Zagazig J. Pharm. Sci., June 1998
Vol. 7, No. 1, pp. 111 - 120

ISSN 1110-5089

FORMULATION AND EVALUATION OF SALICYLIC ACID-KERATOLYTIC TOPICAL FILMS

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ABSTRACT

Eudragit polymeric films were investigated as a potential drug delivery system for the controlled release of salicylic acid. The effects of modification in polymeric ratio of both Eudragit RS 100 and RL 100, drug loading and nature of plasticizer on the in vitro release of salicylic acid have been examined. The films containing salicylic acid and plasticizer were cast upon plastic substrate and the in vitro release of drug from each film into a receiving medium of citrate buffer (pH 5.03) was measured. The obtained results indicated that the film containing Eudragit polymer and plasticizer affected the drug release rate and that the release followed Higuchi-diffusion model. The release rate was found to enhance with increasing Eudragit RL 100 ratio. The release rate was also found to be directly proportional to drug concentration. Salicylic acid was slowly released from Eudragit RL 100/dimethyl phthalate films and Eudragit RL 100/glycerol tributyrate films. Eduragit films plasticized with glycerol triacetate or polyethylene glycol 400 or propylene glycol produced a fast drug release. Based upon these results, a water soluble highly polar, non complexing plasticizer would tend to increase the drug release from the film. This study demonstrated the in vitro release of Salicylic acid from Eudragit polymeric film as a function of the solubility of the drug in both the polymer matrix and the receiving citrate buffer medium. The results indicated that Salicylic acid was compatible with Eudragit RL 100 as indicated by the clear and transparent formed films. Also, the characterizations of Eudragit films were conducted by IR-Spectroscopy and Differential Thermal Analysis to explore the possibility of the drug polymer interaction occurring between salicylic acid and either Eudragit RS 100 or Eudragit RL 100.

INTRODUCTION

The use of drugs dispersed in inert polymers matrixes to achieve controlled release by diffusion has received considerable attention. The method has long been favored for the preparation of sustained release tablets for oral ingestion (1). This concept has also been suggested for other uses including catheters coated with antibiotics impregnated polymers (2), prolongation of the release of ophthalmic preparations in eye administration (3), long term absorption of drugs in buccal and dermatological applications (4,5), and long acting implants (6,7).

The polymeric films are usually used as barriers in the design of controlled release devices. Additives are usually homogeneously dispersed or dissolved into the pharmaceutical film formulations. Plasticizers are usually added to polymeric films to enhance their flexibility and to reduce their brittleness. A decrease in the cumulative intermolecular forces along the polymer chains may be responsible for these changes. In order to obtain a tough but flexible film, the amounts of plasticizer and other additives must be optimized.

Donbrow et al (8) stated that whilst plasticizers are incorporated in the polymeric films to prevent embrittlement, they may cause modification of drug release profile. **Samuelov et al** (9) have shown that drug release from ethyl cellulose films could be related to the content of a water leachable plasticizer, polyethylene glycol (PEG), in the film. **Okor** (10) has shown that the inclusion of the poorly leached glycerol tributyrate in film composition could enhance the permeability of hydrophilic films only.

Eudragit RS 100 and RL 100 form water-insoluble, permeable films. They are copolymerizates based on esters of acrylic and methacrylic acids with low content of quaternary ammonium groups. The ammonium groups are present as salts, and they are responsible for the permeability of the films, which is independent of pH in the physiological region. The molar ratio of these hydrophilic components to the other neutral (methacrylic acid esters) is 1:20 for Eudragit RL (high permeability), and 1:40 for Eudragit RS (low permeability). Because of the unlimited miscibility of the two types, the permeability of the films can be adjusted for the diffusion of drugs on the basis of their solubility and the desired rate of release. To improve films properties, the addition plasticizer is recommended.

The primary objective of this work was to study the effects of drug loading, nature of plasticizer, and modification of the ratio of Eudragit RS 100 to Eudragit RL100 on the release behavior utilizing Salicylic acid (SA) as a model drug. In this study, SA not only serves as a model drug but also acts as an additive interacting with the film. The possibility of drug-polymer interactions were conducted by DSC and infrared studies to explore the drug-polymer compatibility.

Salicylic acid is not employed internally as an analgesic due to its local irritating effect on the gastrointestinal tract. It is employed externally on the skin, where it exerts a slight antiseptic action and a marked keratolytic action. The latter property makes SA a beneficial agent in the local treatment of warts,

crans, fungous infections, and certain forms of eczematoid dermatitis. SA plaster is used for the destructive effect of SA on hardened, keratinized tissue (11).

EXPERIMENTAL

Materials:

Salicylic acid and Propylene glycol (El-Nasr Co., Egypt), Glycerol triacetate, Glycerol tributyrate and Dimethyl phthalate (Merck, Germany), Polyethylene glycol 400 (BDH, England), Eudragit RS 100 and RL 100 (Rohm Pharma, Germany).

Equipments:

- Spectrophotometer, UV 1601(Shimadzu Co., Japan).
- Dissolution test apparatus, SR11 6 flask (Hanson research, USA).
- IR spectrophotometer, IR-470 (Shimadzu Co., Japan).
- Differential Thermal Analysis, Shimadzu DTA-50, equipped with a computerized data station (Shimadzu Co., Japan).

Methods:

Film preparation:

Six Eudragit films of different polymeric ratios were prepared to investigate the effect of modification in polymeric ration on SA release profile. The ratio of Eudragit RS100 to Eudragit RL100 for the six films were 10 : 0, 8: 2, 6 : 4, 4 : 6, 2 : 8 and 0 : 10. Each film was containing 50 mg SA. The films were cast from a solution containing 3% w/v Eudragit polymer, using chloroform as a solvent and a hard plastic small plates as a substrate. The solvent was allowed to evaporate for 24 h.; the film was removed from the plastic plate and air dried for 24 hr, and the drug content was calculated from the weight ratio of drug and polymer used. Complete evaporation was ensured by drying to a constant weight. The films were stored in a desiccator (anhydrous calcium chloride). For 24 hr. The Eudragit films were then removed, packed in aluminum foil.

Release Rate Determination:

Circular films (28.26 cm^2) were obtained by removal the cast films from the plastic plates. The film was weighed on an analytical balance and a thin coating of silicone adhesive was applied to a 10 x 6.2 cm glass support. The film was carefully pressed into the glass support, making sure that all edges are adhered and the lubricant does not touch the exposed surface. Silicone lubricant was superior to other solvent based adhesives due to its non-interacting compatibility with the film. In addition to its ability to maintain adhesion of the film to the glass support, its water repellence provided secondary assurance of only single surface release. When the exposed surface of film was coated with silicone lubricant, only insignificant drug release was obtained (12). The glass support was placed at an angle into the dissolution vessel containing 250 ml of citrate buffer (pH 5.03) prewarmed to 35°C. Periodic assay samples were obtained by removing the glass support, stirring the solution and pipeting a 5 ml sample. The glass support was quickly reinserted again. The dissolution vessel was kept covered throughout the run to prevent evaporation, the run was continued for at least 6 hr or until the assays indicated that complete release had occurred. At selected time intervals over 6 hr, samples of the receiving medium were removed and assayed spectrophotometrically for the released drug at 296 nm. Accumulative correction was made for the previously removed samples in determining the total amount dissolved according to the following formula:

$$C_n = C_n \text{ meas} + \frac{5}{250} \sum^{n-1} Cs \text{ meas} \quad (3)$$

where C_n meas is the spectrophotometrically measured concentration, C_n is the concentration of the n th sampling expected in the medium, **n-1** is the total volume of all samples removed prior to the sample being measured, and $C_s$meas is the total of all spectrophotometrically measured concentrations at **n-1** samples.

Compatibility and transparency study:

The transparency of five films of Eudragit RL100 plasticized with different plasticizers was determined spectrophotometrically. The plasticizers used were Glycerol triacetate (GTA), Polyethylene glycol 400 (PEG 400) , Propylene glycol (PG), Glycerol tributyrate (GTB) and Dimethylphthalate (DMPh) in a concentration of 25% w/w of the polymer. The drug concentration was 50 mg SA per each film. Strips of SA/Eudragit films plasticized with different plasticizers were mounted separatelly on the cell holder of the spectrophotometer, its wave length was set at 600 nm to measure the transmittance of the film. The air signal was used as a blank and the percentage of transparency of each tested film was determined.

Salicylic acid / Eudragit polymer interaction studies :

The infrared (IR) spectra of SA, Eudragit RS100, RL100 and loaded films were obtained individually with an IR-spectrophotometer using KBr pellets .

RESULTS AND DISCUSSION

Compatibility and transparency study :

All SA/Eudragit RL100 films plasticized with the previously mentioned plasticizers exhibited more than 90 % transparency. The high film transparency may due to the similar solubility parameters of each

plasticizer used and Eudragit RL.100 polymer, also implies that SA was molecularly dispersed in the plasticized films. The date concerning these results were depicted in Table 1.

Table (1): The percentage of transparency of Eudragit RL 100 films each containing 50 mg Salicylic acid and plasticized with different plasticizers (25 % w/w of polymer)

Plasticizers	% of Transparency
GAT	95.6
PEG 400	95.0
GTB	96.8
PG	94.6
DMPh	94.2

Effect of drug loading:

Three Eudragit RL100 films loaded with different concentrations of SA (5, 10 and 15 % w/w of dry film) were prepared to investigate the effect of drug loading on the release profile. The percentages of drug concentration were corresponding to 50, 105 and 165 mg drug per film. The volume of receiving medium (citrate buffer, pH 5.03) was adjusted for film to afford sinking conditions and to obtain a spectrophotometrically measurable samples for low drug concentrations.

The obtained results were listed in Tables 2 and 3, and graphically represented by Figure 1. From the obtained data, it could be observed that the release rate constant increased as the concentration of the drug in the film increased and when the amounts of drug released were plotted against the square root of time, a straight lines of high correlation coefficient were also obtained. These linear plots appear to indicate that the drug release from these films is diffusion controlled, and agree with Higuchi's equation.

The observed increase in the release rate constant upon increasing drug concentration in the film could be explained by assuming that matrix porosity necessary for the diffusion pathways may be due to the pores created by the dispersed drug. Therefore, increasing drug concentration in the film would result in increasing the degree of internal porosity. This would consequently increase the film area exposed to the release medium. Similar results were obtained by **Lopidus and Lordi**[14,15] who studied the release of chlorpheniramine and sodium salicylate from ethylcellulose/polyethylene glycol films. The obtained results proved that the gradual increase in drug loading caused a significant increase in the value of $t_{1/2}$ and a pronounced decrease in the values of t lag (Tables 2, 3 and Fig. 1).

Table (2): Release of Salicylic acid from Salicylic acid-Eudragit RL 100 films plasticized with triacetin at different drug concentrations.

Time (min.)	% of drug released after the following time intervals		
	5% w/w	10% w/w	15% w/w
30	21.12	25.37	27.40
60	31.20	35.08	40.17
120	44.38	49.97	55.18
180	57.53	62.47	67.70
240	62.50	72.51	80.11
300	69.31	80.18	86.47
360	77.46	88.41	95.22

Table (3): Effect of drug concentration on the release rate constant (K), half - life ($t_{1/2}$) and t lag for Eudragit RL 100 plasticized with triacetin and containing different concentrations of Salicylic acid according to Higuchi - diffusion model.

Drug % concentration (w/w of drug film)	Release rate constant (k) (% $t^{1/2}$)	Correlation coefficient (r)	$t_{1/2}$ (min.)	t lag (min.)
5	4.5604	0.989	51.12	2.760
10	4.7177	0.999	129.28	0.058
15	5.0091	0.999	266.10	0.0169

Effect of polymeric ratio:

Tables 4 and 5 showed an acceleration of the release rate constant and a decrease in both $t_{1/2}$ and t lag. This could be explained through the high degree of hydration of the more hydrophilic polymer upon immersion the films in the buffer. Increased porosity, hydrated channels formation and decreased tortuosity explain the greater hydration of Eudragit films containing higher ratios of the more hydrophilic polymer, RL100, containing higher content of quaternary ammonium groups. The existence of a linearity with high correlation coefficient between the logarithmic value of release rate constant (log k) and the fraction of the more hydrophilic polymer greatly confirms that the release of salicylic acid from Eudragit films follows Higuchi diffusion model. Similar results were obtained by **Borodkin et al** (12) who stated that there was a linear relationship between log K and fraction of hydroxypropyl methylcellulose (HPMC) in films composed of polyvinyl acetate/HPMC containing either methapyrilene or salicylic acid or pentobarbital. The obtained results were depicted in Tables 4 and 5 and graphically illustrated in Figures 2 and 3.

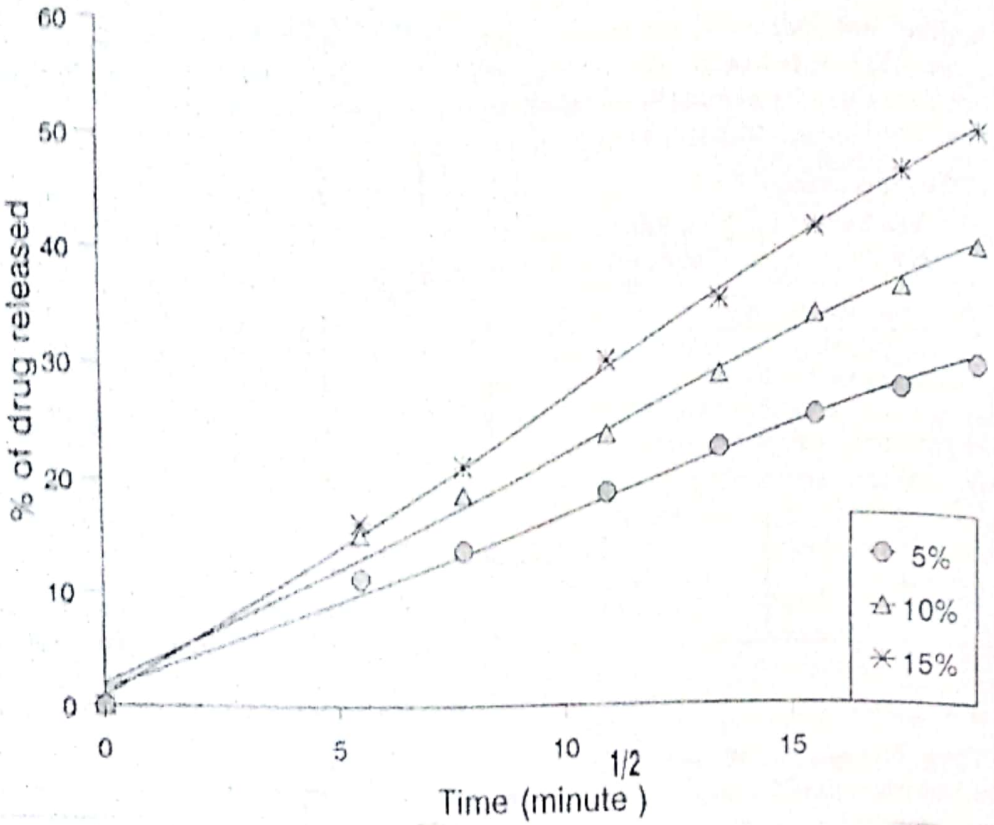

Fig. (1) : Release profile of salicylic acid from salicylic acid - Eudragit RL 100 at different drug concentrations .

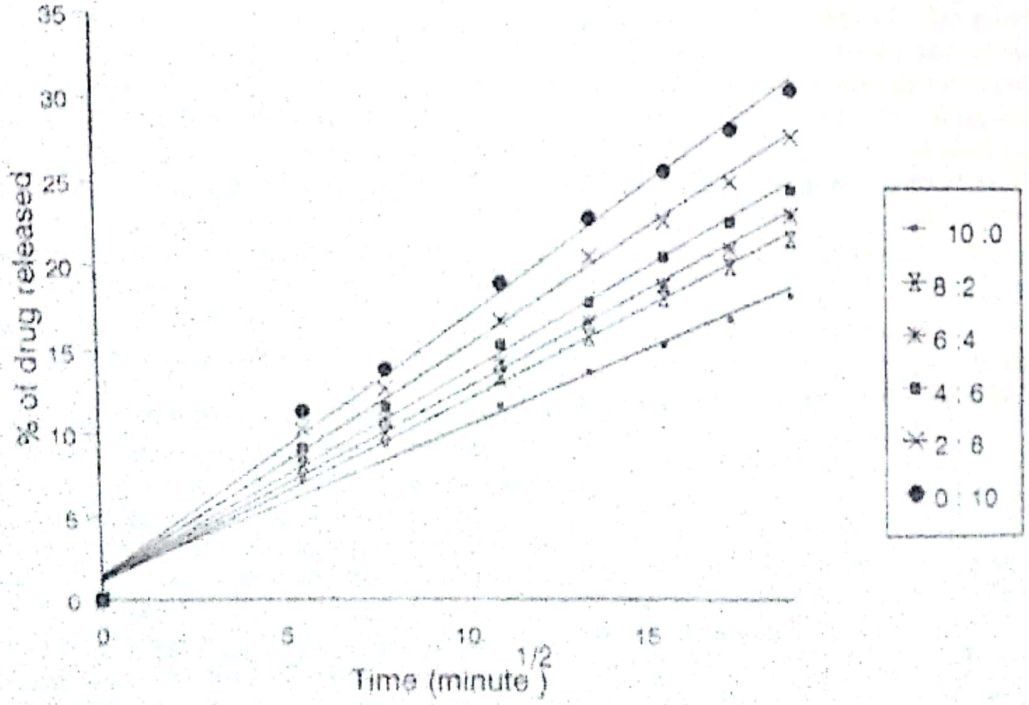

Fig. (2) : Release profile of salicylic acid from films composed of Edragit RS 100 and RL 100 at different polymeric ratios.

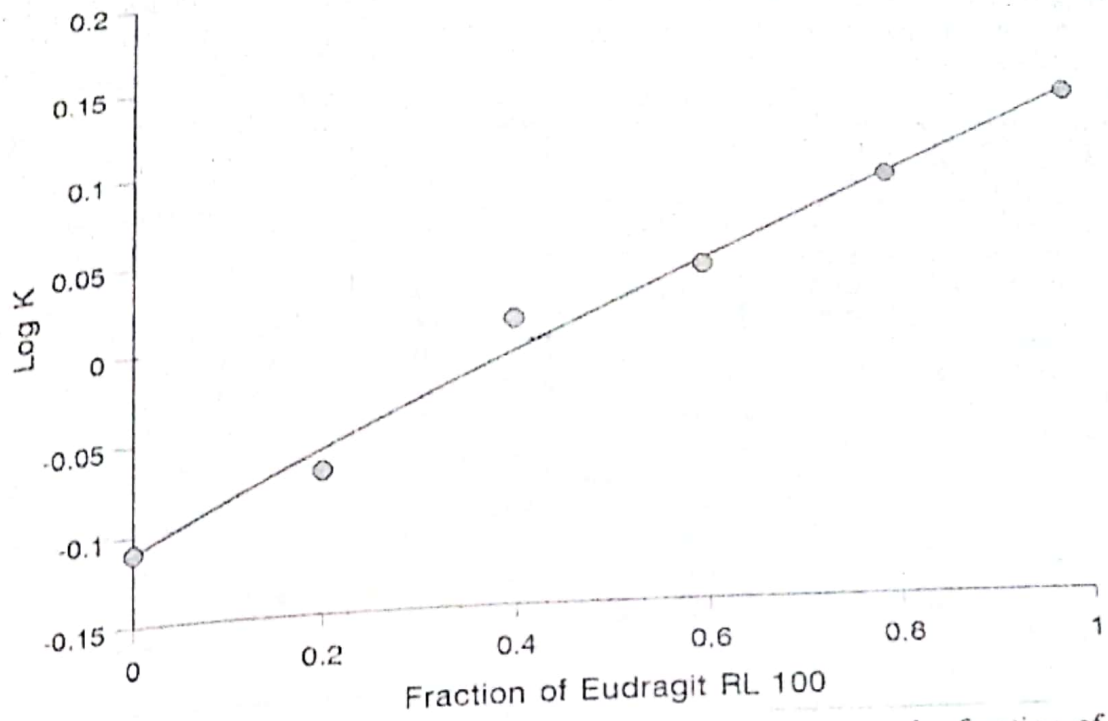

Fig. (3) : Relationship of Log K (release rate constant) to the fraction of Eudragit RL 100 for films containing 50 mg salicylic acid at different Eudragit RS 100 : RL 100 ratios.

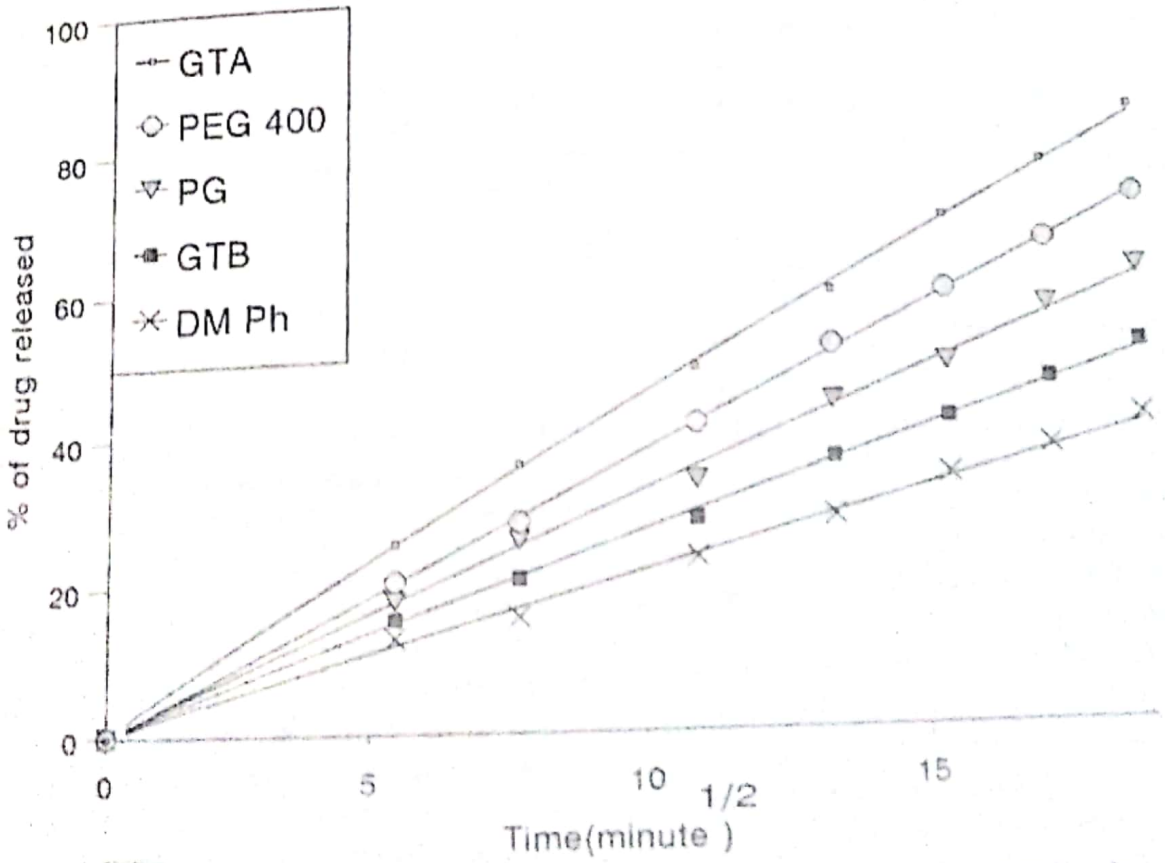

Fig. (4) : Release profile of salicylic acid from films composed of Edragit RL 100 using different plasticizers.

Table (4): Release of Salicylic acid from films composed of Eudragit RS 100-RL 100 plasticized with triacetin at different polymeric ratio.

Time (min.)	% of drug released after the following time intervals					
	RS:RL 10 : 0	RS:RL 8 : 2	RS:RL 6 : 4	RS:RL 4 : 6	RS:RL 2 : 8	RS:RL 0 :10
30	7.48	8.71	11.01	11.25	13.69	21.12
60	10.11	11.08	13.72	15.92	17.53	31.20
120	12.39	15.03	17.66	20.77	23.40	44.38
180	14.81	18.38	21.28	24.63	27.32	57.53
240	16.09	20.61	23.71	27.50	31.22	62.50
300	18.55	22.41	26.22	29.69	34.00	69.31
360	20.17	23.92	27.58	32.38	37.50	77.46

Table (5) : Effect of Eudragit RS 100 - Eudragit RL 100 ratio on Salicylic acid release rate constant (k), half-life ($t_{1/2}$) and t_{lag} for Salicylic acid films 50 mg/ film) plasticized with triacetin according to Higuchi-diffusion model.

RS100 : RL 100 ratio	Fraction of Eudragit RL 100	Release rate constant (k) (%/ $t^{1/2}$)	Log k	Correlation coefficient (r)	$t_{1/2}$ (min.)	t_{lag} (min.)
10 : 0	0.00	0.9084	-0.0417	0.997	606.20	8.39
8 : 2	0.20	1.1571	0.0634	0.999	381.86	6.26
6 : 4	0.40	1.2619	0.1010	0.999	275.51	5.33
4 : 6	0.60	1.5284	0.1842	0.998	195.18	4.69
2 : 8	0.80	1.7486	0.2427	0.999	143.18	3.45
0 : 10	1.00	4.1190	0.6148	0.998	38.32	0.03

Correlation coefficient for the relation between fraction of RL 100 per film and log K equals to 0.991

Effect of plasticizer's nature on release profile:

Five Eudragit RL100 films containing different plasticizers were prepared to investigate the effect of plasticizer's nature on SA release. The concentration of each plasticizer was 25 % w/w of polymer and each film was containing 50 mg SA. The obtained results were listed in Tables 6 and 7, and graphically represented in Figure 4. when the medicated plasticized Eudragit film were immersed in citrate buffer, two factors would be taken into consideration to explain the effect of plasticizer content on drug release profile. The first is the solubility of the plasticizer in water (i.e the probability of hydrogen bonding between plasticizer and water molecules), while the second is the extent of channels pathways through which the plasticizer will be leached throughout the polymeric matrix.

The obtained results showed that the effect of different plasticizers used can be arranged according to the effect on the rate of drug release from medicated plasticized Eudragit films in a descending order as follows: GTA > PEG 400 > PG > DMPh > GTB.

It can be concluded that GTA, PEG 400 and PG would be leached through a continuous hydrated capillary network of channels which is a major characteristic feature for all tested water-soluble plasticizers. Also, the hydrophilic nature or the solubility of the plasticizer in the release medium can be considered as an important factor in controlling this process. The effect of water-soluble plasticizers used arranged according to their hydrophilic nature into the following descending order: GTA > PEG 400 > PG.

Dimethyl phthalate (DMPh) and glycerol tributyrate (GTB) were investigated in this study as water-insoluble plasticizers. Upon diffusion of the buffer inside the film, SA would diffuse through the hydrated voids created by those water-insoluble plasticizers. This may explain the small amount of SA released from Eudragit films plasticized with either DMPh or GTB compared to those films plasticized with water-soluble plasticizers.

SA / Eudragit interaction studies:

IR spectra proved a pronounced confirmation about drug/polymer interactions. Figures 5 and 6 show the wavelength of some characteristi bands for SA, Eudragit RS/100, RL100 physical mixtures and SA / Eudragit film. From the Figures 5 and 6 the intensities of the characteristic bands significantly decreased in the physical mixtures and disappeared in the evaporates.

Also, the thermograms in Figures 7 and 8 showed the disappearing of the endothermic peak (at 161.75°) of SA in both the physical mixtures and evaporates. The results strongly suggest the complete molecular dispersion and incorporation of SA in Eudragit polymers.

Conclusion :

Thus, this study demonstrated the potential application of Eudragit polymeric films in both controlled drug delivery systems and in formulation of salicylic acid topical Keratolytic films. Kinetic analysis suggests that the unidirectional release of salicylic acid from these films follows a diffusion controlled granular matrix model. The rate and extent of drug release from these films can be effectively manipulated by varying the drug concentration, film composition, and choice of proper plasticizer. The study further demonstrated that the drug Polymer interaction between salicylic acid and Eudragit polymers can significantly influenced the release characteristics of salicylic acid - loaded Eudragit films.

Table (6): Release of Salicylic acid from films composed of Eudragit RL100 different plasticizers.

Time (min.)	% of drug released after the following time intervals				
	GTA	PEG 400	PG	GTB	DMPh
30	21.12	19.23	17.56	14.87	15.68
60	31.20	27.48	24.06	20.02	21.25
120	44.38	37.03	34.75	28.33	30.86
180	57.53	46.50	41.58	35.08	37.58
240	62.50	54.17	47.51	39.69	44.01
300	69.31	59.16	52.60	44.03	47.51
360	77.46	66.19	57.49	48.75	53.08

Table (7): Effect of plasticizer's nature on release rate constant (K), half-life ($t_{1/2}$) and t_{lag} for Eudragit RL 100 films each containing 50 mg salicylic acid according to Higuchi-diffusion model.

Plasticizer	Release rate constant (K) (% $t_{1/2}$)	Correltion coefficient (r)	$t_{1/2}$ (min.)	t_{lag} (min.)
GTA	4.1190	0.998	38.82	0.026
PEG 400	3.4453	0.999	51.57	5.740
GTB	2.9631	0.999	62.74	0.270
PG	2.5110	0.999	92.12	0.130
DMPh	2.7763	0.999	79.40	8.840

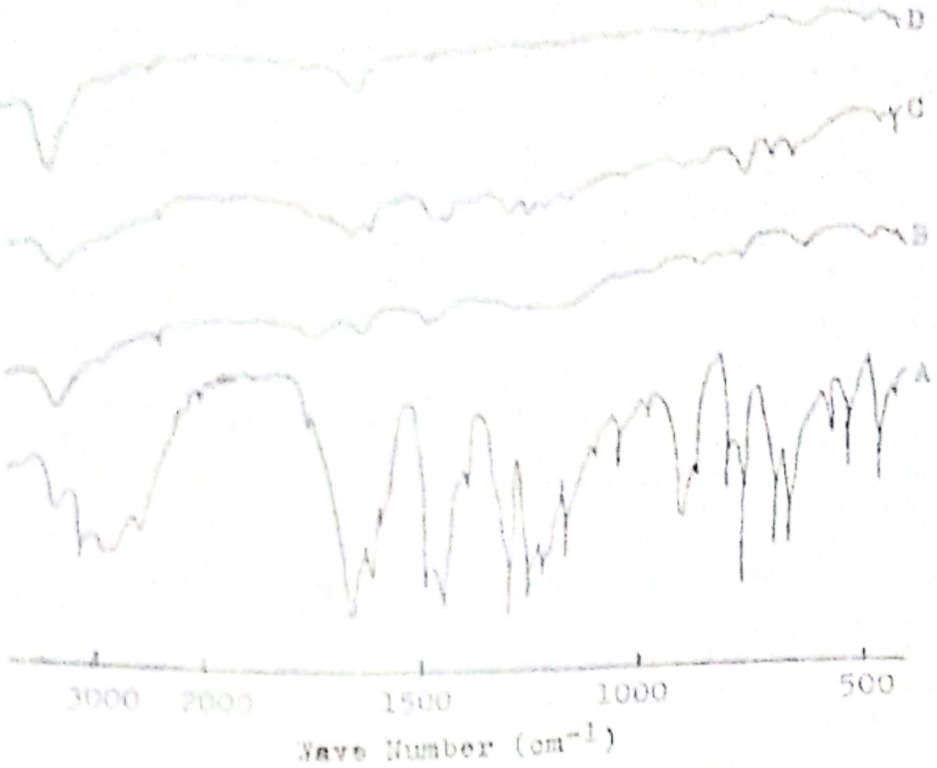

Fig. (5) : IR Spectrum of 1 : 1 w/w Salicylic acid / Eudragit RL Systems: **(A)** Salicylic acid ; **(B)** Eudragit RL ; **(C)** Physical mixture **(D)** Coevaporate .

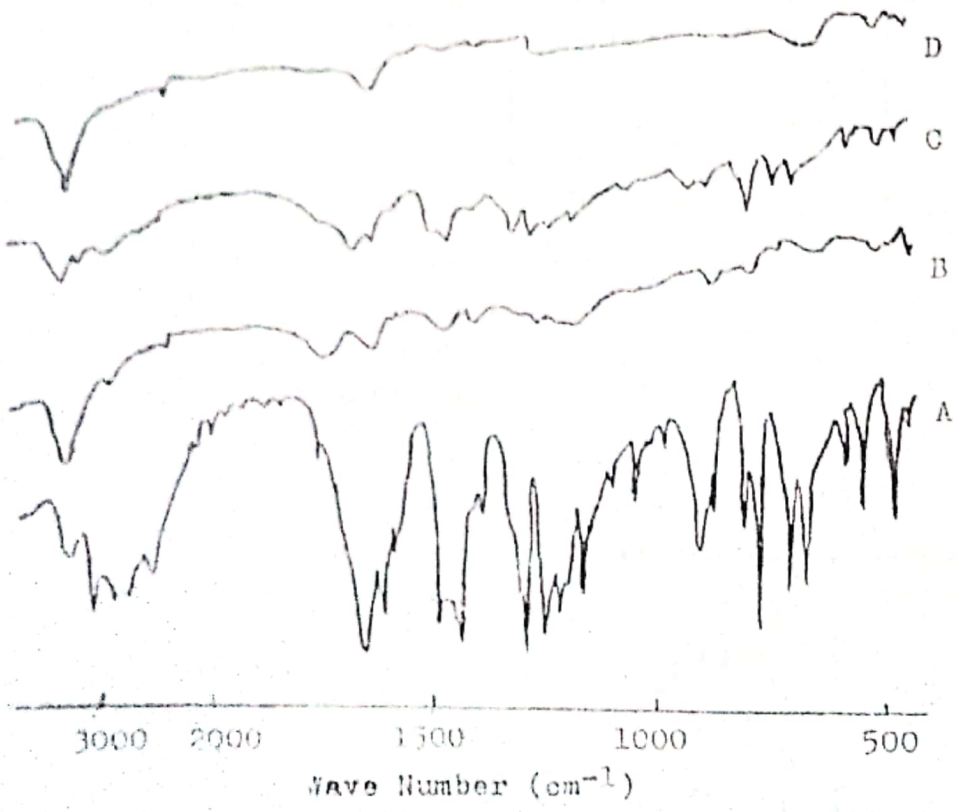

Fig. (6) : R Spectrum of 1 : 1 w/w Salicylic acid / Eudragit RS Systems: **(A)** Salicylic acid ; **(B)** Eudragit RS ; **(C)** Physical mixture **(D)** Coevaporate .

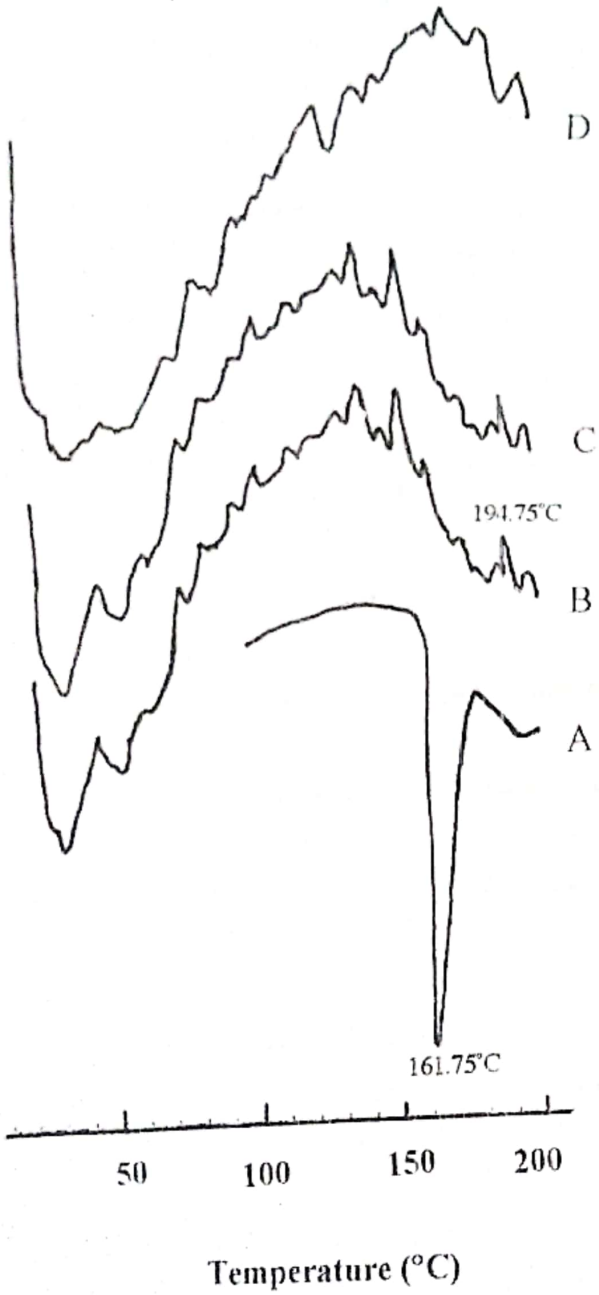

Fig. (7) : DTA thermograms of 1:1 w/w Salicylic acid / Eudragit RL Systems : **(A)** Salicylic acid; **(B)** Eudragit RL; **(C)** Physical mixture ; **(D)** Coevaporate.

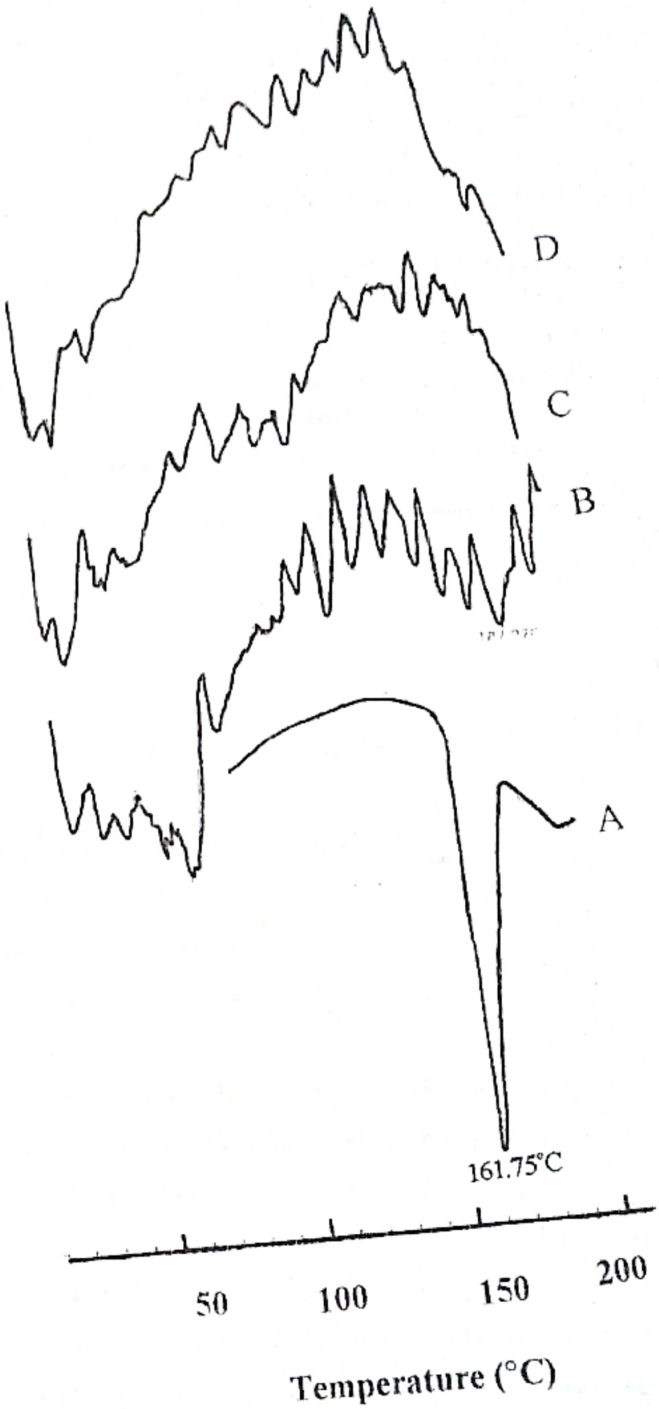

Fig. (8) : DTA thermograms of 1:1 w/w Salicylic acid / Eudragit RS Systems : **(A)** Salicylic acid; **(B)** Eudragit RS; **(C)** Physical mixture ; **(D)** Coevaporate.

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Received : April 8 , 1998
Accepted : May 15, 1998

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تمت دراسة أغشية الأيدراجيت كأنظمة حاملة للدوا ، للأنطلاق البطئ لحمض السالسليك كما تم فحص تأثير تغير نسبة البوليمر من الأيدراجيت آر - اس ١٠٠ وآيدراجيت آر - ال ١٠٠ كذلك تحميل الدوا ، وطبيعة المادة الملدنه على الانطلاق المعملى لحمض السالسليك كما أن الأغشية المحتوية على حمض السالسليك والمادة الملدنه تم صبهم فى وعاء حامل وتمت دراسة انطلاق العقار فى محلول سترات منظم الأس الايدروجينى (pH 5.03) وقد دلت النتائج على أن الأغشية المحتوية على الأيدراجيت والمادة الملدنه قد أثرت على درجة انطلاق حمض السالسليك وأن هذا الأنطلاق يتبع معادلة هيجوشى للانتشار وقد ثبت أن زيادة نسبة الأيدراجيت آر - ال ١٠٠ تؤدى إلى زيادة فى انطلاق العقار . كما أن درجة الانطلاق تتناسب تناسباً طردياً مع تركيز العقار فى الأغشية . كما أن حمض السالسليك ينطلق ببطء من الايدراجيت آر - ال ١٠٠ مع فثالات الداى مثيل وكذلك من الأيدراجيت آر - ال ١٠٠ مع ثلاثى بيوتيرات الجلسرين . وتعطى الأغشية المحتوية على الأيدراجيت مع مادة ملدنه مثل ثلاثى خلات الجلسرين أو عديد أثيلين الجليكول ٤٠٠ أو بروبيلين الجليكول سرعة فى انطلاق العقار . وأعتمادا على هذه النتائج فأن المادة الملدنه إذا كانت ذائبة فى الماء وشديد القطبية فأنها تزيد من سرعة انطلاق الدوا .

كما دلت النتائج على أن حمض السالسليك كان متوافقاً مع الأيدراجيت آر - ال ١٠٠ حيث ثبت ذلك بتكون اغشية رائقة وشفافة كما تم تحديد خواص الأغشية المتكونه من الأيدراجيت باستخدام الأشعة تحت الحمراء وكذلك تحليل التفاعل الحرارى لاثبات أى تفاعلات بين حمض السالسليك وكل من الأيدراجيت آر -اس ١٠٠ والأيدراجيت آر - ال ١٠٠ .