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Formulations and evaluation of multivitamin chewable Tablets

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ABSTRACT:

In the present study examining the melting points of ascorbic acid, folic acid, nicotinamide, and riboflavin, the study verified their purity. Whereas folic acid was soluble in alkali, ascorbic acid was soluble in water. While riboflavin was very weakly soluble in ethanol, nicotinamide was soluble in ethanol, water, and glycerine. The UV-Spectroscopy study verified that ascorbic acid's maximum wave length is 292 nm. There was little variance in the weight, hardness, thickness, and friability of chewable multivitamin tablets. Crosspovidone-containing formulations performed better in terms of dissolving. Using a variety of excipients, the study created and assessed chewable multivitamin pills containing riboflavin, nicotinamide, folic acid, and ascorbic acid. The most promising batch, F7, which contained 6 mg of crosspovidone, had strong mechanical strength, high drug content, superior dissolving, and great disintegration. The product is appropriate for fast-acting chewable formulations because the addition of superdisintegrants increased the drug release rate and disintegration time. This method can be applied to additional water-soluble vitamins or medicinal substances.

Keywords: Chewable tablets, Multivitamins, Direct compression, Disintegration, etc.

Introduction

Depending on the needs of the formulation, direct compression or wet granulation methods are usually used in the manufacturing of chewable tablets. Direct compression is frequently chosen because of its affordability and simple, but throughout production, issues like taste masking and preserving tablet hardness without sacrificing chewability must be resolved. It's crucial to strike a balance between mouthfeel and mechanical strength; tablets should be soft enough to chew easily but robust enough to survive packaging and transit.

To sum up, chewable tablets are a significant and developing area of oral medication delivery systems. They are becoming a more appealing choice for enhancing patient care because of their patient-friendly design and developments in pharmaceutical formulation. Therapeutic results and medication adherence. It is anticipated that chewable dose forms will play an even bigger part in contemporary medicine as study into the science underlying them advances, benefiting both patients and medical professionals.

When it comes to the creation and marketing of chewable tablets, stability and storage are major issues. Chewable tablets are frequently more hygroscopic than regular tablets due to their texture and composition, which means they have a tendency to absorb moisture from the surroundings. Physical and chemical instability, such as softening, cracking, microbial development, or degradation of the active substance, may result from this moisture absorption. For example, tablets may become sticky or lose their structural integrity when exposed to excessive humidity, which makes packaging and administration challenging.

Materials and Methods

Preformulation Studies

A preformulation study is a crucial stage in drug development, evaluating a drug's physicochemical properties before formulating it into a dosage form. It provides insights into the drug's intrinsic characteristics, aiding in designing a safe, effective, and stable formulation. Preformulation studies establish a solid foundation for subsequent formulation development, identifying potential challenges and risks, and enabling rational decision-making.

The **melting point** of Ascorbic acid, Folic acid, Nicotinamide, and riboflavin was determined using a capillary method, where a fine powder was filled and a thermometer was used. The **solubility** of Ascorbic acid, Folic acid, Nicotinamide, and riboflavin was assessed in various solvents, using excess drugs in different solvent-containing beakers. The study focuses on the preparation of Ascorbic acid, a key component in the pharmaceutical industry, and its compatibility with various excipients. **UV Spectroscopy** was used to scan the UV spectrum in the 200-400nm range. The study was conducted using I**.R. Spectroscopy**, and the spectra of the drug and other ingredients were compared with the pure drug.

Multivitamin chewable tablets were prepared using direct compression technique, using aspartame as sweetener, mannitol as filler, crosspovidone as disintegrant, and talc and magnesium striate as glident and lubricant. The standard calibration curve was obtained by preparing a **stock solution** of

Ascorbic acid and dilution. Drug-excipient compatibility studies are crucial for evaluating potential interactions between the drug substance and excipients, identifying any chemical, physical, or mechanical interactions that could affect the final dosage form's stability, efficacy, or safety.

Table 01: Formulation of Multivitamin Chewable Tablets

Ingredients (mg)	FN1	FN2	FN3	FN4	FN5	FN6	FN7	FN8
Ascorbic Acid	60	60	60	60	60	60	**60**	60
Folic Acid	1	1	1	1	1	1	**1**	1
Riboflavin	2	2	2	2	2	2	**2**	2
Nicotinamide	20	20	20	20	20	20	**20**	20
Crosspovidone	-	-	-	-	2	4	**6**	8
Aspartame	4	4	4	4	4	4	**4**	4
Talc	1	1	1	1	1	1	**1**	1
Mg. stearate	2	2	2	2	2	2	**2**	2
Mannitol	30	40	50	60	60	60	**60**	60
Avicel PH 102	80	70	60	50	48	46	**44**	42
Total Weight	200	200	200	200	200	200	**200**	200

Evaluation of Chewable Tablets

The evaluation of prepared tablets by evaluating the weight variation test, hardness, thickness, friability, In vitro disintegration time, content uniformity, in vitro dissolution study and stability study were evaluated and result mentioned in further.

Result and discussion

Determined melting point as reported Ascorbic acid Reported Melting Point Observed Melting Point 190 – 192oC 2 Folic acid 250 - 252 °C 190°C 251°C 3 Nicotinamide 128–131 °C 130-131°C 4 Riboflavin 280–290 °C 284-286°C.

Solubility of Ascorbic Acid, Folic Acid, Nicotinamide, and Riboflavin are all soluble in water, ethanol, glycerine, and chloroform, respectively, while varying in ether and soluble in alcohol and acetone.

The Shimadzu **UV spectrophotometer** was used to analyze a solution containing 10 ug/ml of Ascorbic acid, revealing a maximum wave length of 292 nm.

The stock solution of Ascorbic acid was prepared and analyzed at 292 nm. The absorbance curve showed a straight line, increasing with concentration, following the Beer-Lamberts Law.

Precompression study

Table 2: Micromeritics Properties 0f Powder Blend (F1 to F8)

Batch	Angle of Repose (θ)	Bulk Density (g/cc)	Tapped Density (g/cc)	Compressibility Index (%)	Hausner's Ratio
FN1	26.82	0.167	0.181	7.73	1.08
FN1	26.30	0.160	0.173	7.51	1.08
FN1	27.14	0.167	0.182	8.42	1.09
FN1	28.48	0.169	0.200	15.50	1.18
FN1	26.32	0.159	0.182	12.64	1.14
FN1	27.28	0.180	0.201	10.45	1.12

FN1	25.46	0.171	0.203	15.76	1.10
FN1	26.67	0.178	0.198	10.10	1.11

Table 3: Post Compression Parameters of Chewable Multivitamin Tablets Containing Ascorbic acid (F1 to F8)

Batch	Weight Variation (mg)	Thickness (mm)	Hardness (Kg/Cm^2)	Friability (%)	Drug Content Uniformity (%)	Disintegration Time (min)
F1	204±1.02	3.12±0.05	6.5±0.60	0.68±1.1	97.74±1.1	139±3.53
F2	203±0.76	2.98±0.07	6.2±0.55	0.65±0.9	97.82±1.2	124±2.10
F3	205±0.67	3.11±0.07	5.5±1.30	0.64±0.12	99.30±1.1	118±2.62
F4	206±0.55	3.18±1.8	6.5±0.80	0.71±0.18	98.04±1.1	104±3.42
F5	204±0.71	2.96±1.2	5.8±0.58	0.67±0.27	97.24±1.3	92±3.25
F6	205±0.48	3.12±1.2	6.4±0.85	0.80±0.16	98.26±0.4	81±2.12
F7	201±0.39	3.10±1.3	6.5±1.26	0.60±0.31	99.84±1.2	58±2.46
F8	202±0.82	3.08±1.4	6.5±1.16	0.67±0.24	98.40±0.9	56±1.50

(SD ± Mean of n=3)

Table 4: Invitro Dissolution Profile of Chewable Tablets of Ascorbic acid (F1 to F8)

Time	Cumulative percentage Drug Release							
	F1	F2	F3	F4	F5	F6	F7	F8
0	0	0	0	0	0	0	0	0
5	30.38 ±1.14	34.62 ±1.15	37.16 ±0.67	41.07 ±0.66	48.42 ±1.39	60.32 ±0.78	84.32 ±1.78	78.49 ±0.78
10	42.46 ±0.66	47.25 ±0.77	53.45 ±1.56	54.87 ±1.12	60.28 ±1.50	72.54 ±1.34	91.54 ±1.56	88.4 ±1.40
15	55.04 ±0.67	58.41 ±1.20	61.23 ±1.33	66.42 ±2.34	74.34 ±1.30	80.12 ±1.27	97.1 ±1.66	93.05 ±2.04
20	61.78 ±1.40	66.67 ±1.35	73.67 ±1.25	70.35 ±1.67	83.64 ±0.83	88.13 ±2.15	98.93 ±1.45	97.24 ±1.10
25	70.45 ±1.21	75.12 ±1.16	80.17 ±2.18	80.76 ±1.66	90.3 ±1.22	95.37 ±0.98	99.51 ±0.90	97.76 ±1.44
30	78.18 ±2.18	84.84 ±1.55	86.39 ±1.29	89.38 ±1.45	96.61 ±1.67	97.74 ±2.05	99.86 ±2.31	98.65 ±1,25

(Values are ±SD, n=3)

Stability Study:

The Multivitamin chewable tablet formulation F7, with its low disintegration time and higher drug release, was selected for stability studies. After 3 months of storage, no significant differences were observed in hardness, drug content, disintegration time, and in vitro drug release.

Conclusion

The study analyzed the melting points of Ascorbic acid, Folic acid, Nicotinamide, and riboflavin, confirming their purity. The results showed that Ascorbic Acid was very soluble in water, slightly soluble in ethanol, and insoluble in ether. Folic Acid was soluble in dilute alkali, insoluble in alcohol, acetone, chloroform, and alcohol. Nicotinamide was freely soluble in water, ethanol, and glycerine, while Riboflavin was slightly soluble in ethanol and practically insoluble in chloroform, ether, and water. The UV-Spectroscopy study determined the maximum wave length of ascorbic acid at 292 nm, which matches the reported wave length. The FTIR compatibility study revealed that the major peak in the drug and polymer mixture's infrared spectra remained unchanged, indicating no physical interaction due to bond formation between the two substances. The pre-compression parameter study showed that all formulations demonstrated desirable micromeritics characteristics, including low compressibility indices, low Hausner's ratios, and favorable angles of repose. The evaluation parameters of Chewable Multivitamin Tablets showed minimal weight variation, tablet hardness, tablet thickness, and friability values. Formulations containing Crosspovidone showed superior performance in terms of rapid disintegration without compromising tablet strength, making them ideal candidates for chewable multivitamin delivery systems. In-Vitro dissolution studies showed that Formulation F1 to F4 released 78.18% to 89.38% of ascorbic acid at the end of 30 minutes, with F7 being the most efficient formulation in terms of immediate release performance. The stability study concluded that Multivitamin chewable tablets formulation F7 was found to be stable at the end of 3 months.

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