

FORMULATION AND EVALUATION OF CHEWABLE TABLETS OF METFORMIN HYDROCHLORIDE

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ABSTRACT

The present study was undertaken to formulate and evaluate a patient-friendly chewable immediate-release tablet of metformin hydrochloride for improved compliance and rapid onset of action. Metformin hydrochloride, a first-line oral anti hyperglycemic agent, is widely prescribed for the management of type 2 diabetes mellitus, but its conventional dosage form often presents swallowing difficulty and poor patient acceptability, especially in pediatric and geriatric populations. The objective of the present work was to develop chewable tablets (immediate-release) with acceptable pre-compression and post-compression properties and to optimize the formulation using suitable disintegrants and excipients. Different formulations were prepared by varying the proportions of starch and sodium starch glycolate. The prepared blends were evaluated for pre-compression parameters such as angle of repose, bulk density, tapped density, Carr's index, and Hausner ratio. The compressed tablets were further evaluated for weight variation, hardness, friability, disintegration time, drug content, and in vitro dissolution profile. Stability studies were also conducted under accelerated and room temperature conditions. Among all formulations, **F9** exhibited the most satisfactory results and showed a drug release profile closely matching the reference product. The optimized formulation contained metformin hydrochloride (500 mg), starch (90 mg), sodium starch glycolate (6.25 mg), talc, methyl paraben, propyl paraben, and gelatin. The formulation demonstrated acceptable flow properties, rapid disintegration, satisfactory mechanical strength, and favorable dissolution behavior. The study concluded that chewable immediate-release tablets of metformin hydrochloride can be successfully developed to enhance convenience, compliance, and therapeutic performance.

KEYWORDS: Metformin hydrochloride, chewable tablets (immediate-release), sodium starch glycolate, starch, dissolution, tablet evaluation etc.

1. INTRODUCTION

Diabetes mellitus is one of the most prevalent chronic metabolic disorders worldwide and is characterized by

persistent hyperglycemia resulting from defects in insulin secretion, insulin action, or both. Among the various forms of diabetes, **type 2 diabetes mellitus**

(T2DM) accounts for the majority of cases and poses a major public health burden due to its associated micro vascular and macro vascular complications. Oral anti hyperglycemic agents remain the cornerstone of T2DM management, and **metformin hydrochloride** is regarded as the first-line drug because of its efficacy, safety, and favorable metabolic profile.

Metformin hydrochloride belongs to the biguanide class of anti-diabetic agents. It exerts its therapeutic effect primarily by decreasing hepatic glucose production, improving peripheral glucose uptake, and enhancing insulin sensitivity without causing significant hypoglycemia. Despite its widespread clinical use, metformin is generally administered in conventional tablet form, which may be inconvenient for patients who have difficulty swallowing, such as children, elderly individuals, and patients with dysphagia.

Chewable tablets (immediate-release) offer a practical alternative to conventional solid oral dosage forms. They are designed to be chewed before swallowing and are particularly advantageous in terms of ease of administration, patient acceptability, and compliance. Such dosage forms can also promote faster disintegration and dissolution, thereby improving the onset of drug action. The development of a chewable immediate-release formulation of metformin hydrochloride is therefore of considerable pharmaceutical and therapeutic interest.

This study was designed to formulate and evaluate chewable immediate-release tablets of metformin hydrochloride using suitable excipients and disintegrants to improve the drug's acceptability and release behavior.

Therapeutic Use of Metformin: Metformin is the first-line treatment for type 2 diabetes worldwide, especially beneficial for overweight patients. The UKPDS (United Kingdom Prospective Diabetes Study) demonstrated its long-term benefits in intensive blood glucose control, reduction in cardiovascular risks, and improvements in lipid profiles. Besides glycemic control, chewable tablet (immediate-release) metformin also contributes to lowering total cholesterol, LDL cholesterol, and triglyceride levels, which are important parameters in diabetic management.

Pharmacokinetics and Pharmacodynamics^[1,2,6]: After oral administration, chewable tablet (immediate-release) metformin is absorbed primarily from the small intestine, with peak plasma levels reached within 1 to 3 hours. It exhibits negligible plasma protein binding and a large volume of distribution. Metformin is excreted unchanged in the urine, with renal clearance being a major elimination pathway. Its half-life in plasma is approximately 6.2 hours. The extended-release formulations have a slower absorption with peak levels occurring between 4 to 8 hours, but chewable tablet

(immediate-release) forms are preferred where rapid onset is desired.^[1]

chewable tablet (immediate-release) **Drug Delivery System**^[4,13]: chewable tablet (immediate-release) drug delivery system are solid dosages forms intended to be chewed prior to swallowing, release active ingredients rapidly, combining tablet stability with ease of administration for patients facing swallowing challenges.

Importance of chewable tablet (immediate-release)

Formulations: chewable tablet (immediate-release) tablets are designed to disintegrate quickly in mouth after oral administration, allowing for rapid drug release and absorption. This is particularly important for drugs like metformin where timely control of blood glucose levels is crucial. chewable tablet(immediate-release) forms promote rapid onset of action, which is beneficial in managing postprandial blood sugar spikes. Chewable release tablets are advantageous especially for patients with swallowing difficulties and improve patient compliance.

Formulation Considerations for Chewable Tablets

(immediate-release): Chewable tablets (immediate-release) offer an alternative for patients who have difficulty swallowing conventional tablets. The formulation of metformin as a chewable tablet (immediate-release) requires consideration of taste masking due to the drug's natural bitterness, stability of the formulation, excipient compatibility, and rapid disintegration and dissolution profiles to ensure prompt therapeutic effect. The direct compression method is often employed to formulate chewable tablets (immediate-release), optimizing factors such as tablet hardness, friability, and dissolution rate.^[2]

Need for chewable tablet (immediate-release)

Metformin Tablets: The increasing prevalence of diabetes, along with patient compliance issues related to swallowing difficulties, creates a demand for patient-friendly dosage forms like chewable tablets (immediate-release). Chewable tablet (immediate-release) ensures that patients receive an accurate dose rapidly absorbed, which is critical for timely blood sugar management. These dosage forms can improve medication adherence and potentially enhance therapeutic outcomes.

2. MATERIALS AND METHODS

Materials: The materials used in the present study included:

- **Metformin hydrochloride**
- **Starch**
- **Sodium starch glycolate**
- **Talc**
- **Gelatin**
- **Methyl paraben**
- **Propyl paraben**
- **Sweeting agent** : Sucralose, sorbitol, Aspartame etc

- Purified water and other analytical grade reagents

Method of Preparation: Chewable tablet (immediate-release) of metformin hydrochloride was prepared by a conventional tablet formulation approach. Different batches were designed by varying the concentration of starch and sodium starch glycolate as are follows.

- **F1–F3:** starch used without sodium starch glycolate
- **F4–F6:** sodium starch glycolate used without starch
- **F7–F9:** both starch and sodium starch glycolate used in combination

The ingredients were accurately weighed, blended uniformly, and compressed using a **double rotary compression machine** as stated in the dissertation.^[3]

A) Pre-Formulation Studies

Pre formulation studies were carried out to assess the physicochemical suitability of the drug and excipients for chewable tablet (immediate-release) development.

Organoleptic Properties: The drug was observed for appearance, color, odor, and taste.

Melting Point: The melting point was determined to assess purity and identity. The thesis also notes melting point as a key physicochemical characterization parameter for dosage form design.

Solubility and Chemical Nature: Solubility and chemical nature were assessed to understand the suitability of the drug for immediate-release tablet development and to support excipient selection.^[4]

Hygroscopicity: Hygroscopicity studies were performed to assess the tendency of the drug or blend to absorb moisture, which can influence stability and tablet quality.

Loss on Drying: Loss on drying was determined to estimate moisture content and volatile loss in the material.

Particle Size Analysis: Particle size was determined by **sieving method**, as described in the uploaded thesis.

B) Evaluation of Powder Blend (Pre-compression Parameters)

Angle of Repose: Angle of repose was measured to evaluate the flow properties of the powder blend. It is a critical parameter for understanding powder handling and die filling during compression.

Bulk Density: Bulk density was measured to assess powder packing behavior.

Tapped Density: Tapped density was determined by mechanically tapping a graduated cylinder containing the powder.

Carr's Compressibility Index: Carr's index was calculated to determine flow ability and compressibility.

Hausner Ratio: Hausner ratio was used to further evaluate powder flow characteristics.

Interpretation: The dissertation reports that the pre-compression parameters indicated that all formulations exhibited **acceptable flow properties**.^[5]

C) Evaluation of Tablets (Post-compression Parameters)

Appearance: All tablets were visually examined for color, surface smoothness, and uniformity.

Weight Variation: Twenty tablets from each batch were weighed individually and compared with the average weight.

Hardness: Tablet hardness was measured using a hardness tester to ensure sufficient mechanical strength.

Friability: Friability was evaluated using a friabilator to determine the tablet's resistance to abrasion.

Thickness: Tablet thickness was measured using a vernier caliper.

Disintegration Time: Disintegration is measured by without Chewings. Disintegration time was evaluated to assess the rapid break-up behavior expected from chewable tablets (immediate-release).^[6]

Drug Content Uniformity: Drug content was determined spectrophotometrically to ensure uniform distribution of metformin hydrochloride in each formulation.

In Vitro Dissolution Study: Dissolution studies were carried out to compare the release behavior of the different formulations and identify the optimized batch.

The uploaded thesis indicates that **disintegration and dissolution** were key post-compression evaluation parameters used to compare the formulations and determine the best-performing batch.^[7]

D) Stability Studies

Stability studies were conducted according to **ICH guidelines** to determine the ability of the optimized formulation to maintain its quality, strength, and performance over time. The thesis notes that stability testing is essential for ensuring quality, safety, and efficacy of the dosage form.

The optimized tablets were stored under the following conditions:

- **40°C ± 2°C / 75% RH ± 5% RH**
- **25°C ± 2°C / 60% RH ± 5% RH**

Samples were evaluated periodically for changes in physical appearance and performance parameters.^[8]

compression into tablets. The observed values of angle of repose, bulk density, and tapped density suggested that the powder mixtures possessed satisfactory flow and compressibility, which are essential for uniform die filling and tablet weight consistency.^[9]

3. RESULTS AND DISCUSSION

A) Pre-compression Evaluation

All powder blends showed acceptable flow characteristics, indicating their suitability for

1. Description

RAW MATERIAL	COLOUR	ODOUR	TASTE
Metformin	White	Odorless	Tasteless

2. SOLUBILITY

RAW MATERIAL	SOLUBILITY
Metformin	It is freely soluble in water and 95% alcohol and is practically insoluble in acetone, ether and chloroform. It also freely soluble as HCL salt.

3. pH

Raw Material	Solution concentration	pH
Metformin	1% aqueous solution of HCL	6.68

4. MELTING POINT

RAW MATERIAL	OBSERVED VALUE
Metformin	222 ⁰ C TO 226 ⁰ C

5. CHEMICAL NATURE

S NO.	PARAMETER	METFORMIN
1	Molecular formula	C ₄ H ₁₁ N ₅ .HCl
2	Molecular weight	165.63
3	IUPAC name	1,1- Dimethyl biguanide hydrochloride
4	Chemical nature	Equimolar amount of dimethylamine and 2- cyanoguanidine are dissolved in toluene with cooling to make a concentrated solution, and an equimolar amount of hydrogen chloride is slowly added. The mixture begins to boil on its own, and after cooling, Metformin hydrochloride precipitates with a 96% yield. ¹⁰

6. LOSS ON DRYING

RAW MATERIAL	OBSERVED LOD
Metformin	Not more than 0.5% determined on 1.0g by drying in an oven at 105 ⁰

7. SIEVE ANALYSIS

RAW MATERIAL	NATURE OF SAMPLE
Metformin	100% pass through the 20#mesh

8. FLOW PROPERTY MEASUREMENT

RAW MATERIAL (API)	ANGLE OF REPOSE (DEGREES)	FLOW PROPERTIES
Metformin	33.69	Good

9. DENSITY

RAW MATERIAL (API)	BULK DENSITY(BD) (g/ml)
Metformin	0.714

TAPPED DENSITY

RAW MATERIAL (API)	TAPPED DENSITY (PI) (g/ml)
Metformin	0.909

COMPRESSIBILITY INDEX

RAW MATERIAL (API)	COMPRESSIBILITY INDEX (%)	FLOW PROPERTY
Metformin	21.45	Passable

HAUSNER RATIO

DRUG	% Drug release		
	Initial	30 days	45 days
Metformin	99.88	99.88	99.87

DRUG CONTENT

RAW MATERIAL (API)	ASSAY (%)
Metformin	It contains not less than 98.5% and not more than 101.0% of C ₄ H ₁₁ N ₅ .HCl

Precompression Parameters Of Metformin Tablets**Table no. 1: Pre compression parameter of Metformin granules trials.**

Formulations	Bulk Density (gm/cm ²)	Tapped Density (gm/cm ²)	C.I (%)	Angle of repose (°)	H.R	Moisture content
F1	0.72	0.90	20.0	35 ⁰ .41 ⁺	1.25	0.0213
F2	0.702	0.93	23.22	37 ⁰ .95 ⁺	1.32	0.0235
F3	0.714	0.95	24.84	42 ⁰ .23 ⁺	1.2	0.026
F4	0.710	0.83	14.45	45 ⁰ .72 ⁺	1.16	0.0231
F5	0.68	0.79	13.92	38 ⁰ .95 ⁺	1.16	0.0245
F6	0.57	0.67	14.92	43 ⁰ .55 ⁺	1.17	0.022
F7	0.59	0.68	13.23	31 ⁰ .63 ⁺	0.09	0.219
F8	0.710	0.82	13.41	32 ⁰ .23 ⁺	1.15	0.274
F9	0.8	0.912	12.28	33 ⁰ .69 ⁺	1.14	0.274

❖ **Inference:** Formulation F1 to F3 has shown in the significant flow property angle of repose and Hausner's ratio because of the absence of sodium starch glycolate and inclusion of starch. And in case of F4-F6 has indicating the high angle of repose due to the poor flow property in the absence of starch. F7-f9 shown good flow as indicating the less angle of repose because of increase in concentration of lubricant Sodium starch glycolate and starch also.^[11]

The tablets were found to be uniform in appearance and weight, with acceptable hardness and low friability, indicating sufficient mechanical Integrity during handling and packaging. The disintegration behavior of the tablets was strongly influenced by the concentration and combination of disintegrants used. Formulations containing only starch or only sodium starch glycolate showed moderate performance, whereas formulations containing both excipients demonstrated improved disintegration and dissolution behavior.^[12]

B) Post-compression Evaluation

The prepared chewable tablets (immediate-release) exhibited satisfactory post-compression characteristics.

Post Compression Parameter Of Metformin Tablets❖ **Table No. 2: Post compression parameter of Metformin tablets.**

Formulations	Weight variations (mg)	Hardness (kg/cm ²)	Thickness (mm)	Disintegration Time(min)	Friability (%)
F1	630-684	8	3.64	7	0.05
F2	625-691	7	3.93	9	0.06
F3	609-674	8	4.82	8	0.07
F4	622-688	5	4.56	9	0.08

F5	623-689	9	3.52	8	0.06
F6	610-674	12	3.29	7	0.07
F7	612-676	14	4.86	7	0.05
F8	626-691	9	3.46	8	0.07
F9	621-687	8	4.56	8	0.06
Innovator (Glucophage)	550-600	11	3	9	0.04

Table No. 3: Comparative release of Metformin from innovator and F7.

Time(min)	% Release of innovator	% Release from F7
0	0	0
5	68.05	65.45
10	79.45	75.43
15	85.87	87.54
30	96.57	90.42
45	99.89	93.09

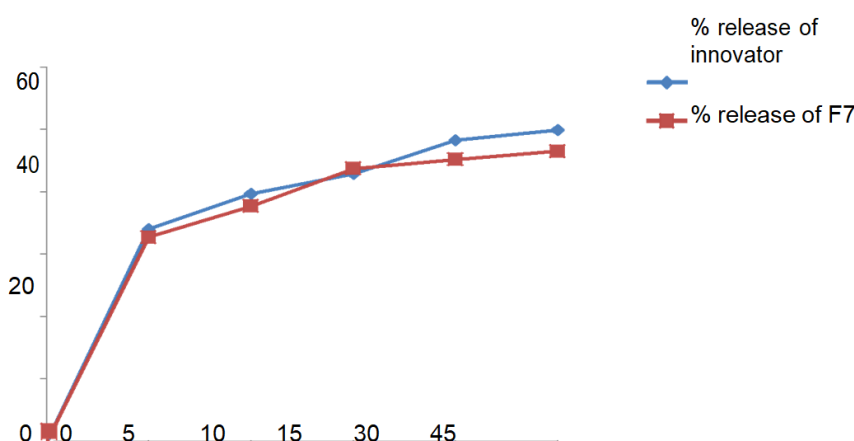


Figure No. 1 Release profile of Metformin in F9 compared with innovator.

Inference: The release profile of Metformin from F7 was compared to innovator and the release rate was less than the innovator at the end of 45 minutes.^[13]

Stability Datas For Optimized Formulations At 25^oc & 60%Rh For Metformin Immediate Release Tablet

❖ **Table No: 4: Stability data for optimized formulations at 25^oC & 60% RH for Metformin immediate release tablet IP.**

S.NO	PARAMETERS	STORAGE CONDITIONS (25 ^o C& 60% RH)		
		INITIAL	30 DAYS	45 DAYS
1	Description	Weight colored, round shaped	N. D	N. D
2	Weight variation	645-655	Within limits	Within limits
3	Hardness	5	5.2	5
4	Thickness	4.9	4.9	4.9
5	Friability	0.32	0.34	0.33
6	Disintegration time	8	8	9
7	Drug release	99.88	99.88	99.87
8	Drug content	650	650	649
9	Moisture content	0.0216	0.0219	0.0321

C) Optimized Formulation

According to the uploaded thesis, the **F9 formulation** was identified as the **optimized batch** because its dissolution Profile most closely matched the innovator product and it demonstrated better overall immediate-release characteristics than the other formulations.

❖ The optimized **F9 formulation** consisted of:

- **Metformin hydrochloride – 500 mg**
- **Starch – 90 mg**
- **Sodium starch glycolate – 20.25 mg**
- **Talc – 25.18 mg**

- Methyl paraben – 1.16 mg
- Propyl paraben – 0.66 mg
- Gelatin – 2 mg

The improved performance of F9 may be attributed to the synergistic effect of starch and sodium starch glycolate,

This enhanced water uptake, swelling, and tablet disintegration, thereby promoting faster drug release.^[14]

Stability Data for Optimized Formulations at 40°C & 75% Rh for Metformin Immediate Release Tablet

Table No. 5: Stability data for optimized formulations at 40°C & 75% RH for Metformin immediate release tablet IP.

S.NO	PARAMETERS	STORAGE CONDITIONS (40° C& 75% RH)		
		INITIAL	30 DAYS	45 DAYS
1	Description	weight colored, round shaped	N. D	N. D
2	Weight variation	645-655	Within limits	Within Limits
3	Hardness	5.3	5.2	5.2
4	Thickness	4.56	4.5	4.5
5	Friability	0.32	0.33	0.33
6	Disintegration time	9	8	8
7	Drug release	99.83	99.83%	99.8%
8	Drug content	650.39	650.05	649.95
9	Moisture content	0.0216	0.0219	0.0231

❖ **Table No 6: Drug release of Metformin at 25°C & 60% RH.**

DRUG	% Drug release		
	Initial	30 days	45 days
Metformin	99.88	99.88	99.87

❖ **STABILITY STUDIES**

• **Table No: release of Metformin at 40°C & 75% RH.**

DRUG	% Drug release		
	Initial	30 days	45 days
Metformin	99.83	99.83	99.8

• **Stability Studies**

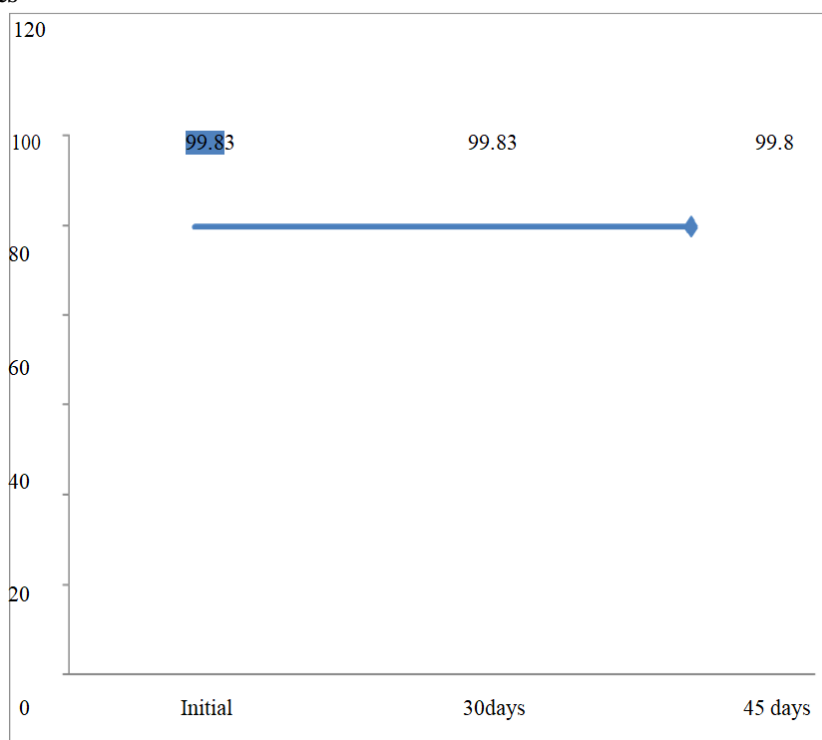


Figure No. 1: Drug release of Metformin at 40°C & 75% RH.

❖ **Inference:** The drug release was not significantly reduced at the end of 30 days and 45 days storage at 40⁰c & 75%RH indicating stability of the formulation. All parameters are within the specified limits at the end of the storage.^[15]

with no significant changes in its critical quality attributes. These findings support the pharmaceutical stability and practical suitability of the developed formulation.^[16]

D) Stability Study

The optimized formulation remained stable under both accelerated and room temperature storage conditions

COMPATIBILITY STUDIES

❖ **Table no 7: Compatibility study of Metformin with excipients.**

DRUG	EXCIPIENTS	1 st DAY	1 st WEEK	2 nd WEEK	3 rd week
		40 ⁰ C&75% RH	40 ⁰ C&75% RH	40 ⁰ C&75% RH	40 ⁰ C&75% RH
M	STARCH	ND	ND	ND	ND
M	GELATIN	ND	ND	ND	ND
M	METHYL PARABEN	ND	ND	ND	ND
M	PROPYL PARABEN	ND	ND	ND	ND
M	SFP	ND	ND	ND	ND
M	TALC	ND	ND	ND	ND
M	SODIUM STARCH GLYCOLATE	ND	ND	ND	ND

Where,
M=Metformin
RH=Relative humidity
ND=Change not detectable

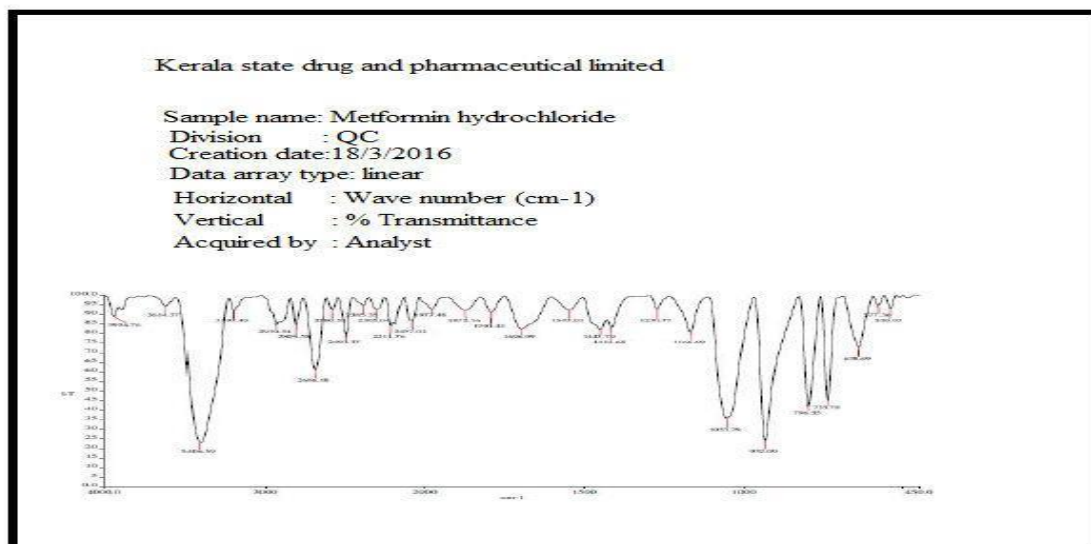


Figure No. 02: FTIR Spectra Of Pure Metformin Tablet.

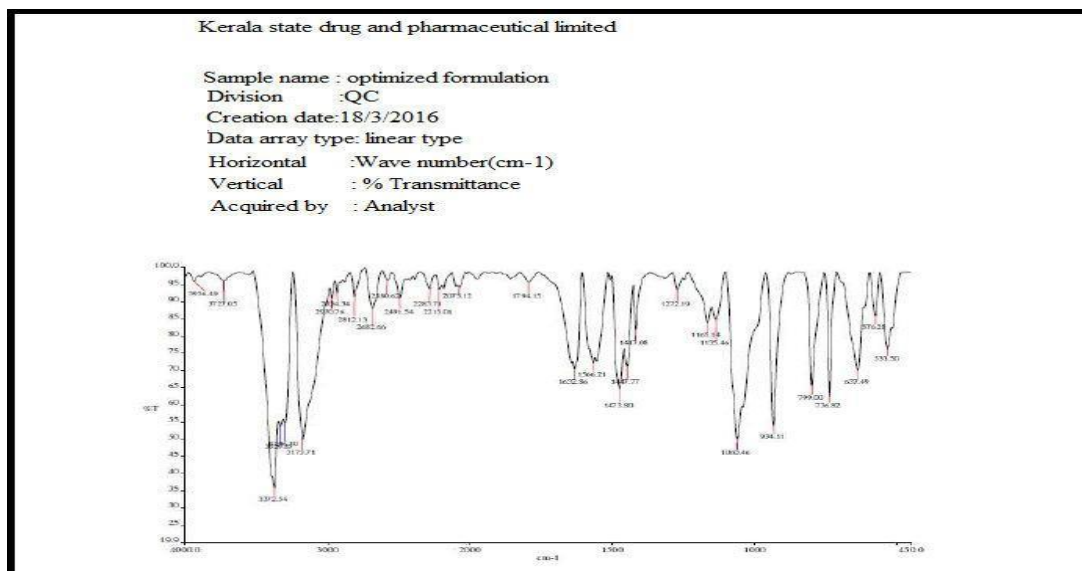


Figure no. 03: FTIR spectrum of optimized formulation.

CONCLUSION

The Present study successfully demonstrated the formulation and evaluation of chewable immediate-release tablets of metformin hydrochloride. The developed tablets showed acceptable physicochemical characteristics, satisfactory mechanical strength, rapid disintegration, and favorable dissolution behavior. Among the different formulations prepared, **F9** was found to be the most optimized and exhibited the best overall performance. The combination of **starch** and **sodium starch glycolate** proved particularly effective in enhancing the release characteristics of metformin hydrochloride.

Thus, the study concludes that chewable immediate-release tablets of metformin hydrochloride represent a promising alternative to conventional oral tablets and may significantly improve patient compliance, especially among pediatric, geriatric, and dysphagic patients.

The present study was aimed at developing, evaluating and optimization of the oral hypoglycemic drug Metformin. Totally 9 formulations are prepared by using different ratios of Metformin, Starch, Gelatin, Talc, Methyl paraben sodium, Propyl paraben sodium and Sodium starch glycolate. Each 9 formulations contain the twenty tablets. The granules are prepared separately in a Max mixer.

Pre compression parameters like Bulk density, True density, Angle of repose indicate all the formulations are showing flow properties. The tablets are compressed by double rotary compression machine and tablets are evaluated for post compression parameters like weight variation, Hardness, Friability, Disintegration and Dissolution parameters.

Formulations F1-F3 sodium starch glycolate is not used, in that formulations starch is used in definite proportions. F4-F6 sodium starch glycolate is used and the starch is

not use in these formulations. Sodium starch glycolate and starch used in case of F7-F9. These formulations can be compared to innovator. In the formulation of F9 is more matched to the innovator (Metformin) according to the drug release profile. A good result is getting by using both sodium starch glycolate and starch. The F9 formulation contains Metformin- 500mg, starch-90mg, Sodium Starch Glycolate-20.25mg, Talc-25.18mg, Methyl Paraben-1.16, Propyl Paraben-0.66mg, Gelatin-2mg.

The compressed tablets are subjected to stability studies at 40°C and 75%RH, 25°C and 60%RH. Samples were analyzed at regular intervals as mentioned in stability protocol. From the study, it may be concluded that formulation F9 (it contains both sodium starch glycolate and starch in suitable proportions) can be prepared as immediate release formulation compared to conventional formulation.

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