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FORMULATION AND CHARACTERIZATION OF FAST DISSOLVING TABLETS OF ROXITHROMYCIN USING NATURAL POLYMERS

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Abstract:

Natural polymers like locustbeangum, banana powder, mangopeel pectin, Mangifera indica gum, and Hibiscus rosa-sinenses mucilage ameliorate the propertiesof tablet and utilized as binder, diluent, and superdisintegrants increasethe solubility of poorly water-soluble drug, decrease the disintegration time, and provide nutritional supplement. Present investigation aim to formulate Roxithromycin fast dissolving tablets using natural polymers. The % drug content of all the formulated tablets were found within the limit. % drug content value of Roxithromycin was within 97.85±0.25%to99.65±0.24%. The results within the range indicate uniform of mixing. The Table no 7.6 shows the %drug content in each formulation. The In vitro drug release studies of the enhanced detailing was subjected to integrity of fit test by linear regression analysis as indicated by zero order, first order kineticandHiguchireleaseequation, inordertodecidethemechanismofdrugrelease. When the regression\ coefficient values of were compared, it was observed that 'r^2' values of First order release kinetics was maximum i.e. 0.996 hence indicating drug release from formulations was found to follow First order release kinetics.

Key words: *Roxithromycin, Natural polymers, fast dissolving tablets, Formulation, Evaluation*

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INTRODUCTION:

The polymers obtained from the natural inchoation are more efficacious and safer. They are facilely available in natural regions around the world therefore they are preferred over synthetic polymer. Natural polymers are utilized in most of the preparationandaremorepropitiousoversyntheticpolymersastheyareeconomical, and they have low cost and are facilely available in the sufficient quantity. Natural polymers are nontoxic; they do not have any adverse effects on the body. Natural polymersareenvironmentalfriendlyastheyarebiodegradableinnaturetheydonot cause any pollution. Natural polymers are devoid of sideeffects astheyare obtained from the natural source. Natural polymers are mainly preferred by the patients as they are safer and more efficacious as compared to the synthetic polymers and have more patient compliance. Natural polymers provide nutritional supplement and are renewable as they are utilized again and again in different reactions [1].

Fast dissolving drug delivery systems were first developed in the late 1970s as an alternative to conventional dosage forms for the pediatric and geriatric patient. These tablets are designed to dissolve or disintegrate rapidly in the saliva generally less than 60 seconds [4]. To fulfill these medical needs, pharmaceutical technologists have developed a novel oral dosage form known as orally disintegrating (dispersible) tablets (FDTs) or Fast disintegrating (dissolving) tablets (FDTs) or mouth melting tablets (MMTs) or mouth dissolving tablets (FDTs), immediate release tablets which disintegrate rapidly in saliva, usually in a matter of seconds, without the need to take water.

Recent market studies indicate that more than half of the patient population prefers FDTstootherdosageforms.Mouthdissolvingtablets areformulatedmainlybytwo techniques first use of super disintegrants like Croscarmellose sodium, sodium starchglycolate and crospovidone. Another method is maximizing pore structure of the tablets by freeze drying and vacuum drying. In all methods, direct compression is preferred because of its effortlessness, quick procedure and cost-effectiveness [2].

Natural polymers like locustbeangum, banana powder, mangopeel pectin, *Mangifera indica* gum, and *Hibiscus rosa-sinenses* mucilage ameliorate the propertiesof tablet and utilized as binder, diluent, and superdisintegrants increase the solubility of poorly water-soluble drug, decrease the disintegration time, and provide nutritional supplement. Natural polymers are obtained fromthenaturalorigin and they are cost efficacious, nontoxic, biodegradable, eco-friendly, devoid of any side effect, renewable, and provide nutritional supplement.

The poor solubility of drug substances in water and their low dissolution rate in the aqueous gastro-intestinal fluids often lead to insufficient bioavailability. According to the equation of Noyes and Whitney, this may be achieved by an increase in the surface area of the drug which is accessible for the dissolution medium of the stomach. Present investigation aim to formulate Roxithromycin fast dissolving tablets using natural polymers.

MATERIAL AND METHODS:

Material:

Roxithromycin was received from pharmaceutical company as a gift sample. Sodium starch glycolate was obtained from S.D fine chemicals limited, Mumbai. Guar Gumwas obtained from LobAChemie Mumbai. All other chemical were purchased from Hi Media, Mumbai. Double distilled water was prepared freshly and used whenever required. All the chemicals used in this work were of analytical grade.

Methods:

Preparation of tablets ofRoxithromycin:

Fast dissolving tablets of Roxithromycin (150mg) were prepared by direct compression method after incorporating different superdisintegrants such as, croscarmellose sodium (Ac-Di-Sol) 10, 15, and 20 mg , crospovidone in different concentrations 10, 15, and 20 mg for optimization of best formulation [3]. The ingredientsgiven below were weighed and mixed in geometric progression in a dry and clean mortar. Then the ingredients were passed through mesh 60.

Magnesium stearate (6mg) as lubricant and talc (5 mg) as glidant and Microcrystalline cellulose as bulking agent (79, 74, 69, 79, 74and 69 mg) were added in a final step and mixed, this blend was subjected to analysis of pre- compression parameters which included Angle of repose, Bulk density, Tap density, Carr's index and Hausner'sratio.

The Blend was compressed on 8 mm (diameter) fat punches on a 'Rimek mini press 16 station rotary compression machine. Six formulations of Roxithromycin granules were prepared and each

formulation contained one of the three disintegrant in different concentration. Each tablet weighing 250 mg was obtained. Composition of tablets is mentioned in Table no 1.

Table No. 1: Composition of Roxithromycin fast dissolving tablets using natural and synthetic polymers

Ingredients (mg)	Formulation code					
	F1	F2	F3	F4	F5	F6
Roxithromycin	150	150	150	150	150	150
SodiumStarch glycolate	10	15	20	-	-	-
Guar Gum	_	_	_	10	15	20
Microcrystallinecellulose	79	74	69	79	74	69
Talc	5	5	5	5	5	5
Magnesium stearate	6	6	6	6	6	6
Total weight	200	200	200	200	200	200

Evaluation of post compression Parameter [4-9]:

Shape and colour of tablets:

Uncoated tablets were examined under a lens for the shape of the tablet and colour was observed by keeping the tablets in light.

Thickness test:

Three tablets were picked from each formulation randomly and thickness was measured individually. It is expressed in mm and standard deviation was also calculated. The tablet th Weight variation test. Twenty tablets were selected randomly from each formulation and average weight was determined (USP, 2005).

Hardness test:

The hardness of tablet was measured by Pfizer hardness tester and results were expressed in Kg/cm^2.

Friability test:

For this, 20 tablets were taken from each formulation and the friability was determined using Roche Friabilator. The equipment was run for 4minat25revolutions per minute. The tablets were taken out, dedusted and reweighted and % friability was calculated. The friability was determined as the mass loss in percent according to Equation:-

The test complies if tablets not loss more than 1% of their weight.

$$\%Friability = (Loss\ in\ weight/Initial\ weight) \times 100$$

Uniformity of drug content:

The test is mandatory for tablets with 10 mg orless weight of active ingredient [52].Ten randomly selected tablets from each formulation (F1 to F6) were finely powdered and Drug equivalentto10mg of drug dissolved in 10 ml phosphate buffer pH6.8) sonicate itf or 20 minutes, till the entire drug leached out from complex, then the solution was filtered through whatman filter paper No. 41. From this Solution take 1 ml and Diluted up to 100 ml with 0.1 N HCl and the drug content was determined spectrophotometrically at 210 nm.

***In vitro* dissolution rate studies:**

The prepared tablets were evaluated for *in vitro* drug release [53]. The drug release studies were carried out using USP XXII paddle type Dissolution test apparatus. The dissolution study was carried out in 900 ml dissolution medium which was stirred at 75 rpm maintained at 37 ± 0.2^0C. The scheme of using the simulated fluids at different timing was as follows:

A tablet placed in dissolution media (900 ml) at 37 ± 0.2^0C. Samples were withdrawn at different time interval and compensated with same amount of fresh dissolution medium. Volume of sample withdrawn was made up to 10ml 0.1 N HCl. The samples withdrawn were assayed spectrophotometrically at 210 nm using UV visible

spectrophotometer.

RESULTS AND DISCUSSION:

The thickness of the tablets was reported in the micrometer (mm).The thickness of tablet indicates that, die fill was uniform. The thickness depends on the size of the punches (8 mm) and the weight of one tablet (250mg). The average weight of each formulation was recorded in shown in Table no 7.6. The value of thickness ranges between 2.3±0.1 to 2.6±0.1mm.

Friability determines the strength of the tablets. The values of friability test were given in the Table no 7.6. The friability for all the formulations was below 1% indicating that the friability was within the prescribed limits. The results of friability test indicate that the tablet possesses good mechanical strength. The friability value ranges from 0.623±0.015 to 0.765±0.036.

The mean hardness values were measured for all the formulation using Monsanto hardness tester. The results were tabulated in Table. The hardness value ranges from 3.1±0.1 to 3.4±0.kg/cm^2.

Twenty tablets were randomly selected from each formulation and evaluated. The average weight of each formulation was recorded and is shown in Table no 7.6. The obtained data were almost uniform. The values of tablets average weight ranging from 248±6 to 254±5mg. All the tablets passed weight variation test as the % weight variation was within the USP Pharmacopoeia's limits of ±5% of the weight.

The % drug content of all the formulated tablets were found within the limit. % drug content value of Roxithromycin was within 97.85±0.25% to 99.65±0.24%.The results within the range indicate uniform of mixing. The Table no 7.6 shows the % drug content in each formulation.

Disintegration time of formulation F1, F2, F3, F4, F5 and F6 was found to be 85±4, 75±6, 65±2, 45±5, 32±2 and 48±4 Sec. respectively. The Minimum disintegration time was found in formulation F5 (32±2), select as optimized formulation.

From the dissolution analysis, Optimized formulation F5 showed the maximum percentage of drug release, formulation F5 containing Guar Gum. The Formulation F5 Showed 36.65, 58.89, 85.65 and 99.12%drugreleaseafter1, 5, 10 and 15min.

The In vitro drug release studies of the enhanced detailing was subjected to integrity of fit test by linear regression analysis as indicated by zero order, first order kinetic and Higuchi release equation, in order to decide the mechanism of drugrelease.

When the regression coefficient values of were compared, it was observed that 'r^2' values of First order release kinetics was maximum i.e. 0.996 hence indicating drug release from formulations was found to follow First order release kinetics.

When the regression coefficient values of were compared, it was observed that 'r^2' values of Higuchi release kinetics was maximum i.e. 0.990 hence indicating drug release from formulations was found to follow Higuchi release kinetics.

Table No 3:Results of evaluation of Hardness test, Friability (%), Weight variation (%), Thickness (mm), Drug content (%)

F. Code	Hardness test (kg/cm^2)	Friability (%)	Weight variation (%)	Thickness (mm)	Drug content (%)
F1	3.2±0.1	0.658±0.021	254±5	2.3±0.1	97.85±0.25
F2	3.1±0.1	0.745±0.038	250±4	2.4±0.2	98.25±0.32
F3	3.3±0.2	0.623±0.015	248±6	2.6±0.1	98.78±0.35
F4	3.2±0.2	0.765±0.036	253±3	2.3±0.2	98.65±0.23
F5	3.4±0.3	0.665±0.022	249±2	2.4±0.1	99.65±0.24
F6	3.3±0.2	0.714±0.021	252±5	2.5±0.1	98.78±0.22

Table No 4: Results of disintegration time parameters of all formulations

Formulation code	Disintegration Time (Sec.) Mean ± SD
F1	85±4
F2	75±6
F3	65±2
F4	45±5
F5	32±2
F6	48±4

***Average of three determinations (n=3)**

Table No 5: *In-vitro* drug release data for optimized formulation F5

Time (min)	Square Root of Time(h)$^{1/2}$	Log Time	Cumulative*% Drug Release	Log Cumulative % DrugRele	Cumulative % Drug Remaining	Log Cumulative % Drug Remaining
1	1	0	36.65	1.564	63.35	1.802
5	2.24	0.698	58.89	1.770	41.11	1.614
10	3.16	1	85.65	1.933	14.35	1.157
15	3.87	1.176	99.12	1.996	0.88	-0.056

Table No 6: Regression analysis data

Batch	Zero Order	First Order	Higuchi
	r^2		
F5	0.977	0.895	0.990

CONCLUSION:

Fast dissolving tablets of Roxithromycin were conveniently formulated by direct compression method. The *In-vitro* dissolution studies showed that Roxithromycin tablets formulation F5 showed maximum 98.85% over a period of 15 min.

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