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Oral Dissolving Films of Ibuprofen.

Anupam Adhikary, *[1] Amlan Bishal, *[2] Saikat Gayen, *[3] Suvojit Karmakar,*[4]Taokir Murshed Khan*[5] Bratati Bandyopadhyay*[6]

*[1,3,4,5] *B. Pharm 4th year student ofBharat Technology, Jaduberia, Uluberia, Howrah, India.*
*[2]*Asst. professor Deportment of pharmaceutics, Bharat Technology, Jaduberia, Uluberia, Howrah, India.*
*[6]*Asst. professorBharat Technology, Jaduberia, Uluberia, Howrah, India*

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ABSTRACT: In the late 1970s, rapid disintegrating drug delivery system was developed asanalternativetocapsules,tabletsandsyrupsforgeriatricandpediatricpatientshavingproblems in swallowing. To overcome the need, number of orally disintegrating tablets whichdisintegratewithinoneminuteinmouthwithoutchewingordrinkingwaterwerecommercialized.Thenlater,oraldrugdeliverytechnologyhadbeenimprovedfromconventional dosage form to modified release dosage form and developed recently rapiddisintegrating films rather than oral disintegrating tablets. Oral disintegrating film or stripscontaining water dissolving polymer retain the dosage form to be quickly hydrated by saliva,adhere to mucosa, and disintegrate within a few seconds, dissolve and releases medication foror mucosal absorption when placed in mouth. Oral film technology is the alternative routewith first pass metabolism. Oral disintegrating films (ODF) is an emerging technology bringsout "formulations taken without water" with quick onset of action and improved patientcompliance. Hence oral film drug delivery is a better alternative in such cases. The oral filmsare formulated using polymers, plasticizers, flavors, colors and sweeteners. The oral films aremanufacturedusingsolvent castingmethod,rollingmethod,extrusionmethodandsoliddispersion method. The films are evaluated for dimensions, disintegration, dissolution, tensilestrength and folding endurance. It has many applications like in taste masking, immediatereleaseandsustainedreleaseformulation.In ourpresentstudy,wehaveinstigatedphytochemicalconstituentsscreening&In-vitroantioxidantactivityofhydro-alcoholic (methanol70%v/v)solution.

Keywords: Fast dissolving oral films, Oral mucosa, Permeability, HPMC (Hydroxy propylmethylcellulose), Ibuprofen

I. INTRODUCTION:

Orallydissolvingfilmsaremostunique&advancedsoliddosageformdue to its flexibility & comfort. It is very easy to use. It improves the API dissolving efficacyintheoralcavityaftercontactwiththesalivaascomparedtotheorallydissolvingtabletwithoutchewing &noneedofwaterforadministration.Thisadvancedsoliddosageformgivesquickabsorption&instantbioavailibilityofthedrugduetohighbloodflow&permeabilityoforalmucosa which is4-1000 timesgreaterthanthatofskin.Weknowsomedrugsareabsorbedfromthemouth,pharynx&esophagusasthesalivapassedintothestomach.Insuchcasesbioavailibilityofthedrugissignificantlygreaterthanthecases observedfromtabletdosageform.Fastdissolvingoralfilmsaremostlyusefulforthepatientssuchasbedridden,emeticpatients, coughingforthosewhohaveaactivelifestyle.Itisalsousefulwheneverlocalactionisdesiredsuchaslocalanaestheticsfor oralulcer, cold sores orteething.

Nowadays Fast dissolving drug delivery system has become a novel & widely acceptabledosage forms by a huge number of consumers & gaining the interest of large number ofpharmaceutical industries, due to its several advantages. This fast-dissolving drug deliverysystem is especially suited for the drugs which undergo first pass metabolism & is used forimprovingthebioavailibilitywithreducingdosagefrequencytomouthplasmapeaklevelswithminimal side effects & also make it cost effective. ODF's due to its unique shape & size likethe postal stampinthicknessitquicklydisintegratesinthe oral cavity.Fast dissolvingtechnologiescanbedividedintothreebroad groups-Lyophilizedsystems,compressedtabletbased systems&thin filmstrips.

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AdvantagesofOralFastDissolvingFilms:

1. Oraldissolvingfilmscanbe administeredwithoutwateranywhere,anytime.
2. Due tothe presence oflargersurface area the filmprovidesrapiddisintegration&dissolutionin theoralcavity.
3. Oraldissolvingfilmsareflexible&portable.
4. Availableinvarioussize&shapes.
5. Oralfilms hydrate&dissolvesinthebuccalcavitywithinafra ctionofseconds.
6. Tastemasking.
7. Polymers usedshouldbenon-toxic&nonirritant.
8. ODF'ssmallinsizefor improvedpatientcompliance.
9. Easeofhandling&transportation.
10. Noriskofchocking.
11. Rapidonsetofaction.
12. Itcanbeusedtoavoidfirst-passmetabolism.

Disadvantagesoforaldissolvingfilms:

1. Itis hygroscopicinnature,soitmustbekeptindryplace.
2. Packagingoffilmsrequiresspecialequipment&iti sexpensive.
3. Highdosecannotbeincorporatedintotheoralfilm.
4. Mouthdissolvingfilmsaremoisturesensitive.

II. APPLICATION OF ORAL STRIPIN DRUG DELIVERY:

1. **Topical applications:** The use of orally dissolving films may be feasible for thedeliveryofactiveagentsthatisanalgesicsoranti microbialdrugsforthecareofwound&in otherapplicationsalso.
2. **Gastroretentivedosagesystems:**Thewatersolu ble&poorlysolubleinwatermolecules of various molecular weights are contained in the orally dissolving filmformat. Dissolution of the films can be measured by enzyme or pH secretions of theGastrointestinaltract&canbepotentiallybeuse dtotreatthegastrointestinaldisorders.
3. **Diagnosticdevices:**oraldissolvingfilmsmaybel oadedwithsensitivereagenttoallowcontrolled release when exposed to a biological fluid or to create isolation barriers forseparatingmultiplereagents toenableatimedreactionwithinadiagnosticdevic e.
4. Oral mucosal delivery through buccal,sublingual & mucosal routes by the use of oralthinfilmscouldbecomepreferentialdelivery methodfortherapiesrequiringrapiddrugabsorpti on including those used to manage pain, allergies, sleep & central nervoussystemdisorders.

DIFFERENCEBETWEEN ODF& ODT:

Orallydissolvingfilms	**Orallydisintegratingtablet**
Greaterdissolutionduetolargersurfacearea	Lesserdissolutiondue tolesssurfacearea
Comparativelybetterdurable	Comparativelylessdurable
Morepatientcompliance	Lesspatientcompliancethanfilms
Lowdosecanonlybeincorporated	Highdosecanbeincorporated
Noriskofchocking	hasafearofchocking

GENERALCOMPOSITION OFFASTDISSOLVINGORALFILMS:

Ingredients	**Quantity**
API	1to30
Filmformingpolymer	45
Plasticizer	0to30
Salivastimulatingagent	2to6
Sweeteningagent	3to6
Flavors,colors,filters	Quantitysufficient

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III. MANUFACTURING PROCESS OF ORAL FAST DISSOLVING FILMS

There are several methods for producing ODF as follows;

1. **Casting and drying**

(a)solvent casting

(b)semi solid casting

2. **Exturssion**;

(a) Hot melt extrusion

(b) Solid dispersion extrusion

3. **Rolling method**

We are use solvent casting method in your research work.

Solvent-casting method

The oral films were mostly prepared by using this method. Prepared using HPMC E15.V. Glycerin was used as plasticizer. The calculated amount of polymer was dispersed in the solvent with continuous stirring using magnetic stirrer and add sweetener and flavor the homogenous solution is formed. Then add the drug solution. Then the solution was kept in sonicator degassing. Then the bubble free solution was cast. The fast-dissolving films were Kept overnight in a hot air oven for drying at 45-60°C. peel out the film and kept in desiccator till further use.

Ingredient of the Oral Dissolving Film

Sl.no	ingredient	Brand name
1	Ibuprofen	pubchem
2	HPMC E15.V	Loba chemie
3	SUCRALOSE	Splenda sucralose
4	Glycerin	Nice chemicals
5	Tween80	Loba chemie
6	peppermint	Murtela
7	Ethanol	Changshu hongsheng fine chemicals Co. Ltd

Ibuprofen

Ibuprofen issue for fever and pain treatment. Effectively alleviates pain & inflammation in condition joint pain, menstrual pain, muscle pain and toothache

HPMC E15.V

HPMC E15.V series with different viscosity grades and pectin using different drug-polymer concentrations. The films were found to be of good quality in nature dissolution, thickness, disintegrating time, folding endurance, drug content.

SUCRALOSE

Sucralose was artificial sweeting agent. The choice of flavors depends on age, tasty and liking the of the people.

Glycerin

Glycerin is a sweet clear viscous liquid with dehydration properties .it generates warm sensation and irritates mucous memnren.it is soluble in water so help to dissolved ODF.

Tween80

Tween80 is nonionic surfactant.it Is derived from polyethoxylated sorbitan and olieic acid. Tween80 used for both solubility and permeability enhancement.

Peppermint

The choice of flavors depends on age, taste and liking of the people.

Ethanol

Ethanol is a organic chemical compound, it is a simple alcohol.

Ethanol is a colorless, volatile, slightly characteristics, volatile liquid. It helps to dissolved the drug.

IV.INSTRUMENT USED FOR RESEARCH WORK

SIEVE

Sieve is a utensil consisting of a plastic or wire mesh held in a frame. Used for separation or reducing soft solid to a pulp.

PH METER

It is a scientific instrument that hydrogen-ion activity in water-based solution.

MAGNETIC STRIRRER

A magnetic stirrer is one type of mixer mainly used in laboratory. device that employs a rotating magnetic field to cause a stir bar immersed in a liquid to spin very quickly, thus stirring it.

HOT AIR OVEN

Hot air oven is a laboratory instrument that use for

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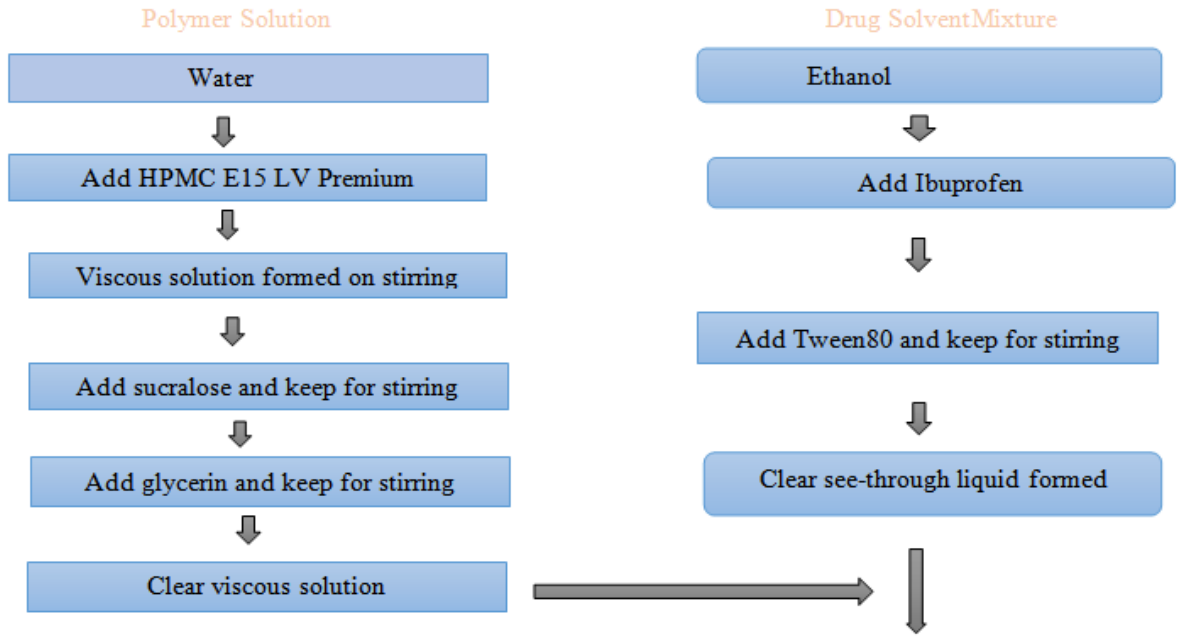
dry heat.

ELECTRONIC BALANCE

Electronic balance is a highly accurate weighing balance and scales

Code	Drug (mg)	HPMC E 15 LV Premium (mg)	Sucralose (mg)	Glycerin (mg)	Tween80 (mg)	Peppermint (ml)	Ethanol (ml)	Water (ml)
F1	200	100	15	15	0.3	0.8	Q. S	Q. S
F2	200	150	15	15	0.3	0.8	Q. S	Q. S
F3	200	150	15	20	0.3	0.8	Q. S	Q. S
F4	200	175	18	20	0.3	0.8	Q. S	Q. S
F5	200	175	18	25	0.3	0.8	Q. S	Q. S
F6	200	200	20	20	0.3	0.8	Q. S	Q. S
F7	200	200	20	25	0.3	0.8	Q. S	Q. S
F8	200	300	25	25	0.3	1.0	Q. S	Q. S
F9	200	300	30	25	0.3	1.0	Q. S	Q. S

V. METHOD



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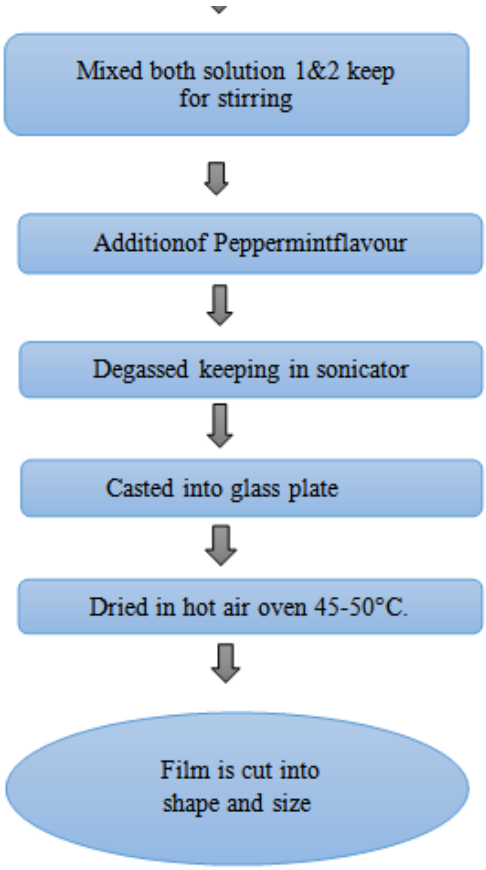

VI. EVALUATION TEST FOR ORAL DISSOLVING FILM:-

1. Thickness

The strip thickness can be measured by calibrated digital Vernier Calipers at different strategic location. At three different spots of the film was measured and average was taken by us. Thickness is essential to ascertain uniformity of film this is directly related to the accuracy of dose in the strip. The measured result is 180 mm.

2. Weight Variation

Size of is 2.5 cm2. Each film weight variation is calculated by us.

3. Folding Endurance

The film aging and aging folded at same point until get breaks. The number of times the film is folded without breaking is computed as the folding endurance value.

4. Surface pH

Taken the prepared formulation in glass plate for 30s containing water. The electrode of the pH meter in contact with surface of formulation and equilibration for one minute then pH is noted by us. The average of three determination for each formulation was done by us. 6.2 pH are measured by us.

5. Disintegration Time

The disintegration time should be 30s or less for mouth dissolving stripe. Formulation and ingredients are very depending on disintegration time. 5 to 30s are typical disintegration time for strips. There are no official guideline available for mouth disintegrating film. We are calculating the disintegration time is 26 sec.

6. Percentage Elongation

At the point when stress is applied, a stripe sample stretches and this is referred to as strain. Strain is basically the deformation of the film divided by the original dimension of the film. Generally, the flexibility of the film increase as the plasticizer content increase. Percentage elongation was calculated by measuring the increase in the length of the film.

Percentage Elongation = Increase in length of strip*100 / Initial length of strip

7. Young's Modulus

Stiffness of strip are measure by young's modulus. It is ratio of applied stress over strain in the region of elastic deformation.

Young Modulus = Slope*100 / strip thickness*cross head speed

8. Tensile Strength

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At a point the strip specimen break because the maximum stress applied this point. It is calculated by the applied load at rupture divided by the cross-sectional area of the strip as given in the equation.

Tensile Strength = load at Failure*100 / strip thickness*strip width

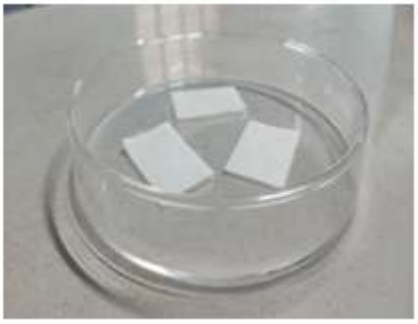
9. Swelling Property

Swelling property study is conduct to use simulated saliva solution. First weight all sample of film and placed on the preweighed stainless steel wire mesh. Collect the saliva solution in plastic container then the film sample are submerged into it. Increase in weight of film was observed until a constant weight was observed.

VII. RESULT &DISCUSSION: -

SL NO.	Thickness	Weight Variation	Folding Endurance	Surface pH	Disintegration Time
F1	0.250	18.21	99.33	6	28
F2	0.240	19.52	103.33	6.2	26
F3	0.246	18.51	98.41	6.2	26
F4	0.210	19.01	101.21	6	24
F5	0.208	19.00	101.10	6	20

The table shown in above part of the is the final result. The best product of our experiment is F5,which cleared all our experimenters with the good results and ithas the disintegration time within 20seconds which is the best of our experiment.So,we choose as the final product as F5.



Future Corresponding: -

We shall continue the experiment with more good resultsHope we can reach the best with more some time.

VIII. CONCLUSION: -

Thestudywasundertaken with an intention to develop Oral fastdissolvingfilms(OFDFs)ofIBBRUFFEN as an analgesic drug and to provide aconvenientmeansofadministrationtothose whoare suffering from difficultiesin swallowingsuch as pediatric and geriatric patients. These filmswerepreparedusingHPMCpolymersbysolventcastingmethod.

All the formulations prepared were evaluated forvariousparameterslikethickness,percentelongation,drugcontentuniformity,weightvariation,disintegrationtime,foldingenduranceandinvitrodrugreleaseand wereshowedsatisfactory results. Disintegration time of the films was increased with increase in the concentration ofthe polymer. Content uniformity study showed thatthe drug is uniformly distributed in the films. Smalldifferenceswereobservedindissolutionofdrugfromthefilmforalltheformulations.

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