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"Formulation and Evaluation Fast-Dissolving Oral Film of Levosalbutamol Sulphate"

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ABSTRACT:
The present study focuses on the formulation and evaluation of a fast-dissolving oral film of **Levosalbutamol sulphate**, intended for rapid onset of action in the treatment of bronchospasm and related respiratory conditions. Hydroxypropyl methylcellulose (HPMC E15) was utilized as the primary film-forming polymer, with **propylene glycol** as a plasticizer, **sodium lauryl sulphate** as a surfactant, **aspartame** as a sweetener, and **citric acid** as a salivary stimulator. A total of nine preliminary batches (G1–G9) were formulated by varying the concentrations of polymer and plasticizer to optimize mechanical properties and drug release profile.
The films were evaluated for **appearance, weight variation, thickness, folding endurance, surface pH, disintegration time, drug content**, and **in-vitro drug release**. Among the formulations, batch **G4** showed optimal characteristics with a disintegration time of **35 seconds**, folding endurance of **173**, surface pH of **6.82**, and drug content of **93.23%**, along with a **90.48% drug release within 300 seconds**. Accelerated stability studies conducted on the optimized batch (G4) over 30 days at **40 ± 2°C / 75 ± 5% RH** confirmed the stability of the formulation in terms of appearance, drug content, and dissolution profile.
Key word: bucalflim ,Levosalbutamol sulphate, in vitro dissolution, stability

I. INTRODUCTION

Asthma is a chronic respiratory condition characterized by airway inflammation and obstruction, often requiring rapid therapeutic intervention. Levosalbutamol sulphate, a selective β2-adrenergic agonist, is commonly used as a bronchodilator to manage asthma symptoms by relaxing the airway muscles and improving airflow. Traditional oral dosage forms, such as tablets and capsules, may not provide the rapid onset of action required in acute asthma attacks and may suffer from poor bioavailability due to first-pass metabolism.

Fast-dissolving drug delivery systems, particularly **Fast-Dissolving Oral Films (FDOFs)**, offer a promising alternative by providing rapid drug disintegration, dissolution, and absorption when placed in the oral cavity. Unlike traditional tablets, which require water for administration, FDOFs dissolve on the tongue within seconds, making them particularly advantageous for pediatric, geriatric, and dysphagic patients who may have difficulty swallowing solid dosage forms. Moreover, in cases where the drug is absorbed through the oral mucosa, the bioavailability can be significantly enhanced, as it bypasses hepatic first-pass metabolism.

Levosalbutamol sulphate has been formulated into various conventional dosage forms, but its incorporation into an FDOF offers the potential for faster onset of action and improved patient compliance. The solvent casting method, commonly used to prepare FDOFs, allows for uniform drug distribution and flexibility in adjusting film thickness and drug concentration. Key formulation components, such as hydrophilic polymers, plasticizers, and sweeteners, play a vital role in determining the mechanical properties, disintegration time, and overall drug release profile of the film.

In this study, the aim was to develop and characterize a fast-dissolving oral film of Levosalbutamol sulphate using **hydrophilic polymer HPMC E15** to ensure rapid dissolution, improved bioavailability, and effective management of asthma symptoms. The formulation was evaluated for critical parameters such as thickness, weight variation, drug content uniformity, disintegration time, mechanical properties, surface pH, and in-vitro drug release. A comparative study was also conducted between the formulated FDOF and a marketed oral tablet to assess the improvement in drug release kinetics.

This research focuses on leveraging the advantages of FDOFs to provide a more effective, patient-friendly, and rapid-acting dosage form for

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asthma management, with the potential to improve therapeutic outcomes for patients.

II. MATERIAL AND METHOD

Levosalbutamol sulphate from Mecloieds pharmaceuticals, Mumbai.HPMC e15, Polypropelene Glycol, Sodium Laury Sulphate, Aspartame, Citric acid, PDP, NaOH.

Infrared absorption spectrophotometry

All the prominent and primary peaks observed in IR spectrum of Levosalbutamol sulphate were in accordance with the reference spectrum of Levosalbutamol sulphate mentioned in Indian Pharmacopoeia (Fig. 1).

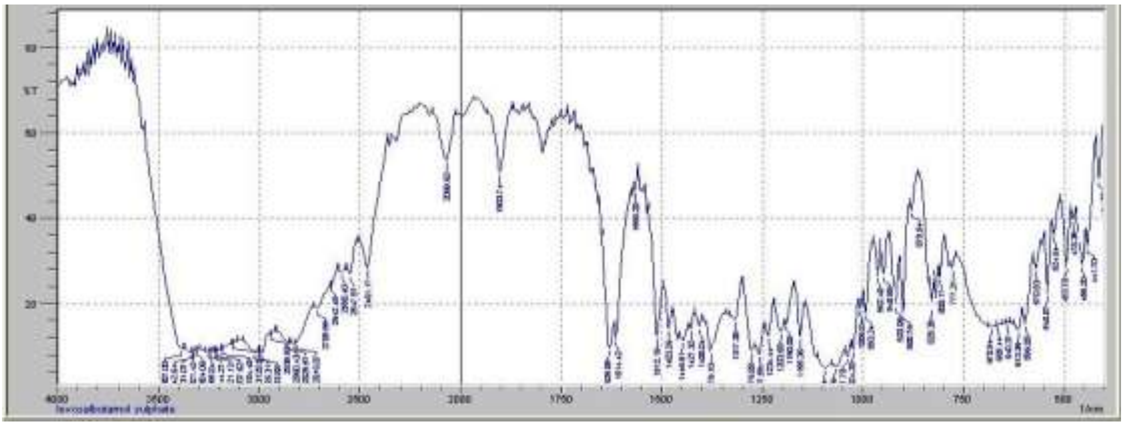

Fig 1: FTIR Spectrum of Levosalbutamol sulphate

Table 1 Details of FT-IR spectrum of Levosalbutamol sulphate

Sr. No.	Assignment	Observed value cm^{-1}	Reported value cm^{-1}
1	C-OH	3620	3640-3610
2	C=C	2099	2260-2210
3	C-C	1586	1600-1585
4	N-H	1629	1650-1580
5	C-H	2860	3000-2850
6	C-O	1317	1320-1000

FORMULATION OF FAST DISSOLVING FILM OF LEVOSALBUTAMOL SULPHATE

HPMC E15 polymer was weighed accurately anddissolved in sufficient water. It was rotated for 30 min on magnetic stirrer for complete solubilization of polymer. Other ingredients like Levosalbutamol sulphate, propylene Glycol, sodium lauryl sulphate and aspartame were dissolved in remaining quantity of water. Levosalbutamol sulphate solution was added drop wise into the polymeric solution on magnetic stirrer untill the drug get completely homogenized and volume made up to10ml with water. About 2.5ml of this solution was poured into a glass petriplate containing bangle and dried at room temperature for 24 h. After drying, the film was removed with the help of sharp blade and kept in desiccator for24 h before cutting into small pieces having area 4 cm^2.

Films with air bubbles, cuts or imperfections were excluded from study, selected films were subjected to different evaluation parameter.

Table No.2:Formulation of preliminary batches of Levosalbutamol sulphatefast dissolving film.

Sr. No.	Ingredients	G1	G2	G3	G4	G5	G6	G7	G8	G9
1.	Levosalbutamol sulphate	16mg	16mg	16mg	**16mg**	16mg	16mg	16mg	16mg	16mg
2.	HPMC E15	700 mg	800 mg	900 mg	**1000 mg**	1100 mg	1200 mg	1300 mg	1400 mg	1500 mg
3.	Propylene glycol	1ml	1ml	1ml	**2ml**	2ml	2ml	3ml	3ml	3 ml
4.	Aspartame	50 mg	50 mg	50 mg	**50 mg**	50 mg	50 mg	50 mg	50 mg	50 mg
5.	Citric acid	2mg	2mg	2mg	**2mg**	2mg	2mg	2mg	2mg	2mg
6.	Sodium lauryl sulphate	q.s.	q.s.	q.s.	**q.s.**	q.s.	q.s.	q.s.	q.s.	q.s.
7.	Water (Up to)	10ml	10ml	10ml	10ml	10ml	10ml	10ml	10ml	10ml

Folding Endurance

Folding endurance was determined by repeated folding of the strip at the same place till the strip breaks. The number of times the film is folded without breaking is computed as the folding endurance value.

Disintegration Time

The film as per the dimensions (2x2cm) required for dose delivery was placed in a glass dish containing 25 ml phosphate bufferpH 6.8 with swirling every 10 sec. Time required for the film to break was noted as in vitro disintegration time.

Table 3 Evaluation of preliminary batches.

Sr. No.	Batch	Film property	Observation	Disintegration time (sec)	Folding endurance
1	G1	Transparent, thin, and slightly hard.	Easily breakable	25	68
2	G2	Transparent, Thin, and Slightly hard	Easily breakable	25	75
3	G3	Transparent, thin and slightly hard.	Easily breakable	28	65
4	G4	Transparent, uniform	Acceptable mechanical strength	30	175
5	G5	Transparent, uniform, thick	Acceptable mechanical strength	34	170
6	G6	Transparent, uniform	Acceptable mechanical strength	40	162

7	G7	Transparent, thick, and hazy, sticky	Difficult to handle	43	201
8	G8	Transparent, thick, and hazy ,sticky	Difficult to handle	48	210
9	G9	Transparent, Thick, and Hazy, sticky	Difficult to handle	52	199

Plasticiser (PG) was added in various volume i.e. 1 ml, 2 ml and 3ml for fast dissolving films of Levosalbutamol sulphate. The result shown in table 3 clearly indicates that a film with 02 ml of PG shows acceptable film formation. As the concentration of plasticizer was increased from 1ml-3ml, stickiness of film was increased, and as the concentration of plasticizer was decreased there were problem in breaking of film. Hence 2 ml PG volume was incorporated in the film formulations. As the quantity of polymer increases the thickness of film also increases, as a result the disintegration time increases respectively.

As per the result obtain in the previous studies the acceptable are result was obtain in polymer quantity 1000mg and plasticizer volume 2ml. further 9 batches were prepared by making some changes in the quantity of plasticizer and polymer as shown in table.

Table no. 4Formulation of fast dissolving films ofLevosalbutamol sulphate

Sr. no	Ingredients	G1	G2	G3	G4	G5	G6	G7	G8	G9
1.	Levosalbutamol sulphate	16mg	16mg	16mg	**16mg**	16mg	16mg	16mg	16mg	16mg
2.	HPMC E15	900 mg	1000 mg	1100 mg	**900 mg**	1000 mg	1100 mg	900 mg	1000 mg	1100 mg
3.	Propylene Glycol	1.9 ml	1.9 ml	1.9.ml	**2ml**	2ml	2.ml	2.1ml	2.1 ml	2.1 ml
4.	Aspartame	50 mg	50 mg	50 mg	**50 mg**	50 mg	50 mg	50 mg	50 mg	50 mg
5.	Citric acid	2mg	2mg	2mg	**2mg**	2mg	2mg	2mg	2mg	2mg
6.	Sodium lauryl Sulphate	q.s	q.s	q.s	**q.s**	q.s	q.s	q.s	q.s	q.s
7.	Water Upto	10ml	10ml	10ml	**10ml**	10ml	10ml	10ml	10ml	10ml

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EVALUATION OF FAST DISSOLVING FILMS [1-6]

The Levosalbutamolsuphate oral films were evaluated for following parameters

Appearance

All prepared films were checked for their appearances whether they were transparent or opaque.

Weight variation

All batches were evaluated for its weight variation. It was evaluated by using analytical balance and average weight was calculated .It is desirable that film should have nearly constant weight and it ensures that a film contains proper amount of excipient and drug.

Thickness

Thickness was evaluated by using Digital Vernier Calliper and thickness was measured from three different spots of film and average was taken.

Folding Endurance

Folding endurance was determined by repeated folding of the strip at the same place till the strip breaks. The number of times the film is folded without breaking is computed as the folding endurance value.

Disintegration Time

The film as per the dimensions (2x2cm) required for dose delivery was placed in a glass dish containing 25 ml phosphate bufferpH 6.8 with swirling every 10 sec. Time required for the film to break was noted as in vitro disintegration time.

Surface pH

The prepared film was placed in a petridish and moistened with 0.5 ml of distilled water and kept for 30 second. The pH was noted after bringing the electrode of the pH meter in contact with the surface of the film and allowing equilibration for 1 min or using pH paper on the surface of film. The average of three determinations for each film was done.

Drug Content

Total drug content per film was estimated by random sampling. Film of 4 cm^2 was cut and placed in 100 ml volumetric flask and diluted to 100ml with buffer pH 6.8. Then 1 ml solution was pipette out and diluted to 10 ml with water So as to get 10 ug/ml of final concentration. The absorbance of the solution was measured at 276 nm. Limit of content uniformity is 85–115 percent.

EVALUATION OF FAST DISSOLVING FILMS

Determination of Weight Variation

The film solutions was cast into sheets and then cut into smaller strips of 4cm² (2 x 2 cm). Oral films were cut from different sheets and weight was taken by using digital weighing balance. The weight of film strip was found to be, 62.57mg to 84.83mg Difference in weight was observed due to increase in concentration of polymer.

Table 5 Evaluation of HPMC E15 films

Evaluation parameter	G1	G2	G3	G4	G5	G6	G7	G8	G9
Weight variation (mg)	66.02 ± 0.52	72.23 ± 1.08	84.83 ± 0.74	**62.57 ± 1.07**	70.86 ± 0.49	84.36 ± 1.32	65.33 ± 1.15	70.41± 1.34	81.48 ± 1.55
Thickness variation (mm)	0.09 ± 0.11	0.12 ± 0.08	0.17 ± 0.02	**0.08 ± 0.14**	0.11 ± 0.12	0.16 ± 0.08	0.08 ± 0.15	0.10 ± 0.12	0.14 ± 0.17
Folding Endurance	161 ± 1.52	163 ± 2.51	164 ± 1.62	**173 ± 1.25**	176 ± 1.54	179 ± 1.27	182 ± 1.84	185 ± 1.97	188 ± 1.84
Surface Ph	6.67	6.88	6.85	**6.82**	6.93	6.98	6.96	6.93	6.89

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Disintegration time (sec)	36 ± 1.02	38 ± 1.03	45 ± 1.05	**35 ± 1.04**	42 ± 1.04	50± 1.05	37 ± 1.07	41 ± 1.05	48 ± 1.12
Drug content (%)	89.74 ± 1.17	91.05 ± 1.24	90.57 ± 1.27	**93.23 ± 1.12**	91.54 ± 1.05	91.06 ± 1.18	92.78 ± 1.15	91.29 ± 1.16	92.50 ± 1.20

***n=3**± S.D

Thickness variation

Thickness of fast dissolving films was measured by using digital Vernier calliper. The thickness of films was found by 0.08 mm to 0.16 mm. Variation in thickness of the films may be due to use of different concentration of polymer in the formulation and the uneven surface of the Petridish.

Folding Endurance

Folding endurance of fast dissolving films was determined manually, by folding the film repeatedly at a point till it cracks.

The result shown in table 5 indicates that folding endurance was found to be 161 to 188.Folding endurance increases with increase in concentration of plasticiser

Determination of Surface pH

The surface pH of the films was determined by using pH meter or pH paper. The results in table 5shows that surface pH of films were found to be 6.67 ± 0.12 – 6.98 ± 0.07 for the formulation G1 to G9. These results helps to conclude that there will be no irritation to the oral mucosa and will not have any compliance problem.

Disintegration Time

The results of disintegration test are shown in table 5which indicates that disintegration time of films was found to be 35sec to 50sec. The increase in the disintegration time may be due to increase in concentration of the polymer.

Determination of Drug Content:

The results shown in table 5 shows that all the films from batch G1to G2, G3, G4, G5, G5, G6, G7, G8 and G9 were found to contain an almost uniform quantity of the drug, as per content uniformity studies. Thus, the preparations met the criteria of USP content uniformity i.e. between 89.74 % - 93.23 %. On this basis, it was found that the drug was dispersed uniformly throughout the film of 4 cm² (2 x 2 cm)

In-vitrodissolution Studies for Levosalbutamol sulphate films

In-vitro drug release was determined by USP Paddle dissolution apparatus-II (Model No. TDT –08L, Electrolab Pvt. Ltd). The release of Levosalbutamol sulphate from fast dissolving film was performed at 37 ± 2^{O}C using a standard dissolution apparatus. The rotation speed was 50 rpm and the volume of the dissolution medium was 900 ml. The pH of the release medium was maintained at 6.8 up to the end of the experiment. Aliquots of 1 ml solution were taken at specific time intervals and volume make upto 10 ml , and the original volume was maintained by adding fresh dissolution medium. The amount of Levosalbutamol sulphate released in the dissolution medium was determined spectrophotometrically at 276 nm using (Shimadzu UV 1800). Results are given as the mean values of three determinations. The cumulative % drug release at different time intervals was calculated using PCP DISSO – V3 software (Poona College of Pharmacy, Pune, India).

Table 6 Cumulative % drug Release of batches G1, G2, G3, G4, G5, G6, G7, G8 and G9

Time (Sec)	G1	G2	G3	G4	G5	G6	G7	G8	G9
0	0	0	0	**0**	0	0	0	0	0
30	47.75± 0.55	43.24 ± 1.14	38.04 ± 0.81	**50.00 ± 1.05**	46.05 ± 0.55	40.00 ± 0.85	44.08± 0.75	41.01 ± 0.57	36.48±0.73
60	61.26± 0.54	52.06 ±	44.55 ± 0.87	**62.00 ± 0.78**	56.09 ±	58.05 ± 0.58	58.05 ± 0.82	52.04 ± 0.78	48.02± 1.12

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		0.72			0.87				
90	72.08± 1.01	60.07 ± 0.81	52.60 ± 1.14	**70.07 ± 0.81**	64.05 ± 0.39	60.06 ± 0.84	64.05 ± 0.74	60.05 ± 0.65	56.12 ± 0.75
120	78.08± 1.26	70.88 ± 0.75	58.80 ± 0.68	**82.09 ± 0.75**	70.02 ± 0.74	66.14 ± 0.52	76.52 ± 0.65	66.02 ± 0.41	64.14 ± 0.72
150	82.95± 0.79	74.09 ± 0.79	66.08 ± 0.57	**86.09 ± 1.12**	74.25 ± 0.22	70.05 ± 0.59	80.05 ± 0.41	72.48 ± 0.85	68.42± 0.95
180	84.00± 0.74	80.01 ± 1.15	78.09 ± 0.62	**88.02 ± 0.52**	80.02 ± 0.41	78.75 ± 0.55	84.02 ± 0.51	78.05 ± 0.45	72.12 ± 0.52
210	86.01± 0.81	82.05 ± 0.54	80.05 ± 0.51	**88.14 ± 0.62**	84.02 ± 0.41	82.02 ± 0.32	86.05 ± 0.82	84.06 ± 0.65	80.22 ± 0.65
240	88.12± 0.54	84.02 ± 0.57	82.02 ± 0.87	**90.05 ± 0.54**	86.20 ± 0.54	82.42 ± 0.51	88.02 ± 0.51	86.24 ± 0.42	84.03 ± 0.45
270	88.21± 0.42	84.54 ± 0.54	82.01 ± 0.52	**90.08 ± 0.64**	86.62 ± 0.61	84.64 ± 0.65	88.28 ± 0.45	86.47 ± 0.41	84.30 ± 0.46
300	88.75± 0.45	86.89 ± 0.48	84.82 ± 0.41	**90.48 ± 0.48**	86.72 ±0.45	84.88± 0.52	88.48 ± 0.75	86.65 ± 0.85	84.42 ± 1.02

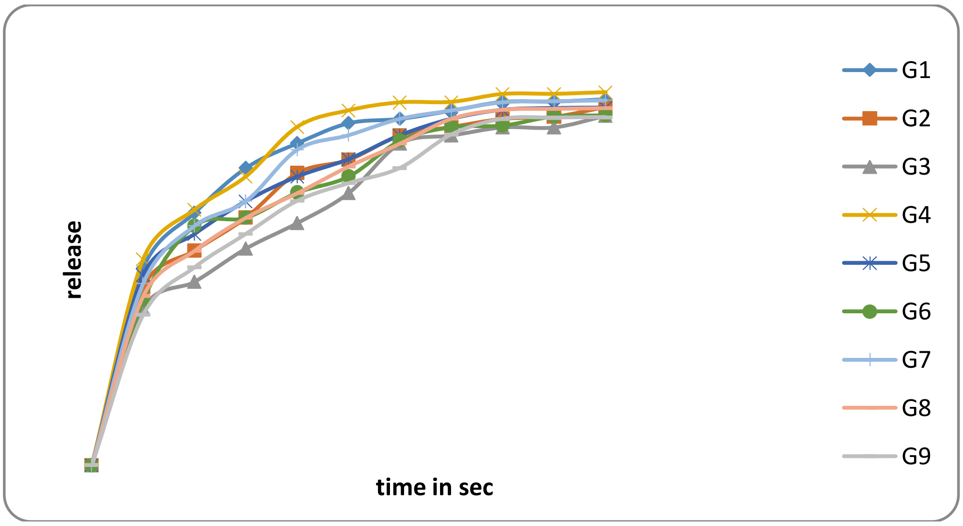

Fig 2Cumulative % drug Release of batches G1 to G9

In-Vitro Drug Release from fast dissolving films of Levosalbutamol sulphate .

Dissolution study was carried out in USP type II apparatus using the phosphate buffer, pH 6.8 as a dissolution medium at 50 rotations per minute. The fast dissolving films of G1, G2, G3, G4, G5, G5, G6, G7, G8 and G9) were found to release 88.75 ± 0.45%, 86.89 ± 0.48%, 84.82 ± 0.41%, 90.48 ± 0.48%, 86.72 ± 0.45%, , 84.88 ± 0.52%, 88.48 ± 0.75%, 86.65 ± 0.85% and 84.42 ± 1.02% of Levosalbutamol sulphate in time 300 sec respectively.

Accelerated stability studies

Film of formulae G4 were stored at storage conditions namely 40 °C/75% RH. G4 film

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was wrapped in a butter paper followed by aluminium foil and placed in an aluminium pouch. The films were evaluated for appearance, disintegration time; drug content and in vitro drug release after storage for 30 days. In vitro % release from the films was calculated and was compared for change in the dissolution profile.

From the result table 5 batch G4 was selected as a optimum batch and stability study was carried out as follows :-

The film G4 batch were wraped using alumimium foil and kept at above specified condition in environmental control chamber(temperature 40±2^{0}C and RH 75±5%) for 30 days. Film were tasted after 30 days for changes in appearance disintegration time drug contain and in vitro drug release and finding were recorded as per the procedure.

Table no. 7 stability study of fast dissolving film.

Sr. No.	Stability studies	Before	After
1	Appearance	Transparent, uniform	Transparent, uniform
2	Disintegration time (sec)	35	36
3	Drug content (%)	93.23	92.26

Table 8 Cumulative % drug Release of batches G4 for stability studies

Time (sec)	**0**	**30**	**60**	**90**	**120**	**150**	**180**	**210**	**240**	**270**	**300**
G4 Before	0	48.21	60.32	71.54	80.18	85.50	88.04	88.50	90.15	90.24	90.75
G4 After	0	47.02	58.65	68.21	79.68	83.45	84.21	85.61	86.97	88.21	88.80

Fig 5 Cumulative % drug Release of batch G4 for stability studies

Discussion : Result of stability study revealed that, there was no significant change in the formulation batch G4 during stability study. Thus the formulation was found to be stable.

Comparison study of formulation and marketed preparation.

In-Vitro Drug Release fast dissolving films of Levosalbutamol sulphate and marketed preparations of Levosalbutamolsulphate uncoated tablet

Table no. 9In-Vitro Drug Release G4 and marketed preparation

	Drug release of film G4		**Drug release of film of marketed preparations**	
Sr. No.	**Time in sec**	**% release of G4**	**Time in min**	**% release of marketed preparations**
1	00	00	00	00
2	30	50.00 ± 1.05	5	47.07
3	60	62.00 ± 0.78	10	63.33
4	90	70.07 ± 0.81	15	85.80
5	120	82.09 ± 0.75	30	90.50
6	150	86.09 ± 1.12	60	94.20
7	180	88.02 ± 0.52	120	98.88
8	210	88.14 ± 0.62		
9	240	90.05 ± 0.54		
10	270	90.08 ± 0.64		
11	300	90.48 ± 0.48		

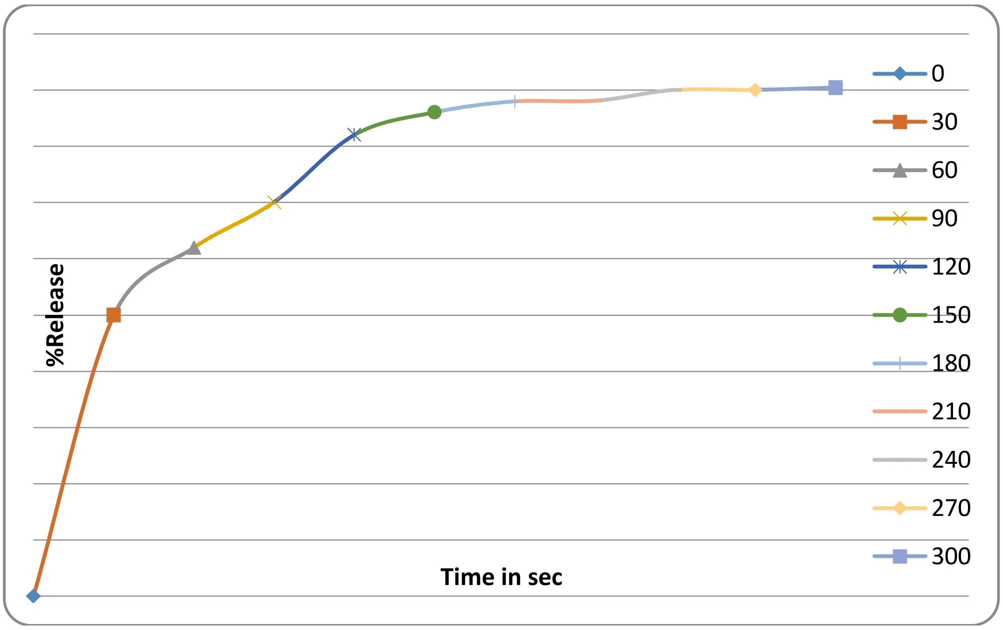

Fig 3 Cumulative % drug Release of batches G4

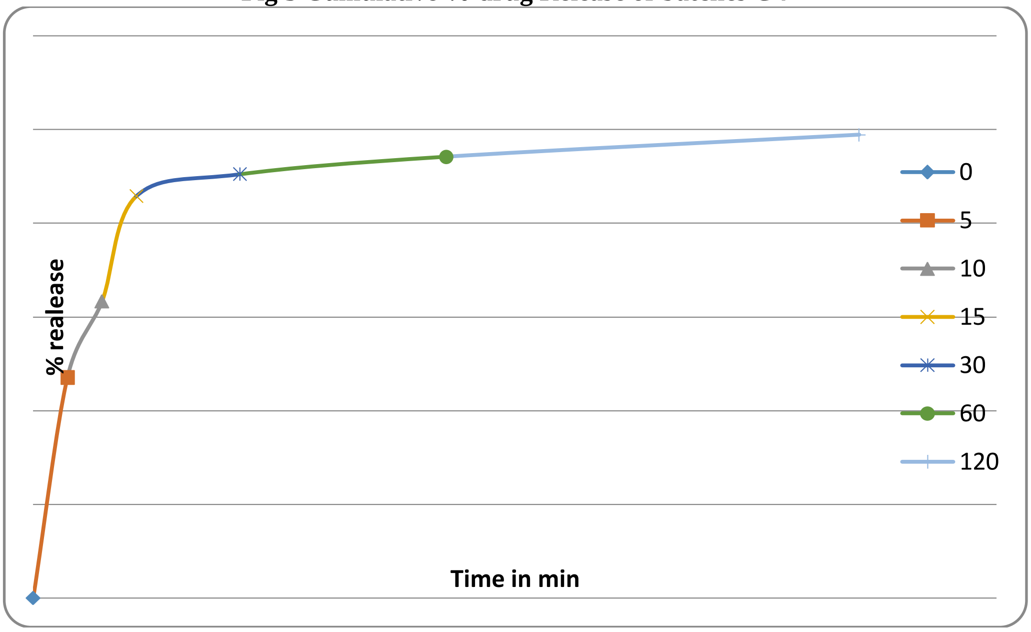

Fig 4 Cumulative % drug Release of marketed preparation

III. DISCUSSION:

The comparative evaluation of fast dissolving film batch G4 with marketed preparation(uncoated tablet) , in vitro dissolution study revealed that drug release of fast dissolving film was 50% release in 30sec and marketed preparation release 47.07% in 5min. and film release 90% in 5min and marketed preparation release 90% in 30min.

IV. CONCLUSION

The present study successfully developed a fast dissolving film of Levosalbutamol sulphate using HPMC E15 as a hydrophilic polymer via solvent casting. The formulation showed good physical and mechanical properties, rapid disintegration, and enhanced drug release compared to marketed tablets. Batch G4 demonstrated superior performance and stability, making it a promising approach for rapid asthma relief and improved bioavailability.

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