FILM COATING POLYMERS–UNDERSTANDING SYNERGY OF BLENDS ON MECHANICAL PROPERTIES OF FILMS IN AQUEOUS SYSTEM

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ARTICLE INFO	ABSTRACT
Key words: Polyvinyl Alcohol, PVA-PEG Graft Copolymer, HPMC, HPC, Mechanical Property, Tensile Strength, Young's Modulus.	Mechanical strength (of casted film) and viscosity (in aqueous media) parameters have been accessed using polymer blend of PVA: Sodium CMC; PVA: PVA-PEG; PVA: HPC and HPMC 6cP: PVA-PEG at concentration ratio's of 90:10, 80: 20, 70:30, 60:40 and 50:50 respectively. The presence of PVA and PVA-PEG polymers in a different ratios resulted in lowering the viscosity of polymer blends in aqueous solution. Similarly, the presence of PVA and PVA-PEG in polymer blend exhibited great impact on Young's Modulus and extension at break of casted film. PVA has high tensile strength and flexibility [23]. Tensile strength properties of the casted films are discussed with particular reference to Young's Modulus and Extension at break for the polymer blends.

INTRODUCTION:

Polymer is a large molecule, or macromolecule, composed of many repeated subunits. The term "polymer" derives from the ancient Greek word *polus*, meaning "many, much" and *meros*, meaning "parts", and refers to a molecule whose structure is composed of multiple repeating units, from which originates a characteristic of high relative molecular mass and attendant properties [1]. Herman Staudinger, who received the Noble Price in Chemistry in 1953, coined the term "macromolecule" in 1922 and used it about polymers [2]. The only difference between the two terms is that polymers are made of repeating units called monomers, whereas macromolecules are generally used to refer to any large molecule not just those made of repeating units. Thus polymers can be considered as subset of macromolecules. Polymers are widely used in pharmaceutical industry from centuries due to wide range of application and advantages offered by them in modern medicine [3]. Most predominantly used group of polymers are the cellulose ethers, which includes hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC) methylcellulose (MC) and acrylates. One of the main applications of these polymers is used in the manufacturing of film coating system. The film coating systems provides a physical protection to the dosage form which is depending on its mechanical characteristics and this is important to predict the stability and release property of film-coated dosage form. The selection of a polymer for coating application depends on many factors, such as polymer solubility, viscosity, film permeability and mechanical properties of film coat. In the development of a film coating system, evaluation of the mechanical properties of free films can readily characterize the fundamental properties of the coating.

The mechanical properties of polymers may range between an almost perfect elastic state (original strain recovers after removal of an applied stress) to an almost Newtonian viscous state (the deformation is permanent and the original strain is not recovered). Lever & Rhys classify the properties of film coat on the basis of their characteristic stress-strain curves (soft and weak, soft and tough, hard and brittle, hard and strong, hard and tough)[4]. Tobolsky observed in deformational behaviour (viscoelasticity behaviour), polymers may undergo different regions such as glassy, transition, rubbery, rubbery liquid and liquid [5]. The mechanical properties of such film coat are often determined on polymeric films prepared by casting or spraying techniques [6] and elucidated in terms of glass transition temperature (T_g), tensile strength, toughness, elastic or Young's modulus, minimum film forming temperature (MFT), moisture effect and plasticiser performance [7-11]. Ideally increasing the tensile strength of the coating reduces the risk of cracking and reducing the elastic modulus decreases the potential of occurrence of bridging and cracking. These properties will be influenced by environmental factors (temperature, humidity, time, and rate of stressing the polymer, pressure, stress and strain amplitude), the chemical composition of the polymer (molecular weight, crosslinking and branching, crystallinity) and the presence of diluent (plasticiser, residual solvent, additives or fillers) [12, 13].The tensile properties of HPMC films depends on the concentration of pigments (e.g., titanium dioxide); the films became more brittle as the concentration of pigments increased, as evidenced by the decrease in elongation and increase in Young's modulus [14]. Hsu et al, showed the addition of titanium dioxide to polyvinyl alcohol also resulted in a decrease in tensile strength [15]. The presence of a plasticizer in the film coating is essential to reduce the brittle properties and to achieve effective coatings of the pellets or tablets without the formation of cracks or defects. Plasticizers lower the T_g and enhance the coalescence of the colloidal polymeric particles to form a uniform homogenous film over the substrate. Rowe noted that, the average molecular weight and molecular weight distribution of polymers are important factors in the coating process since it will influence not only solution viscosity but also the mechanical properties of the final film coat [16]. For a given polymer-solvent system, the viscosity varies with the molecular weight of the polymer. During the film coating process, the film coating formulations are encountered a wide range of share rates. These range from the low values in the tubing delivering solutions to the spray gun, to values of around 300 to 20,000 s^{-1} as it passes through the spray nozzle to highly variable shear rates produced by the high-velocity atomizing air [17]. Newtonian solutions are likely to exhibit the same rheological behaviour at all stages of the coating process irrespective of the share rate encountered, whereas non-Newtonian behaviour may vary in viscosity at various stages during the coating process and different coating conditions. Most of present scientific work on mechanical properties, rheological profile of film coating system is based on the utilisation of different types of polymers either alone or in combination with other additives (plasticizer, pigments and solvent system); also commercially formulated coating system are available with either single polymer or combination of polymers at different ratios along with other additives to enhance the effectiveness of films coat for providing better protection to the pharmaceutical dosage form, however, limited data is available on mechanical properties of film coat formulated using blends of polymer in aqueous system. Therefore, present work of determination of mechanical properties (of casted film) and viscosity (of aqueous solution) is emphasized on blends of polymers to find the best ratio of polymer blends that can be used in coating system. The main objective of this work was to investigate the mechanical properties of polymer blends at different ratios in aqueous system. Two most useful assessments of polymer blends are described in this article; viscosity and tensile testing.

METHODS AND PROCEDURES

Materials:

Following polymers were used for preparation of polymer blend:

- Poly (vinyl alcohol) (PVA), Manufacturer: Nippon Gohsei

(Gohsenol GL-05FS), Lot No.: 64M52T, Viscosity: 5.3 cP.

- Polyvinyl alcohol - Polyethylene glycol graft copolymer (PVA-PEG), Manufacturer: BASF (Kollicoat IR), Lot No.: 38230468E0, Viscosity: 120cP.
- Sodium Carboxymethyl Cellulose (Sodium CMC), Manufacturer: Montello (Cellogen HP-8A), Lot No.: 2543B1, Viscosity: 43cP for 2% aqueous solution.
- Hydroxypropyl cellulose (HPC), Manufacturer: Ashland (Klucel LF), Lot No.: 4673, Viscosity: 80 cP for 5% aqueous solution.
- Hydroxypropyl methylcellulose (HPMC 6cP), Manufacturer: DOW (Methocel E6 Premium LV), Lot No.: D011G4CL02, Viscosity: 5.9 cP for 2% aqueous solution.

Preparation of Polymer Blends:

The following polymers were selected for preparation of polymer blends (PVA: Sodium CMC, PVA: PVA-PEG, PVA: HPC and HPMC 6cP: PVA-PEG) at a concentration ratio of 90:10, 80: 20, 70:30, 60:40 and 50:50 respectively. Selected polymers were blended by first weighing the polymer having higher ratio and then followed by another polymer having lower ratio. The two are blended using domestic blender for 10 min duration. The complete system is in dry form with no liquids in the formula.

Determination of Viscosity of polymer blends in aqueous solution:

The solution of polymer blends was prepared in purified water at 20% solids (for PVA: PVA-PEG O) and 15% solids (for PVA: Sodium CMC, PVA: HPC and HPMC 6cP: PVA-PEG). Accurately weighed purified water in the mixing vessel, stir vigorously to form a vortex and polymer blend powder was then slowly added under stirring into the vortex. After all the powder was added, the mixer speed was reduced to nearly eliminate the vortex and mixed for 30 minutes and kept aside the solution for overnight to remove the air bubbles from the solution. Viscosity testing was performed using Brookfield Pro DV II + pro viscometer equipped with Spindle S01

(except for PVA: Sodium CMC at 50: 50 ratios, viscosity was measured using Spindle S05) and temperature of the solution was maintained at 25ºC (±0.5). The rpm of spindle was maintained at a different speed level during determination of viscosity (Table 1). Viscosity of individual polymers (Sodium CMC, HPMC 6 cP, PVA-PEG, PVA and HPC) was also determined at different % solids as a control. Procedure used for preparation of solution and viscosity as mentioned above. Refer to Table 2 for details of viscosity parameters.

Determination of tensile strength

The solution of polymer blends was prepared in purified water at 20% solids (PVA: PVA-PEG for all ratios) and 15% solids (PVA: Sodium CMC, PVA: HPC and HPMC 6cP: PVA-PEG for all ratios). Films of these solutions were casted at an approximate thickness of 100 μ on glass plates with the help of a film casting knife. These casted films were allowed to dry overnight at room conditions (~ 25°C ±2°C, 65% RH ± 2% RH). The films were cut into pieces of uniform shape (75 mm x 10 mm) with the help of Dogbone cutter (RR/HCP, Ray-Ran Test Equipment, UK). Tensile strength of these casted film pieces was determined using Tensile strength tester (5942, Instron, UK). Ten samples of each type of film was tested using Instron 5942 equipment and the tensile strength properties were determined through Bluehill 3 software. In the similar way tensile testing of individual polymers (Sodium CMC, HPMC 6 cP, PVA-PEG and PVA) was also determined as a control. Tensile testing of HPC polymer alone was not determined as casting the film using this polymer did not result in satisfactory film.

RESULT AND DISCUSSION

Determination of Viscosity of polymer blends in aqueous solution

Among all polymer blends, PVA: PVA-PEG blend showed lowest viscosity as compared to that of other polymer blend. Although 20% solids solution was prepared for PVA: PVA-PEG blend as this blend showing very low viscosity at 15 % solids, whereas other polymer blends solution was prepared at 15% solids.

Also there is gradual decrease in viscosity for the polymer blend PVA: PVA-PEG from the ratio of 90:10 (viscosity: 1360 cP) to 50:50 (Viscosity: 483 cP). In case of PVA: Sodium CMC polymer blend, lowest viscosity (763 cP) was observed at (90:10 ratio). Other polymer blends HPMC 6cP: PVA-PEG and PVA: HPC showed lowest viscosity at 50: 50 ratios (725 cP) and 90:10 ratios (485 cP) respectively. Individual polymer viscosity showed lowest viscosity for PVA-PEG (155 cP at 20% solids) followed by PVA (1960 cP at 20% solids), HPMC 6cP (2220 cP at 15% solids), HPC (2060 cP at 10% solids) and Sodium CMC (8933 cP at 8% solids). These finding indicates that, the contribution of PVA and PVA-PEG resulted in lowering the viscosity of polymer blends in aqueous solution. Additionally, PVA and PVA-PEG are co-polymers which have lower chain mobility when interacting with water molecule and also act as surface active agent to reduces the surface tension of aqueous solutions and thus cumulative impact is lowering the viscosity of polymer blend [18-21]. Results of viscosity for polymer blends and individual polymers are depicted in Table 1 & 2 respectively.

Determination of tensile strength

Tensile strength measurement alone is not useful in predicting the mechanical performance of films; however, higher values of tensile strength are indicative of abrasion resistance [22].

Polymer blend PVA: PVA-PEG showed gradual decrease in Young's Modulus from the ratio of 90:10 (1304 MPa) to 50:50 (532 MPa), whereas changes in the extension at break value (40 to 60 mm) in all ratios. In case of PVA: Sodium CMC polymer blend, lowest Young's Modulus (858.32 MPa), highest extension at break (23.30 mm) was observed at 90:10 ratios. For HPMC 6cP: PVA-PEG polymer blend showed lowest Young's Modulus (1146.64 MPa) with extension at break 1.98 mm at 50: 50 ratios. Highest extension at break (16.22 mm) was observed at 90:10 ratios for PVA: HPC polymer blend with Young's Modulus 1905.15 mPa. Individual polymer showed lowest Young's Modulus for PVA (24.22 MPa) followed by PVA-PEG (87.15 MPa), Sodium CMC (2752.88 MPa) and HPMC 6cP (2877.43 MPa).

The above findings indicate that the presence of PVA and PVA-PEG in polymer blend has great impact on Young's Modulus and extension at break of casted film. PVA has high tensile strength and flexibility [23]. The presence of PVA in polymer blend at higher ratio showed higher Young's Modulus and extension at break (PVA: PVA-PEG at 90:10 ratios: 1304.02 MPa Young's Modulus and 59.20 mm Extension at break), (PVA: HPC at 90:10 ratios: 1905.15 MPa Young's Modulus and 16.22 mm Extension at break). However, in case of PVA: Sodium CMC polymer blend, the Young's Modulus increases and Extension at break decreases as the concentration of PVA is decreases in the polymer blend (at 90:10 ratios 858.32 MPa Young's Modulus and 23.30 mm extension at break and at 50:50 ratios Young's modulus increases to 2402.57 MPa and Extension at break decreases to 1.37 mm. Figure 1 and 2 represent the relationship between the ratio of polymer blends verses Young's Modulus and Extension at break respectively.

Also, the presence of PVA-PEG in HPMC 6cP, showed marginal decrease in Young's Modulus and extension at break as the concentration of PVA increases in the polymer blend. Other tensile testing properties such as Tensile stress at maximum load, Tensile strain at break, Toughness and Energy at Break was also monitored for all polymer blends and respective data represented in Table 3 to 7.

Table 1: Result of viscosity for polymer blends solution in aqueous media

Sr. No.	Blend Details			Viscosity (cP)	Spindle Number	Spindle Speed (rpm)	Torque (%)
	Polymer blend	% w/w solids	Polymer ratio				
1.	PVA:PVA-PEG	20 %	90: 10	1360	S01	3.0	40.8
2.			80: 20	1147	S01	3.0	34.4
3.			70: 30	1090	S01	3.0	32.7
4.			60: 40	628	S01	6.0	37.2
5.			50: 50	483	S01	12.0	58.0
6.	PVA: Sodium CMC	15 %	90: 10	763.3	S01	6.0	45.7
7.			80: 20	2647	S01	1.5	39.7
8.			70: 30	12383	S01	0.6	74.4
9			60: 40	17640	S01	0.5	88.2
10.			50: 50	32800	S05	5.0	41.0
11.	HPMC 6cP:PVA-PEG	15 %	90: 10	2447	S01	3.0	73.4
12.			80: 20	1550	S01	3.0	46.5
13.			70: 30	1470	S01	3.0	44.1
14.			60: 40	1060	S01	3.0	31.8
15.			50: 50	725.3	S01	6.0	43.3
16.	PVA: HPC	15 %	90: 10	485	S01	10.0	48.3
17.			80: 20	660	S01	10.0	66.0
18.			70: 30	720	S01	3.0	21.6
19.			60: 40	1387	S01	1.5	20.8
20.			50: 50	1607	S01	3.0	48.2

Table 2: Result of viscosity for individual polymersolution in aqueous media

Sr. No.	Blend Details		Viscosity (cP)	Spindle Number	Spindle Speed (rpm)	Torque (%)
	Polymer	% w/w solids				
1.	PVA-PEG	20 %	154.6	S01	30.0	45.3
2.		25 %	1930	S01	3.0	57.9
3.		40 %	32960	S05	5.0	41.2
4.	HPMC 6 cP	15 %	2220	S01	3.0.	65.4
5.	HPC	10 %	2060	S01	3.0	61.8
6.		15 %	6400	S02	3.0	48.1
7.	PVA	20 %	1960	S01	3.0	58.8
8.	Sodium CMC	08 %	8933	S01	0.6	53.6
9.		15 %	137000	S07	6.0	20.7

Figure 1: Graphical presentation of Young's Modulus for the polymer blends of different ratios
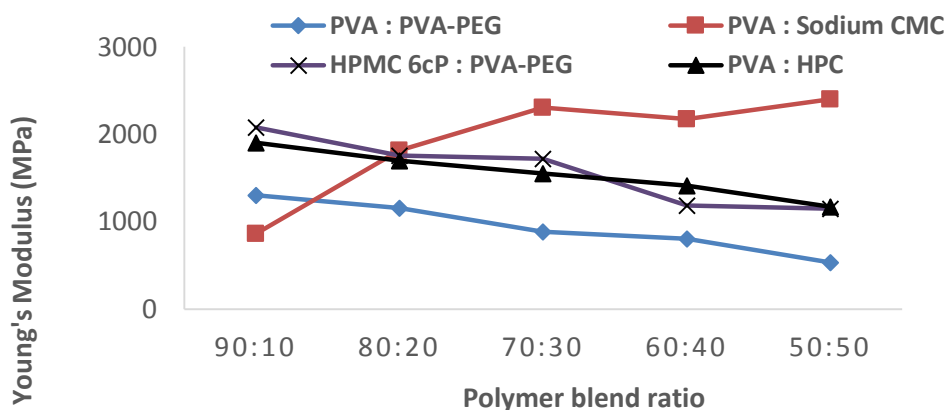

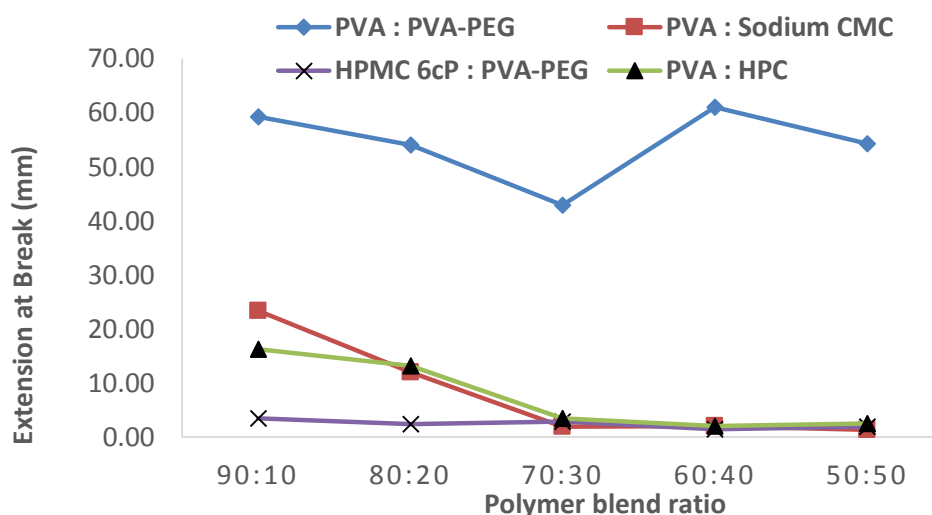Figure 2: Graphical presentation of Extension at break for the polymer blends of different ratios

Table 3: Tensile strength properties of polymer blend (PVA: PVA-PEG)

PVA: PVA-PEG combination	% w/w solids	Young's Modulus (MPa)	Tensile stress at maximum load (MPa)	Tensile strain at break (%)	Toughness (Tensile/modulus)	Energy at break (J)	Extension at break (mm)
90: 10	20 %	1304.02 ± 144.52	25.79 ± 1.85	107.47 ± 16.79	0.02002 ± 0.00	0.54207 ± 0.15	59.20 ± 9.23
80: 20		1152.87 ± 122.81	23.49 ± 1.77	97.93 ± 23.21	0.02053 ± 0.00	0.39712 ± 0.11	53.97 ± 12.76
70: 30		880.53 ± 253.52	19.64 ± 3.94	77.41 ± 28.27	0.02332 ± 0.01	0.27854 ± 0.15	42.84 ± 15.60
60: 40		802.56 ± 185.07	21.75 ± 2.62	110.48 ± 22.22	0.02828 ± 0.01	0.42261 ± 0.17	61.00 ± 12.24
50: 50		532.65 ± 190.97	16.76 ± 2.98	98.15 ± 32.06	0.03690 ± 0.02	0.24669 ± 0.08	54.29 ± 17.71

Table 4: Tensile strength properties of polymer blend (PVA: Sodium CMC)

PVA: Sodium CMC combination	% w/w solids	Young's Modulus (MPa)	Tensile stress at maximum load (MPa)	Tensile strain at break (%)	Toughness (Tensile/modulus)	Energy at break (J)	Extension at break (mm)
90: 10		858.32 ± 228.61	7.37 ± 2.03	41.84 ± 3.49	0.00857 ± 0.00	0.04005 ± 0.02	23.30 ± 1.87
80: 20		1814.14 ± 473.87	21.87 ± 2.81	21.56 ± 9.79	0.01290 ± 0.00	0.09525 ± 0.05	11.97 ± 5.45
70: 30	15 %	2302.46 ± 167.51	23.86 ± 4.41	3.51 ± 1.91	0.01043 ± 0.00	0.01759 ± 0.01	1.94 ± 1.06
60: 40		2171.68 ± 210.67	27.30 ± 1.06	3.80 ± 0.79	0.01270 ± 0.00	0.02007 ± 0.01	2.11 ± 0.44
50: 50	10 %	2402.57 ± 109.53	30.61 ± 1.58	2.48 ± 0.51	0.01276 ± 0.00	0.01345 ± 0.00	1.37 ± 0.28

Table 5: Tensile strength properties of polymer blend (HPMC 6cP: PVA-PEG)

HPMC 6cP: PVA – PG combination	% w/w solids	Young's Modulus (MPa)	Tensile stress at maximum load (MPa)	Tensile strain at break (%)	Toughness Tensile/modulus	Energy at break (J)	Extension at break (mm)
90: 10		2079.99 ± 319.05	27.18 ± 4.40	6.32 ± 1.46	0.01308 ± 0.00	0.02105 ± 0.01	3.48 ± 0.81
80: 20		1753.74 ± 109.54	32.28 ± 2.59	4.31 ± 0.91	0.01848 ± 0.00	0.01779 ± 0.01	2.38 ± 0.50
70: 30	15 %	1719.87 ± 111.40	35.48 ± 1.59	5.33 ± 1.04	0.02068 ± 0.00	0.02704 ± 0.01	2.93 ± 0.57
60: 40		1185.02 ± 77.51	19.00 ± 1.96	2.76 ± 0.59	0.01605 ± 0.00	0.00722 ± 0.00	1.52 ± 0.32
50: 50		1146.64 ± 224.61	21.33 ± 5.18	3.59 ± 1.17	0.01847 ± 0.00	0.01221 ± 0.01	1.98 ± 0.64

Table 6: Tensile strength properties of polymer blend (PVA: HPC)

PVA: HPC combination	% w/w solids	Young's Modulus (MPa)	Tensile stress at maximum load (MPa)	Tensile strain at break (%)	Toughness (Tensile/modulus)	Energy at break (J)	Extension at break (mm)
90: 10		1905.15 ± 313.40	23.77 ± 1.44	29.38 ± 13.89	0.01271 ± 0.00	0.16288 ± 0.11	16.22 ± 7.67
80: 20		1696.42 ± 315.29	21.19 ± 4.15	23.71 ± 22.53	0.01266 ± 0.00	0.06266 ± 0.04	13.15 ± 12.53
70: 30	15 %	1550.31 ± 370.62	19.80 ± 5.05	6.33 ± 3.25	0.01294 ± 0.00	0.02760 ± 0.02	3.49 ± 1.80
60: 40		1412.63 ± 277.94	15.01 ± 2.52	3.72 ± 2.50	0.01087 ± 0.00	0.00983 ± 0.01	2.05 ± 1.37
50: 50		1168.26 ± 148.45	15.40 ± 0.95	4.49 ± 1.80	0.01335 ± 0.00	0.01097 ± 0.01	2.48 ± 0.99

Table 7: Tensile strength properties of individual polymers

Polymers	% w/w solids	Young's Modulus (MPa)	Tensile stress at maximum load (MPa)	Tensile strain at break (%)	Toughness (Tensile/modulus)	Energy at break (J)	Extension at break (mm)
HPMC 6 cP*	15 %	2877.43 ± 350.99	57.47 ± 9.48	8.30 ± 2.45	0.01882 ± 0.00	0.04586 ± 0.02	4.59 ± 1.35
Sodium CMC+	8 %	2752.88 ± 793.24	50.74 ± 13.68	12.96 ± 2.05	0.01851 ± 0.00	0.09622 ± 0.02	7.16 ± 1.13
PVA*	20 %	24.22 ± 9.19	16.67 ± 3.06	221.77 ± 31.1	0.76414 ± 0.24	0.94581 ± 0.30	125.44 ± 17.7
PVA – PG^	25 %	87.15 ± 25.46	4.23 ± 1.53	25.18 ± 16.52	0.04832 ± 0.01	0.00646 ± 0.00	14.64 ± 9.64

CONCLUSION:

This work describes the fundamental mechanical properties of polymer blends. The viscosity of the polymer HPC, Sodium CMC and HPMC 6cP is greatly reduced when it is blended with PVA and PVA-PEG. Young's Modulus, Extension at break of the casted film is influenced by varying the ratio of PVA and PVA-PEG in polymer blends. While using polymer blends, the ultimate tensile properties of the films depend on the mechanical properties of individual polymer.

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