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Formulation Evaluation and Stability Studies of Dietary Supplements

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ABSTRACT

In the present work, mouth dissolving tablets of Dietary Supplements were designed with a view to enhance patient compliance by direct compression method. In the direct compression method, Sodium Bicarbonate and Tartaric acid as a Effervescent mixture were used along with directly compressible Mannitol and Maltodextrin to enhance mouth feel. The prepared batches of tablets were evaluated for hardness, friability, drug content uniformity, water absorption ratio and in *vitro* dispersion time. Short-term stability (25^0C/ 60% RH and 40°C/ 75% RH for 3 months) and drug-excipient interaction study (IR spectroscopy). Among all the formulations, the formulation prepared by using 80 mg Sodium bicarbonate and 40 mg Tartaric acid was found to have minimum dispersion time (52 - 58 s). Short-term stability studies on the promising formulations indicated that there were no significant changes in drug content and *in vitro dispersion* time

INTRODUCTION: -

Many patients find it difficult to swallow tablets and hard gelatin capsules and thus do not comply with prescription, which results in high incidence of non-compliance and ineffective therapy[1]. Recent advances in novel drug delivery systems (NDDS) aim to enhance the safety and efficacy of drug molecule by formulating a convenient dosage form for administration and to achieve better patient compliance[1-4].

Nearly 35-50% of the general population, especially the elderly and children suffer from dysphagia or difficulty in swallowing, which results in high incidence of non-compliance and ineffective therapy. Swallowing problems also are very common in young individuals because of their poorly developed muscular and nervous systems. Other groups who may experience problems in swallowing conventional oral dosage forms are the patients with tremors of extremities, mentally ill, developmentally disabled, non-cooperative and patients with reduced liquid intake or patients suffering from nausea, as well as patients travelling or who do not have easy access to water. The swallowing problems are also common in some cases such as patients with motion sickness, sudden episodes of allergic attack or coughing and due to lack of water.

To overcome these problem, scientists have developed innovative drug delivery system known as "fast dissolving tablets", are the novel solid oral dosage form which disintegrates and dissolves rapidly in saliva without need for drinking water. This tablet disintegrates instantaneously or disperses in saliva[5]. These tablets usually dissolve within 15 s to 2 min. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach and produce rapid onset of action. In such cases bioavailability of drug is significantly greater than those observed from conventional tablet dosage forms[1,6].

The advantages of rapidly disintegrating tablets are increasingly being recognized in both industry and academia. Their growing importance was underlined recently when European Pharmacopoeia[7] adopted the term "orodispersible tablet" as a tablet to be placed in the mouth where it disperses rapidly before swallowing.

Desired Criteria for Mouth Dissolving Tablets (MDTS):

Mouth dissolving tablet should address the following:

- Requires no water for oral administration, but it should dissolve or disintegrate in the mouth in matter of seconds.
- Be compatible with taste masking agent.
- Be portable without fragibility concern.
- Have a pleasing mouth feel.
- Leave minimal or no residue in the mouth after oral administration.
- Exhibit low sensitivity to environmental conditions as humidity and temperature.
- Allow high drug loading.
- Allow the manufacturing of tablets using conventional processing and packaging equipments at low cost.

Salient Features of Mouth Dissolving Tablets:

- Ease of administration to patient who refuses to swallow a tablet, such as pediatric, geriatric and psychiatric patients.
- No need of water to swallow the dosage form, which is highly convenient feature for patients who are travelling and do not have immediate access to water.
- Rapid dissolution and absorption of drug, which will produce quick onset of action.
- Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach, in such cases bioavailability of drug is increased.
- Pregastric absorption can result in improved bioavailability and as a result of reduced dosage; improve clinical performance through a reduction of unwanted effects.

Direct compression is the easiest method to manufacture fast dissolving tablets (FDTs) and fast melting tablets (FMTs). The great advantage of direct compression is

its low manufacturing cost. It uses conventional equipment, commonly available excipients and a limited number of processing steps.

Direct compression is the method of choice in tablet manufacture to produce high quality finished product and applied to prepare dispersible tablets[8].

In many cases the disintegrants used have a major role in the disintegration and dissolution process of fast dissolving tablets made by direct compression method.

The choice of a suitable type and an optimal amount of disintegrant is important for ensuring a high disintegration rate. The addition of other formulation components such as water-soluble excipient or effervescent agents can further enhance dissolution or disintegration properties.

The understanding of disintegrants properties and their effect on formulation has advanced significantly during last few years, particularly regarding so called super disintegrants.

In direct compression method[9], previously only crystalline compounds or materials were considered to be directly compressed, but now a days the scenario is changing and this technique is being applied for many non- crystalline materials too. The approach mainly employs importation or modification of certain physical properties of the material under consideration, such as cohesiveness, compactness and flow properties. Formulations constituted by ≤25% w/w of drug material are easy to be directly compressed by simply using such diluents, which are easy to be compressed and which act as a carrier for the drug. In any rational drug design or evaluation of dosage forms for drugs, the stability of the active component must be a major criterion in determining their acceptance or rejection. Stability of a drug can be defined as the time from the date of manufacture and the packaging of the formulation, until its chemical or biological activity is not less than a predetermined level of labeled potency and its physical characteristics have not changed appreciably or deleteriously.

The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity and light, enabling recommended storage conditions, re-test periods and shelf-lives. The International Conference on Harmonization (ICH) Guidelines

titled “Stability Testing of New Drug substance and Products” (QIA) describes the stability test requirements for drug registration applications in the European Union, Japan and the United States of America.

ICH specifies the length of study and storage conditions.

Long-term Testing: $25^0C \pm 2^0C$ / 60 % RH ± 5 % for 12 Months.

Accelerated Testing: $40^0C \pm 2^0C$ / 75 % RH ± 5 % for 6 Months.

Stability studies were carried out at 25^0C / 60 % RH and 40°C/75% RH for the selected formulation for the period of 3 months.

Method: [11]

The selected formulation was packed in flip top polypropylene container with desiccant integrated inside the wall of the container; polypropylene spiral spring designs inside the lid with tamper evident seal. They were then stored at 25^0C / 60 % RH and 40°C and 75% RH for 3 months and evaluated for their physical appearance, drug content and *in vitro* dispersion time at specified intervals of time.

Formulation of Mouth Dissolving Tablets of Dietary Supplements: [12]

Mouth dissolving tablets of Dietary Supplements were prepared by direct compression according to the formulae given in the table 2.

All the ingredients except magnesium stearate were passed through # 60 mesh sieve separately and Magnesium Stearate was passed through # 80 sieve. All the ingredients were mixed properly in order to get uniform mixture and kept aside.

The tablets were compressed using hydraulic press. Compression force of the machine was adjusted to obtain the hardness in the range of 40-60 Newtons for all batches. The weight of the tablets was kept constant for all formulations F_0 to F_7 (400 mg).

Processing Environment:

The manufacturing of effervescent tablets requires careful control of environmental factors. It is essential to maintain Relative humidity (RH) throughout the plant of no more than 20%. In

addition, a uniform temperature of 21°C also was desirable.

A maximum of 25% RH at a controlled room temperature of 25°C or less is usually sufficient to avoid problems caused by atmospheric moisture.

Sources of Acid materials:

Citric acid

Tartaric acid

Fumaric acid

Malic acid

Adipic acid

Sources of Carbon dioxide:

Sodium bicarbonate

Sodium carbonate

Potassium carbonate

Potassium bicarbonate

Calcium carbonate

Sodium glycine carbonate

Table no.1: composition of different batches of mouth dissolving tablets of dietary supplements

Ingredients(mg/tab)	**Formulation Code**							
	F_0	**F_1**	**F_2**	**F_3**	**F_4**	**F_5**	**F_6**	**F7**
Zinc Gluconate USP	76	76	76	76	76	76	76	76
Ascorbic acid	78	78	78	78	78	78	78	78
Tartaric acid	20	30	30	30	40	40	40	25
Sodium bicarbonate	40	40	60	70	70	80	40	50
Mannitol DC	170	158	90	84.5	79.5	74.5	100.5	110.5
Maltodextrin	-	-	35	30	25	20	44	39
Sucralose	5	7	10	10	10	10	10	10
Strawberry Flavor	7	7	7	7	7	7	7	7
Colloidal Silicon dioxide	-	-	-	0.5	0.5	0.5	0.5	0.5
Magnesium Stearate	4	4	4	4	4	4	4	4
Total Weight	**400**	**400**	**400**	**400**	**400**	**400**	**400**	**400**

Evaluation of Mouth Dissolving Tablets:-

Evaluation was performed to assess the physicochemical properties and release characteristics of the developed formulations.

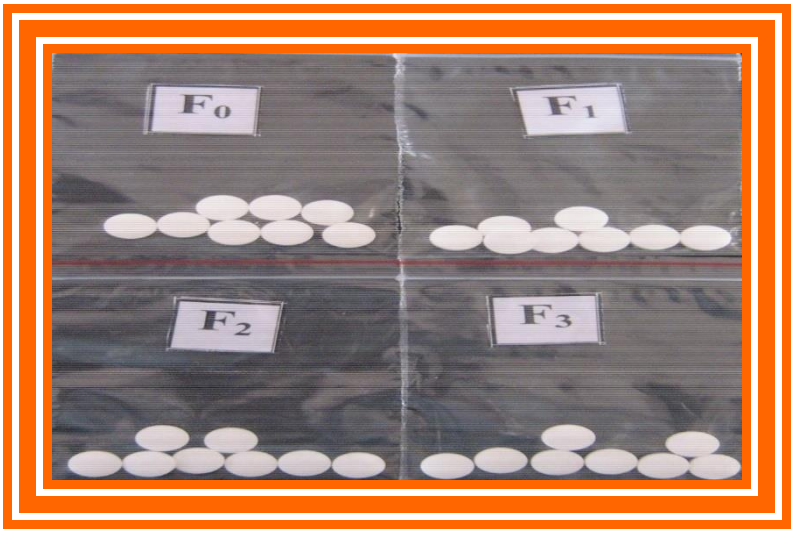
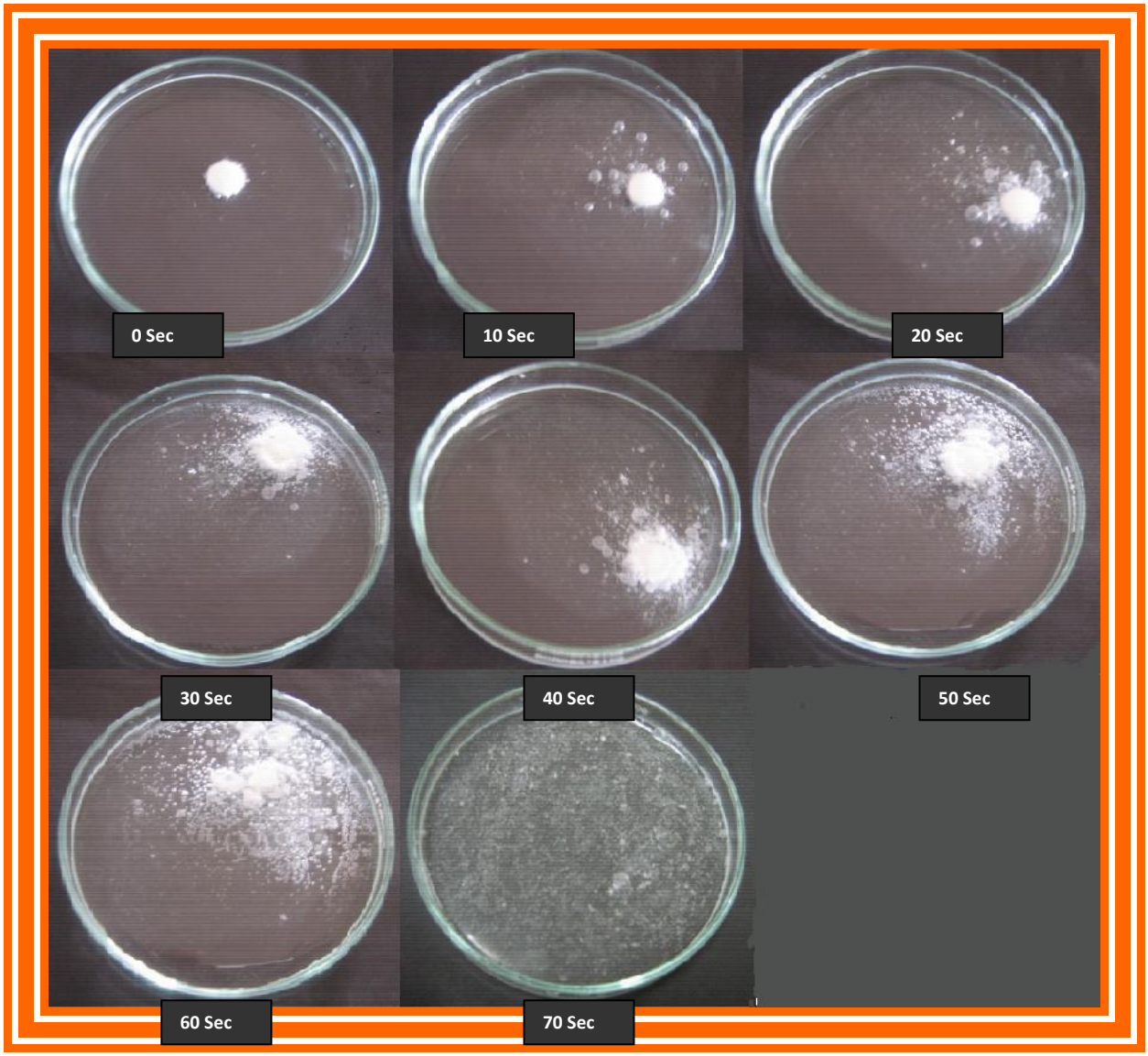


Fig. 1: Picture depicting the formulations F_0-F_4

Fig. 2: Picture depicting the formulations F_4-F_7



II) COMPATIBILITY STUDY:

Compatibility studies were performed using FT-IR spectrophotometer. The IR spectrum of pure drug and physical mixture of drug and polymer were studied by making a KBr disc. The characteristic absorption peaks of montelukast sodium were obtained at different wave numbers in different samples.

The peaks obtained in the spectra of each formulation correlates with the peaks of drug spectrum. This indicates that the drug is compatible with the formulation components. The spectra for all formulations are shown below.

The spectral details for all types of formulations are shown as follows:

A. Table 2: Pure drug Zinc Gluconate.

IR Spectrum	S.No	(KBr Disc) peaks at	Indications
	1.	3291 cm^{-1}	OH Stretching
	2.	1589 cm^{-1}	C=C stretching
	3.	1369 cm^{-1}	C=C stretching
	4.	1037 cm^{-1}	C-O stretching

B. Pure drug Ascorbic acid.

IR Spectrum	S.No	(KBr Disc) peaks at	Indications
	1.	3527, 3409 cm^{-1}	OH Stretching
	2.	3027 cm^{-1}	C-H str of Furan group
	3.	1675 cm^{-1}	C=O stretching
	4.	1321 cm^{-1}	C=C stretching
	5.	1027 cm^{-1}	C-O stretching

C. Mixture of Zinc Gluconate + Ascorbic acid.

IR Spectrum	S.No	(KBr Disc) peaks at	Indications
	1.	3527 cm^{-1}	OH Stretching
	2.	2050cm^{-1}	C-H str of methyl group
	3.	1752 cm^{-1}	C=O stretching
	4.	1027 cm^{-1}	C-O stretching

D. Mixture of Zinc Gluconate + Ascorbic acid + Excipients.

IR Spectrum	S.No	(KBr Disc) peaks at	Indications
	1.	3284 cm^{-1}	OH Stretching
	2.	2938 cm^{-1}	C-H str of methyl group
	3.	1388 cm^{-1}	C=C stretching
	4.	1020 cm^{-1}	C-O stretching

Table no. 3: Pre-pression parameters of all formulations

Formulations	Bulk density* (g/cc)	Tapped density* (g/cc)	Angle of repose* (θ)	Compressibility Index (%)	Hausner's ratio
F_0	0.8698	0.9454	$25^0.84'$	7.996	1.086
F_1	0.528	0.586	$26^0.15'$	9.890	1.109
F_2	0.8052	0.892	$26^0.82'$	9.730	1.107
F_3	0.6419	0.7241	$25^0.14'$	11.35	1.128
F_4	0.4832	0.5371	$27^0.35'$	10.03	1.111
F_5	0.5198	0.5803	$25^0.96'$	10.42	1.116
F_6	0.6392	0.7015	$27^0.63'$	8.880	1.097
F_7	0.4926	0.5428	$28^0.05'$	9.248	1.101

*mean±SD, n=3

Table No. 4: Physical Properties of Tablets of All Formulations

Formulations	Diameter* (mm)	Thickness*(mm)	Weight variation* (mg)	Hardness* (Newton)	Friability (%)
F_1	10.98±0.052	3.59±0.007	398.2±3.58	46.0±1.2	0.526
F_2	11.02±0.049	3.59±0.013	401.0±4.37	50.2±1.5	0.492
F_3	10.96±0.053	3.57±0.042	398.8±4.13	48.6±1.1	0.391
F_4	10.98±0.043	3.55±0.048	400.6±3.83	45.4±1.2	0.428
F_5	11.00±0.026	3.57±0.021	399.1±4.06	45.2±1.3	0.502
F_6	11.00±0.023	3.60±0.004	397.8±4.22	46.5±1.0	0.465
F_7	10.97±0.024	3.58±0.008	398.0±4.05	48.3±1.3	0.621

mean±SD, n=3

Table No. 5: Post Compression Parameters of Tablets of All Formulations

Formulations	*In vitro* dispersion time* (in sec)	Drug content* (%)	
		Zinc Gluconate	Vitamin C
F0	134 – 139	99.97	100.08
F1	112 – 117	99.98	100.05
F2	89 – 95	100.02	100.12
F3	73 – 78	100.01	100
F4	64 – 67	99.98	100.14
F5	52 - 58	100.01	100.15
F6	108 -114	99.96	100.1
F7	90 - 96	99.99	100.22

*mean±SD, n=3

Table no. 6: moisture uptake studies at 25°c & 75% rh

Sl.No	Initial Wt (gm)	2nd Hour	4th Hour	6th Hour	8th Hour	12th Hour	24th Hour	32nd Hour	48th Hour
Petriplate-1	21.2863	21.291	21.3031	21.3388	21.3815	21.5062	21.5832	21.7419	21.9602
Petriplate-2	24.2763	24.3015	24.3287	24.5173	24.5418	24.5836	24.6137	24.6425	24.8539
Petriplate-3	17.21	17.2385	17.2481	17.2568	17.2631	17.2792	17.2885	17.2954	17.3172
Petriplate-4	16.024	16.0492	16.0608	16.0794	16.0933	16.1107	16.1318	16.1496	16.1672

Table No. 7: Moisture Uptake Studies at 25°C & 40% RH

Sl.No	Initial Wt (gm)	2nd Hour	4th Hour	6th Hour	8th Hour	12th Hour	24th Hour	32nd Hour	48th Hour
Petriplate-1	12.7523	12.7542	12.7638	12.7692	12.7713	12.7795	12.7814	12.7903	12.8014
Petriplate-2	16.2689	16.2705	16.2748	16.2792	16.2824	16.2873	16.2917	16.2958	16.2983
Petriplate-3	12.8845	12.8931	12.8974	12.9036	12.9104	12.9186	12.9253	12.9289	12.9374
Petriplate-4	16.7659	16.7752	16.783	16.7905	16.7982	16.7852	16.7921	16.8042	16.8175

Table No. 8. Stability Studies at 25°C & 60% RH

Product:	Dietary Supplement	Batch Size:	50 tablets	Stability Condition	25°C±2°C/60%±5%RH
Pack Details:	Flip top Polypropylene container with desiccant integrated inside the wall of the container; polypropylene spiral spring designed inside the lid with tamper evident seal.	Mfg. Location:	Strides Arcolab Ltd, Bangalore	Batch No:	655047

Period ↓ Test →	Description	Identification By Titrimetric Method Must comply	Disintegration Time	Hardness	Loss on Drying	Assay Each Mouth Dissolving Tab Contains	
						Zinc Gluconate (76mg)	Ascorbic Acid (78mg)
Initial	White colored, circular, biconvex tablets, plain on both sides.	Complies	37 – 42 sec	44 – 60 N	2.75%	76.01 mg (100.01%)	78.12 mg (100.15%)
1 Month	White colored, circular, biconvex tablets, plain on both sides.	Complies	38 – 44 sec	47 – 61 N	2.81%	75.99 mg (99.98%)	78.08 mg (100.10%)
2 Month	- DO -	Complies	41 – 46 sec	51 – 64 N	2.86%	75.98 mg (99.97%)	78.08 mg (100.10%)
3 Month	- DO -	Complies	42 – 49 sec	54 – 68 N	2.89%	75.98 mg (99.97%)	78.08 mg (100.10%)

Table.No.11. Stability Studies at 40°C & 75% RH

Product:	Dietary Supplement	**Batch Size:**	50 tablets	**Stability Condition**	40°C±2°C/75%±5%RH
Pack Details:	Flip top Polypropylene container with desiccant integrated inside the wall of the container; polypropylene spiral spring designed inside the lid with tamper evident seal.	**Mfg. Location:**	Strides Arcolab Ltd, Bangalore	**Batch No:**	655047

Period ↓ Test →	**Description**	**Identification By Titrimetric Method Must comply**	**Disintegration Time**	**Hardness**	**Loss on Drying**	**Assay Each Mouth Dissolving Tab Contains**	
						Zinc Gluconate(76mg)	Ascorbic Acid (78mg)
Initial	White colored, circular, biconvex tablets, plain on both sides.	Complies	37 – 42 sec	44 – 60 N	2.75%	76.01 mg **(100.01%)**	78.12 mg **(100.15%)**
1 Month	White colored, circular, biconvex tablets, plain on both sides.	Complies	39 – 44 sec	47 – 63 N	2.83%	75.98 mg **(99.97%)**	78.06 mg **(100.07%)**
2 Month	- DO -	Complies	41 – 48 sec	49 – 65 N	2.89%	75.96 mg **(99.94%)**	78.05 mg **(100.06%)**
3 Month	- DO -	Complies	43 – 51 sec	54 – 69 N	2.91%	75.95 mg **(99.93%)**	78.01 mg **(100.01%)**

Evaluation of Mouth Dissolving Tablet Formulations:

1. Pre-compression Parameters:

a) Bulk Density:- The values obtained for bulk density for all (F_0-F_7) formulations are tabulated in Table 3. The values were found to be in range of 0.4832 to 0.8698 gm/cm^3.

b) Tapped Density:- The values obtained for bulk density for all (F_0-F_7) formulations are tabulated in Table 3. Tapped density ranges from 0.5371 to 0.9454 gm/cm^3.

c) Angle of Repose (θ): - The values were found to be in the range from 25^0 - 28^0, tabulated in Table 3. This indicates good flow property of the powder blend.

d) Compressibility Index: - Compressibility index value ranges between 7.99% - 11.35%, tabulated in Table 3, indicating that the powder blends have the required flow property for direct compression.

e) Hausner's Ratio:- The values were found to be in the range from 1.086 – 1.128, tabulated in Table 3.

2. Post-compression Parameters:

a) Shape of the tablet: - Microscopic examination of tablets from each formulation batch showed circular shape with no cracks.

b) Tablet dimensions: - The dimensions determined for formulated tablets are tabulated in Table 4.

Tablets mean thicknesses were almost uniform in all the formulations and were found to be in the range of 3.55 mm to 3.60 mm. The diameter of the tablet ranges between 10.96 mm to 11.60 mm.

c) Hardness test: - The measured hardness of tablets of each batch ranged between 40 to 60 Newtons and was tabulated in Table 4. Tablet hardness was increased as increasing the compression force. This ensures good handling characteristics of all batches.

d) Friability Test: - The values of friability test are tabulated in Table 4. The % friability was less than 1% in all the formulations ensuring that the tablets were mechanically stable.

e) Weight Variation Test: - The percentage weight variation for all formulations was shown in Table 4. All the tablets passed weight variation test as the % weight variation was within the pharmacopoeial limits. The weights of all the tablets were found to be uniform with low standard deviation values.

f) Drug Content Uniformity: - The percentage of drug content was found to be between 95.54 and 100.5 of montelukast sodium, which was within acceptable limits. Table 5 showed the results of drug content uniformity in each batch.

g) In vitro Dispersion Time: - The most important parameter that needs to be optimized in the development of fast dispersible tablets is the dispersion time in tablets. In the present study, all the tablets dispersion in ≤ 1.2 min fulfilling the official requirement (<3 min) for dispersible tablets.

The *in vitro* dispersion times for all formulations are shown in Table 5. The tablets prepared by using Sodium bicarbonate and Tartaric acid as effervescent mixture, all the formulations have different dispersion time. With F0 formulation the dispersion time is more (134 – 137 sec) as it contains Sodium bicarbonate and Tartaric acid in lesser concentration. F5 had

showed least dispersion time 52 – 58 sec as it contains higher concentration of Sodium bicarbonate and Tartaric acid.

The dispersion time of all formulations depends on the concentration of effervescent mixture, dispersion time decreases as the concentration of effervescent mixture increases.

l) Stability Studies: - The selected formulations was evaluated for stability studies which was stored at 25°C & 60% RH and 40^0C & 75% RH tested for 3 month and were analyzed for their physical parameters, *In vitro* dispersion time and drug content at 1 month interval. The residual drug contents of formulations were found to be within the permissible limits and the results were shown in the Table which was estimated by seeing drug content uniformity.

SUMMARY AND CONCLUSION

In the present work, mouth dissolving tablets of Dietary Supplements (Zinc Gluconate and Ascorbic acid) were prepared by direct compression method using effervescent disintegrants such as sodium bicarbonate and Tartaric acid. Zinc Gluconate and Ascorbic acid is soluble in water but its bioavailability is limited and hence this method is useful for improving its bioavailability of the drug. The dispersibility of tablets was increased by increasing the concentration of effervescent disintegrants like sodium bicarbonate and tartaric acid, use of Maltodextrin and mannitol improves binding property cooling effect of the tablets respectively.

Colloidal silicon dioxide (Aerosil) prevents capping problem of the tablets, the use of Sucralose is helpful for diabetic patients as it is sugar free and contains zero calories.

From the findings obtained, it can be concluded that:-

- The flow properties of excipients and drug were good.
- FT-IR studies revealed that there is no chemical interaction between Dietary Supplements and the excipients used in the study.
- The tablets prepared were found to be good without any chipping, capping and sticking.
- Formulated tablets gives satisfactorily result for various physico-chemical evaluations of tablets like tablet dimension, hardness, friability, weight variation, *in vitro* dispersion time, water absorption ratio and drug content.

➢ The low values of standard deviation for average weight and drug content of the prepared tablets indicate weight and drug content uniformity within the batches prepared.

➢ Based on *in vitro* dispersion time, formulation F_4 and F_5 were found to be promising and displayed a dispersion time of approximately 52-67 s.

➢ Short-term stability studies of promising formulation indicated that there is no significant change in drug content and *in vitro* dispersion time.

➢ From the present study, it may be concluded that the mouth dissolving tablets of Dietary Supplements can be prepared by direct compression method using effervescent mixtures (sodium bicarbonate & tartaric acid).

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