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Effect of Superdisintegrants on Immediate Release Tablets of Tizanidine Hydrochloride

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ABSTRACT

The aim of this study is to formulate and significantly improve the bioavailability and reduce the side effects of immediate release tablets Tizanidine Hydrochloride. The precompression blends of Tizanidine Hydrochloride were characterized with respect to angle of repose, bulk density, tapped density, Carr's index and Hausner's ratio. The precompression blend of all the batches indicates well to fair flowability and compressibility. Immediate release tablets were prepared with various polymers like Sodium starch glycolate, Crospovidone, Cross carmellose sodium at different concentration ratios and were compressed in to tablets. The formulated tablets were evaluated for various quality control parameters. The tablets were passed all tests. Among all the formulations F9 formulation containing, drug and Cross carmellose sodium showed good result that is 99.50% in 35 min. Hence from the dissolution data it was evident that F9 formulation is the better formulation.

Key Words: Crospovidone, Cross carmellose sodium, Sodium starch glycolate, Tizanidine Hydrochloride.

INTRODUCTION

Oral route is the most convenient and extensively used for drug administration [1]. Oral administration is the most popular route for systemic affects due to its ease of ingestion, pain, voidance, versatility and most importantly, patient compliance suitable for industrial production, improved stability and bioavailability [2]. The concept of immediate release tablets emerged from the desire to provide patient with more conventional means of taking their medication when emergency treatment is required [3]. Recently, immediate release tablets have gained prominence of being new drug delivery systems [4].

Desired criteria for immediate release drug delivery system
In the case of solid dosage it should dissolve or disintegrate in the stomach within a short period.

1. In the case of liquid dosage form it should be compatible with taste masking.
2. Be portable without fragility concern.
3. Have a pleasing mouth feel.
4. It should not leave minimal or no residue in the mouth after oral administration.
5. Exhibit low sensitivity to environmental condition as humidity and temperature.
6. Be manufactured using conventional processing and packaging equipment at low cost.
7. Rapid dissolution [5].

Advantages of immediate release drug delivery systems:

- Release the drug immediately.
- Unit dose system and Long shelf life.
- Cost effective.

- More flexibility for adjusting the dose.
- It can be prepared with minimum dose of drug.
- Tastelessness and Elegance.
- Improved stability, bioavailability.
- There is no dose dumping problem [6].

The main aim and objective is to study the effect of these superdisintegrants on immediate drug release of Tizanidine Hydrochloride, to perform various quality control evaluation parameters for the immediate release tablets of Tizanidine Hydrochloride.

MATERIALS AND METHODS

Tizanidine Hydrochloride was obtained as a gift sample from Aurobindo Ltd., (Hyderabad). Sodium starch glycolate, Crospovidone, Cross carmellose sodium, di basic calcium phosphate, Micro Crystalline Cellulose (SD Fine Chemicals) served as diluents. Vanillins, Magnesium stearate, Talc are obtained from SD Fine Chemicals.

Table 1: Formulation composition of IR tablets Tizanidine Hydrochloride

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Tizanidine Hydrochloride	2	2	2	2	2	2	2	2	2
Sodium starch glycolate	2	4	6	-	-	-	-	-	-
Crospovidone	-	-	-	2	4	6	-	-	-
Cross carmellose sodium	-	-	-	-	-	-	2	4	6
Vanillin	5	5	5	5	5	5	5	5	5
Di basic calcium phosphate	5	5	5	5	5	5	5	5	5
Talc	2	2	2	2	2	2	2	2	2
Mg. Stearate	2	2	2	2	2	2	2	2	2
MCC	82	80	78	82	80	78	82	80	78
Total weight	100	100	100	100	100	100	100	100	100

EVALUATION

Preformulation studies

Selection of wavelength for analysis of Granisetron: the prepared concentration of 10µg/ml and it was used for initial spectral scan in the UV range of 200-400 nm to detect maximum wavelength and further dilutions for linearity were prepared from the stock solution by allegation method [7].

Post-compression parameters

Thickness, Weight variation test, Friability study, Hardness, Drug content and *In-vitro* dissolution studies and release kinetics were done [8, 9, 10, 11].

RESULTS AND DISCUSSION

Drug-Excipient compatibility studies by FTIR studies

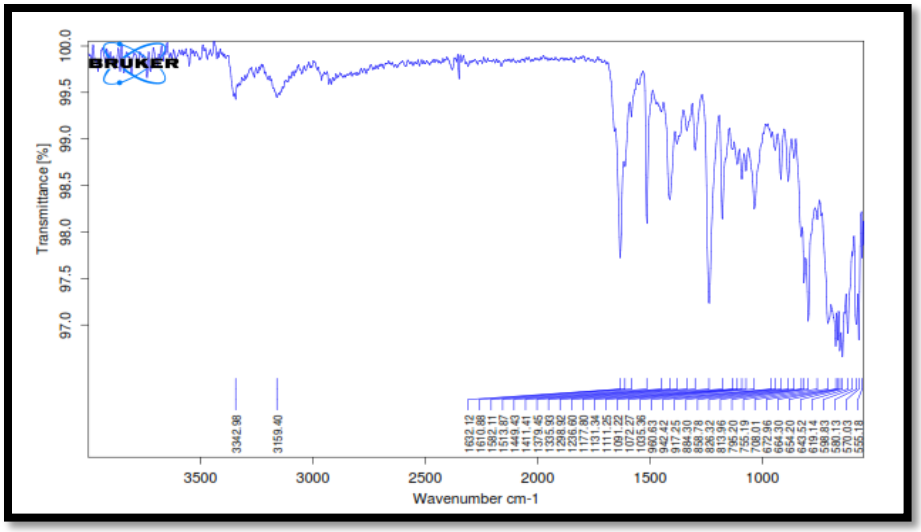

Fig.1- FTIR spectra of pure drug

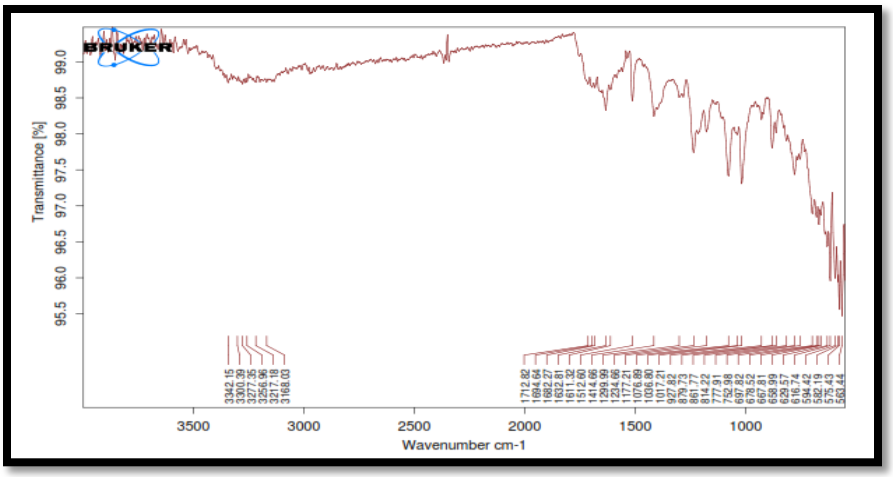

Fig.2- FTIR spectra of optimized formulation

Table 2: Evaluation of pre-compression parameters of powder blend

Batch code	Angle of repose	Bulk density (gm/mL)	Tapped density (gm/mL)	Carr's index (%)	Hausner's ratio
F1	30.48±0.02	0.515±1.47	0.610±0.01	15.57±1.4	1.18±0.01
F2	31.24±0.04	0.523±0.45	0.612±0.01	14.95±0.66	1.17±0.02
F3	30.86±0.03	0.518±0.25	0.613±0.02	15.35±0.3	1.18±0.01
F4	33.28±0.01	0.517±1.05	0.617±0.03	15.66±0.10	1.185±0.15
F5	32.19±0.02	0.525±0.99	0.611±0.01	14.91±0.33	1.175±0.03
F6	31.10±0.02	0.522±0.36	0.623±0.02	14.56±0.20	1.170±0.01
F7	39.23±0.01	0.527±0.45	0.618±0.01	16.53±1.6	1.198±0.21
F8	32.21±0.01	0.516±0.24	0.622±0.05	14.96±0.15	1.186±0.03
F9	33.54±0.04	0.522±0.25	0.615±0.04	15.64±0.26	1.175±0.02

Table 3: Evaluation of Tizanidine hydrochloride tablets

Formulation code	Weight (mg)	Thickness (cm)	Hardness (Kg/cm^2)	Friability (%)	Assay (%)
F1	99.05	3.02±0.63	2.65±0.024	0.42±0.02	98.20
F2	98.85	3.05±0.47	2.70±0.03	0.54±0.04	99.1
F3	99.20	3.01±0.45	2.60±0.14	0.48±0.02	96.89
F4	97.45	3.03±0.42	2.5±0.03	0.34±0.01	97.96
F5	98.62	3.05±0.47	2.75±0.01	0.65±0.02	99.12
F6	97.98	3.01±0.63	2.60±0.03	0.29±0.009	98.87
F7	99.09	3.00±0.63	2.65±0.01	0.36±0.03	99.87
F8	99.38	3.02±0.35 2	2.65±0.02	0.35±0.02	99.9
F9	98.86	3.04±0.45	2.45±0.01	0.45±0.01	99.02

Table 4: Results of Wetting time, water absorption ratio and Disintegration time of formulations F1-F9

Formulation code	Wetting time (sec)	Water absorption Ratio (%)	Disintegration time (sec)
F1	48±0.1	58.2±0.1	42
F2	45±0.3	60.5±0.6	35
F3	39±0.2	64.1±0.2	30
F4	29±0.3	56.5±0.7	38
F5	22±0.6	60±0.1	29
F6	58±0.5	66.4±0.9	25
F7	62±0.5	61.5±0.01	38
F8	60±0.7	64.7±0.4	30
F9	63±0.6	68.5±0.3	21

Table 5: *In vitro* data for formulation F1-F9

Time (Min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
5	25.31	32.28	45.92	33.43	46.72	40.70	38.85	41.32	44.64
10	46.40	47.24	55.34	59.64	54.82	53.82	51.56	49.98	57.87
15	67.34	65.83	69.56	69.54	69.64	65.84	72.20	60.52	79.91
20	78.54	79.26	82.64	85.48	78.42	89.46	86.24	78.41	92.61
25	86.63	83.38	91.31	90.56	92.63	94.24	90.32	86.12	96.62
30	89.82	92.68	94.23	94.82	97.45	96.50	93.54	93.92	98.1
45	95.3	96.81	98.49	97.31	98.58	99.10	97.62	96.91	**99.50**

CONCLUSION

Tizanidine hydrochloride medication is used to treat muscle spasms caused by certain conditions (such as multiple sclerosis, spinal cord injury). It works by helping to relax the muscles. The tablets prepared by direct compression method using different concentrations of Sodium starch glycolate, cross povidone and Cross carmellose sodium as superdisintegrants. The powdered blend was evaluated as bulk density, tapped density, Carr's index and Hausner's ratio. The precompression blend of all the batches indicates well to fair flowability and compressibility. Among all the formulation F9 formulation containing drug and Cross carmellose Sodium showed good result that is 99.50% in 45 minutes, at the concentration of 6 mg. Hence from all the formulation it is evident that F9 formulation is the better formulation. Hence from the dissolution data it was evident that F9 formulation is the better formulation.

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