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Preparation and Evaluation of Polymeric Films

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ABSTRACT:

The objective of the study was to prepare and evaluate films prepared using hydrophilic and hydrophobic polymers. The effect of plasticiser on the prepared films was also studied. Polymeric films were prepared using HPMC, PVP, PVA, and ethyl cellulose by the solvent casting method and evaluated for their physicochemical, mechanical, and performance characteristics. Plain films showed uniform appearance, acceptable thickness, non-tacky nature, and surface pH near neutrality. Hydrophilic polymer films exhibited faster disintegration and higher moisture uptake, whereas ethyl cellulose films showed better moisture resistance and higher folding endurance. Plasticization significantly influenced film properties. Glycerol improved flexibility, tensile strength, and folding endurance of hydrophilic polymer films but increased moisture uptake, particularly in PVP films. Propylene glycol enhanced mechanical strength and reduced disintegration time, though it caused tackiness and higher moisture loss in PVP films. Dibutyl phthalate effectively plasticized ethyl cellulose films, providing improved tensile strength, flexibility, and low moisture sensitivity with controlled disintegration behaviour.

Keywords: Polymeric Films, Plasticizer, Solvent Casting.

1. INTRODUCTION:

AIM: To prepare, evaluate and study the properties of various polymeric films.

OBJECTIVE:

- Preparation of hydrophilic films HPMC/ PVP/ PVA & hydrophobic film EC.
- To study the effect of various plasticizers like glycerol, propylene glycol, di butyl phthalate on prepared films.
- Evaluation of prepared polymeric films.

POLYMER

Polymer is a large molecule (macromolecule) composing of repeating structural units called monomers, which are chemically bonded together[1]. A polymer is a chain-like structure made up of many small molecules (monomers) joined together[1].They are widely used in the formulation and development of drug delivery systems because of their unique physicochemical and mechanical properties[2].Polymeric films are thin, flexible sheets made from natural or synthetic polymers. They are widely used in pharmaceutical, medical, food and packaging industries because of their light weight, flexibility, and good mechanical strength[3].

Application of polymers:

Polymers are used as

1. Binders to hold the powder particles together and provide adequate strength to tablets. Examples: PVP, HPMC[1].
2. Film-forming agents to coat tablets and capsules to improve appearance, stability, and patient acceptance[1].

3. In sustained and controlled drug delivery systems to release the drug slowly over a prolonged period of time. Examples: Ethyl cellulose, Eudragit (Poly methacrylate), HPMC[8].

4. For enteric coating to protect acid-sensitive drugs from gastric fluid and allow drug release in the intestine. Examples: Cellulose acetate phthalate, Eudragit L & S[9].

5. Disintegrants to help tablets break apart quickly after administration for rapid drug release. Examples: Cross linked PVP, sodium starch glycolate.[1]

6. As suspending agents to maintain uniform dispersion of insoluble drugs in liquid dosage forms. Examples: Tragacanth, CMC, Carrageenan.[10]

7. In transdermal drug delivery systems to control drug release through the skin. Examples: Sodium CMC, Xanthan gum.[11]

8. As emulsifying agents to stabilize emulsions and prevent separation of oil and water phases Examples: Acacia, Gelatin.[1]

9. In mucoadhesive drug delivery systems to increase the residence time of drugs at the site of absorption Examples: Carbopol, Chitosan.[12]

10. For taste masking to reduce or eliminate the bitter taste of drugs and improve patient compliance. Examples: Eudragit E, HPMC.[13]

POLYMERIC FILM: Film is a thin, flexible, and often single-layered dosage form composed of active ingredients (APIs) incorporated into a water-soluble or organic-soluble.

polymer matrix[4]. Polymeric films are thin layers of polymeric materials formulated to deliver drugs in a controlled, targeted, or improved manner[4]. These films act as drug delivery systems that can modulate drug release, improve contact with biological tissues, and enhance patient compliance compared to conventional solid dosage forms such as tablets and capsules[5].

PLASTICIZER

The plasticizer is a vital ingredient incorporated into a polymeric material to increase its flexibility, softness by reducing intermolecular forces between polymer chains. It helps to improve the film flexibility and reduce brittleness. Plasticizers improve the mechanical properties of pharmaceutical dosage forms without causing any significant chemical changes in the polymer.[19]

2. MATERIALS AND METHODOLOGY

HPMC

NATURE: HPMC is hydrophilic in nature.

CATEGORY: It is a Cellulose derivative (Semi-synthetic polymer)

SOURCE

- Cellulose is obtained from natural plant fibres such as: wood pulp, cotton linters.
- Cellulose is chemically modified using methyl chloride and propylene oxide to form HPMC.

PVA

NATURE: PVA is hydrophilic in nature.

CATEGORY: It is a Synthetic polymer.

SOURCE

- Prepared from polyvinyl acetate (PVA c)
- PVA c is produced from polyvinyl acetate monomer.
- Vinyl acetate is obtained from petrochemical sources.[10]

PVP

NATURE: PVP is hydrophilic in nature.

CATEGORY: It is a Synthetic Polymer**.**

SOURCE

- Prepared from N-vinyl-2-pyrrolidone (NVP)
- Origin of monomer NVP is derived from petrochemical raw materials.

ETHYL CELLULOSE

NATURE: Ethyl cellulose is hydrophobic in nature.

CATEGORY: It is a Cellulose derivative (Semi-synthetic polymer)

SOURCE

- Cellulose is obtained from natural plant fibres such as: wood pulp, cotton fibres.
- Cellulose is chemically modified by ethylation to produce ethyl cellulose.

Methodology:

Preparation of Different Polymeric Films (Plane films) Using Solvent Casting Method

A. Hydrophilic Polymer Film

The polymer (HPMC/PVA/PVP) was accurately weighed and dispersed in water with continuous stirring or slight heating (PVA) until completely dissolved. A measured volume of the solution was poured onto a clean Teflon-coated surface and spread uniformly using a glass rod to obtain consistent thickness. The film was dried at room temperature until complete evaporation of the solvent occurred, while being protected from dust and rapid airflow. Finally, the dried film was carefully peeled off and stored in a desiccator under controlled temperature and humidity conditions until further evaluation.

Table 1: Formulation

	HPMC	PVA	PVP
POLYMER	0.5g	1g	0.5g
SOLVENT	10 ml	10 ml	15 ml

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Figure 1: HPMC FILM

Figure 2: PVP FILM

Figure 3: PVP FILM

B. Hydrophobic Polymer Film

The polymer (Ethyl Cellulose) was accurately weighed and dispersed in 1:1 ratio of chloroform and toluene with continuous stirring or slight heating until completely dissolved. A measured volume of the solution was poured onto a clean Teflon-coated surface and spread uniformly using a glass rod to obtain consistent thickness. The film was dried at room temperature until complete evaporation of the solvent occurred, while being protected from dust and rapid airflow. Finally, the dried film was carefully peeled off and stored in a desiccator under controlled temperature and humidity conditions until further evaluation.

Table 2: Formulation

Ethyl cellulose (polymer)	0.5g
solvent	10ml

Figure 4: ETHYL CELLULOSE FILM

PREPARATION OF DIFFERENT TYPES OF POLYMERIC FILMS WITH PLASTICISIZER BY SOLVENT CASTING METHOD

A. Hydrophilic Polymeric Films

Polymer solutions were prepared by accurately weighing required quantities of HPMC/PVP/ PVA. HPMC was dispersed in cold water, PVP was dissolved in purified water, and PVA was dissolved in purified water with heating at 80–90°C under continuous stirring until clear solutions were obtained. A 5% v/v concentration of plasticizers (glycerol or propylene glycol) was then added with stirring for uniform distribution. The solutions were allowed to stand at room temperature to remove air bubbles. A measured volume was poured onto a clean Teflon-coated surface and spread evenly to form films, which were dried at room temperature until complete solvent evaporation. Finally, the dried films were peeled off and stored in a desiccator under controlled conditions until further evaluation.

Table 3: Formulation

	HPMC	PVP	PVA
POLYMER	0.5g	1g	0.5g
SOLVENT	10ml	10ml	15ml
PLASTICIZER	5%	5%	5%

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Hydrophilic Polymeric films with Plasticizers (Glycerol, Propylene glycol)

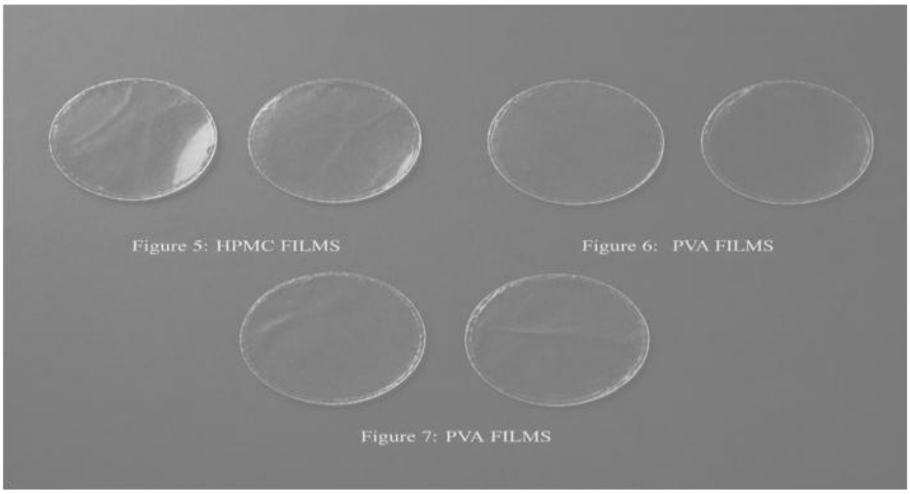

Figure 7

B. Hydrophobic Polymeric Film

The required quantity of ethyl cellulose polymer was weighed and dissolved in an appropriate organic solvent consisting of a 1:1 mixture of chloroform and toluene with continuous stirring until a transparent solution was obtained. A 5% v/v concentration of dibutyl phthalate was then added as a plasticizer with continuous stirring to ensure uniform distribution. The prepared solution was allowed to stand at ambient temperature to remove entrapped air bubbles. A measured volume of the solution was poured onto a clean Teflon-coated surface and spread evenly using a glass rod to maintain uniform thickness. The film was dried at ambient temperature until complete evaporation of the solvent, after which the dried film was carefully peeled off and stored in a desiccator under controlled conditions until further analysis.

Table 4 : Formulation

Ethylcellulose (Polymer)	0.5 g
Solvent	10 ml
Platicizer	5 %

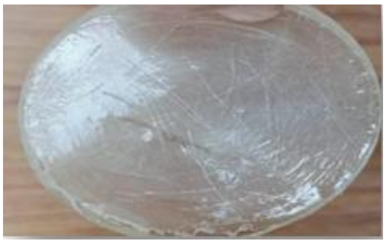

Figure 8: Hydrophobic Film with plasticizer Di butyl Phthalate

3. Evaluation of films:

1.Tack Test: A piece of a paper was pressed on a film to check the tackiness. The paper was quickly removed to evaluate how well the film adhered to the paper after brief contact.[1,2]

2. Tensile Strength: The film was cut into 2×2 cm. The film was stretched until it broke, and the time taken for breakage was recorded[3,4].

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3.Transparency: The film was placed over printed text, and the clarity and legibility of the letters were observed. Place the film over printed text and observe the clarity and legibility of the letters. Transparency is graded visually based on how clearly text can be read through the film[5].

4.Thickness: The thickness of the film was measured using a vernier calipers at different places.[6]

5.Weight of Film: The film was placed on a weighing balance, and the weight of film was recorded in grams.

6.Surface pH: The pH meter was calibrated using the buffer solutions (4,7&9) to avoid errors. In another beaker, 100 ml of distilled water was taken, and a film of size 2 × 2 cm was added and stirred until it dissolved completely. The pH of the film solution was then measured by placing the glass electrode into the sample solution, and the values were recorded.[8,9]

7.Percentage Moisture Lost: The fresh film was weighed to obtain the initial weight. It was then dried in a desiccator containing activated silica gel for 24 hours or until a constant weight was reached, and the final weight was recorded.[10]

$$\text{Moisture Lost (\%)} = \frac{\text{Initial Weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

8.Percentage Moisture Uptake: The dry film was weighed to obtain the initial weight. It was then placed in a desiccator containing saturated sodium chloride solution (75% RH) for 72 hours. After exposure, the film was weighed again to obtain the final weight.[10,11]

$$\text{Moisture Uptake (\%)} = \frac{\text{Final Weight} - \text{Initial weight}}{\text{Initial weight}} \times 100$$

9.Folding Adherence (Folding Endurance): A cut strip of the film was folded repeatedly at the same location until it broke. The number of folds endured before breaking was counted and recorded, and this value represented the folding endurance.[12]

10. Disintegration: The film was cut into 2×2 cm and placed in a petri dish filled with water. The time taken for the film to dissolve completely was noted.[13]

Figure 9: Tack test

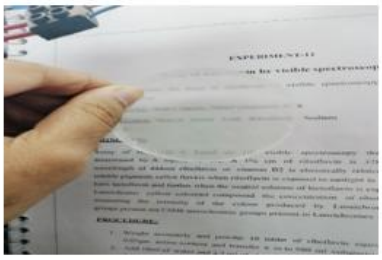

Figure 10: Transparency

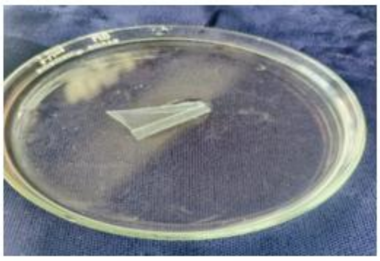

Figure 11: Disintegration

4. RESULTS AND DISCUSSION

TABLE 5: PLAIN FILMS

Evaluation test	HPMC	PVP	PVA	Ethyl cellulose
Appearance	Pale white in colour, Hard	Pale white in colour, hard	Pale white in colour, smooth	Pale white in colour, opaque
Drying time	48hours	72hours	24hours	24hours
Weight of film(grams)	0.49g	0.50g	0.44g	0.52g
Thickness(mm)	0.04mm	0.02mm	0.06mm	0.05mm
Transparency	clear	Not clear	clear	clear
Tack test	Non tacky	Non tacky	Non tacky	Non tacky
Tensile strength	<1 min	1min	2 mins	<1 min
Surface pH	7.1	6.7	6.9	6.2

Folding Endurance	182 folds	159 folds	98 folds	224 Folds
%Moisture loss	5%	3.5%	4%	3%
% Moisture Uptake	9%	8%	7%	5%
Disintegration time	< 1min	2 min	4 min	6 min (toluene)

♦ The evaluation of plain films prepared using HPMC, PVP, PVA, and ethyl cellulose showed that the type of polymer significantly influenced film properties. All films were pale white in appearance and non-tacky, indicating good uniformity and handling characteristics. Drying times varied among polymers, with PVA and ethyl cellulose films drying faster than HPMC and PVP.

♦ The weight and thickness of films were within acceptable limits, showing uniform casting. HPMC, PVA, and ethyl cellulose films were clear, while PVP films were not clear. Folding endurance and tensile strength results indicated good mechanical properties, with ethyl cellulose and HPMC films showing better flexibility and strength.

♦ Surface pH values were near neutral, suggesting suitability for pharmaceutical use. Moisture uptake was higher in hydrophilic polymers, especially HPMC, whereas ethyl cellulose showed lower moisture sensitivity. Hydrophilic films disintegrated faster, while ethyl cellulose films showed longer disintegration time due to their hydrophobic nature.

♦ Overall, the results confirm that hydrophilic polymers are suitable for fast-dissolving films, whereas ethyl cellulose is more appropriate for films requiring higher mechanical strength and controlled behaviour.

TABLE 6: PLASTICIZED FILMS - GLYCEROL:

Evaluation test	**HPMC**	**PVP**	**PVA**
Appearance	Pale white colour, hard	Pale white colour, sticky	Pale white colour, smooth
Drying time	48hours	72hours	48hours
Weight of a film(grams)	0.65g	0.45g	0.57g
Thickness(mm)	0.02mm	0.03mm	0.02mm
Transparency	clear	Not clear	clear
Tack test	Non tacky	Non tacky	Non tacky
Tensile strength	2 mins	3 mins	2 mins 30 secs
Surface pH	6.83	6.25	6.67
Folding Endurance	220 folds	280 folds	402 folds
%Moisture loss	9.04%	9.24%	5.14%
% Moisture Uptake	11%	25%	7%
Disintegration time	5 min 30 sec	4 min	6 min

♦ The incorporation of glycerol as a plasticizer significantly improved the mechanical and flexibility properties of HPMC, PVP, and PVA films. All glycerol-plasticized films appeared pale white, with PVA films showing a smooth surface, while PVP films exhibited slight stickiness due to the hygroscopic nature of glycerol.

♦ Drying time was longest for PVP films, indicating higher moisture retention. The films showed acceptable weight and uniform thickness. Transparency was observed in HPMC and PVA films, whereas PVP films were not clear. Glycerol enhanced tensile strength and folding endurance, with PVA films showing the highest folding endurance (402 folds), indicating superior flexibility.

♦ Surface pH values were near neutral, suggesting suitability for pharmaceutical use. Moisture uptake was highest in PVP films, confirming increased water affinity in the presence of glycerol. Disintegration time was moderately increased compared to plain films, indicating improved film integrity.

♦ Overall, glycerol effectively enhanced the flexibility and mechanical strength of hydrophilic polymer films, making them suitable for pharmaceutical film formulations.

TABLE 7: PROPYLENE GLYCOL:

Evaluation test	HPMC	PVP	PVA
Appearance	Pale colour	Pale colour	Pale colour
Drying time	48hours	36hours	48hours
Weight of a film(grams)	0.50g	1.13g	0.43g
Thickness(mm)	0.02mm	0.03mm	0.02mm
Transparency	Not clear	Sticky, not clear	Not clear
Tack test	Non tacky	tacky	Non tacky
Tensile strength	2 mins	2 mins	3 mins
Surface pH	6.88	6.68	6.65
Folding Endurance	100 folds	sticky	250 folds
%Moisture loss	6.94%	14.65%	3.71%
% Moisture Uptake	7%	8.5%	8%
Disintegration time	5 min	2 min	3 min

♦ The films plasticized with propylene glycol showed acceptable physical and mechanical characteristics. All films appeared pale in colour with uniform thickness. Drying time varied among polymers, with PVP films drying faster compared to HPMC and PVA.

♦ Propylene glycol increased flexibility and tensile strength, particularly in PVA films, which showed the highest tensile strength and folding endurance. PVP films exhibited tackiness and higher moisture loss, indicating greater hygroscopicity of propylene glycol in PVP matrices. Transparency was reduced in all films, especially in PVP films.

♦ Surface pH values were near neutral, indicating compatibility with pharmaceutical use. Moisture uptake was moderate across all films. Disintegration time was shortest for PVP films, while HPMC films showed comparatively longer disintegration time.

♦ Overall, propylene glycol improved mechanical properties but increased tackiness and moisture sensitivity in PVP films, whereas PVA films demonstrated better overall stability and flexibility.

TABLE 8:

DI BUTYL PTHALATE:

Evaluation test	Ethyl cellulose
Appearance	Pale white colour
Drying time	36hours
Weight of a film(grams)	0.53g
Thickness(mm)	0.03mm
Transparency	Not clear
Tack test	Non tacky
Tensile strength	3 mins 25 secs
Surface pH	7.0
Folding Endurance	190 folds
%Moisture loss	3%
% Moisture Uptake	5%
4Disintegration time	5 min (in toluene)

♦ Ethyl cellulose films plasticized with dibutyl phthalate showed acceptable physical and mechanical properties. The films were pale white in appearance, non-tacky, and dried within 36 hours, indicating effective solvent evaporation. Uniform weight and thickness confirmed good film formation.

♦ The films were not clear, which is characteristic of ethyl cellulose films. Dibutyl phthalate significantly improved tensile strength and flexibility, as indicated by higher tensile strength (3 min 25 sec) and folding endurance (190 folds). The surface pH was neutral, suggesting suitability for pharmaceutical applications.

♦ Low moisture loss and moisture uptake values confirmed the hydrophobic nature of ethyl cellulose and the moisture-resistant effect of dibutyl phthalate. The film showed slower disintegration time in toluene, indicating good film integrity and suitability for controlled or sustained release application.

5. CONCLUSION

The study concludes that both polymer type and plasticizer selection play a crucial role in determining the quality and performance of polymeric films. Hydrophilic polymers such as HPMC and PVA are suitable for fast-disintegrating film formulations, while ethyl cellulose is more suitable for films requiring higher mechanical strength and moisture resistance. Glycerol and propylene glycol were effective plasticizers for hydrophilic polymers, whereas dibutyl phthalate was more suitable for hydrophobic polymers like ethyl cellulose. Overall, the solvent casting technique combined with appropriate polymer–plasticizer selection proved to be an effective approach for the development of pharmaceutical films with desired properties.

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