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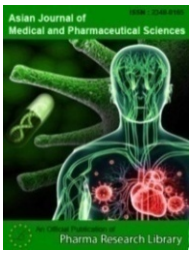

Formulation and In-Vitro Evaluation of Terbutaline Sulphate Sublingual Tablets

[1]T Anusha, [2]GS. Valluri, [3]Kishore Kamere, [4]Vijay Kumar Gampa

[1,2,3,4] Department of Pharmacy, KGR Institute of Technology and Management, Rampally, Keesara, Medchal–501301, Telangana, India

A B S T R A C T

In the present work, an attempt has been made to develop Sublingual tablets of Terbutaline sulfate. Chitosan, Cross povidone and Croscarmellose sodium were employed as super disintegrating agents to enhance the solubility and dissolution rate of selected drug molecule. 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. Among all the formulations F2 formulation showed maximum % drug release i.e., 98.36 % in 8 min hence it is considered as optimized formulation. The F2 formulation contains chitosan as super disintegrate in the concentration of 10 mg.

Keywords: Terbutaline sulfate, Chitosan, Cross povidone, Croscarmellose, Sublingual tablets

A R T I C L E I N F O

Corresponding Author
Kishore Kamere
Department of Pharmacy,
KGR Institute of Technology and Management,
Rampally, Keesara, Medchal–501301, Telangana, India

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C O N T E N T S

1. Introduction

Sublingual means under the tongue and refer to the pharmacological route of administration by which drugs diffuse into the blood through tissues under the tongue. Sublingual route offers direct contact of drug with oral mucosa which will leads to come directly in to systemic circulation which leads to enhance bioavaibility of dosage foam. Sublingual drug administration is applied in the field of cardiovascular drugs, steroids, some barbiturates and enzymes. It has been a developing field in the administration of many vitamins and minerals which are

found to be readily and thoroughly absorbed by this method. Drugs like lisinopril could be delivered through sublingual route for the treatment of hypertension which is caused by obesity, stress, decreased physical activity, increased salt intake, and decreased calcium and potassium intake.

Advantages

- Rapid onset of action is achieved as compared to the oral route.
- Liver is bypassed and also drug is protected from metabolism due to digestive enzymes of the middle gastro intestinal tract
- Improved patient compliance due to the elimination of associated pain with injections; administration of drugs in unconscious or incapacitated patients; convenience of administration as compared to injections or oral medications.
- Low dosage gives high efficacy as hepatic first pass metabolism is avoided and also reduces the risk of side effects.
- The large contact surface of the oral cavity contributes to rapid and extensive drug absorption.
- Due to rapidity in action these sublingual dosage forms are widely used in emergency conditions e.g. asthma.

2. Materials and methods

Terbutaline sulphate, Microcrystalline cellulose, Chitosan, Cross povidone, Cross carmellose sodium, Magnesium stearate, Talc all the chemicals were laboratory grade.

Formulation of Sublingual tablets of Terbutaline sulphate:

Preparation of tablets:

Composition of Terbutaline sulphate Sublingual Tablet by direct compression. 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 6mm flat punch, B tooling. Each tablet contains 5 mg Terbutaline sulphate and other pharmaceutical ingredients. Total weight of tablet was found to be 60 mg.

Evaluation of post compression parameters for prepared Tablets: The designed formulation tablets were studied for their physicochemical properties like weight variation, hardness, thickness, friability and drug content.

3. Results and Discussion

Weight variation test:

Tablets of each batch were subjected to weight variation test, difference in weight and percent deviation was calculated for each tablet and was shown in the Table 4. The average weight of the tablet is approximately in range of 59 to 63 mg, so the permissible limit is ±10% (=60mg). The results of the test showed that, the tablet weights were within the pharmacopoeia limit.

Hardness test:

Hardness of the three tablets of each batch was checked by using Monsanto hardness tester and the data's were shown in Table 4. The results showed that the hardness of the tablets is in range of 2.3 to 2.7 kg/cm^2,which was within IP limits.

Thickness:

Thickness of three tablets of each batch was checked by using Vernier Caliper and data shown in Table 4 .The result showed that thickness of the tablet is raging from 1.56 to 1.64.

Friability:

Tablets of each batch were evaluated for percentage friability and the data's were shown in the Table 4. The average friability of all the formulations lies in the range of 0.35 to 0.49% which was less than 1% as per official requirement of IP indicating a good mechanical resistance of tablets.

In vitro disintegration time:

Tablets of each batch were evaluated for in vitro disintegration time and the data's were shown in the Table 4. The results showed that the disintegration time of prepared tablets were in the range of 12.66 to 30.33 seconds.

Assay:

Assay studies were performed for the prepared formulations. From the assay studies it was concluded that all the formulations were showing the % drug content values within 97.33 -99.63%.

In-vitro Dissolution studies:

In-vitro dissolution studies were carried out by using 900ml of pH 6.8 Phosphate buffer in USP dissolution apparatus by using paddle method. The dissolution studies were carried out for about 8 min.

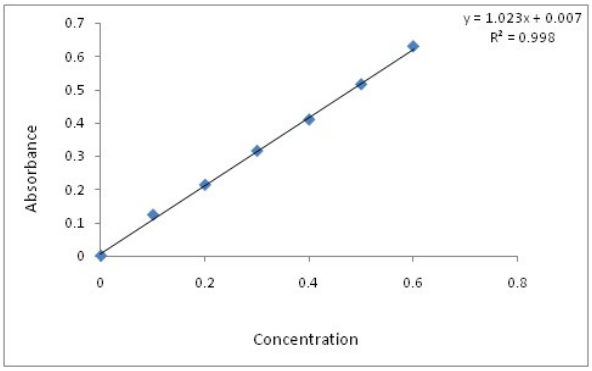

Fig 1: Standard graph of Terbutaline sulfate in pH 6.8 Phosphate buffer

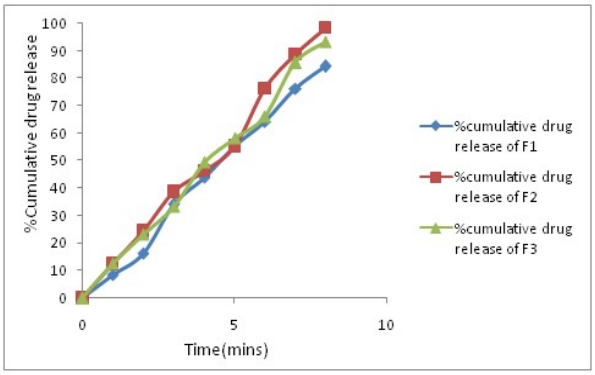

Fig 2: Dissolution profile of formulations prepared with Chitosan as super disintegrate

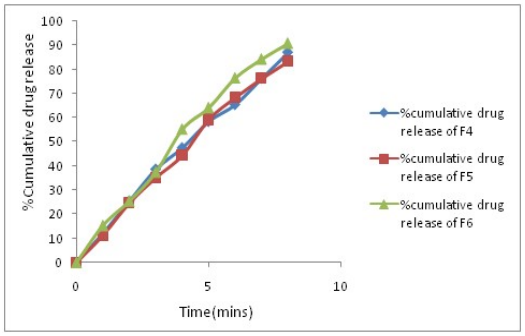

Fig 3: Dissolution profile of formulations prepared with Cross Povidone as super disintegrate

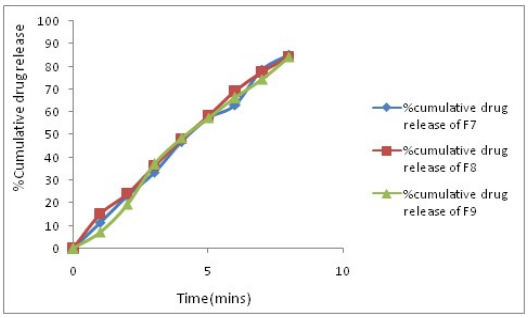

Fig 4: Dissolution profile of formulations prepared with Croscarmellose sodium as super disintegrate

From the tabular column 5 it was evident that the formulations prepared with super disintegrate chitosan showed maximum % drug release in 8 min i.e 98.36% (F2 formulations and the concentration of super disintegrate was 10 mg). So the principle of super disintegrates was found to be useful to produce Sublingual tablets. F2 formulation was considered as optimized formulation.

4. Conclusion

In the present work, an attempt has been made to develop Sublingual tablets of Terbutaline sulfate. Chitosan, Cross povidone and Croscarmellose sodium were employed as super disintegrating agents to enhance the solubility and dissolution rate of selected drug molecule. 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. Among all the formulations F2 formulation showed maximum % drug release i.e., 98.36 % in 8 min hence it is considered as optimized formulation. The F2 formulation contains chitosan as super disintegrate in the concentration of 10 mg.

Table 1 Composition of various tablet formulations

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Terbutaline sulphate (mg)	5	5	5	5	5	5	5	5	5
Chitosan(mg)	5	10	15	-	-	-	-	-	-
Cross Povidone (mg)	-	-	-	5	10	15	-	-	-
Cross Carmellose Sodium (mg)	-	-	-	-	-	-	5	10	15
Magnesium Stearate (mg)	2	2	2	2	2	2	2	2	2
Talc(mg)	2	2	2	2	2	2	2	2	2
Vanilla	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 Terbutaline sulfate in pH 6.8 Phosphate buffer

S. No.	Concentration (µg/ml)	Absorbance* (at 283 nm)
1	0	0
2	0.1	0.123
3	0.2	0.213
4	0.3	0.315
5	0.4	0.409
6	0.5	0.515
7	0.6	0.629

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)
F1	0.42	0.52	16.76	1.20	28.32
F2	0.47	0.50	15.31	1.18	25.42
F3	0.41	0.55	14.09	1.15	28.21
F4	0.45	0.58	13.23	1.18	27.39
F5	0.41	0.57	18	1.21	26.54
F6	0.50	0.54	17.45	1.19	29.13

F7	0.43	0.51	15.54	1.22	28.98
F8	0.48	0.55	17	1.14	25.24
F9	0.44	0.56	14	1.14	28.41

Table 4: Post-Compression parameters

Formulation code	Weight variation (mg)	Hardness (kg/cm^2)	Thickness (mm)	Disintegration Time (sec)	Friability (%)	Assay (%)
F1	63	2.3	1.31	35	0.44	99.63
F2	61	2.5	1.29	61	0.37	97.31
F3	62	2.7	1.25	70	0.48	99.46
F4	50	2.4	1.33	56	0.43	98.42
F5	60	2.6	1.30	61	0.35	97.65
F6	61	2.3	1.27	59	0.49	99.55
F7	63	2.4	1.29	74	0.47	97.33
F8	59	2.5	1.32	53	0.38	98.49
F9	60	2.7	1.35	57	0.34	97.45

Table 5: In-vitro dissolution studies of all formulations

Time(min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	8.45	12.34	12.54	12.09	11.23	15.32	11.32	15.33	7.32
2	16.35	24.42	23.21	25.47	24.65	25.43	23.34	24.19	19.33
3	34.14	38.67	33.45	38.67	35.09	37.45	33.42	36.48	37.09
4	43.87	46.14	49.39	47.54	44.32	55.19	46.98	48.04	48.56
5	55.54	55.32	58.35	58.47	59.24	64.09	57.43	58.55	57.43
6	64.34	76.13	66.22	65.48	68.25	76.42	63.11	69.07	66.21
7	76.37	88.65	85.65	76.35	76.13	84.21	78.59	77.43	74.42
8	84.29	98.36	93.44	87.13	83.22	90.76	85.24	84.12	84.39

4. Conclusion

In the present work, an attempt has been made to develop Sublingual tablets of Terbutaline sulfate. Chitosan, Cross povidone and Croscarmellose sodium were employed as super disintegrating agents to enhance the solubility and dissolution rate of selected drug molecule. 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. Among all the formulations F2 formulation showed maximum % drug release i.e., 98.36 % in 8 min hence it is considered as optimized formulation. The F2 formulation contains chitosan as super disintegrate in the concentration of 10 mg.

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