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Formulation and Evaluation of Matrix Tablets of Salbutamol Sulphate with reference to effects of Polymers

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Abstract

Salbutamol sulphate is an antiasthamatic and bronchodilator agent, with half life of 1.6 hours and requires multiple daily doses to maintain adequate plasma concentrations. The objective of this present study is to develop a sustained release tablet of salbutamol sulphate which releases the drug in a sustained manner over a period, by using different polymers. The drug was formulated and evaluated as per standard procedure and it was found that F6 formulation gives optimum results.

Keywords: Sustain release, Salbutamol sulphate, Polymers

Introduction

Oral route of drug administration is oldest and safest mode of drug administration. It posses several advantage. It provides accurate dosing without assistantship of administration. In conventional oral drug delivery system, there is little or no control over release of drug, and effective concentration at the target site can be achieved by administration of grossly excessive dosage form. Sustained release technology is relatively new field and as a consequence, research in the field has been extremely fertile and has produced many discoveries. With many drugs, the basic goal is to achieve a steady state blood level that is therapeutically effective and non-toxic for an extended period of time. The design of proper dosage form is an important element to accomplish this goal.

The present study was undertaken with an aim to formulate develop and evaluate Salbutamol sulphate sustained release tablets using different polymers as release retarding agent.

Material and Methods

Evaluation of granules

Determination of bulk density and tapped density

An accurately weighed quantity of the powder (W) was carefully poured into the graduated cylinder and the volume (v_o) was measured. then the graduated cylinder was closed with lid, set into the density determination apparatus (bulk density apparatus, electro lab, Mumbai).

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The density apparatus was set for 500 taps and after that, the volume (V_f) was measured and continued operation till the two consecutive readings were equal. The bulk density, and tapped density were calculated.

Compressibility index

The Compressibility index and Hausner ratio are measures of the propensity of a powder to be compressed. As such, they are measures of the relative importance of interparticulate interactions. In a free-flowing powder, such interactions are generally less significant, and the bulk and tapped densities will be closer in value. For poorer flowing materials, there are frequently greater interparticle interactions, and a greater difference between the bulk and tapped densities will be observed. These differences are reflected in the Compressibility Index and the Hausner Ratio.

Loss on drying

Determination of loss on drying of granules is important drying time during granulation was optimized depending LOD value. LOD of each batches were tested at 105ºc for 2.5 minutes by using "Sartorius" electronic LOD apparatus.

Angle of repose

The flow characteristics are measured by angle of repose. Improper flow of powder is due to frictional forces between the particles. These frictional forces are quantified by angle of repos

Formulation of salbutamol matrix tablet

Each quantity mentioned will be taken in mgs
Total weight of the tablet = 200mg
Each tablet contains = 4mg of the drug (mentioned in table 1)

Evaluation of tablet

All the prepared Sustained release tablets were evaluated for following official and unofficial parameters like Weight Variation, Thickness, Hardness Test, Friability Test, Drug content.

Table 1: composition of tablet formulation

Batch > ingredients	F.1	F 2	F3	F 4	F 5	F 6	F 7	F 8	F 9	F10	F11	F 12
Drug	4	4	4	4	4	4	4	4	4	4	4	4
Ethyl cellulose	10	-	-	20	-	-	30	-	-	10	20	30
Carbopol 934P	-	10	-	-	20	-	-	30	-	10	20	30
Xanthan gum	-	-	10	-	-	20	-	-	30	10	20	30
Compressible Lactose	180	180	180	170	170	170	160	160	160	160	130	100
Magnesium Sterate	4	4	4	4	4	4	4	4	4	4	4	4
Talc	2	2	2	2	2	2	2	2	2	2	2	2

Results and Discussion

The results of preformulation studies were mentioned below:

Parameters> Batch	Bulk Density	Tapped Density	Carrs Index	Hausners Ratio	Angle Of Repose(degree)
F1	0.488	0.526	7.22	1.08	22.14±0.03
F2	0.512	0.574	10.80	1.12	19.16±0.06
F3	0.486	0.526	7.22	1.08	24.18±0.057
F4	0.502	0.581	13.60	1.16	18.16±0.042
F5	0.523	0.602	13.12	1.15	19.14±0.02
F6	0.543	0.592	8.47	1.09	21.14±0.026
F7	0.499	0.564	11.52	1.13	20.42±0.01
F8	0.544	0.601	9.48	1.10	18.21±0.02
F9	0.561	0.611	8.19	1.08	24.14±0.042
F10	0.491	0.566	13.25	1.15	19.42±0.41
F11	0.544	0.601	9.48	1.10	20.64±0.026
F12	0.442	0.506	12.65	1.14	21.42±0.042

The results of the thickness, Hardness, weight variation, drug content, friability, disintegration time of tablet are shown in below Tables. The results of drug content of tablets are shown.

Table 2: Thickness and Disintegration time

Parameter/ Batch	Thickness (mm)*	Disintegration Time(sec)*
F 1	3.3	190±
F 2	3.1	210
F 3	3.3	145
F 4	3.3	205
F 5	3.2	250
F 6	3.3	197
F 7	3.1	240
F 8	3.2	300
F 9	3.2	243
F 10	**3.3**	207
F 11	3.1	275
F 12	3.3	310

Table 3: Weight variation, Hardness and Friability

Parameter/ Batch	Weight Variation (mg)	Hardness (Kg/cm2)*	Friability (%)
F 1	200.1	5.53	0.52
F 2	198.9	5.60	0.58
F 3	202.1	5.86	0.62
F 4	201.4	6.00	0.55
F 5	199.3	6.18	0.64
F 6	198.4	6.23	0.59
F 7	200.7	6.40	0.67
F 8	201.5	6.46	0.70
F 9	199.3	6.63	0.66
F 10	200.1	6.73	0.54
F 11	203.1	6.80	0.53
F 12	199.3	6.93	0.64

Table 4: Drug content uniformity

Parameter/ Batch	Drug Content (%)
F 1	99.50
F 2	92.89
F 3	100.02
F 4	99.59
F 5	99.38
F 6	97.05
F 7	99.60
F 8	91.69
F 9	95.62
F 10	99.50
F 11	100.02
F 12	99.60

Conclusion

Various formulations of sustained release tablets of Salbutamol sulphate were developed using various polymers viz, Ethyl cellulose,Carbopol and Xanthan Gum in different proportions and combinations by Direct compression technique. The tablets were evaluated. Observations of all formulations for physical characterization had shown that, all of them comply with the specifications of official pharmacopoeias and/or standard references.

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