, Oro-dispersible tablets of Tramadol Hydrochloride were prepared by direct compression method.

- The tablets prepared by using Crosspovidone and Crosscarmellose sodium in 2:1 ratio gave 100.30 % drug release within 15 minutes which shows F15 is optimised one.
- A result of the accelerated stability study indicates that Tramadol Hydrochloride mouth dissolving tablets ware stable for a period of 3 months.

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