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Formulation and evaluation of praziquantel chewable tablet for helmenthiasis treatment

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ABSTRACT

The preparation and assessment of chewable tablets of Praziquantel were studied in order to produce Praziquantel chewing tablet. The chewing tablets were created using a direct compression technique with different quantity of binder (PVP K30) and super disintegrants (SSG). On development of the chewing tablets there were no interaction found in between thedrug and excipients which was used during this process which was agreed by the infra-redspectral analysis. Therefore, all the chewing tablets which was prepared were consistent indrug content. Results of disintegration studies revealed a quick & rapid disintegration in formulation 5 and formulation 6 as per USP. In dissolution studies, % cumulative drug release was rapidly increased I formulation5 and formulation 6. In those two formulations were using less amount of binder and higheramount of super disintegrant. As per USP the dissolution time period is 60 min, meanwhilein that time % cumulative drug release in formulation 5 is 97.50% and in formulation 6 is98.82%. The medication quality in all tablet batches was found to be consistent. Friability testin all the formulation was found to be less than 1% which indicates the resistant to abrasion.The Hardness of prepared tablets ranged from 3.82-4.2kg/cm^2.All the prepared tablet was observed to be uniform in weight, and variation in weight was within the limit of ±5%. The *invitro* dissolution profile of chewing tablets was found to be increased with increase in super disintegrant level. Hence, it has been concluded that the amount of super-disintegrants increases and lessamount of binder which makes best combination in the tablet formulation containing hydrophilic carriers of drug is a promising approach to prepare efficient chewing tablets ofnon-aqueous soluble drug Praziquantel.

Keywords: Praziquantel, PVP K30, SSG, chewing tablets, Helminthiasis

INTRODUCTION

Oral Solid Dosage Forms

Strong types of drugs include pills, capsules, bags, pills, and bulk powders and granules, which otherwise have a unit dose. Oral solid dosage forms are the most important and play an important role amongst various dosage forms in the pharmaceutical industry. There is a wide recognition of the oral route of drug administration and the majority are solid dosage forms of medication. More than 90 percent of drugs with systemic effects are produced using strong dosingtypes. Because of these reasons, the pharmaceutical company first questions whether oral administration of the substance is possible in the event of a new chemical entity (NCE) with adequate pharmacological activity. When a tree or shrub's bark is injured, it releases aqueous thick exudates as a natural defence mechanism to prevent infection or dehydration. Natural gum is the name given to this solid mass. The drug types such as tablets, capsules, lotions, suspensions, syrups and oints contain important excipients. Plant products are a viable alternative to synthetic products because they are easily accessible, ecologically sound and

less costly than synthetic products produced. In a quick-dissolution tablet, Plantago ovata mucilage was examined. The objective of this test was to demonstrate that Moringa gum is decay. The oral route remains the most frequent due to its many benefits, including:

- Tablets and capsules are device quantity types into which a precise quantity of medication may be given to achieve adequate pharmacological action. Patients are instructed to prescribe 5-30 mL of liquid oral drug formulations such as syrups, suspensions, emulsions, solutions, and elixirs. When the treatment is self-administered by the patient, such dose calculations are usually inaccurate by a factor of 20-50 percent.
- As compared to liquid dosage formulations, solid dosage forms are not as much of costly to transport and less vulnerable to deterioration.

Helminthiasis

Helminthiasis, also known as a worm infection, is a macro-parasitary disease that affects humans and animals and causes parasitary worms called helminths to infect a part of the body. Three categories of parasites are divided: tapestry, flukes, and redworms. They are usually foundin their hosts' gastrointestinal tracts but also can burst into other bodies and cause physiological damage. SOID Helminthiasis and Schistosomiasis, all regarded as neglected tropical diseases, are the most common helminthiasis. Helminthiasis was associated with low birth rates, neurological growth, academic and working achievements, social progress, and poverty. Someside effects include chronic tiredness, hunger and anaemia. The soil-transmitted helminthiasis causes the parasite infections of up to one fifth of the world population. Ascariousness is a well-known example of a soil-borne helminthiasis. Signs & Symptoms: Helminthiasis symptoms are determined by the location of the infestation inside the body. There could be no signs if the parasite load in the body is low. Taeniasis, for example, can cause seizures due to neurocysticercosis.Mass and volume: The weight and volume can tear out the external layers of the intestinals such as the muscle layer in extreme cases of intestinal infestation. All possible outcomes include peritonitis, volvulus, and intestinal gangrene. Immunological response: Because helminths are bacteria, they elicit an immune response in the body. The inflammatory changes in the skin, lungs, liver, stomach, central nervous system and eyes are immune-mediated. Eosinophilia and arthritis are signs of the immune system. An allergic reaction is an anaphylaxis-causing hypersensitivity reaction. Another example is the ascaristic larvae that migrate to the lung's bronchi causing asthma. The current study's aim is to develop and test praziquantel chewable tablets using thedirect compression process.

METHODOLOGY

Pre-Formulation Parameters

Table 1: Quantity of ingredients used for preparation

Ingredients	F 1 Mg	F 2 Mg	F 3 Mg	F 4 mg	F 5 mg	F 6 Mg
Praziquantel	150	150	150	150	150	150
PVP k30	25	23	21	19	17	15
Sodium starch glycolate	15	17	19	21	23	25
Mannitol	170	170	170	170	170	170
Sodiumlauryl sulphate	15	15	15	15	15	15
Magnesium stearate	10	10	10	10	10	10
Talc	5	5	5	5	5	5

RESULT AND DISCUSSION

Infra Red Spectral studies

The IR spectral studies of pure Praziquantel showed characteristics peaks at its respective range, and tabulated below

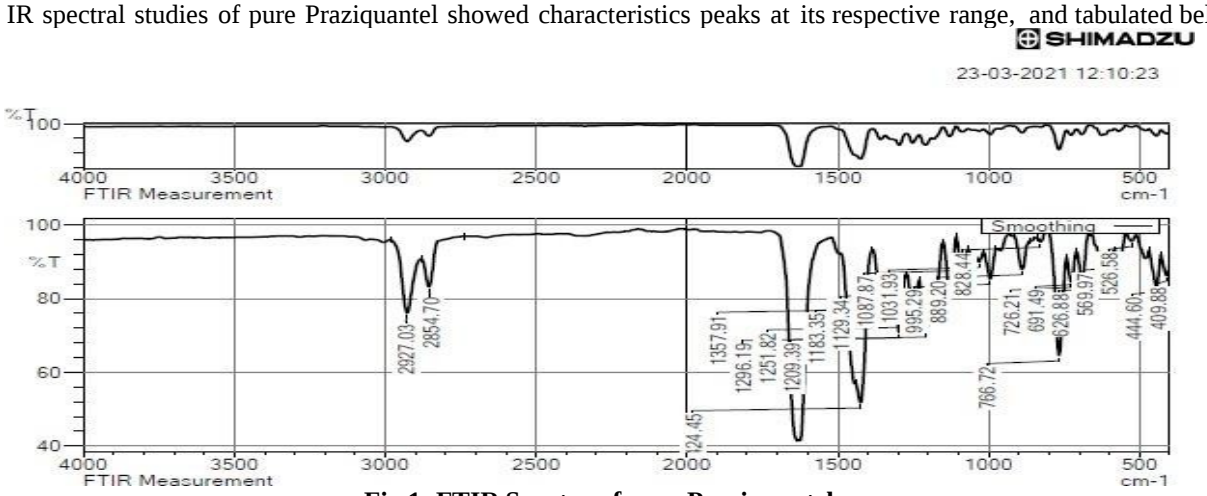

Fig 1: FTIR Spectra of pure Praziquantel

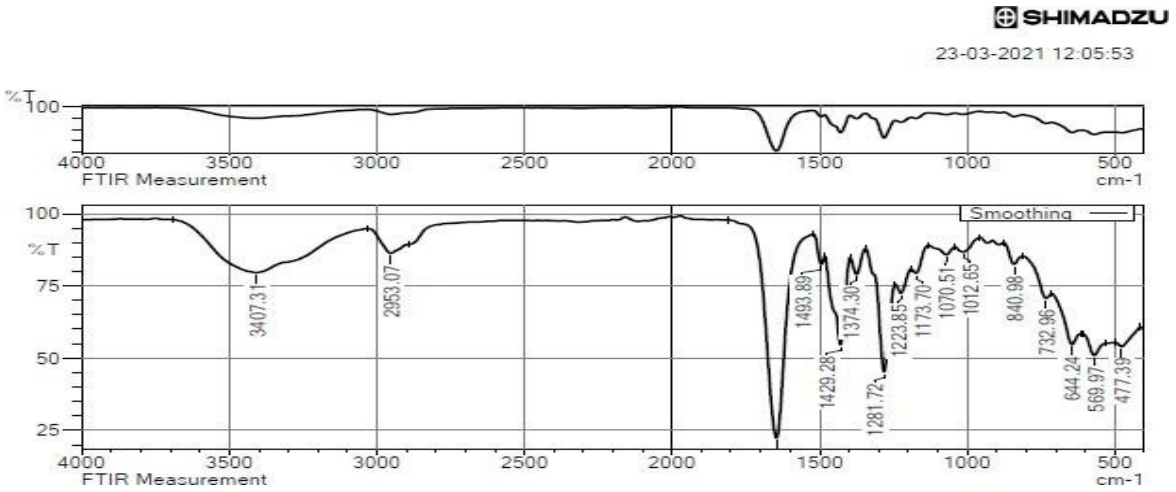

Fig 2: FTIR Spectra of PVP K30

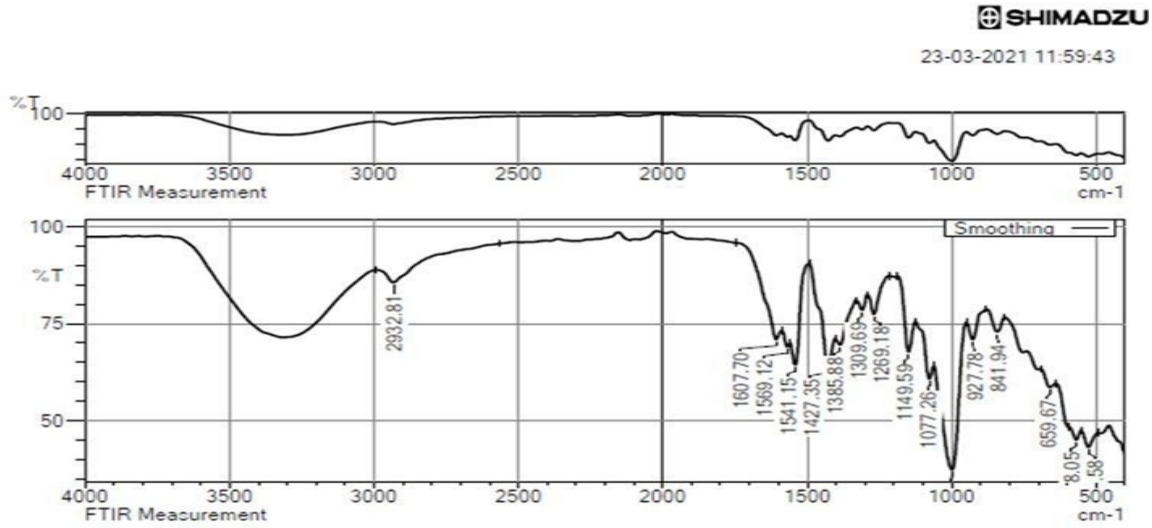

Fig 3: FTIR Spectra of SSG

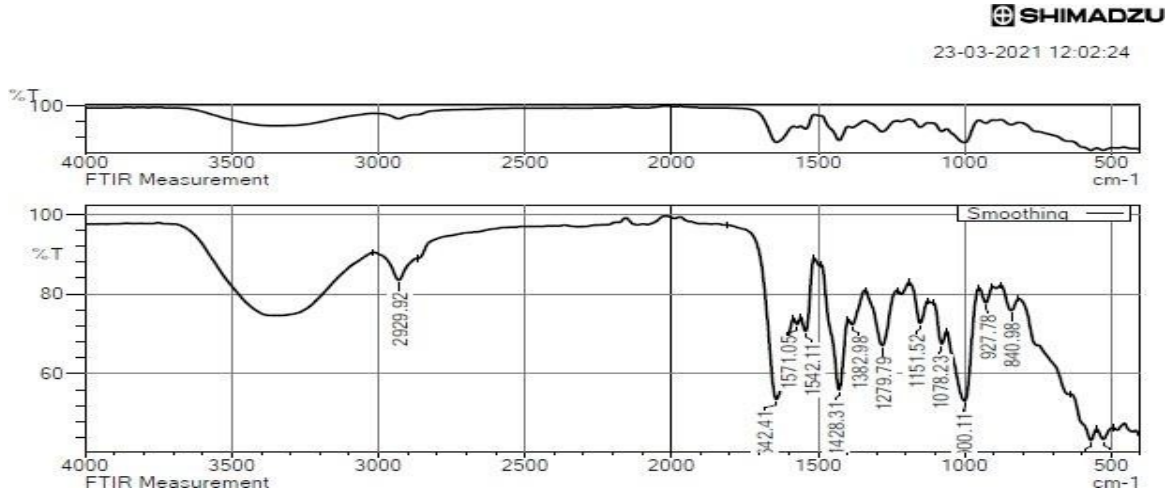

Fig 4: FTIR Spectra of Drug and Excipients

Post Compression Studies

Weight Variation Test

The results obtained from weight variation test shows that the average weight of all tablets is having variation within the limit of ± 5 from the total weight of each tablet in formulation. The results indicated that the formulated tablets are uniform in weight.

Table 2: Percentage deviation in each formulation

S. No	Formulation	Weight variation
1	F1	393.33 ± **5**
2	F2	391.5 ± **5**
3	F3	388.9 ± **5**
4	F4	387.66 ± **5**
5	F5	390.33 ± **5**
6	F6	391.63 ± **5**

Hardness Test

The formulated tablets are having the hardness in the range of 7.6 to 7.1 kg/cm^2.Theresults showed resistance of prepared tablets to abrasion, capping, breakage, during storage and transportation.

Table 3: Hardness evaluation of each formulation

S. No	Formulation	Hardness (kg/cm^2)
1.	F1	7.6 kg/cm^2
2.	F2	7.5 kg/cm^2
3.	F3	7.47 kg/cm^2
4.	F4	7.41 kg/cm^2
5.	F5	7.28 kg/cm^2
6.	F6	7.1 kg/cm^2

Friability Test

The outcomes of the friability test showed the weight loss in all the prepared tabletswere less than one percentage. Hence the prepared tablet passes the friability test.

Table 4: Friability test for each formulation

S. No	Formulation	Friability %
1.	F1	0.165%
2.	F2	0.2%
3.	F3	0.26%
4.	F4	0.3%
5.	F5	0.39%
6.	F6	0.48%

Disintegration Test

The disintegration test showed that when the proportion of super-disintegrants used in the formulation increased, which decreases the disintegration time of the tablets. This signified that the increasing level of super disintegrants was found to have a positive impact in disintegration time of Praziquantel chewing tablets.

Table 5: Disintegration test for all formulation

S. No	Formulation	Disintegration time (minutes)
1.	F1	3min 7sec
2.	F2	3min
3.	F3	2min 51sec
4.	F4	2min 44sec
5.	F5	2min 38sec
6.	F6	2min 29sec

Drug Content Test

The formulate Praziquantel chewing tablet passes the drug content assay. The results of all tablet batches showed average percentage drug content is 90 to 110% as per USP.

Table 6: It represent % drug content in each formulation

S. No	Formulation	Drug content %
1.	F1	94%
2.	F2	97.5%
3.	F3	102%
4.	F4	107.33%
5.	F5	101%

6.	F6	99.8%

In-Vitro Dissolution Test

An extensive dissolution study was done for all the 6 formulations.

- Time duration - 1 hour
- Buffer used- 0.1N HCL
- Rotation speed - 50 rpm
- Temperature- 37±0.5˚C

Increasing the *invitro* super disintegrant level, which makes better dissolution. In this case, the level of super disintegrants gradually increased fromformulation 1 to formulation 6. The result, the formulation contain higher super disintegrant have higher drug release percentage when compared to others. Hence, it has been concluded that the amount of super-disintegrants increases and less amount of binder which makes best combination in the tablet formulation containing hydrophilic carriers of drug is a promising approach to prepare efficient chewing tablets of non-aqueous soluble drug Praziquantel.

Table 7: Comparison of % cumulative drug release of different formulation

Time	F1	F2	F3	F4	F5	F6
5	6.14	7.13	7.23	8.81	18.67	19.95
10	13.87	13.68	14.27	16.55	30.41	33.97
15	27.75	22.63	23.82	27.19	46.55	47.67
20	35.50	36.66	38.74	39.97	50.16	53.55
25	41.32	46.82	47.34	48.67	62.37	67.85
30	57.92	57.73	55.69	58.01	76.62	78.58
35	63.56	63.87	66.35	66.02	85.72	88.37
40	76.04	72.90	78.35	73.38	92.50	93.39
45	81.38	83.55	85.97	87.69	94.18	95.58
50	95.04	91.70	93.54	93.78	95.58	97.77
55	95.65	92.39	94.05	95.38	96.98	98.29
60	96.27	92.99	94.55	95.89	97.50	98.82

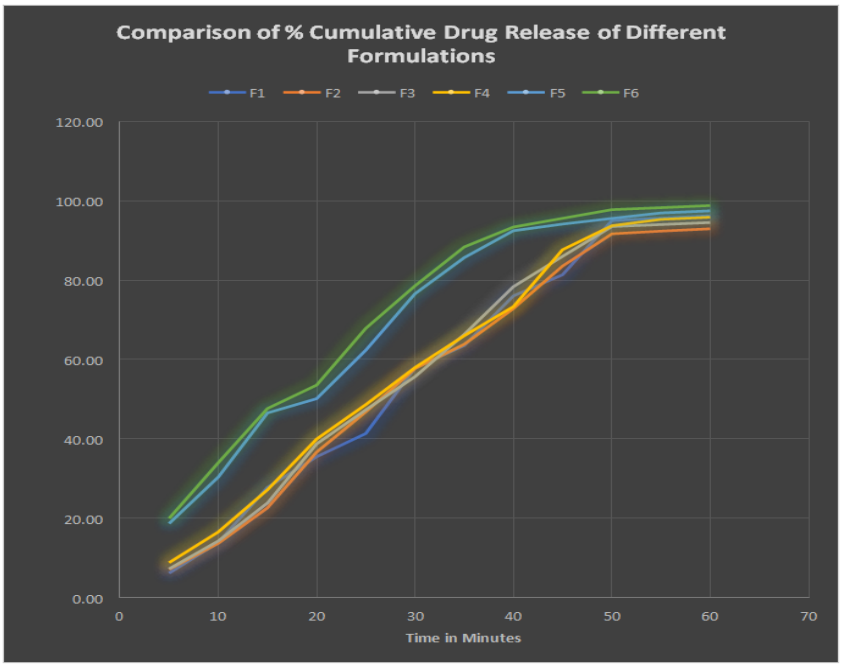

Fig 5: Comparison of % cumulative drug release of all formulation

SUMMARY AND CONCLUSION

The preparation and assessment of chewable tablets of Praziquantel were studied in order to produce Praziquantel chewing tablet. The chewing tablets were created using a direct compression technique with different quantity of binder (PVP K30) and super disintegrants (SSG). On development of the chewing tablets there were no interaction found in between the drug and excipients which was used during this process which was agreed by the infra-red spectral analysis. Therefore, all the chewing tablets which was prepared were consistent in drug content. Results of

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