

## Formulation and Evaluation of Ascorbic Acid Medicated Lollipops for Improved Oral Drug Delivery

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### ABSTRACT:

The present study focuses on the formulation and evaluation of medicated lollipops containing ascorbic acid as an innovative oral drug delivery system. Conventional oral dosage forms often face challenges related to patient compliance, especially in pediatric and geriatric populations. Medicated lollipops offer a palatable, patient-friendly alternative that allows prolonged residence time in the oral cavity, enhancing local as well as systemic therapeutic effects. Ascorbic acid lollipops were prepared using the heating and congealing method with different polymers—agar, hydroxypropyl methylcellulose (HPMC), and carboxymethyl cellulose (CMC)—to study their influence on physicochemical properties and drug release behavior. The formulated lollipops were evaluated for physical appearance, thickness, weight variation, hardness, friability, drug content, moisture content, disintegration time, and in-vitro drug release. Compatibility of the drug with excipients was confirmed using UV and IR spectroscopic analysis. All formulations showed acceptable organoleptic and mechanical properties, with friability below 1% and drug content ranging from 98.45% to 99.63%. In-vitro release studies demonstrated that polymer-free formulation exhibited rapid drug release, while polymer-containing formulations showed controlled release behavior. Among all formulations, the CMC-based lollipop (F4) exhibited optimal hardness, minimal friability, highest drug content, and sustained yet complete drug release. The study concludes that medicated lollipops of ascorbic acid are a safe, effective, and innovative dosage form with improved patient compliance and potential benefits in managing vitamin C deficiency, sore throat, and minor oral infections.

**Keywords:** Ascorbic acid, Medicated lollipop, Oral drug delivery, Controlled release, Pediatric dosage form, Vitamin C, Polymer-based formulation.

### I. INTRODUCTION

In oral drug delivery, there are voluminous scientific tasks that could be studied for years to originate and innovation technologies are required to engender novel dosage forms raising drug delivery to higher level. This object examines quite a few in oral drug delivery necessitating implementation of novel ideas to improve oral drug delivery systems. Drug delivery is an escalating field that represents one of the foremost research and development concentration areas of pharmaceutical industry today, with new drug delivery system sales exceeding 10 billion dollars per year.

Lollipops are solid dosage forms, containing medicament in a sweetened & flavored base, intended to dissolve slowly in the mouth. Lollipops are mainly contained sweetening agent, flavoring agent, coloring agent, opacifiers & stabilizing agent. Lollipops are the flavored medicated dosage forms intended to be sucked and held in the mouth or pharynx containing one or more medicaments usually in the sweetened base. Lollipops are intended to relieve oropharyngeal symptoms, which are commonly caused by local infections and also for systemic effect provided the drug is well absorbed through the buccal linings or when it is swallowed.



Fig: 1 Marketed Lollipop

## II. DRUG PROFILE

Ascorbic acid (vitamin C) is used to prevent or treat low levels of vitamin C in people who do not get enough of the vitamin from their diets. Most people who eat a normal diet do not need extra ascorbic acid. Low levels of vitamin C can result in a condition called scurvy. Vitamin C is a water-soluble vitamin found in various foods and sold as a dietary supplement. It is used to prevent and treat scurvy. Vitamin C is an essential nutrient involved in the repair of tissue, the formation of collagen, and the enzymatic production of certain neurotransmitters.

- **Formula:**  $C_6H_8O_6$
- **Molarmass:**  $176.124 \text{ g}\cdot\text{mol}^{-1}$
- **Density:**  $1.694 \text{ g}/\text{cm}^3$
- **Meltingpoint:**  $190^\circ \text{ to } 192^\circ \text{ C}$  ( $374 \text{ to } 378^\circ \text{ F}$ )
- **Boilingpoint:**  $552.7^\circ \text{ C}$  ( $1,026.9^\circ \text{ F}$ )
- **Proteinbinding:** Negligible
- **Tradenames:** Ascor, Cevalin, others
- **Eliminationhalf-life:** Varies according to plasma concentration
- **Bioavailability:** Rapid and complete
- **Excretion:** Kidney

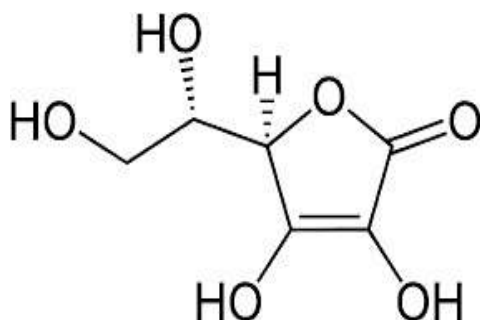


Fig: 2 Structure Of Ascorbic Acid

### 2.1 Pharmacodynamics:

Vitamin C – specifically, in the form of ascorbate– performs numerous physiological functions in the human body by serving as an enzyme substrate and/or cofactor and an electron donor. These functions include the synthesis of collagen, carnitine, and neurotransmitters; the synthesis and catabolism of tyrosine; and the metabolism of microsome. During biosynthesis, ascorbate acts as a reducing agent, donating electrons and preventing oxidation to keep iron and copper atoms in their reduced states.

### 2.2 Pharmacokinetics:

**Absorption:** From the U.S. National Institutes of Health: [In humans] "Approximately 70%–90% of vitamin C is absorbed at moderate intakes of 30–180 mg/day. However, at doses above 1,000 mg/day, absorption falls to less than 50%." It is transported through the intestine via both glucose-sensitive and glucose-insensitive mechanisms, so the presence of large quantities of sugar in the intestine can slow absorption. Ascorbic acid is absorbed in the body by both active transport and simple diffusion. Sodium-Dependent Active Transport—Sodium-Ascorbate Co-Transporters (SVCTs) and Hexose transporters (GLUTs)—are the two transporter proteins required for active absorption. SVCT1 and SVCT2 import the reduced form of ascorbate across plasma membranes. GLUT1 and GLUT3 are glucose transporters, and transfer only the dehydroascorbic acid (DHA) form of vitamin C. Although dehydroascorbic acid is absorbed in higher rate than ascorbate, the amount of dehydroascorbic acid found in plasma and tissues under normal conditions is low, as cells rapidly reduce dehydroascorbic acid to ascorbate.

**Transport:** SVCTs appear to be the predominant system for vitamin C transport in the body, the notable exception being red blood cells, which lose SVCT proteins during maturation. In both vitamin C synthesizers (example: rat) and non-synthesizers (example: human) cells with few exceptions maintain ascorbic acid concentrations much higher than the approximately 50 micromoles/liter ( $\mu\text{mol}/\text{L}$ ) found in plasma. For example, the ascorbic acid content of pituitary and adrenal glands can exceed  $2,000 \mu\text{mol}/\text{L}$ , and muscle is at  $200\text{--}300 \mu\text{mol}/\text{L}$ . The known coenzymatic functions of ascorbic acid do not require such high concentrations, so there may be other, as yet unknown functions. Consequences of all this organ

content is that plasma vitamin C is not a good indicator of whole-body status, and people may vary in the amount of time needed to show symptoms of deficiency when consuming a diet very low in vitamin C.

**Excretion:** Excretion can be as ascorbic acid, via urine. In humans, during times of low dietary intake, vitamin C is reabsorbed by the kidneys rather than excreted. Only when plasma concentrations are 1.4 mg/dL or higher does re-

absorption decline and the excess amounts pass freely into the urine. This salvage process delays onset of deficiency. Ascorbic acid also converts (reversibly) to dehydroascorbate (DHA) and from that compound non-reversibly to 2,3-diketogluconate and thenoxalate. These three compounds are also excreted via urine. Humans are better than guinea pigs at converting DHA back to ascorbate, and thus take much longer to become vitamin C deficient.

### III. MATERIALS AND METHODS

#### 3.1 Formulation Of Ascorbic Acid Lolli Pop:

S.NO	INGREDIENTS	F1	F2	F3	F4
1	ASCORBIC ACID	1g	1g	1g	1g
2	SUCROSE	6g	6g	6g	6g
3	GLUCOSE	30g	-	-	-
4	CORN SYRUP	-	30g	30g	30g
5	AGAR	-	1g	-	-
6	HPMC	-	-	1g	-
7	CMC	-	-	-	1g
8	CITRIC ACID	10g	10g	10g	10g
9	CALCIUM CARBONATE	0.5g	0.5g	0.5g	0.5g
10	PEPPERMINT OIL	2.5ml	2.5ml	2.5ml	2.5ml
11	COLOUR AGENT	Q.S	Q.S	Q.S	Q.S
12	FLAVOURING AGENT	Q.S	Q.S	Q.S	Q.S
13	WATER	Q.S	Q.S	Q.S	Q.S

Table No: 1 Formulation Table Of Ascorbic Lollipops

**Formulation:** Ascorbic acid Lollipops are prepared by heating and congealing method.

#### 3.2 Heating And Congealing Technique:

1. Syrup base to be prepared by dissolving the required amount of sugar by heating at 110°C for about 90 minutes.

2. Addition of base syrup by rising the temperature to 160°C.
3. Cooling to obtain the plastic mass.
4. Addition of drug, polymer, colour and flavour with mixing.
5. Size roping of the materials in a moving roller after drying.



Preparation Of Corn Syrup



Mould Filling



Ascorbic acid Lollipop

Fig: 3 Preparation Of Lollipop

### 3.3 Evaluation Parameters:

**3.3.1 Physical Parameter:** The general appearance of a lollipop including size, shape, colour, odour, taste having should be observed. It is must to have a good appearance for consumer acceptance. Physical changes may occur during storage, which can be determined  $P^H$  and melting point using pH meter and melting point apparatus

**3.3.2 Thickness:** The thickness and diameter of the formulated lollipops were measured by using Vernier callipers.

**3.3.3 Weight Variation:** The formulated lollipops were tested for weight uniformity. 20 tablets were collectively and individually. From the collective weight, average weight was calculated. Each lollipop weight was then compared with average weight to ascertain whether it is with in permissible limits or not.

$$\% \text{ Weight Variation} = \frac{\text{Average weight} - \text{Individual weight}}{\text{Average weight}} \times 100$$

**3.3.4 Hardness:** The lollipops crushing strength, which is the force required to break the lollipop by compression in the diametric direction was measured in triplicate using Monsanto tablet hardness tester.

**3.3.5 Friability:** The Roche friability test apparatus was used to determine the friability of the lollipops. 5 pre- weighed lollipops were placed in the apparatus, which was subjected to 100 revolutions. Then the lollipops were reweighed.

$$\% \text{ Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

**3.3.6 Drug Content:** Lollipops were weighed and powdered. The quantity of powder equivalent to 100 mg of Ascorbic acid was dissolved in 6.8 pH phosphate buffer diluted to 100ml with 6.8 pH phosphate buffer then the solution was filtered and suitably diluted. The drug content was estimated spectrometrically at 280 nm

**3.3.7 Disintegration Test:** Disintegration study performed by disintegration apparatus. Put one Lollipop into each tube suspend the assembly in the beaker containing pH 6.8 phosphate buffer and operate without the discs 30 min. Remove the assembly from the liquid. The lollipops pass.

**3.3.8 In-Vitro Drug Release:** In vitro release studies were performed using USP Apparatus II (Paddle type). The dissolution test was performed using 900 ml of phosphate buffer (pH 6.8),  $37 \pm 0.5^\circ\text{C}$ , 50 rpm. Samples (5 ml) were collected at predetermined time intervals and replaced with equal volume of fresh medium, and analyzed using UV-Visible spectrophotometer at  $\lambda = 280 \text{ nm}$ .

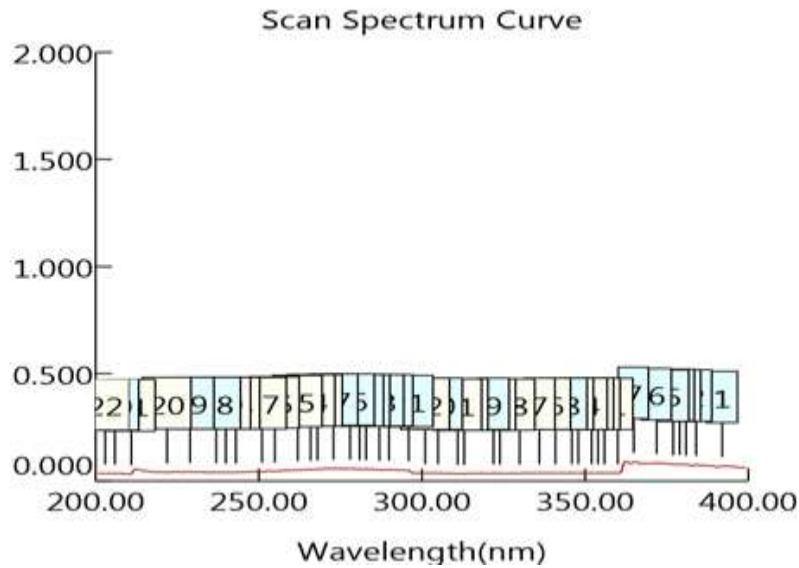
## IV. RESULTS AND DISCUSSION

### 4.1 Physical Evaluation:

S.NO	PARAMETER	F1	F2	F3	F4
1	COLOUR	White	Yellow	Orange	Green
2	ODOUR	Aromatic	Aromatic	Aromatic	Aromatic
3	TASTE	Sweet	Sweet	Sweet	Sweet
4	pH	7.6	7.3	7.5	7.5
5	MELTING POINT	140°C	130°C	130°C	130°C
6	THICKNESS (mm)	5.5	5.6	5.4	5.5
7	WEIGHT VARIATION (gm)	5.98	6.11	6.13	6.12
8	HARDNESS (Kg/Cm <sup>2</sup> )	7kg	8.4kg	8.2kg	8.7kg
9	FRIABILITY %	0.2%	0.1%	0.1%	0.1%
10	DRUG CONTENT %	98.45	99.31	99.15	99.63
11	MOISTURE CONTENT	0.9	0.7	0.8	0.6
12	DISINTEGRATION TEST	15min	16min	16min	18min

Table: 2 Physical Evaluation

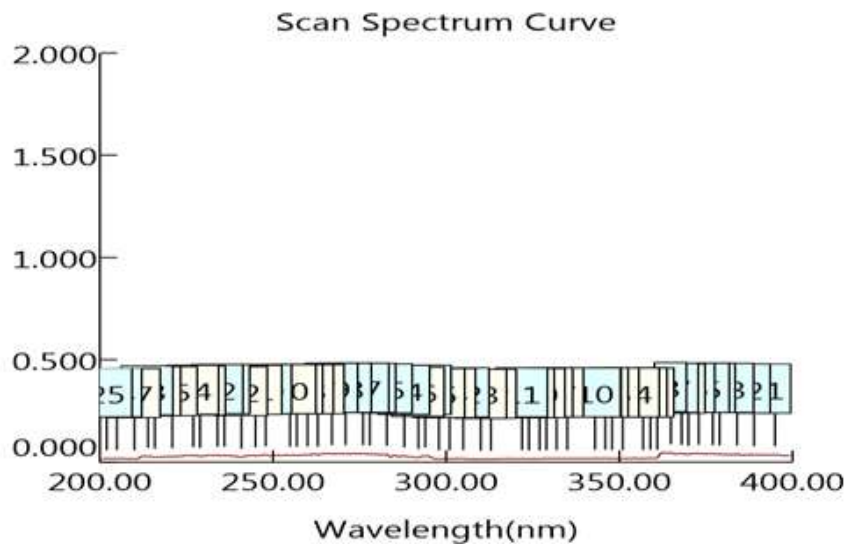
**4.2 UV Analysis Report:**



**Fig: 4 Pure Drug (Ascorbic Acid)**

No.	P/V	Wavelength(nm)	Abs
1	Peak	392.00	0.069
2	Peak	384.00	0.076
3	Peak	381.00	0.076
4	Peak	379.00	0.078
5	Peak	377.00	0.078

**Table: 3Pure Drug (Ascorbic Acid)**



**Fig: 5 Ascorbic Acid Lollipop**

No.	P/V	Wavelength(nm)	Abs
1	Peak	395.00	0.035
2	Peak	389.00	0.036
3	Peak	384.00	0.040
4	Peak	379.00	0.040
5	Peak	377.00	0.041

Table: 4Ascorbic Acid Lollipop

4.3 IR Analysis Report:

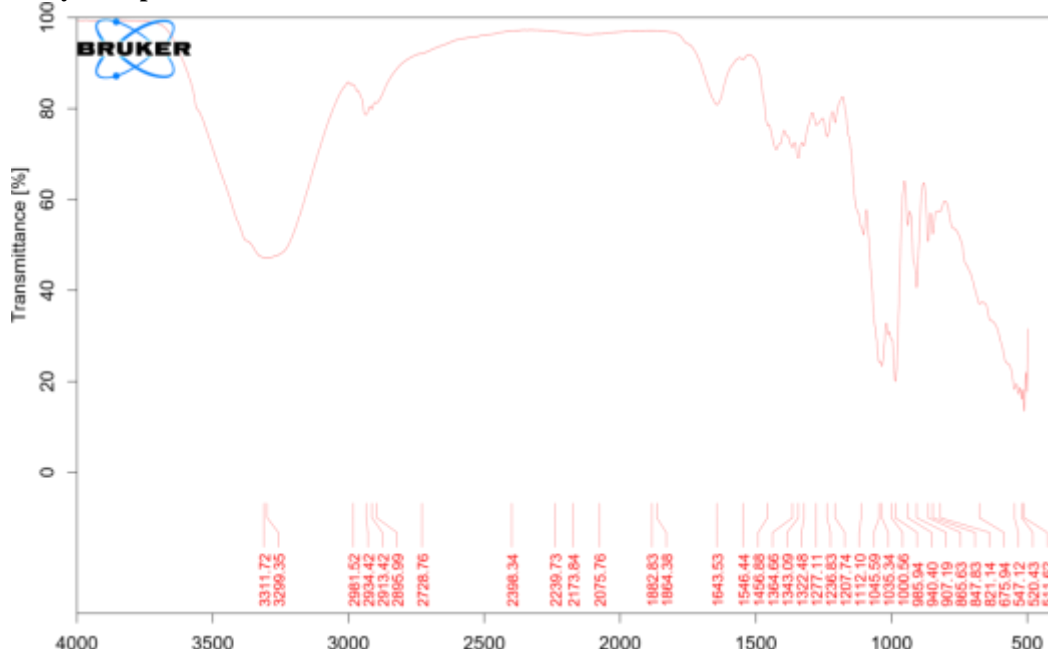


Fig: 6 Ascorbic Acid + Excipients

4.4In-Vitro Drug Release:

S.NO	TIME (min)	FORMULATION PREPARED			
		WITH OUT POLYMER	WITH AGAR	WITH HPMC	WITH CMC
		F1	F2	F3	F4
1	5	11.21	10.12	11.11	11.21
2	10	24.77	21.34	21.32	22.43
3	15	51.77	44.12	43.13	45.32
4	20	85.12	65.21	66.32	70.32
5	25	96.31	81.23	79.31	85.21
6	30	-	96.21	99.32	99.45

Table: 5 Dissolution Test

Discussion:

Physical evaluation of the formulations indicated acceptable organoleptic properties, with all formulations exhibiting an aromatic odor and sweet taste. Variations in color were observed among formulations due to differences in polymer composition. The pH values ranged from 7.3 to 7.6,

indicating suitability for oral administration. Melting point, thickness, and weight variation results were found to be within acceptable limits, suggesting good formulation uniformity.

Hardness values indicated sufficient mechanical strength, while friability values below 1% confirmed adequate resistance to abrasion.

Drug content ranged between 98.45% and 99.63%, demonstrating uniform distribution of ascorbic acid within the lollipops. Moisture content was minimal, reducing the risk of instability. Disintegration time increased slightly with polymer incorporation, indicating a controlled release tendency.

UV spectroscopic analysis of pure ascorbic acid and the formulated lollipops showed characteristic absorption peaks, confirming the presence and stability of the drug in the formulation. IR analysis further supported the compatibility of ascorbic acid with the selected excipients, as no significant shifts or disappearance of characteristic peaks were observed.

In-vitro drug release studies revealed that the formulation without polymer (F1) exhibited faster drug release, achieving nearly complete release within 25 minutes. In contrast, polymer-containing formulations (F2, F3, and F4) showed a more sustained release pattern, with HPMC and CMC-based formulations achieving almost complete drug release at 30 minutes. This indicates the role of polymers in controlling the release rate of ascorbic acid.

## V. CONCLUSION

The medicated lollipop formulated with ascorbic acid was successfully developed as a patient-friendly and palatable dosage form. Ascorbic acid, known for its antioxidant and immune-boosting properties, is effectively delivered through the lollipop, allowing prolonged contact with the oral cavity and throat.

The lollipop dosage form improves patient compliance, especially in pediatric and geriatric populations, due to its ease of administration, pleasant taste, and non-invasive nature. It also avoids first-pass metabolism to some extent and provides gradual drug release during sucking. Overall, the medicated lollipop of ascorbic acid represents a safe, effective, and innovative alternative to conventional oral dosage forms, with potential benefits in both therapeutic efficacy and patient acceptance. The medicated lollipop formulated with ascorbic acid was successfully developed as a patient-friendly and palatable dosage form. This enhances local therapeutic action and may help in relieving sore throat, minor oral infections, and vitamin C deficiency-related conditions.

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enhances local therapeutic action and may help in relieving sore throat, minor oral infections, and vitamin C deficiency-related conditions.

Based on comparative evaluation, formulation F4 containing CMC was found to be the most optimized formulation due to its superior hardness, lowest friability, highest drug content, and controlled yet complete drug release profile. Formulation F3 (HPMC) also demonstrated comparable performance with sustained drug release and good physical stability. Formulation F1, lacking polymer, showed rapid drug release and lower mechanical strength, making it less suitable for controlled delivery. Therefore, incorporation of polymers—particularly CMC—significantly improved the overall quality and performance of ascorbic acid lollipop formulations.

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