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DESIGN AND EVALUTION OF ORAL DISPERSIBLE TABLET OF MODEL DRUG CONTAINING HYDROCORTISONE FUMRATE

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1.Abstract

Oral Dispersible Tablets Are Patient Friendly Dosage Form That Rapidly Disintegrate Or Dispersed In Mouth Without The Need Of Water. Oral dispersible tablet of Hydrocortisone was develop in present study to get rapid onset of action to increase bioavailability and to increase patient compliance In The Present Investigation Ten ODT Formulations Of Hydrocortisone its is used Arthritis, Blood ,Hormone ,Immune System Disorders, Skin And Eye Conditions, Breathing Problems And Severe Allergies.Were Prepared different formulation by Using Different Superdisintegrants like Sodium Starch Glycolate , Crospovidone Cross Carmellose,Sodium Microcrystalline Cellulose , Aspartame, Magnesium Stearate , Talc , Aerosil Pineapple Flavour Mannitol By Direct Compression Method. The Effects Of Different Concentration On The Release Profile Of Hydrocortisone ODT Were Studied. Developed ODT Were Studied For Their Physicochemical Properties And In Vitro Drug Release Profile. The Studied Parameters Were Found To Be Satisfactory For All ODT Formulations Of Hydrocortisone Disintegration Time For All The Formulations Was Found To Be Less Than 30 Seconds. Disintegration Time For All ODT Decreased With Increase In Disintegrant Concentration. The aim of study is to develop and evaluate the oral dispersible tablets of Hydrocortisone To improve patient compliance,develop cost effective product. and enhanced the onset of action of Hydrocortisone also enhance the safety and efficacy of Hydrocortisone.

KEY WORDS- Oral Dispersible Tablet , Hydrocortisone Fumrate

2.Introduction

oral route of medicine administration is the most common and favored system of delivery as it's the simplest and easiest way of administering medicines. the rout offers ease of drug administration in a convenient manner and patients are more familiar with this rout. so, patient compliance and thus drug treatment is typically more effective with orally given medications. the tablet is most widely used dosage form existing today because of its convenience in term of self-administration, compactness and ease in manufacturing. however, geriatric,

paediatric and mentally ill patient's experiences difficulty in swallowing conventional tablets, which is common among all age groups, especially in elderly which leads to poor patient compliance.

3.Formulation Design Of Hydrocortisone Fumarate Oral Dispersible Tablets.

3.1. Selection of Superdisintegrants:

The best type of superdisintegrants are incorporated in the formulation of odts like,Sodium starch glycolate, Crospovidone, Cross carmellose sodium. Before the tablet formulation the superdisintegrants was screened out and taken into formulation with other excipients for compression by direct compression method. The superdisintegrant shows good parcels like, when the tablet comes in contact with liquid, it breaks up into lower patches because of superdisintegrants are swells, hydrate, change the volume and produce a disruptive change in the tablet.In this work, the direct compression method with aid of superdisintegrants was attempted for the formulation development of orodispersible tablets of Hydrocortisone fumarate. The superdisintegrants like Sodium starch glycolate, Crospovidone, Cross carmellose sodium were taken for the formulation development. The Hydrocortisone fumarate tablets are available in 5mg and 10mg doses in the market. Dose of 10mg is selected for the present study. The development of the formulation of orodispersible tablets in the present study was mainly based on the type and concentration of superdisintegrants. Various superdisintegrants in different concentrations (3.3%, 5%, and 6.66%) were used so as to get tablets with good physical properties. constituents like Microcrystalline cellulose and Mannitol as directly compressible diluents, magnesium stearate and talc as lubricant, aerosil as inflow protagonist, aspartame as enhancing agent and pineapple flavor as enhance the delectability. And Sodium Starch Glycolate (Carboxymethy Starch), Crospovidone (Polyplasdone XL) and Cross Carmellose Sodium (Ac-Di-Sol) were taken in the different concentrations such as 3.3%, 5%, and 6.66%.The formulation design of orodispersible tablets of Hydrocortisone fumarate is shown in Table 8.1 which contains superdisintegrants in different concentration, Microcrystalline cellulose as diluent, Mannitol as directly compressible diluent, aspartame was selected as sweetening agent due to its intense sweetness, magnesium stearate and talc as lubricant, aerosil as flow promoter and flavor (Pineapple flavor) was added it enhance the palatability of tablets.

3.2 Preparation of powder blend of drug and excipients:

The powder blend for orodispersible tablets were prepared by taking ingredients given in Table 8. All the constituents were passed through 60 mesh sieve independently and collected. also constituents were counted and mixed in a geometrical order. First Microcrystalline cellulose, Mannitol and Superdisintegrants were weighed and mixed together in glass mortar using a pestle. also Drug and Aspartame were mixed and added in first mixer. also Magnesium stearate, Talc and Aerosil were added and mixed. Eventually flavor(Pineapple flavor) was added and mixed for 10- 20 twinkles. Before tablets preparation, the mixture blends of all the formulations were subjected for compatibility studies (IR) and pre-compression parameter like Angle of repose, Bulk density, Tapped density, Percentage compressibility and Hausner ratio.

3.4 Preparation of Hydrocortisone Oral dispersible Tablets by Direct Compression:

Hydrocortisone Fumarate orodispersible tablets were prepared in nine formulations MF1 to MF9 using the ingredients given in the below Table keeping the total weight of the tablet (150mg) kept constant in all the formulations. All the ingredients were passed through 60 mesh sieve separately and collected. also constituents were counted and mixed in a geometrical order. First microcrystalline cellulose, Mannitol and superdisintegrants were weighed and mixed together in glass mortar using a pestle. Then drug and aspartame were mixed and added in first mixer. The mix was also waxed by mixing with magnesium stearate, talc and aerosil. Finally the mixture was blended with flavor. Then the powder blend was compressed. Tablets were prepared using 8 mm round flat-faced punches of the 16-station (Cadmach Machineries ltd.) Rotary tablet compression machine. Compression force was kept constant for all formulation. The Orodispersible tablets were prepared and subjected to post compression parameters like hardness, friability, thickness, and weight variation, *In-vitro* dispersion time, wetting time, water absorption ratio, drug content, *In-vitro* disintegration time and *In-vitro* dissolution.

Ingredients (Mg)	MF1	MF2	MF3	MF4	MF5	MF6	MF7	MF7	MF9
Hydrocortisone Fumarate	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Sodium Starch Glycolate	8	12	16	-	-	-	-	-	-
Crosspovidone	-	-	-	8	12	16	-	-	-
Cross Carmellose Sodium	-	-	-	-	-	-	8	12	16
Microcrystalline Cellulose	100	100	100	100	100	100	100	100	100
Aspartame	13	13	13	13	13	13	13	13	13
Magnesium Stearate	2	2	2	2	2	2	2	2	2
Talc	3	3	3	3	3	3	3	3	3
Aerosil	2	2	2	2	2	2	2	2	2
Pineapple Flavour	2	2	2	2	2	2	2	2	2
Mannitol	90	86	82	90	86	82	90	86	82
Total	**240**	**240**	**240**	**240**	**240**	**240**	**240**	**240**	**240**

4.List of Materials Used

The Following Materials Of Pharma Grade Or The Best Possible Laboratory Reagent (Lr) Were Used As As following table

Sr. No.	Materials Used	Category
1	Hydrocortisone	Active Ingredient
2	Sodium Starch Glycolate	Super Disintegrant
3	Crosspovidone	Super Disintegrant
4	Crosscarmellose Sodium	Super Disintegrant
5	Microcrystalline Cellulose	Diluents
6	Aspartame	Sweetener
7	Mannitol	Sweetener
8	Talc	Glidant
9	Pineapple Flavour	Flavour
10	Magnesium Stearate	Lubricant

5.The Following used Equipment's

Sr. No	Equipment	Sr. No	Equipment
1	Tablet Compression Machine	10	FTIR Spectrophotometer -84005
2	Digital Balance	11	LOD (Loss On Drying) Tester
3	Melting Point Apparatus	12	Hardness Tester
4	Digital Ph Meter	13	Density Tester
5	Rapid Mixer Granulator	14	Blender
6	Planetary Mixer (Plm)	15	Roche Friabilator USP
7	Disintegration Tester	16	Vernier Caliper
8	Dissolution Apparatus	17	UV-Visible Spectrophotometer
9	Rapid Dryer		

6. RESULTS AND DISCUSSION

6.1. Active Pharmaceutical Ingredient (API) Characterization: For Hydrocortisone:

Appearance: A White or nearly White, Crystalline Powder
Colour: White
Odour: Odourless

6.2. Physical Parameters Of Drug

Sr. No	Parameters	Observations
1	Water Solubility	320 MG/ML At 25°C
2	Loss On Drying	0.23% (W/W)
3	Melting Point	214-215°C
4	Angle Of Repose	32

6.3. Powder Flow Characterization Of Drug

Sr. No	Parameter	Observations
1.	Bulk Density	0.364 GM/ ML
2.	Tapped Density	0.606 GM/ ML
3.	Hauser's Ratio	1.25
4.	Compressibility Index	25.27%

6.4 Solubility Of Hydrocortisone In Various Solvents And With Different Ph

SOLVENTS/PH	USP SPECIFICATIONS
Water	Slightly Insoluble
Methanol	Slightly Soluble
DMF	Soluble
Acetone	Insoluble
Ph 1.2 (0.1 N HCL)	Soluble
Ph 4.5 Acetate Buffer	Slightly Soluble
Ph 6.8 Phosphate Buffer	Insoluble

solubility study was performed in water and different buffers solutions from the solubility data concluded that hydrocortisone shows ph dependent solubility. at lower ph solubility is low and as ph increases solubility increases. & media at 37°c the results are shown in below table solubility study of hydrocortisone

Sr. No	MEDIUM USED	SOLUBILITY IN MG / ML
1.	0.1 N HCL (Ph 1.2)	37.48
2.	Acetate Buffer (Ph 4.5)	4.92
3.	Purified Water	20.40
4.	Phosphate Buffer (Ph 6.8)	3.10

Observation:
Study Shows That The Solubility Of Hydrocortisone Was Found To Be More In Ph 1.2 [0.1 N Hcl]

6.5 Drug– Excipients Compatibility Study:

Compatibility Of Drug With Different Excipients Was Done Using Open Glass Vials And Closed Glass Vials At Specific Storage Conditions And Checked At Various Time Intervals For Any Physical Or Chemical Change. The Powder Mix In The Vials Was Observed For Any Physical Change Compared To Its Initial Property.

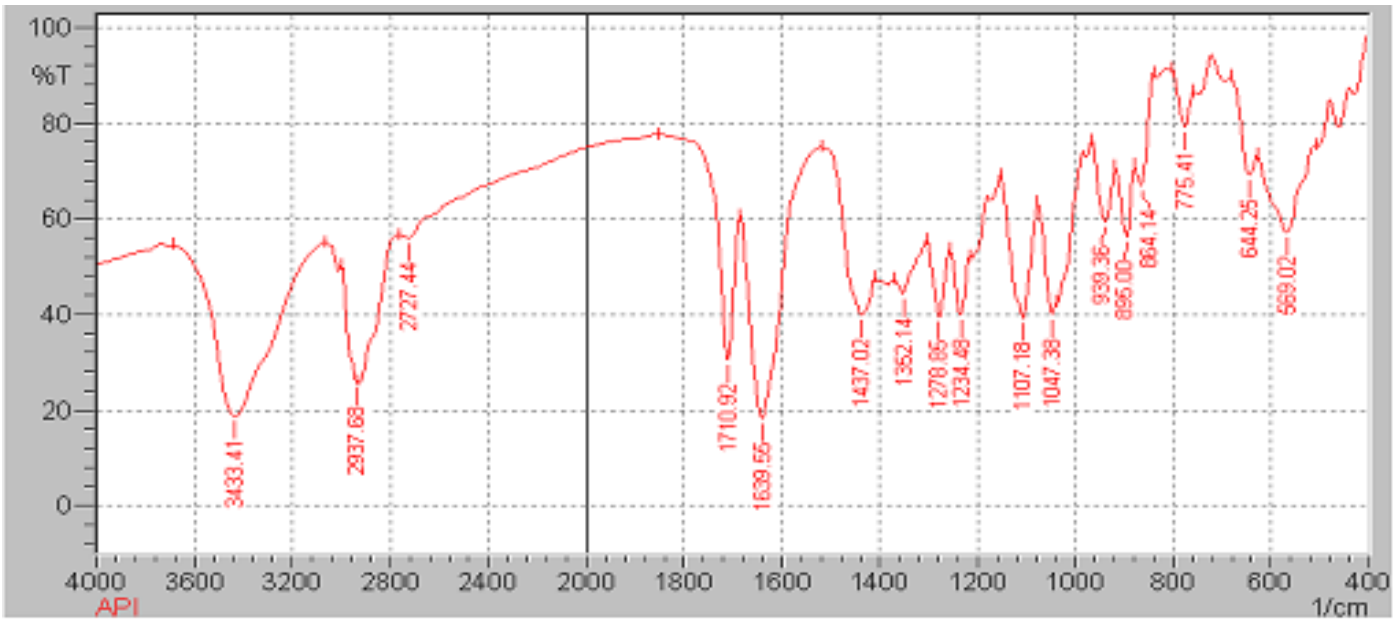
Drug-Excipients Compatibility Study Result.

Sr. No	Drug + Excipient	Ratio	Parameter	Conditions	
				40^0c±2/75±5%Rh	
				2 Week	4 Week
01	API	1:0	Appearance	√	√
				√	√
02	API + MICROCRYSTALLINE CELLULOSE	1:10	Appearance	√	√
				√	√
03	API + SODIUM STARCH GLYCOLATE	1:5	Appearance	√	√
				√	√
04	API + CROSPOVIDONE	1:1	Appearance	√	√
				√	√
05	API + CROSS CARMELLOSE SODIUM	1:1	Appearance	√	√
				√	√

Observations: Based On The Physical And Chemical Data Provided In Above Table Significant Changes Observed With Respect To Physical Appearance Of The API And There Was No Much Increase In The Impurity Levels With The Total Obtained Impurities (Known And Unknown) Were Within The Limit . Thus, From The Above We May Conclude That Hydrocortisone With The Excipients Used In Final Formulation. Since There Was No Significant Change Observed At Storage Condition 40°C/ 75% Rh, It Was Decided Not To Analyze The Samples Stored At 25°C/60% Rh. Excipients That Used In Present Formulation Were Found To Be Compatible With Drug.

6.6 FTIR SPECTROSCOPY

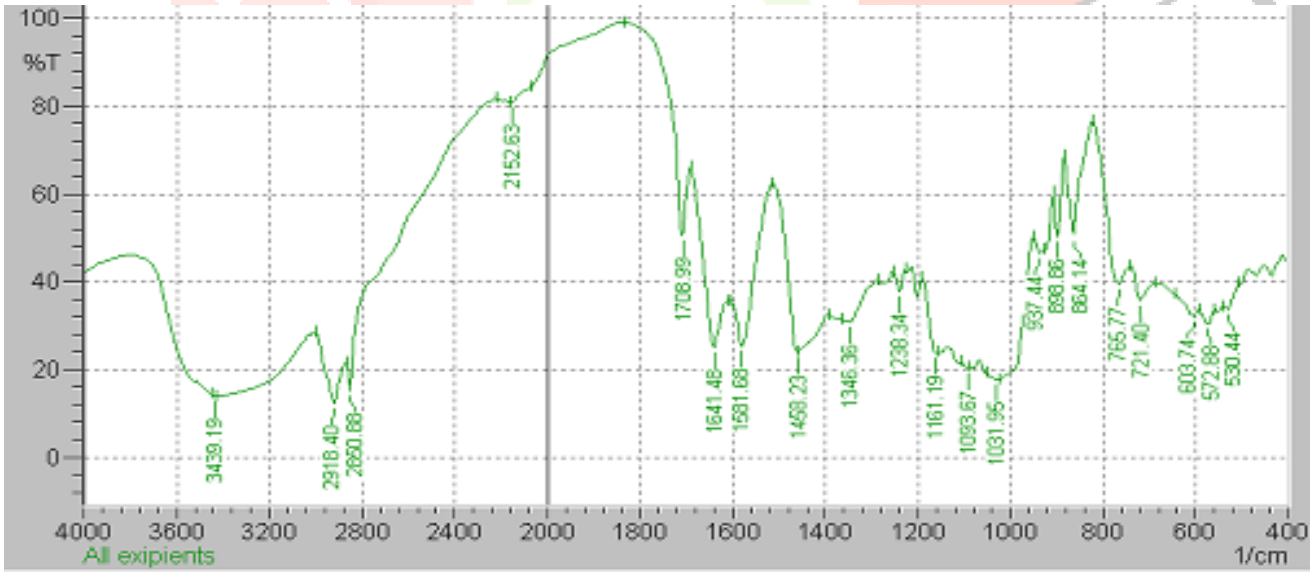
The IR Spectrum Was Obtained In The Solid State As Potassium Bromide Dispersion. The IR Spectrum Of Hydrocortisone Are Presented In These Peaks Are Similar To Reported Peaks Of Hydrocortisone. Assignments Of Characteristic Absorbance Bands Are Given Below Table.



FT-IR SPECTRUM OF PURE DRUG.

Hydrocortisone Infrared Band Assignment

Chemical Bonding	Reported Frequency (Cm^{-1})	Observed Frequency (Cm^{-1})
C——H Alkenes (Stretch)	3000-2850	2937.68
Stretch /Alkyne/Aldehyde	2800-2700	2727.44
C=O Ketone	1745-1705	1710.92
Bend (Ch3) Alkenes	1650-13.75	1639.55
(Stretch) Alkenes	1000-650	895.00
Aromatics (Stretch)	900-690	864.14



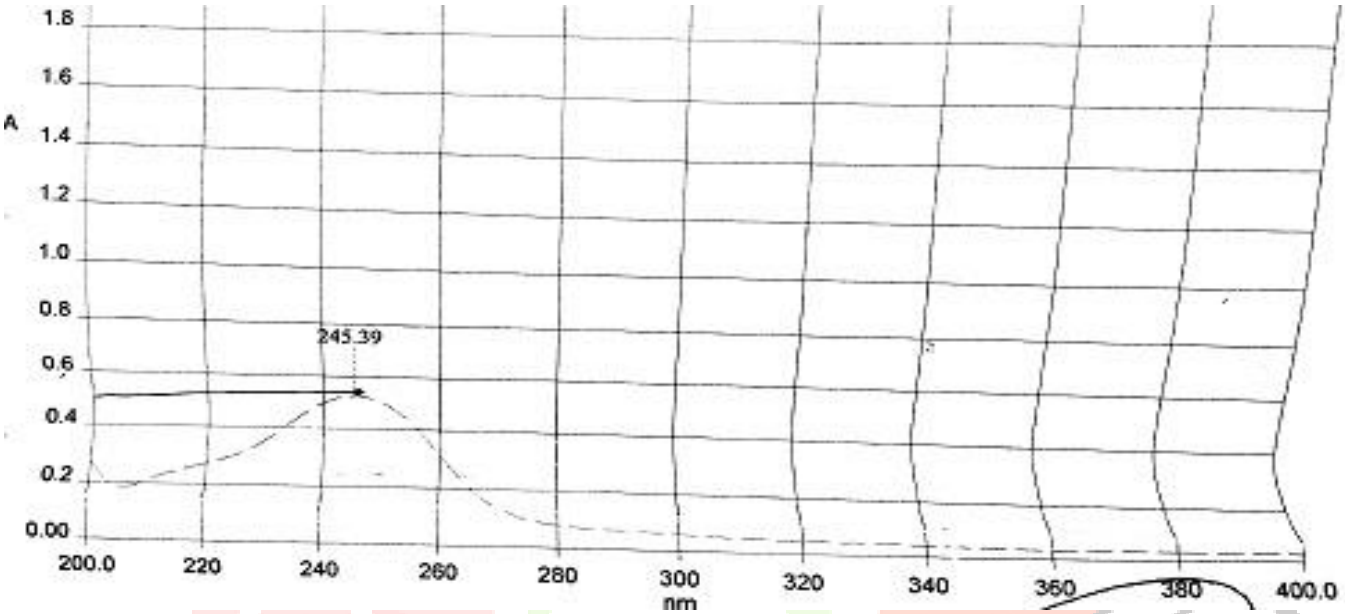
FT-IR SPECTRUM OF PHYSICAL MIXTURE

Physical Mixture Infrared Band Assignment.

Chemical Bonding	Reported Frequency (Cm^{-1})	Observed Frequency (Cm^{-1})
C——H Alkanes (Stretch)	3000-2850	2918.40 And 2850.68
Aromatics (Stretch)	1900-650	937.44
Alcohol ,Ether, Acid	1300-1000	128.34
Aromatic (Stretch)	900-650	937.44 And 721.40

6.7. UV SPECTROSCOPY

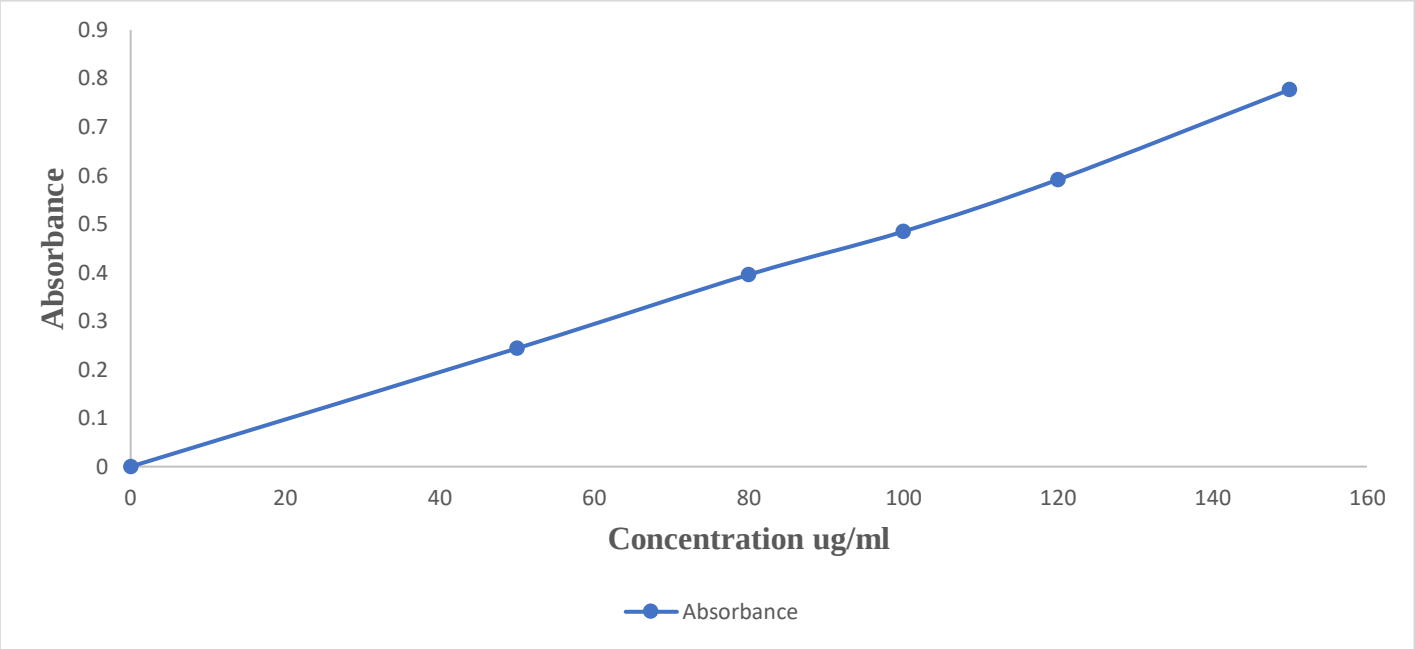
Determination Of Analytical Wavelength By Uv-Spectroscopy: (Hydrocortisone) Detector: UV-VIS Wavelength: 245 Nm UV Spectroscopy (Determination Of Λ Max):The UV Spectrum Of Hydrocortisone Is Obtained By Scanning From 200-400 Nm .The Drug Shows Maximum Absorption At Wavelenth 245nm. Spectrum Is Shown Figure



6.8 The Linear Regression Analysis For Standard Curve:

Graph Of Absorbance Vs. Concentration Was Plotted And Found To Be Linear Over The Range Of 50 To 150µg/Ml Indicating Its Compliance With Beer-Lambert Law With **R^2 = 0.9986.** A Straight Line Equation **(Y= Mx + C)** Was Generated To Facilitate The Calculation Of Amount Of Drug.

Standard Area In 0.1 Hcl



Sr.	Concentration µg/Ml	Absorbance
1.	0	0
2.	50	0.2215
3.	80	0.3956
4.	100	0.4846
5.	120	0.5915
6.	150	0.7651

Standard Calibration Curve Calibration Curve Hydrocortisone

6.9 Pre-Compression Study Of Tablet Blend: Nine Formulations Were Prepared By Using 3.33%, 5%, 6.66% Concentration Of Super Disintegration Of Superdisintegrants Sodium Starch Glycolate, Crospovidone And Croscarmellose Sodium. For Each Designed Formulation, Powder Mixed Blend Of Drug And Excipients Was Prepared And Evaluated For Various Parameters As Follow

6.9.1.Angle Of Repose (Θ): The Angle Of Repose Of Various Powders Mixed Blend, Prepared With Different Superdisintegrants, Was Measured By Cylinder Method. Angle Of Repose Was Found In The Range From 25.80 To 32.36 The Good Flowability Of Powder Blend Was Also Evidenced With Angle Of Repose Which Is Indicated A Good Flowability. The Result Are Given In Below Table

Batch Code	MF1	MF2	MF3	MF4	MF5	MF6	MF7	MF8	MF9
Angle Of Repose (Θ)	30.61	32.12	31.60	29.60	32.20	32.36	31.16	25.80	28.50

6.9.2 Bulk Density (Gm/Cm^3): The Bulk Density Of Various Powder Mixed Blends. Prepared With Different Superdisintegrants Was Measured By Graduated Cylinder. The Bulk Density Was Found In The Range From 0.5 To 0.520. The Result Are Given In Below Table

Batch Code	MF1	MF2	MF3	MF4	MF5	MF6	MF7	MF8	MF9
Bulk Density (Gm/Cm^3)	0.512	0.510	0.511	0.501	0.508	0.520	0.518	0.519	0.520

6.9.3 Tapped Density: The Tapped Density Of Various Powder Mixed Blends Prepared With Different Superdisintegrants, Was Measured By Measuring Cylinder. The Tapped Density Was Found In The Range From 0.606 To 0.628. The Result Are Given In Below Table

Batch Code	MF1	MF2	MF3	MF4	MF5	MF6	MF7	MF8	MF9
Tapped Density (Gm/Cm^3)	0.608	0.625	0.625	0.606	0.617	0.609	0.621	0.628	0.627

6.9.4. Compressibility Index: The Compressibility Index Of Various Powder Mixed Blends Prepared With Different Superdisintegrants Using Bulk Density And Tapped Density Data, Compressibility Index Was Calculated. It Was Found In The Range 14.61 To 20.00.The Result Are Given In Below Table

Batch Code	MF1	MF2	MF3	MF4	MF5	MF6	MF7	MF8	MF9
Compressibility Index (%)	17.76	18.04	20.00	17.49	17.66	14.61	16.58	17.35	16.08

6.9.5. Hausner Ratio: The Hausner Ratio Of Various Powder Mixed Blends Prepared With Different Superdisintegrants, It Was Calculated By Using Bulk Density And Tapped Density Data. It Was Found In The Range Of 1.17 To 1.25. The Result Are Given In Below Table

Batch Code	MF1	MF2	MF3	MF4	MF5	MF6	MF7	MF8	MF9
Hausner Ratio	1.216	1.225	1.250	1.212	1.214	1.171	1.198	1.210	1.205

7.Evaluation Of Oral Dispersible Tablets Tablets Of Hydrocortisone Fumarate:

7.1 Hardness: Tablets Were Evaluated By Using Hardness Tester. Hardness Of The Tablets Was Found In The Range 1.90 To 2.20. The Result Are Given In Below Table

Batch Code	MF1	MF2	MF3	MF4	MF5	MF6	MF7	MF8	MF9
Hardness (Kg/Cm2)	1.98	1.98	2.02	1.95	1.96	2.0	1.90	2.20	1.96

7.2 Friability: Tablets Were Evaluated By Using Roche Friabilator And Friability Of Tablets Was Observed In Acceptable Range 0.48 To 0.81 (Less Than 1%). The Result Are Given Below Table

Batch Code	MF1	MF2	MF3	MF4	MF5	MF6	MF7	MF8	MF9
Friability (%)	0.650	0.771	0.589	0.718	0.819	0.705	0.489	0.489	0.788

7.3Thickness Uniformity: Tablets Were Evaluated By Using Verniercaliper. The Thickness Of Tablets Was Found To Be Exact 2.5 Uniform Thickness Was Obtained Due To Uniform Die Fill. The Result Are Given In Below Table**.**

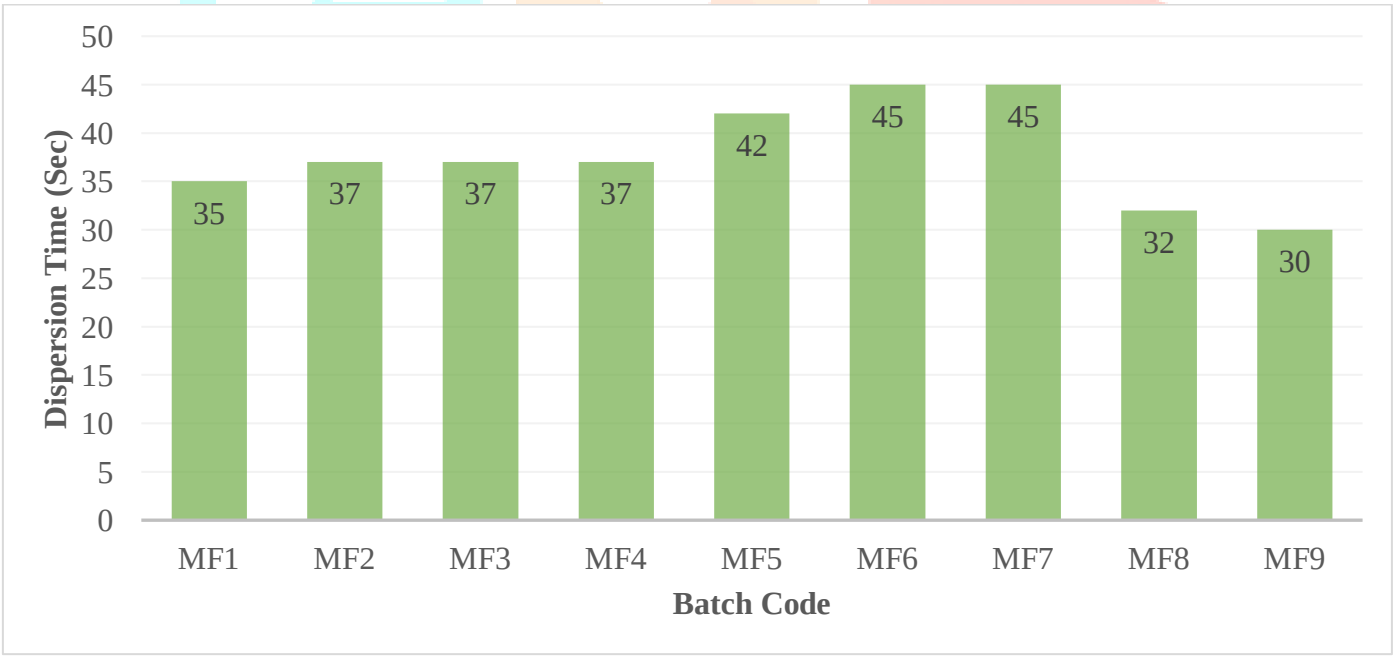
Batch Code	MF1	MF2	MF3	MF4	MF5	MF6	MF7	MF8	MF9
Thickness (Mm)	2.571	2.552	2.558	2.573	2.568	2.568	2.571	2.574	2.590

7.4 Weight Variation: Tablets Were Prepared Using Direct Compression Technique. Since The Material Was Free Flowing, Tablets Were Obtained Of Uniforms Weight Due To Uniform Die Fill. The Tablets Were Obtained In The Range With Acceptable Weight Variations As Per Pharmacopoeia Specifications Less Than 7.5%. The Result Are Given In Below Table

Batch Code	Weight (Mg) ± S.D)	Weight Variation (7.5%)
MF1	240.85 ±0.6	Passes
MF2	240.25±0.4	Passes
MF3	239.75±0.2	Passes
MF4	240.75±0.2	Passes
MF5	239.75±0.2	Passes
MF6	240.48 ±0.4	Passes
MF7	240.55 ±0.4	Passes
MF8	239.60 ±0.2	Passes
MF9	240.11±0.3	Passes

7.5 In-Vitro Dispersion Time: In-Vitro Dispersion Time Was Measured By Dropping A Tablet Into A Petri Dish Containing 10ml Of 0.1 N HCL Ph 1.2.
Solution At 37± 0.5^0c. The Dispersion Time Was Found In The Range 29 To 45 For All Batches. The Batch Mf9 Showed The Fast Dispersion. The Result Are Given In Below Table

Batch Code	MF1	MF2	MF3	MF4	MF5	MF6	MF7	MF8	MF9
Dispersion Time (Sec)	35	37	37	37	42	45	45	32	32



7.6 Water Absorption Ratio: A Piece Of Tissue Paper Folded Twice Was Placed In A Small Petri-Dish (6.5cm)Containing 6ml Of Water, A Tablet Was Placed On The Paper And The Time For Complete Wetting Was Measured The Wetted Tablet Was Then Weighed And The Water Absorption Ratio Was Calculated For Each Batch. The Ratio Was Calculated For Each Batch. The Ratios Are Given In Below Table

Batch Code	Water Absorption Ratio ±S.D
MF1	62.65±5.90
MF2	91.03±2.42
MF3	67.76±6.04
MF4	62.60±2.50
MF5	67.56±5.40
MF6	67.56±5.40
MF7	67.56±5.40
MF8	84.10±2.45
MF9	61.65±5.90

7.7.Disintegration Time: Tablets Were Evaluated For Disintegration Time In The Disintegration Test Apparatus (I.P) The Disintegration Time Was Found In The Range 26 To 36 For All The Batches. The Batch **Mf9** Showed The Fastest Disintegration. The Result Are Given In Below Table

Batch Code	Mf1	Mf2	Mf3	Mf4	Mf5	Mf6	Mf7	Mf8	Mf9
Disintegration Time (Sec)	31	33	32	32	32	36	28	27	26

Disintegration Time Comparison Of All Batches

7.8.Content Uniformity:

The Results For Content Uniformity Are Presented In The Results Showed Drug Content Were Lying Within The Limits. The Assay Limit Of Hydrocortisone Tablets As Per USP Is 90-110%. The Assays Of The Tablets Were Carried Out As A Process Given In USP And Data Table Are As Follows.

Batch Code	Content Uniformity (%)
MF1	97.55
MF2	99.89
MF3	100.25
MF4	98.51
MF5	101.83
MF6	100.97
MF7	99.04
MF8	97.98
MF9	99.80

7. 9. In –Vitro Dissolution Test:

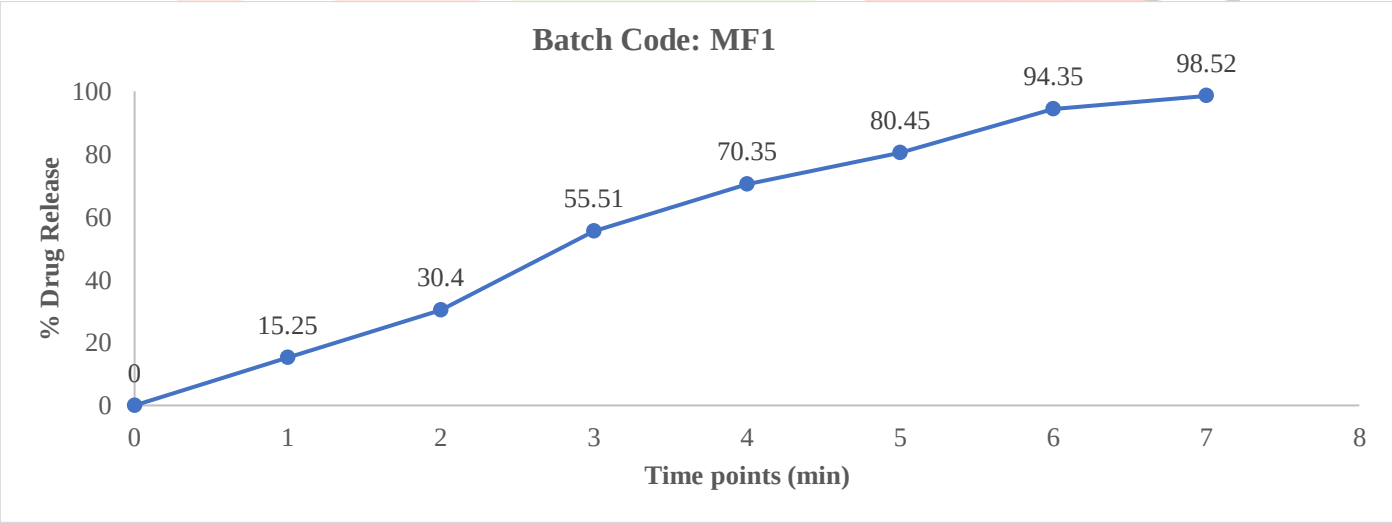
The Comparative Analysis Of Each Formulation Was Based On In Vitro Kinetic Parameters, Which Elucidated The Release Profile. The In-Vitro Drug Release Of Orodispersible Tablets Of Hydrocortisone Fumarate For All Formulation Is Given As Follows.

***In Vitro* Drug Release Parameters:**

Apparatus Used: Usp Ii Dissolution Test Apparatus
Dissolution Medium: 0.1 N Hcl (P^h1.2)
Dissolution Medium Volume: 900 ML
Temperature: 37±0.5ºc
Speed Of Basket Paddle: 50 Rpm
Sampling Intervals: 1 Min
Sample Withdrawn: 10 ML
Absorbance Measured: 245 Nm

7.9.1In-Vitro Release Studies Of Batch Mf1 In Ph 1.2 Buffer (0.1 N Hcl)

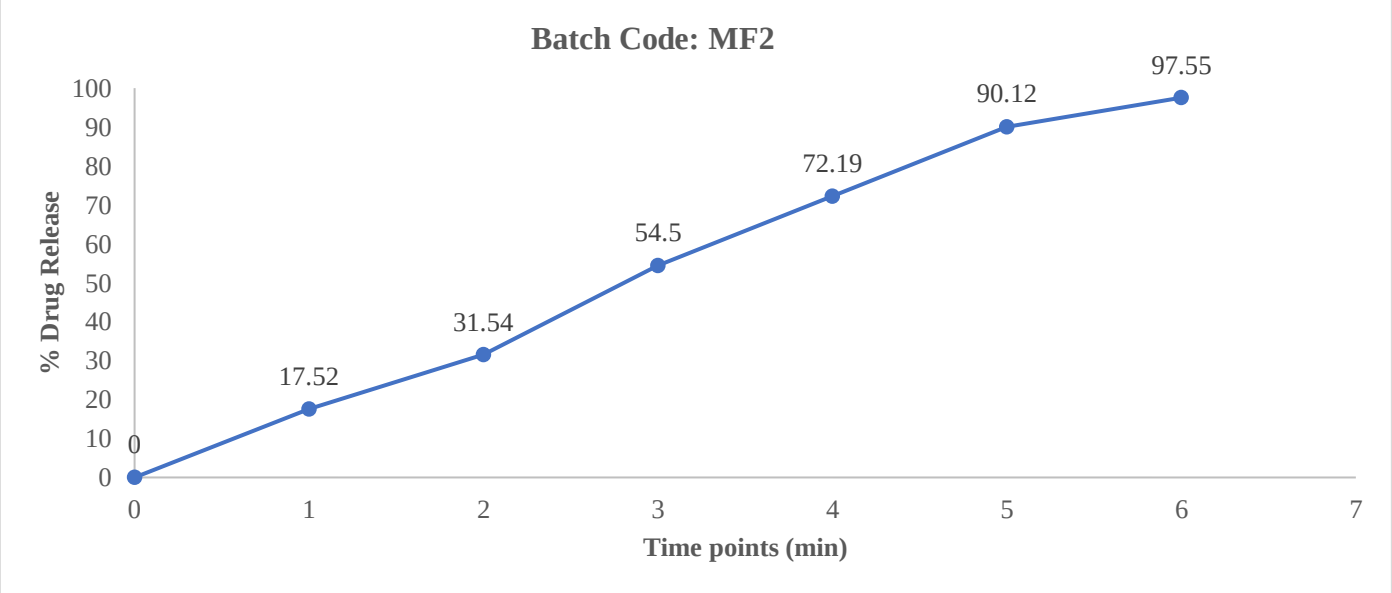
Time Points (Min)	% Drug Released
0	00
1	15.25
2	30.40
3	55.51
4	70.35
5	80.45
6	94.35
7	98.52



7.9.2 In-Vitro Release Studies Of Batch Mf1 In Ph 1.2 Buffer

7.9.3. In-Vitro Release Studies Of Batch Mf2 In Ph 1.2 Buffer (0.1 N HCL)

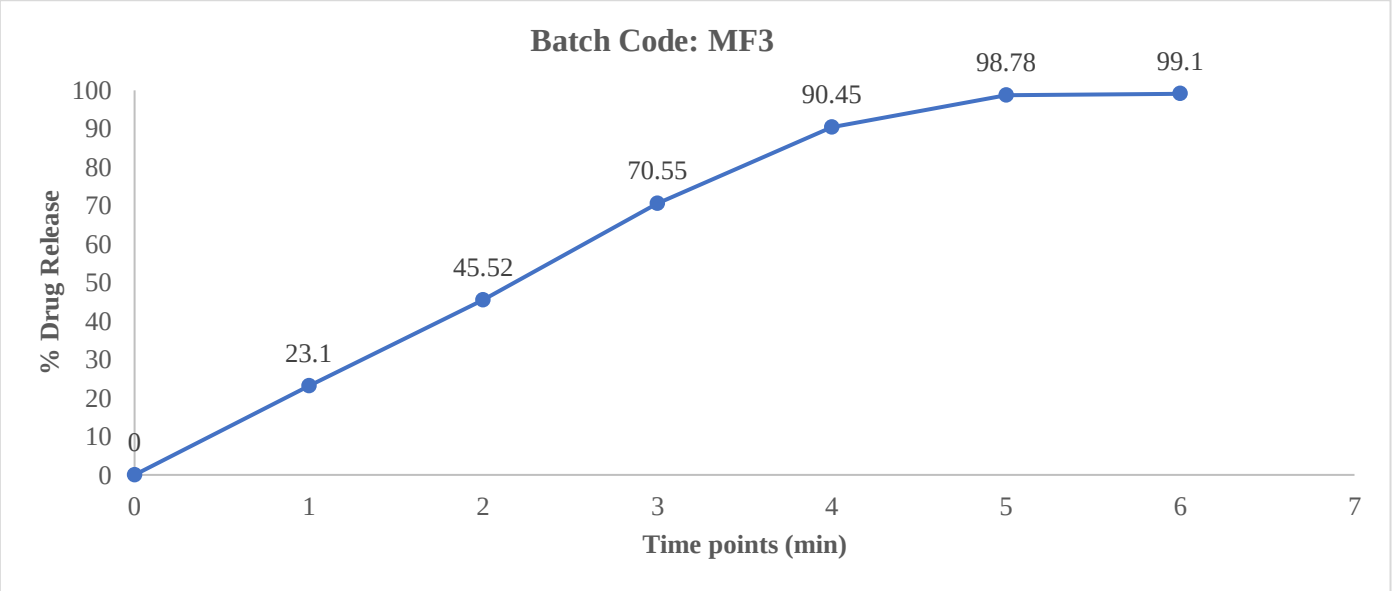
Time Points (Min)	% Drug Release
0	00
1	17.52
2	31.54
3	54.5
4	72.19
5	90.12
6	97.55
7	



7.9.4.In-Vitro Release Studies Of Batch Mf2 In Ph 1.2 Buffer

7.9.5 In-Vitro Release Studies Of Batch Mf3 In Ph 1.2 Buffer (0.1 N HCL)

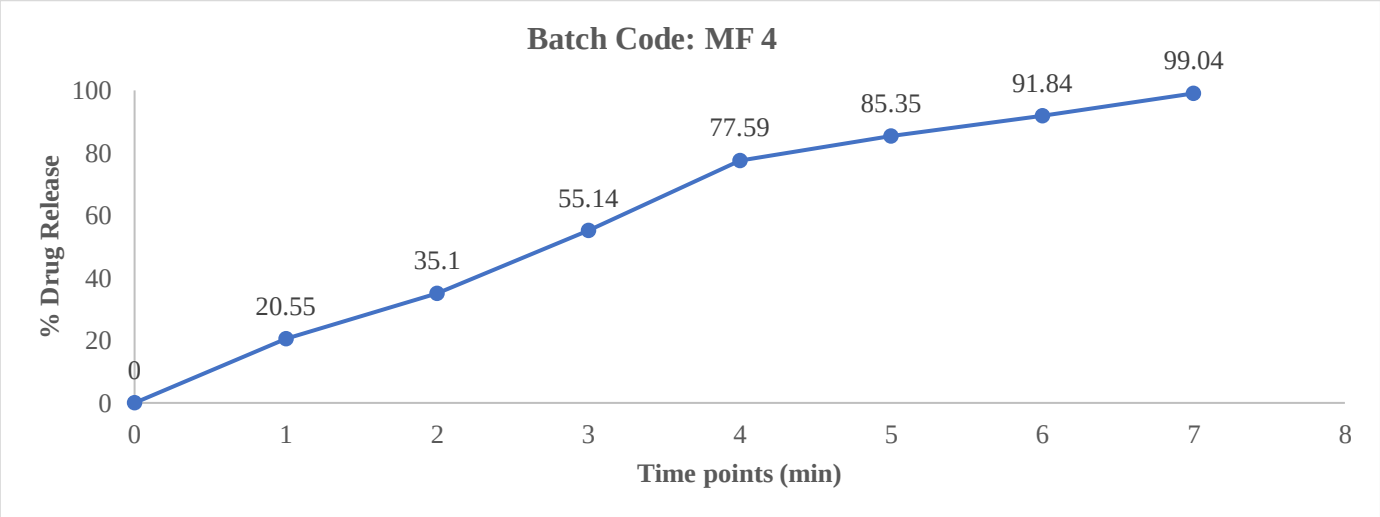
Time Points (Min)	% Drug Release
0	00
1	23.1
2	45.52
3	70.55
4	90.45
5	98.78
6	99.1
7	



7.9.6.In-Vitro Release Studies Of Batch Mf3 In Ph 1.2 Buffer

7.9.7.In-Vitro Release Studies Of Batch Mf4 In Ph 1.2 Buffer (0.1 N HCL)

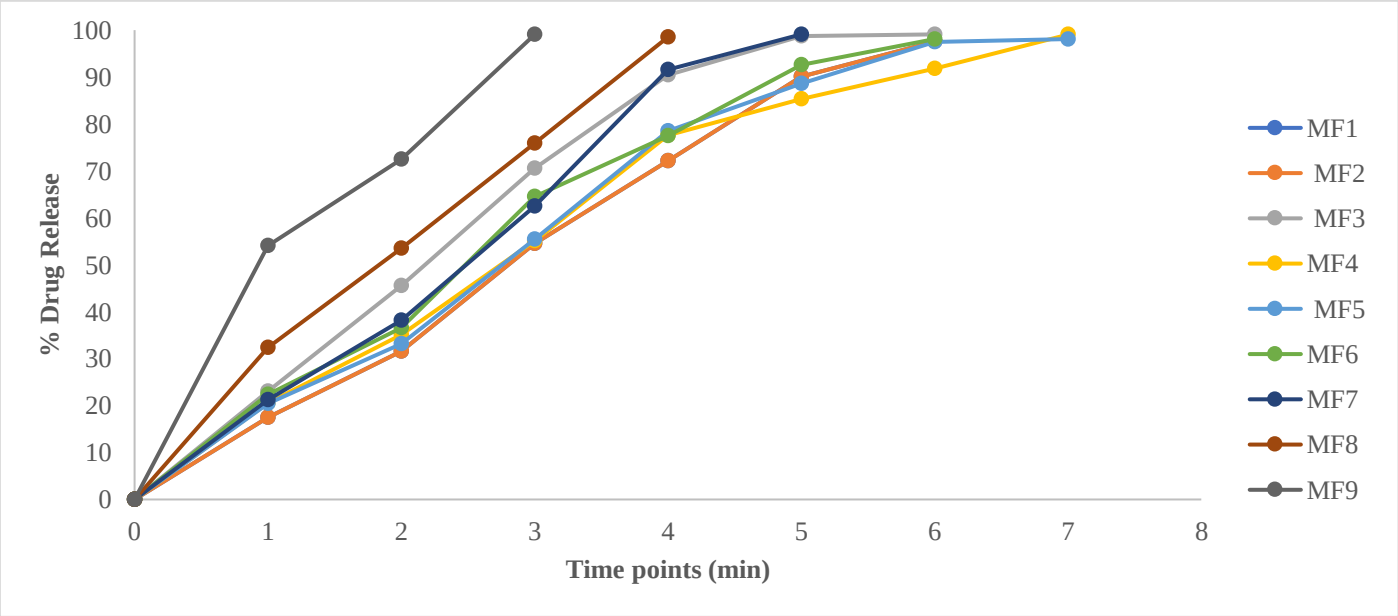
Time Points (Min)	% Drug Release
0	00
1	20.55
2	35.1
3	55.14
4	77.59
5	85.35
6	91.84
7	99.04



7.9.8.Comparative In-Vitro Drug Release Profile Of All Batches.

Time Points (Min)	MF1	MF2	MF3	MF4	MF5	MF6	MF7	MF8	MF9
0	00	00	00	00	00	00	00	00	00
1	17.52	17.52	23.1	20.55	20.41	22.37	21.2	32.39	54.1
2	31.54	31.54	45.52	35.1	33.21	36.52	38.2	53.56	72.5
3	54.5	54.5	70.55	55.14	55.41	64.5	62.5	75.89	99.04
4	72.19	72.19	90.45	77.59	78.54	77.52	91.52	98.52	-
5	90.12	90.12	98.78	85.35	88.64	92.55	99.1	-	-
6	97.55	97.55	99.1	91.84	97.54	98.1	-	-	-
7	-	-	-	99.04	98.1	-	-	-	-

7.9.9.Comparative In Vitro Drug Release Profile Of Batches MF1 TO MF9



8.Results Of Three Month Stability Studies

Stability Study Was Performed As Per Ich Guideline. Following Tables Describes The Result Of Different Quality Control Tests And Its Comparison With Specification Limits.

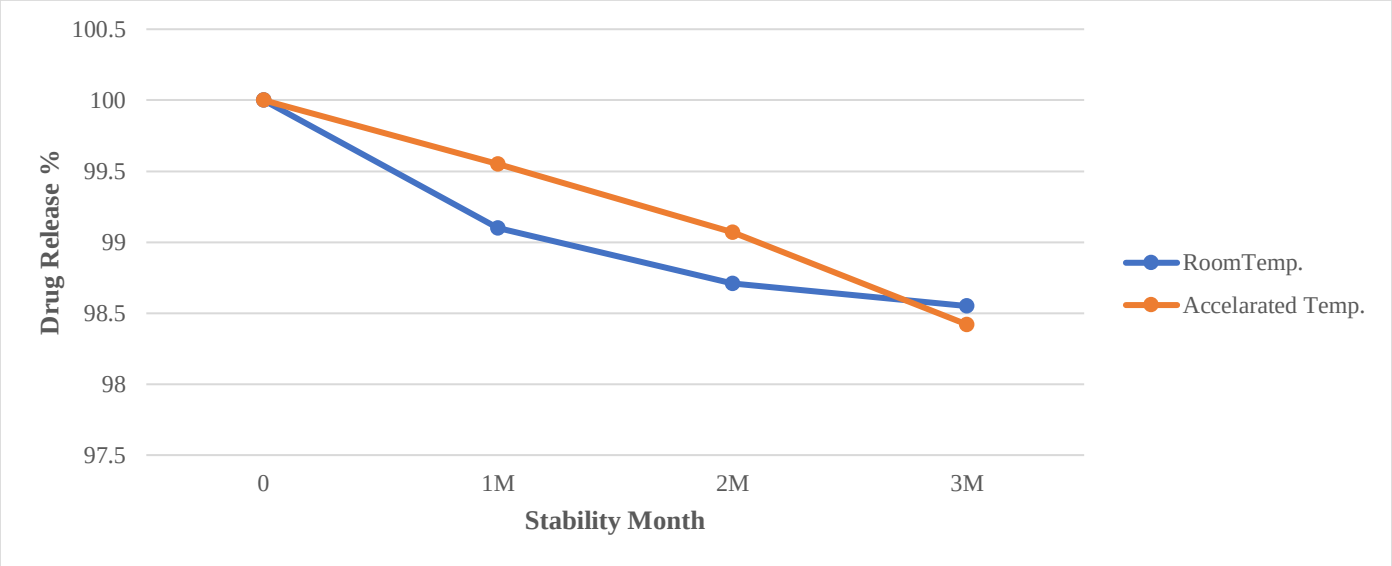
8.1.Three Month Stability Data Of Formulation MF9 At 25°C/60% Relative Humidity

Months	Hardness (Kg/Cm2)	Friability (%)	Drug Content (%)	Dissolution (At 3 Min)
1m	1.96 ±0.11	0.59 ±0.012	99.10	97.65
2m	1.90 ±0.04	0.55 ±0.011	98.71	97.01
3m	1.88 ±0.10	0.53 ±0.014	98.55	98.10

8.2.Three Month Stability Data Of Formulation MF9 At 40°C/75% Relative Humidity

Months	Hardness (Kg/Cm2)			Friability (%)	Drug Content (%)	Dissolution (At 3 Min)
1m	1.97 ±0.01			0.53 ±0.010	99.55	97.02
2m	1.92 ±0.11			0.54 ±0.013	99.07	98.54
3m	1.90 ±0.12			0.56 ±0.018	98.42	97.77

SSSSSSSSSS



8.3Showing Stability Study For Formulation MF9 At Various Temperature

9.Summary

Hydrocortisone Is A Natural Substance (Corticosteroid Hormone) Made By The Adrenal Gland. It Is Used To Treat Conditions similar As Arthritis, Blood/ Hormone/ Immune System diseases, Skin And Eye Conditions, Breathing Problems, Cancer, And Severe disinclinations. They Inhibit Phospholipase A2, Which Decreases The conformation Of Arachidonic Acid derivations; They Inhibit Nf- Kappa B And Other seditious Recap Factors; They PromoteAnti-Inflammatory Genes Like Interleukin. It Also Decreases Immune System's Response To Various Diseases To Reduce Symptoms Such As Pain, Swelling And Allergic-Type Reactions. Hydrocortisone Is Also Used To Treat Low Hydrocortisone Levels Caused By Diseases Of The Adrenal Gland (Such As Addison's Disease, Adrenocortical Insufficiency). Corticosteroids Are Needed In Many Ways For The Body To Function Well. They Are Important For Salt And Water Balance And Keeping Blood Pressure Normal.

10.Conclusion:

From The Present Study Carried Out On Hydrocortisone Fumarate Oral Dispersible Tablet Using By Direct Compression Method, The Following Conclusion Can Be Drawn.The Total Weight Of MF9 Batch Was 240 Mg Contained Hydrocortisone Fumarate-8.33%, Croscarmellose Sodium-6.66%, Microcrystalline Cellulose-41.66%, Aspartame-5.41%, Magnesium Stearate-0.83%, Talc-1.25%, Aerosil-0.83%, Pineapple Flavor-0.83%, Mannitol-34.18%. Likewise The Preformulation Study Gives The Following Information Of Optimize Batch Angle Of Repose-28.50(Θ), Bulk Density-0.520, Tapped Density-0.627, Compressibility Index-16.08 Good To Flow, Hausner Ratio-1.205.Post Parameter Evaluation Of Tablets Hardness-1.96, Friability-0.788, Thickness-2.590, Weight Variation-240.11±, Dispersion Time-32 Sec, Water Absorption Ratio-61.65, Disintegration Time-26 Sec, Content Uniformity-99.80%, And 99.04% *In-Vitro* Drug Release Studies- In 3 Min.If The Concentration Of Croscarmellose Sodium Is Increases It Gives Quickly The Disintegration And Dissolution Was Observed. So The Results Give Information That Decomposition Time In 26 Sec And Dissolution In 3 Min

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