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Formulation and Evaluation of Isoniazid Tablets

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Abstract

Sustained release tablets of isoniazid were prepared from guar gum and Carbopol, Tragacanth Gum and PEG-6000, in varying proportions and combinations by direct compression method, Bulk density, tapped density, compressibility index, Hausner ratio prior to punching as tablets. The tablets were tested for physical attribute such as hardness, weight variation, friability, and drug content. All the observations for physical characterization had revealed that all of them meet official pharmacopoeias and or standard references' specifications. In vitro release profile results had shown that formulation (F2) was the most potential formulation since the percentage of drug release from the formulation was greater compared to other formulations. From the above results and discussion, it is concluded that development of sustained release tablet of Isoniazid with Guar gum (1.5%), Batch F2 is taken as an ideal or optimized formulation of sustained release tablets for 12-hour release since it meets all the requisites for sustained release tablet.

Keywords: Isoniazid; Carbopol; Guar Gum; Tragacanthin; Sustained Release

1. Introduction

Drug products that make dosing less frequent by changing the rate of drug absorption have existed for decades. Constant study is being conducted in the area of use of natural occurring biocompatible polymeric material in dosage form designing of oral controlled release administration1. Natural gums are nontoxic and biodegradable, which swell and hydrate when exposed to aqueous media, and these have been employed for dosage form preparation Guar gum a derivative of polysaccharide with glycoside linkage has been utilized as matrix former for the controlled release of diltiazem2. Tragacanth gum, a high molecular weight polysaccharide gum, has D-glucose and D-mannose as the major hexose units and D-glucuronic acid, and is marketed as the sodium, potassium, or calcium salt3. Isoniazid is a first line medication in the treatment of tuberculosis and it is a prodrug and needs to be activated by bacterial catalyse. It is activated by catalase-peroxidase enzyme kat to produce is nicotinic acyl anion or radical. These structures will then interact with a NADH anion or radical to give rise to isonicotinic acylNADH complex. This complex binds well to ketoenoyl reductase referred to as inhA and inhibits access of the natural enoyl-AcpM substrate 4. This inhibits the process of mycolic acid synthesis in the mycobacterial cell wall. Isoniazid is bactericidal towards actively-dividing mycobacteria, but bacteriostatic if the mycobacterium is slow-growing5. The current research is intended to develop the sustained release matrix tablet of isoniazid using guar gum, tragacanth and Carbopol.

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2. Material and methods

Preparation of SR matrix tablets: SR matrix tablets of isoniazid were prepared employing varied drug: polymer ratios viz. 1:1, 1:1.5, 1:2 for P1,P2, P3, P4, 1:1, 1:1.5, 1:2 for G1, G2, G3, G4 and 1:1,1:1.5,1:2 for P1, P2, P3, P4 respectively were utilized as matrix forming material, where lactose was used as diluent, Magnesium stearate was added as Lubricant. All the ingredients were sifted through a #100 sieve, weighed, and mixed. The lubricated products were compressed using a direct compression method, with 12 mm flat faced punches.

Table 1 Formulation of isoniazid matrix tablet

Batch > ingredients	F1	F 2	F3	F 4	F 5	F 6	F 7	F 8	F 9	F10	F11	F12
Drug	100	100	100	100	100	100	100	100	100	100	100	100
Guar gum	100	150	200	-	-	-	-	-	-	-	-	-
Tragacanth- gum	-	-	-	100	150	200	-	-	-	-	-	-
PEG-6000	-	-	-	-	-	-	100	150	200	-	-	-
Carbopol-934p	-	-	-	-	-	-	-	-	-	100	150	200
Magnesium- Stearate	7	7	7	7	7	7	7	7	7	7	7	7
Talc	7	7	7	7	7	7	7	7	7	7	7	7
Starch	21	21	21	21	21	21	21	21	21	21	21	21
Compressible Lactose	115	65	15	115	65	15	115	65	15	115	65	15

2.1. Evaluation of granules

2.1.1. Angle of repose

Angle of repose was determined using funnel method6. The blend was poured through a funnel that can be raised vertically until a maximum cone height (h) was obtained. The radius of the heap(r) was measured and the angle of repose (θ) was calculated using the formula7. θ=tan-1(h/r)

- **Bulk density:** Apparent bulk density (pb) was determined by pouring the blend in to a graduated cylinder. The bulk volume (VB) and weight of the powder (M) was calculated using the formula7. pb = M/ Vb
- **Tapped density:** The measuring cylinder containing a known mass of blend was tapped for a fixed time. The minimum volume (Vt) occupied in the cylinder and the weight (M) of the blend was measured. The tapped density (pt) 6 was calculated by using formula. pt = M/ Vt
- **Compressibility index:** The easiest method for free flow measurement of powder is compressibility, a measure of the ease with which a product can be caused to flow is provided by compressibility index (I)6 calculated using the following formula. I = (V0 - Vt/ V0) 100

Where, vow is tapped volume and vet is bulk volume. Below 15% value signifies a powder with normally give rise to good flow characteristics, whereas above 25% signifies poor flowability.

- **Loss on drying:** Determination of loss on drying of granules is important drying time during granulation was optimized depending LOD value. LOD of each batch were tested at 105o c for 2.5 minutes by using “Sartorius” electronic LOD apparatus.

Table 2 Evaluation of tablets blends

Parameter Batch	Bulk Density	Tapped Density	Carrs Index	Hausners Ratio	Angle Of Repose(degree)
F 1	0.442	0.638	7.22	1.08	18.10±0.03
F 2	0.522	0.513	7.29	1.10	18.19±0.06
F 3	0.510	0.601	7.31	1.04	19.51±0.057
F 4	0.521	0.711	7.63	1.06	20.33±0.042
F 5	0.560	0.730	7.59	1.14	21.494±0.02
F 6	0.493	0.513	7.86	1.09	21.11±0.026
F 7	0.591	0.509	8.30	1.12	23.962±0.01
F 8	0.601	0.600	8.14	1.15	18.21±0.02
F 9	0.630	0.609	9.11	1.11	24.14±0.042
F 10	0.616	0.510	11.62	1.00	24.18±0.41
F 11	0.592	0.611	13.60	1.18	20.64±0.026
F 12	0.660	0.731	13.11	1.13	24.13±0.042

2.2. Evaluation of Tablets

- **Weight variation:** Twenty tablets were selected at a random and average weight was determined. Then individual tablets were weighed and were compared with average weight.
- **Friability:** Friability of the tablets was measured by Roche fabricator. The apparatus exposes the tablets to the simultaneous effect of abrasion and shock in a plastic chamber rotating at 25rpm and dropping the tablets at a height of 6inches per revolution. Reweighed quantity of tablets was put in the fabricator and were given 100 revolutions. Tablets were removed using soft muslin cloth and weighed. The friability (f) is expressed by the formula. F = (1-W0/W) 100 Where, W0 is initial weight of the tablets and W is final weight of the tablets after testing.
- **Hardness:** Hardness was measured using Monsanto tablet hardness tester.
- **Thickness:** Ten tablets were taken from each formulation and their thickness was measured using digital Vernier caliper (Mitutoyo Corp, Kawasaki, Japan).
- **Uniformity of content:** Dissolve one finely powdered tablet into a 500ml volumetric flask with the assistance of 200ml of water. Shake by mechanical action for 30min. Add water to volume and mix filter and discard first 20ml of the filtrate dilute a portion of the filtrate quantitatively and stepwise if required with a 3 in 100 mixture of 0.1N HCL and water to give a solution containing about 10µg/ml. Dissolve a accurately weighed amount of USPRF in an amount of water equal to that used for dissolving an equivalent amount of Isoniazid obtained from tablet and make suitable dilution with a 3 in 100 mixture of 0.1n HCl read in 1 cm cells at wave length max absorbance at 263nm.

Table 3 Evaluation of prepared tablets

Parameter Batch	Thickness (mm)*	Disintegration Time(sec)*	Weight Variation (mg)	Hardness (Kg/cm2)*	Friability (%)	Drug Content (%)
F 1	4.4	196	350.1	5.51	0.55	99.50
F 2	4.0	240	348.9	5.80	0.59	98.60
F 3	4.3	210	325.2	5.93	0.61	100.02
F 4	4.1	243	351.4	6.20	0.58	99.59
F 5	4.5	191	349.3	6.11	0.63	99.38
F 6	4.2	200	348.4	6.35	0.76	99.05
F 7	4.6	317	350.7	6.41	0.70	99.60
F 8	4.3	250	351.5	6.44	0.66	102.06
F 9	4.1	213	349.3	6.68	0.53	100.62
F 10	4.2	300	350.1	6.71	0.71	99.50
F 11	4.6	144	353.1	6.89	0.69	100.02
F 12	4.1	231	349.2	6.91	0.68	101.01

3. Results And Discussion

Oral drug administration route is oldest and safest route of drug administration. It has a number of advantages. It offers precise dosing without the aid of administration. In traditional oral drug delivery system, there is minimal or no control over drug release, and desired concentration at the target site can be obtained through administration of grossly excessive dosage form. Sustained release technology is quite a novel area and therefore, research work in the area has been highly productive and yielded numerous breakthroughs. In most drugs, the fundamental aim is to provide a constant state blood level that is therapeutically potent and non-toxic Suresh. S et al Der Pharmacia Latter, 2011, 3(1): 237- 246 -245 Scholar Research Library for a long period of time. The formulation of an appropriate dosage form is a critical factor to achieve this objective. Isoniazid is an antitubercular drug, having a half-life of 1.5-4 hours and needs to be given in multiple doses daily to have sufficient plasma levels. Therefore, it is chosen to formulate a sustained release tablet. The aim of this current research is to formulate a sustained release tablet of Isoniazid releasing the drug in sustained form over a duration of 12 hours using various polymers and investigation on polymer concentration effect on release pattern. Current research was carried out with an objective to formulate develop and evaluate Isoniazid sustained release tablets employing various polymers as release retarding agent. Reformulation investigation was carried out first and findings guided for the future direction of formulation. In accordance with Reformulation studies, various batches of Isoniazid were prepared employing suitable excipients. Granules were tested for Bulk density, tapped density, compressibility index, Hausner ratio prior to punching as tablets. IR spectra studies indicated that drug and employed polymers were compatible. Different formulations of sustained release tablets of Isoniazid were prepared by employing different polymers viz, Guar gum, Tragacanth Gum, PEG-6000 and Carbopol in different ratios and combinations by direct compression method. The tablets were analysed for physical characterization, in vitro swelling studies, in vitro release study and stability studies. All the observations of formulations for physical characterization had revealed that all of them meet official pharmacopoeias and/or standard reference specifications. In vitro release profile results revealed that the most promising formulation was formulation (F2) since the degree of drug release from this formulation was high compared to other formulations. Results of in vitro swelling study reveal that formulation F2 was exhibiting significant swelling index. Stability study was performed on room temperature stored Batch F2 tablets at 370 C for one month. Tablets were examined for hardness, friability, in-vitro release profile and drug content. No remarkable changes were noted in any of the parameters that were under investigation throughout the study period after one month, and hence it was possible to conclude that formulation was stable. The tablets of batch F2 were concluded to possess noteworthy swelling characteristics and in vitro drug release. Tablets of batch F2 were found to follow the Zero order release profiles.

4. Conclusion

Results of in vitro release profile showed that formulation (F2) was the most suitable formulation since the extent of drug release from this formulation was maximum compared to other formulations. Results of in vitro swelling study show that the formulation F2 was exhibiting significant swelling index. Stability study was carried out on tablets of Batch F2 at room temperature, 370 C for one month. Tablets were tested for hardness, friability, in-vitro release profile and drug content. No significant change was noticed in any of the parameters studied within one month of study period,

therefore it could be concluded that formulation was stable. It was concluded that tablets of batch F2 exhibited significant swelling behaviors and in vitro drug release. Based on above findings and discussion, it can be concluded that Isoniazid sustained release tablet formulation containing Guar gum (1.5%), batch F2 can be used as an ideal or optimized 12-hour release sustained release tablet formulation because it meets all the demands of sustained release tablet.

Compliance with ethical standards

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Disclosure of conflict of interest

No conflict of interest to be disclosed.

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