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Stability study of O/W emulsions using zeta potential

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Abstract

Emulsions are widely used as medicinal and cosmetic delivery systems on account of general observations that emulsified materials normally possess the properties being exhibited by its bulk components. In order to widen scope of application of the conclusions drawn, o/w emulsions covering almost all routes of administration were considered for the study. These included parenteral emulsion, oral Emulsion and topical emulsion. Zeta potential including zeta deviation and peak position, and effective particle size of the emulsions including Z-average diameter, poly dispersity index and peak position were studied using a Zeta sizer (Malvern instrument). Employing Laser Doppler Electrophoresis and dynamic light scattering technique, Zeta potential and particle size distribution of the droplet as a function of time can be determined, which was done in this paper. Zeta potential is used to study the chemistry involved in determining whether or not an emulsion will remain stable in the environment where it will be used. Hence it is very much essential. The stability of all diluted emulsions (1% v/v) of samples in milli-Q water was studied. The parameters Zeta potential, particle size and pH were measured at 1, 2, 3, 6, 8, 10, 12, 15, 20, 30, 45, 60, 75, 90 days after dilution of the emulsions by mechanical mixing. On the stability study of all these parameters it was found that topical emulsion were most stable followed by oral and parenteral.

Key Words: Zeta potential. Particle size, pH and Emulsion.

Introduction

The concept of emerging global trade and open marketing system all over the world, the fittest would service. Hence introduction of new drug quality product in the market as earliest as possible has become increasingly challenging opportunity. In case of heterodispersed system like emulsions, apart from chemical stability of the drug in the dosage form, the existence of the dosage form at least over its shelf life claim is required to be assessed in as much short time as possible once the formulation development exercise is undertaken [1].

A potential exists between the particle surface and the dispersing liquid, which varies according to the distance from the particle surface , this potential at the slipping plane is called the Zeta potential [2-3].

In recent years it has been observed that higher zeta potential does not necessarily lead to emulsion stability. The rate of decrease in zeta potential, as a matter of fact, controls emulsion stability. Increase in the rate of decay of zeta potential will reduce emulsion stability. This indicates that emulsion stability is governed by the rate with which desorption of emulgent from interfacial film takes place during ageing.

The stronger is the interfacial film, lesser would be the zeta potential decay rate & high would be the stability of emulsion. This reveals that emulsion stability is primarily governed by the strength of interfacial film. Thus it may be realized that the rate of decrease in zeta potential reflects the strength of emulsifier film [4-12].

The role of measurable properties of interfacial film such as thickness of emulsifier film is thought to be of rarely any significance in influencing strength of interfacial film. Thus practically at the moment cannot measure the strength of emulsifier film [13]. The zeta potential of the sample will determine whether the particles within a liquid will tend to flocculate (stick together) or not. Therefore, knowledge of zeta potential is useful and very effective for emulsion stability study.

To accomplish the aim of present investigation directed at, checking the suitability of marketed product over shelf- life claim, identifying the dominant forces & their interplay in emulsion stabilization, and therefore, to identify the stability indicating parameter that is expected to be most appropriate in predicting the shelf life of this class of product when subjected to long term storage.

In order to achieve the goal, perhaps no emulsified products other than those already in commercial practice seems to be most appropriate. To extend this study to diversified emulsified products, the marketed emulsions meant for oral administration, topical application & parenteral administration were chosen.

Instrumentation

I have used Zeta sizer [14], Nano Series (Nano ZS, Malvern or DLS Instrument) for the determination of zeta potential and particle size analysis, which are based on the principle of

Dynamic Light Scattering (DLS), also known as Photon Correlation Spectroscopy. It measures Brownian motion and relates this to the size of the particles. It does this by illuminating the particles with a laser and analyzing the intensity fluctuations in the scattered light and pH was determined by using pH meter.

Materials and Methods

Materials

I.V Emulsion: Intralipid^{R}; manufactured by Fresenius Kabi India Pvt. Ltd. Oral Emulsions: Cremaffin; manufactured by Abbott India Ltd and Agarol manufactured by Pfizer Ltd. Topical Emulsions: Ascabiol; manufactured by Nicholas Piramal India Ltd, B. B. Application I.P manufactured by Sisla Laboratories and Bioscab; manufactured by Unichem Laboratories Ltd. Milli Q Water (Millipore, USA)

Procurement of commercial emulsions

The fresh samples of each of the parenteral, oral and topical emulsion products were picked up from the market of their respective same batch number. The contents of all the bottles were brought together and shake gently. Each of the products was then subjected to further characterization.

To characterize the ζ potential and particle size for standard

Took all six freshly procured products, shake gently and withdrawn the 1 ml of samples in 100 ml volumetric flask and were diluted with milli Q water up to the mark. These samples were then analyzed for particle size including size distribution volume curves, Z-average diameter (nm), poly dispersity index (PDI) and peak position (nm) and zeta potential including zeta potentials distribution curve, zeta potential (mv), zeta deviation (mv) and peak position (mv), using Malvern instrument (Zeta sizer). Before the dilution of samples with milli Q water, every time pH of all the samples was noted with the help of pH meter.

Accelerated stability studies using zeta (ξ) potential and particle size

Creation of suitable Accelerated environment

All six freshly procured products were shake gently and then stored at 37^{o} C, 47^{o} C, 55^{o}C, 62^{o}C, 70^{o}C & 04^{o}C temperatures in airtight containers (iodine flask). The airtight positions of stoppers were ensured after about half an hour of elevated temperatures & at high temperatures in particular. Then sample were withdrawn at suitable time intervals of 8, 15, 30, 45, 60, 75 and 90 days were subjected to characterization for the determination of particle size, zeta potential and pH. The samples of each product being stored at each temperature were withdrawn over the protracted storage of 3 months or till the separation of oily layer at the top of the sample became conspicuous, whichever was earlier. The each sample so withdrawn was subjected to all the analysis documented under characterization in terms of zeta potential and particle size.

Preparation of Samples for stability studies

At suitable time intervals, withdrawn the 1 ml of samples of all six products in 100 ml volumetric flask and were diluted with milli Q water up to the mark. These samples were then analyzed for particle size and zeta potential using Malvern instrument (Zeta sizer). Before the

dilution of samples with milli Q water, every time pH of all the samples was noted with the help of pH meter.

Determination of zeta (ξ) potential and particle size of samples

All six freshly diluted samples were taken separately in specified cuvette and put in the ξ sizer instrument and got the ξ potential distribution curve including ξ potential (mv), ξdeviation (mv) and peak position (mv), and size distribution volume curves including Z-average diameter (nm), poly dispersity index (PDI) and peak position (nm). Each time data's were taken after stabilization of the instrument at room temperature.

Data Presentation, Treatment

The experimental observation noted from time to time for each product & stored at each temperature were pooled together, duplicates or triplicate were averaged. This would provide the glance at the changes in zeta potential, particle size distribution & pH that each product experienced. Under variable storage conditions, to quantify the profile of changes being followed graphical presentations were made involving appropriate order kinetics. From the results so summarized finally efforts were made to establish the relationship between the changes in each parameter with time at individual temperature of storage. In case of I.V. emulsion, since the particle size & PSD is the parameter crucial in concluding its suitability care was taken to follow / design the method ensuring reproducibility beyond any element of doubt.

Result and Discussion

The ζ potential and particle size for standard

The observations gathered during the periodic examination of integral features of all commercial products, representative of different routes of administration. All the parameters (ζ potential, particles size and pH) were recorded which are reported in table 1. Curves for the ζ potential and particle size of all the standard samples are reported in Fig 1-12, respectively.

ζ Potential and particle size for sample

The parameters were collected during the periodic examination of integral features of commercial products, representative of parenterally, orally and topically administered emulsion over an extended storage of as much as 3 months under variable temperature conditions are recorded which are reported in Table 2-4 and Figures are reported in Fig. 13-30.

It may be pointed out that the samples of the same emulsion, being stored at relative high temperature of 70^0c and 62^0c, were characterized much frequently with smaller time intervals such that at least 4-5 readings could be obtained before the conspicuous oil separation were noticed. This investigation was continued until emulsion broke or up to 90 days, which one was earlier.

The product seems to have broken when zeta potential was reduced below 30mv. Thus, a zeta potential decrease of a few mv below the initial value of 34-35 mv was suffered to induce oil separation. This appears to suggest that zeta potential plays hardly any role in the gross stability of this emulsion product. Particle size seems to have been gradually increased, Table 3. At all storage temperatures, particle size tended to increase whereas zeta potential appeared to exhibit

decreasing trend. The changes in the pH of this product under variable temperature storage are recorded in Table 4. It was noticed that rise in pH appear to have taken place for first 15 days. In case of the product maintained at 70^0C, only sustained decrease in pH was observed. At 4^0C, the pH also seemed to remain consistently the same.

Cremaffin emulsion produced oil separation at the end of about 2 months storage at remaining all elevated temperature storage at 55^0C, 62^0C as well as 70^0C which exhibited as low zeta potential as 5-8mv.

There was general tendency of decrease in pH, which grossly increased with the elevating temperature storage conditions. This may be attributed to the description of less basic emulgent from o/w interface and/or the breakdown of the alkaline component of emulsion present in the aqueous phase to relatively more acidic degradation product.

The commercial product, Agarol has been seen the average zeta potential varied from -26.9mv to 28.2mv with the corresponding mode values of 32.6mv and 28.2mv. It concluded that Agarol emulsion for oral purpose exhibit the electrical charge corresponding to 27.55±10.50mv. Such a widely varying zeta potential with non uniform distribution of charges about mode perhaps indicate the poor formulation with respect to long term shelf storage physical existence of the product. Because of non-suitability of instrument for the product having size-exceeding 6µm,no definite conclusion could be drawn about the changes in the property of this product, although it may be said that stable samples of the products being stored at 4^0C, 37^0C and 47^0C maintain the particle size distribution within close range.

Agarol emulsion during early characterization had the acidic pH of 4.76 units. The remarkable difference in pH of this (Agarol) and previously studied (Cremaffin) emulsions, in spite of the fact that the both were derived from emulsification of light liquid paraffin, may well be attributed to the presence of hydrated magnesium oxide.

Three topical products included are Ascabiol, Bioscab and B.B.Application. The results of investigations on these products directed to their physical stability aspects being carried out in the manner analogous to those conducted on previous two categories of the products were discussed.

Homogeneity of the charge distribution on one hand suggests that the product would be satisfactory in terms of physical stability. But quite a broad standard deviation values ranging from 17.6-27.0 mv with the average of 22.3mv appears to suggest that the product is not of exceptional quality with respect to its existence in the form prepared.

The benzyl benzoate emulsion exhibited the average particle size of 2.93µm. While reported value seen to have correctly displayed in size distribution, the same appears not to have an extended particle size distribution in excess of 2.0 µm so as to prove the correctness of the auto recorded average particle size of 2.43µm. The changes in electrical charge density existing on droplets of benzyl benzoate in Ascabiol marketed product have been recorded which may be noticed that the product sample maintained at elevated temperatures above 50^0C, exhibited the

breaking phenomenon while maintaining zeta potential at the level 82-85 mv (which were all in excess of initial value of 70.55 mv).

In the last product of this series was found that the product having poor surface charge distribution maintained the same during the storage independent of whether they broken or not. This does not indicate any role of zeta potential in the stabilization of this emulsion.

Tab 1: Zeta Potential, particle size and pH of standard samples.

S. No	Formulation	Product	Zeta potential (avg)		Particle size (avg)			pH (avg)
			(mv) ±zeta deviation	Peak position (mv)	Z-Avg dia. (nm)	PDI	Peak position (nm)	
1.	I.V Emulsion	Intralipid	-34.45±8.115	-34.45	328	0.194	351	4.43
2.	Oral emulsion	Cremaffin	-11.7±5.625	-11.7	4205	0.531	1785	10.11
		Agarol	-27.55±10.5	-30.4	7550	0.288	3410	4.76
3.	Topical Emulsion	Ascabiol	-70.55±22.3	-70.25	2930	0.690	833.5	8.38
		Bioscab	-42.95±10.6	-45.85	4500	1.00	470.5	4.64
		B.B Application	-25.8±12.5	-28.3	7835	0.26	3575	7.36

B. B. -Benzyl Benzoate

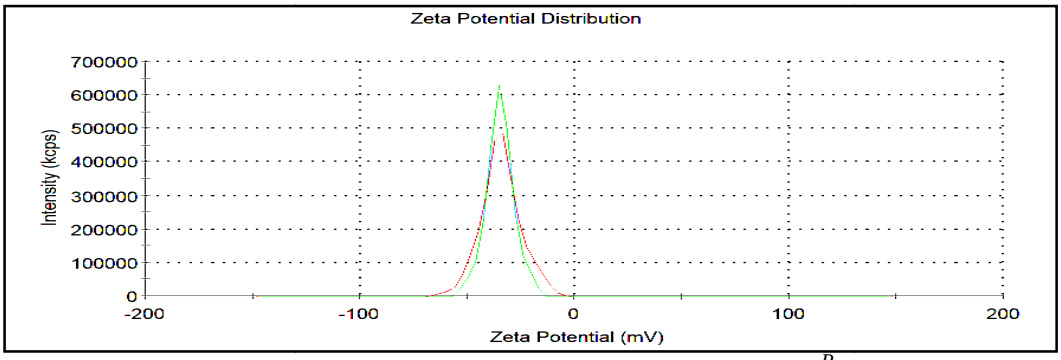

***Fig. 1**: Zeta Potential Distribution of Intralipid*^{R}

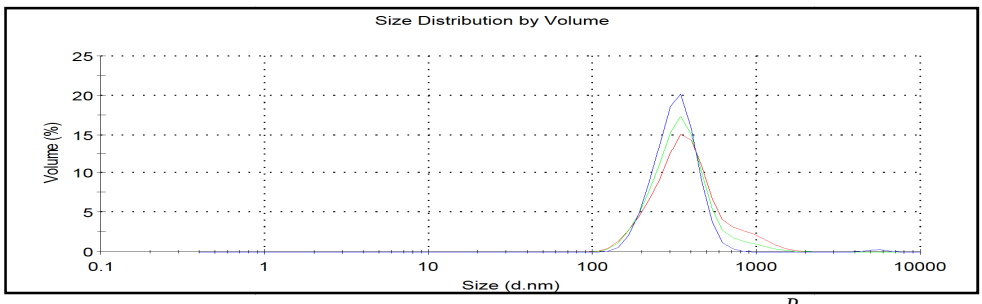

***Fig. 2**: Volume % Size Distribution of Intralipid*^{R}

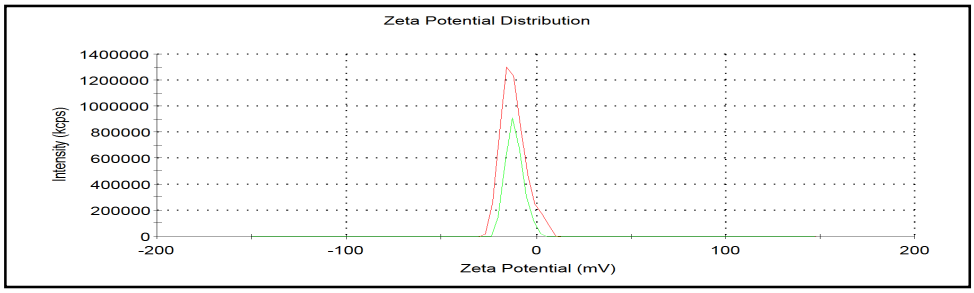

***Fig. 3**: Zeta Potential Distribution of CREMAFFIN.*

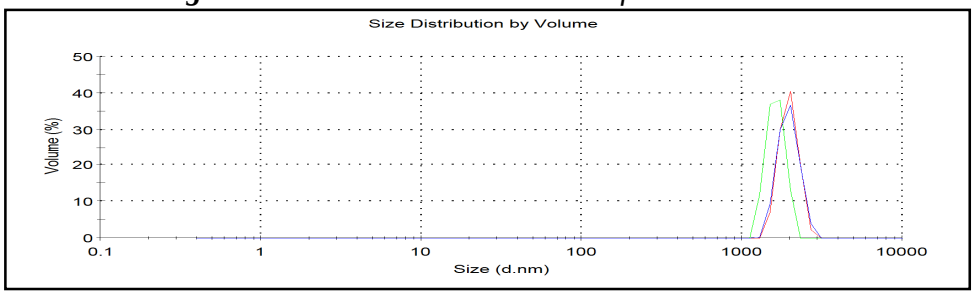

***Fig. 4**: Volume % Size Distribution of CREMAFFIN.*

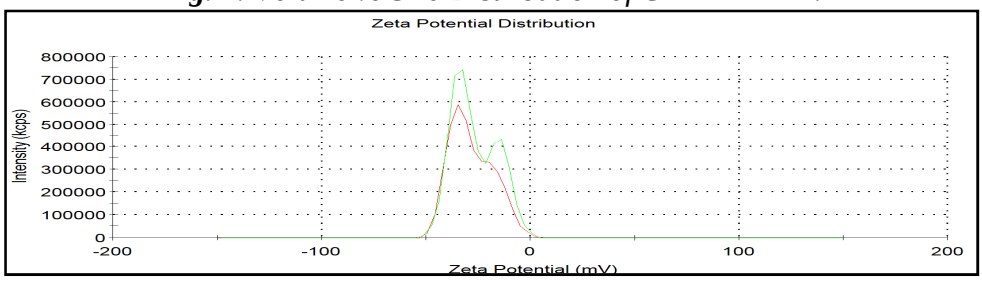

***Fig. 5:** Zeta Potential Distribution of AGAROL.*

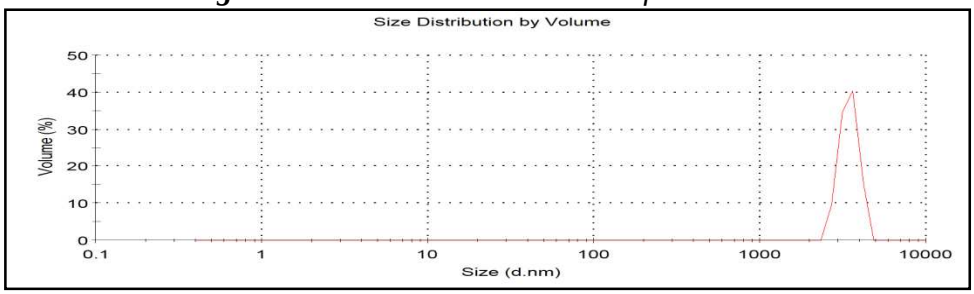

***Fig. 6**: Volume % Size Distribution of AGAROL.*

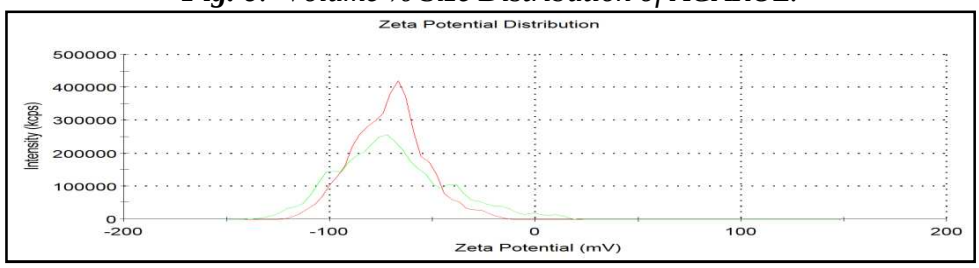

Fig. 7: Zeta Potential Distribution of Ascabiol.

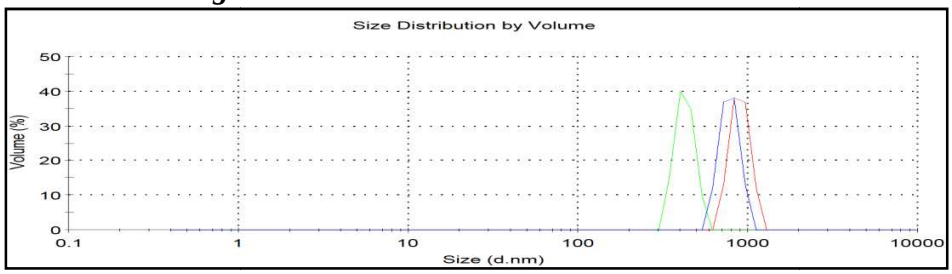

Fig 8*. Volume % Size Distribution of Ascabiol.*

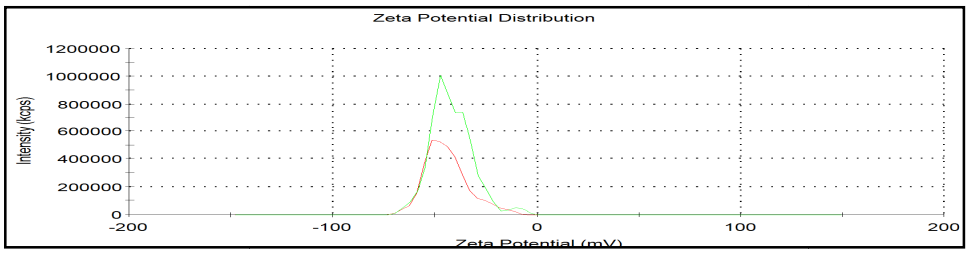

Fig. 9*: Zeta Potential Distribution of bioscab*

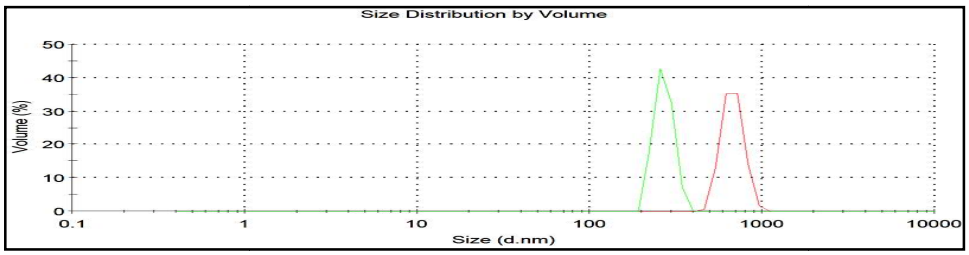

Fig. 10: *Volume % Size Distribution of bioscab.*

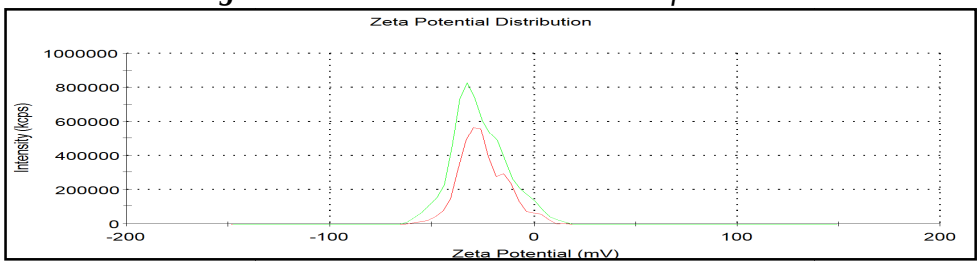

Fig. 11*: Zeta potential distribution B.B. application.*

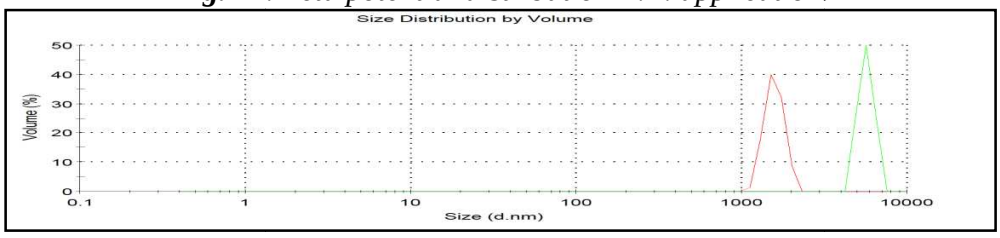

Fig. 12: *Volume % Size Distribution of B.B. application.*

__Tab 2__: Zeta Potential (mv) of samples on ageing under variable storage conditions

Days		1	2	3	4	6	8	10	12	15	20	30	45	60	75	90
Intra Lipid at accele rated Temp (^{0}C)	37	-	-	-	-	-	24.15	-	-	25.65	-	28.70	-	-	-	-
	47	-	-	-	-	-	21.30	-	-	39.10	-	26.50	-	-	-	-
	55	-	-	-	-	-	29.60	-	27.05	25.50	23.95	-	-	-	-	-
	62	-	27.20	-	30.60	36.90	21.00	37.70	36.10	27.35	29.00	-	-	-	-	-
	70	21.40	24.00	21.20	22.00	24.45	28.40	28.20	-	-	-	-	-	-	-	-
	4	-	-	-	-	-	28.00	-	-	19.45	-	24.90	26.00	22.70	30.70	32.20
Crema ffin at accele rated Temp (^{0}C)	37	-	-	-	-	-	8.01	-	-	11.50	-	9.69	8.42	9.34	9.99	11.70
	47	-	-	-	-	-	8.56	-	-	10.40	-	10.11	8.89	8.53	13.79	11.20
	55	-	-	-	-	-	7.33	-	-	12.50	-	9.67	5.66	7.91	17.30	-
	62	-	-	-	-	-	9.46	-	-	9.15	-	6.23	6.24	6.53	-	-
	70	-	-	-	-	-	7.27	-	-	5.86	-	5.69	6.60	4.77	-	-
	4	-	-	-	-	-	8.31	-	-	9.30	-	6.31	9.48	9.01	10.85	11.40
Aga rol at accele rated Temp (^{0}C)	37	-	-	-	-	-	20.35	-	-	23.65	-	22.60	28.70	33.50	28.15	24.50
	47	-	-	-	-	-	26.90	-	-	22.70	-	23.90	24.65	29.25	21.70	26.00
	55	-	-	-	26.85	-	24.80	-	29.65	27.65	27.00	29.00	33.40	-	-	-
	62	-	22.75	-	27.95	-	27.50	29.50	28.55	25.55	-	-	-	-	-	-
	70	-	28.80	-	20.10	23.50	21.35	-	20.50	-	-	-	-	-	-	-
	4		-	-	-	-	25.70	-	-	20.55	-	26.20	22.50	27.25	21.86	22.00
Ascabiol At accele Rated Temp (^{0}C)	37	-	-	-	-	-	73.90	-	-	73.00	-	84.95	79.90	74.60	70.50	80.90
	47	-	-	-	-	-	65.30	-	-	76.45	-	55.45	75.30	78.00	77.25	78.90
	55	-	-	-	-	-	72.50	-	-	65.40	-	83.25	84.28	86.10	-	-
	62-	-	-	-	-	-	82.35	-	-	74.30	-	84.75	-	-	-	-
	70	-	-	-	-	-	66.20	-	-	67.95	-	82.05	-	-	-	-
	4	-	-	-	-	-	68.80	-	-	70.55	-	78.20	78.50	71.25	83.35	61.10
Bioscab At accele rated Temp (^{0}C)	37	-	-	--	-	-	39.15	-	-	32.05	-	34.30	31.35	36.50	33.90	32.35
	47	-	-	--	-	-	42.80	-	-	43.85	-	46.00	40.60	40.40	41.80	41.60
	55	-	-	--	-	-	44.40	-	-	47.55	-	43.50	43.50	42.40	-	-
	62	-	-	--	-	-	42.60	-	-	41.10	-	40.30	-	-	-	-
	70	-	-	--	-	-	41.30	--	-	39.20	--	-	-	-	-	
	4	-	-	--	-	-	45.10	-	-	44.35	-	41.35	44.40	42.40	40.50	42.80
B.Ba ppl ication at accele rated Temp (^{0}C)	37	-	-	--	-	-	20.05	-	-	24.75	-	23.80	24.00	32.60	22.60	28.85
	47	-	-	--	-	-	21.05	-	-	21.00	-	23.6	25.35	32.55	27.80	23.50
	55	-	-	--	-	-	22.15	-	-	28.65	-	28.50	25.70	-	24.20	-
	62	-	-	--	-	-	28.40	-	-	25.65	-	27.40	27.75	-	22.50	-
	70	-	-	--	-	-	22.95	-	-	28.75	-	33.95	23.40	-	-	-
	4	-	-	--	-	-	24.95	-	-	27.55	-	29.46	24.54	20.05	-	-

__Tab 3:__ Particles size of samples on ageing under variable storage conditions

Days		1	2	3	4	6	8	10	12	15	20	30	45	60	75	90
Intra Lipid At accele rated Temp (^{0}C)	37						0.51			0.40		0.51				
	47						0.37			0.34		0.47				
	55						0.35		0.41	0.42	0.40					
	62		0.44		0.47	0.33	0.47	0.33	0.40	0.43	0.47					
	70	0.47	0.42	0.41	0.50	0.48	0.43	0.60								
	4						0.45			0.45		0.41	0.31	0.26	0.32	0.36
Crema ffin At accele rated Temp (^{0}C)	37						7.02			4.38		5.27	8.33	5.36	7.07	7.68
	47						6.42			6.86		7.83	9.98	3.86	8.95	5.38
	55						6.58			7.49		7.49	3.75	5.83	3.68	
	62						9.65			5.36		6.18	8.72	2.56		
	70						5.66			6.65		7.51	7.34	6.43		
	4						4.79			8.31		4.17	5.73	2.48	5.75	7.94
Aga rol	37						8.40			8.82		8.02	5.80	5.79	5.73	5.12
	47						8.49			7.37		7.32	6.82	6.29	5.97	5.92

At accele rated Temp (^{0}C)	55				7.03		6.87		8.27	7.90	7.83	6.63	9.25			
	62		8.01		6.33		6.82	7.95	7.44	6.80						
	70		9.51		3.23	2.47	8.02		6.97							
	4						9.03			8.82		8.98	8.69	5.62	5.51	5.02
Ascabiol At accele rated Temp (^{0}C)	37						4.61			3.80		6.02	2.88	2.63	3.67	2.24
	47						4.30			2.63		7.66	4.23	2.37	2.44	2.75
	55						4.04			4.75		3.24	1.6	1.90		
	62						4.50			4.29		4.48				
	70						7.54			6.42		5.96				
	4						2.81			4.39		2.86	3.32	2.22	2.87	2.88
Bioscab At accele rated Temp (^{0}C)	37						4.57			6.87		4.98	4.47	4.75	3.32	3.05
	47						4.39			4.26		5.35	2.76	2.87	4.26	2.28
	55						6.5			6.47		6.29	4.03	3.66		
	62						6.19			4.54		6.15				
	70						6.56			4.59						
	4						4.55			4.66		4.47	2.87	4.00	4.10	3.85
B.B Application At accele rated Temp (^{0}C)	37						3.69			6.47		6.77	6.63	6.22	5.52	4.15
	47						3.36			3.34		3.95	3.73	6.85	5.13	4.42
	55						3.16			3.59		7.47	6.85		4.69	
	62						4.29			6.38		6.44	6.2		4.84	
	70						7.49			5.47		5.11	6.44			
	4						7.02			8.38		6.79	6.91	6.16		

Tab 4: *pH of samples on ageing under variable storage conditions*

Days		1	2	3	4	6	8	10	12	15	20	30	45	60	75	90
Intra Lipid At accele rated Temp (^{0}C)	37						5.77			5.55		3.34				
	47						6.27			5.71		5.42				
	55						4.04		5.35	3.93	3.02					
	62		3.04		2.90	2.86	6.25	2.69	4.03	6.23	3.96					
	70	3.96	3.6	3.63	3.60	3.04	3.89	2.90								
	4						6.05			6.00		5.80	5.61	4.03	3.25	4.40
Crema ffin At accele rated Temp (^{0}C)	37						9.35			9.96		9.53	9.77	9.36	8.95	8.78
	47						9.00			9.53		9.34	9.20	8.55	8.42	8.67
	55						9.64			9.92		9.30	9.25	8.09	8.44	
	62						9.35			9.59		9.35	9.56	7.64		
	70						9.41			9.62		9.52	9.20	8.21		
	4						10.17			9.87		9.55	9.28	9.54	9.32	9.84
Aga rol At accele rated Temp (^{0}C)	37						4.74			4.69		5.15	4.92	5.13	4.65	4.92
	47						4.73			4.70		4.53	5.55	5.65	4.57	4.90
	55				4.38		5.13		4.80	4.60	4.34	4.08	5.73			

	62		4.71		4.76		4.83	5.00	4.78	4.69						
	70		4.61		4.63	4.53	4.73		3.91							
	4						4.69			4.67		4.80	5.17	4.88	3.76	4.95
Ascabiol At accele rated Temp (^{0}C)	37						8.60			8.32		8.43	8.51	8.78	7.42	8.61
	47						7.80			8.44		7.66	8.20	7.69	5.90	8.53
	55						8.49			7.67		8.54	7.58	7.61		
	62						7.31			7.74		6.68				
	70						8.26			7.66		7.35				
	4						8.52			8.42		7.70	8.08	8.53	6.57	6.71
Bioscab At accele rated Temp (^{0}C)	37						5.63			6.74		6.46	6.73	6.28	6.97	7.48
	47						4.43			4.54		5.94	6.84	4.62	4.94	4.18
	55						4.46			3.83		2.83	2.36	2.69		
	62						2.64			2.21		3.63				
	70						2.22			5.02						
	4						4.45			4.39		4.76	7.86	2.29	3.67	3.20
B.B Application At accele rated Temp (^{0}C)	37						7.37			6.41		7.33	7.37	6.49	5.82	6.58
	47						6.05			5.76		6.27	8.19	4.55	6.05	4.99
	55						7.19			5.92		7.45	8.13		6.18	
	62						6.5			7.19		6.67	6.58		6.88	
	70						6.24			6.3		6.67	6.77			
	4						7.33			7.14		7.48	7.16	5.29		

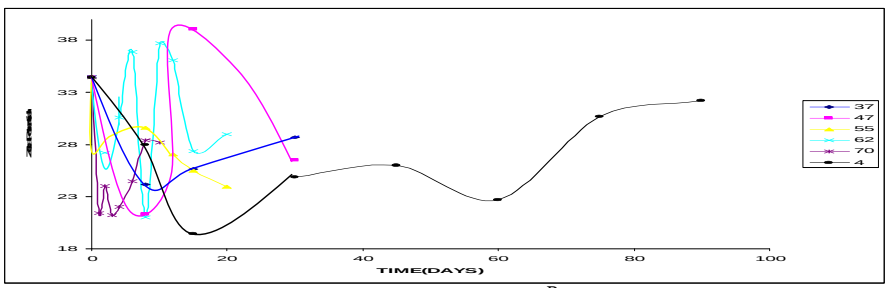

Fig.13. *Changes in Zeta Potential of INTRALIPID^R at different storage temperatures*

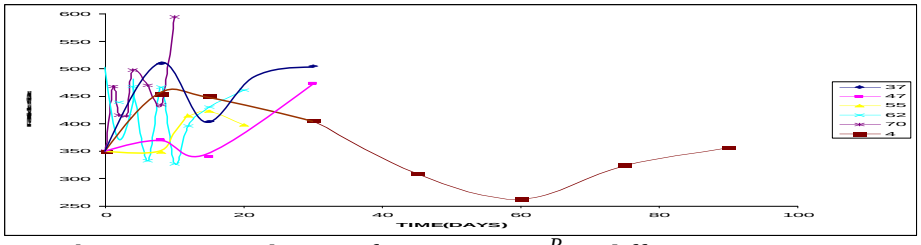

Fig. 14*: Change in Particle size of INTRALIPID^R at different storage temperatures*

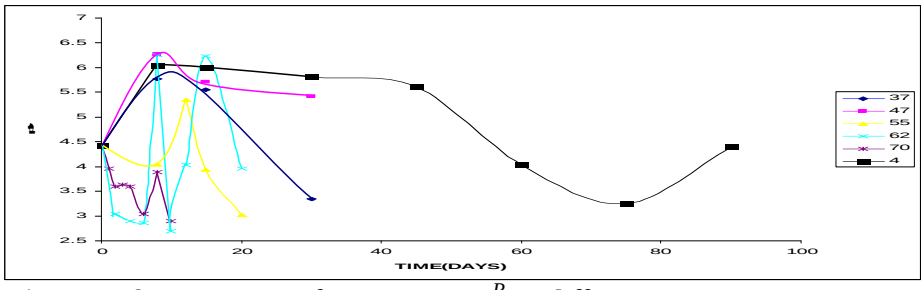

Fig. 15: *Change in pH of INTRALIPID^R at different storage temperatures*

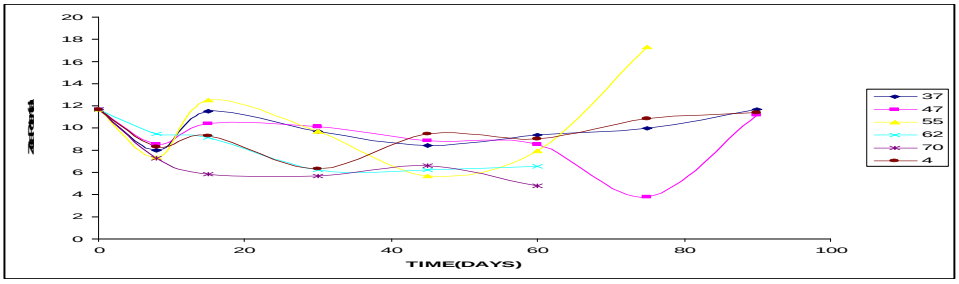

Fig. 16: *Change in Zeta potential of CREMAFFIN at different storage temperatures*

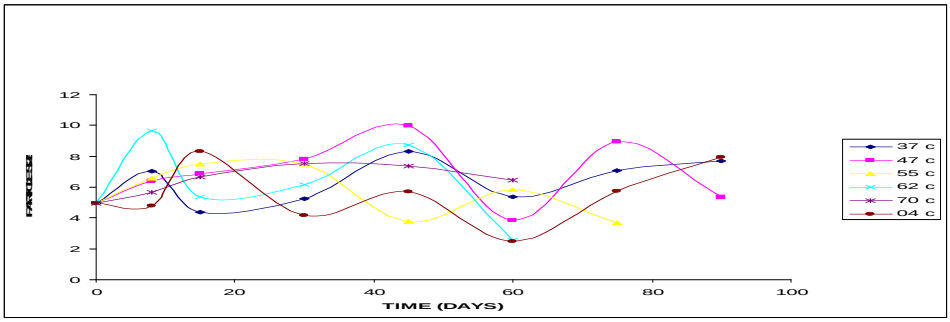

Fig. 17: *Change in Particle size of CREMAFFIN at different storage temperatures*

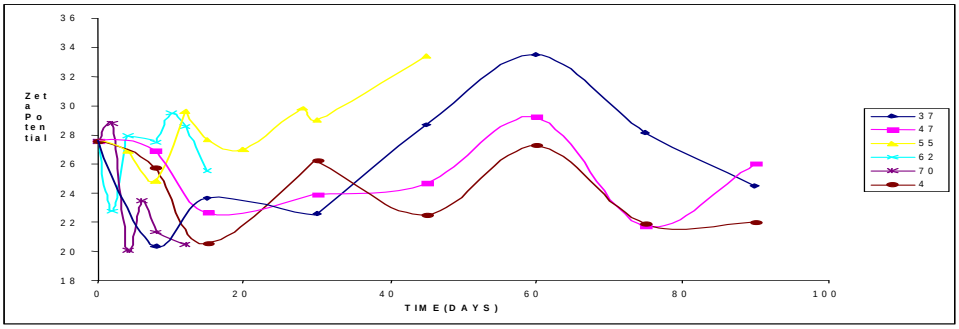

***Fig. 18**: Change in pH of CREMAFFIN at different storage temperatures*

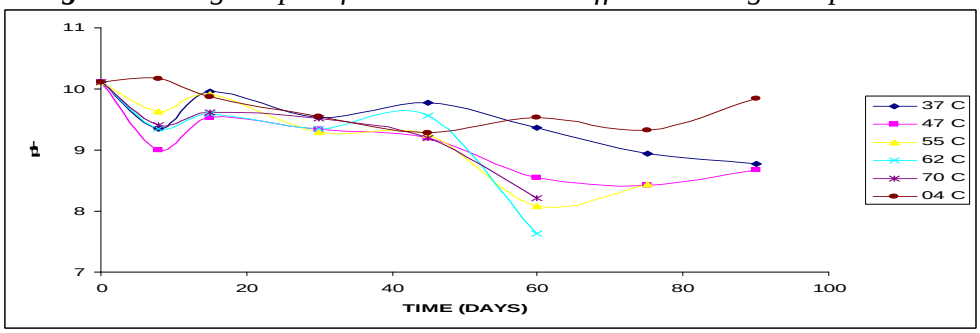

***Fig. 19**: Change in Zeta potential of AGAROL at different storage temperatures*

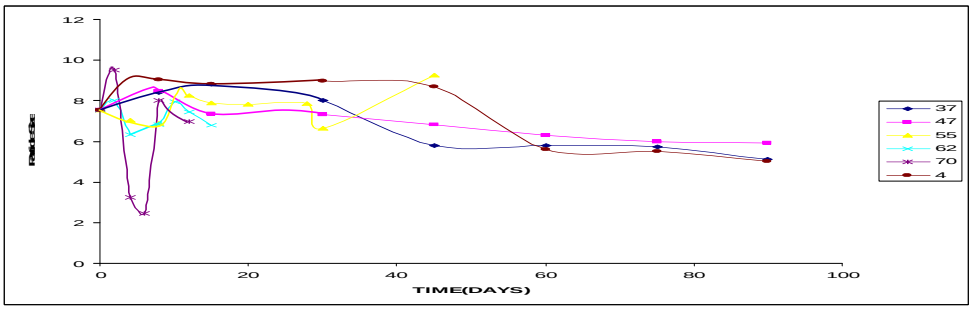

***Fig. 20:** Change in Particle size of AGAROL at different storage temperatures*

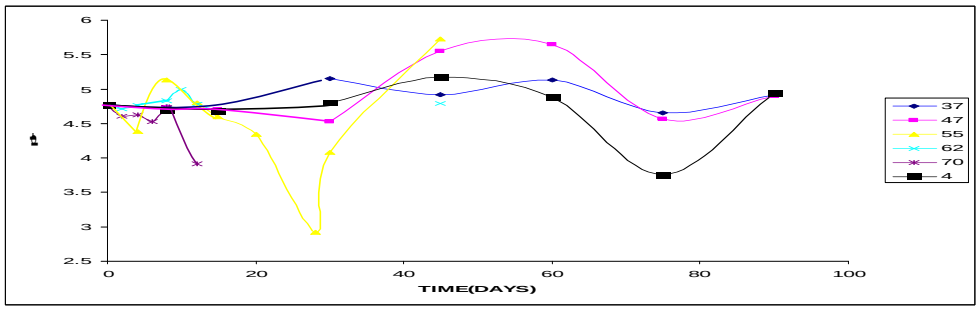

***Fig.21:** Change in pH of AGAROL at different storage temperatures*

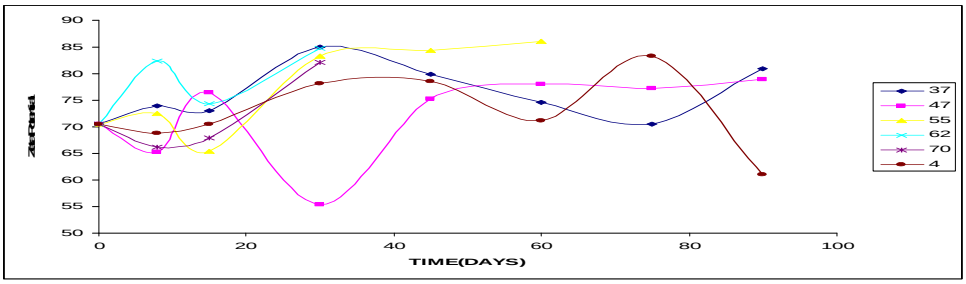

***Fig. 22:** Change in Zeta Potential of Ascabiol at different storage temperatures*

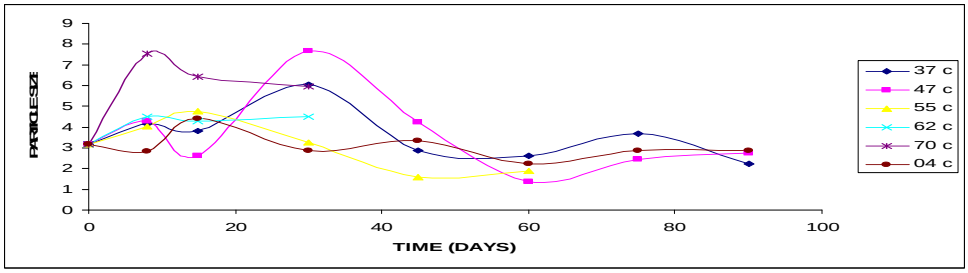

Fig. 23: *Change in Particle Size of Ascabiol at different storage temperatures*

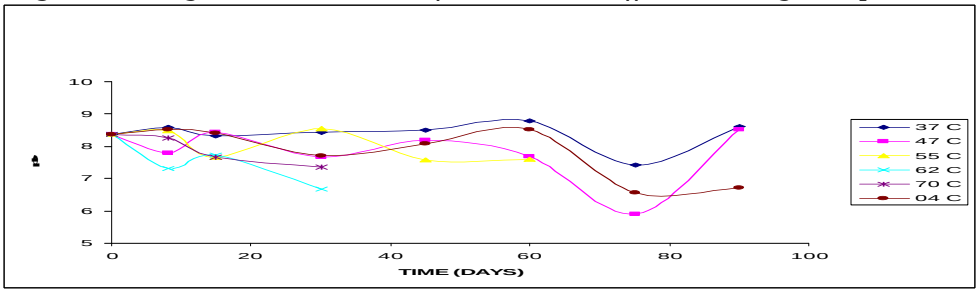

Fig. 24: *Change in pH of Ascabiol at different storage temperatures.*

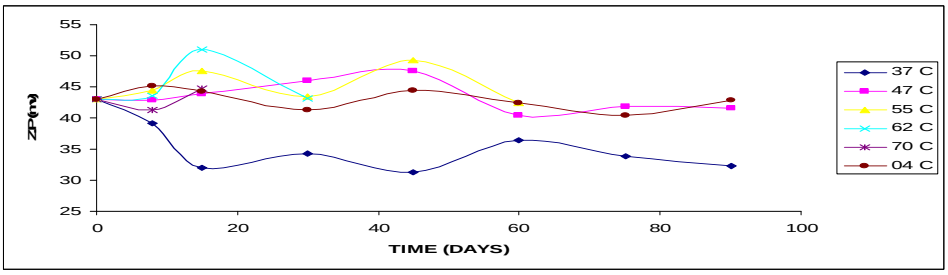

Fig. 25: *Change in Zeta Potential of Bioscab at different storage temperatures*

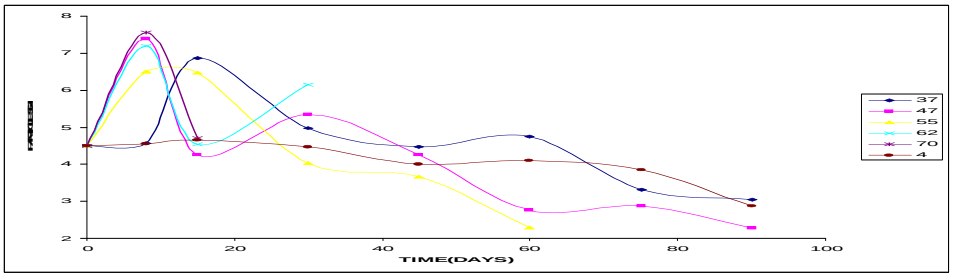

Fig. 26: *Change in Particle Size of Bioscab at different storage temperatures*

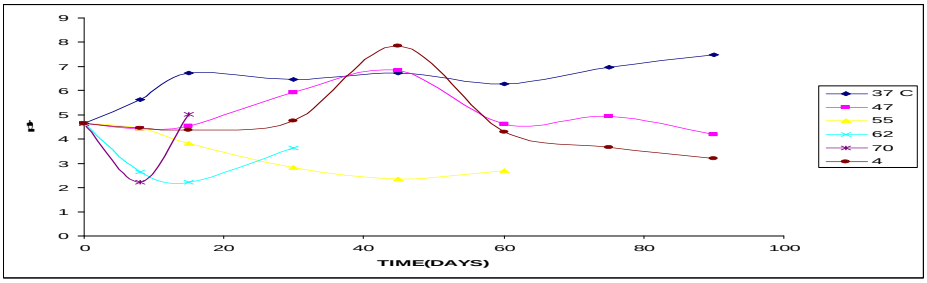

Fig. 27*: Change in pH of Bioscab at different storage temperatures*

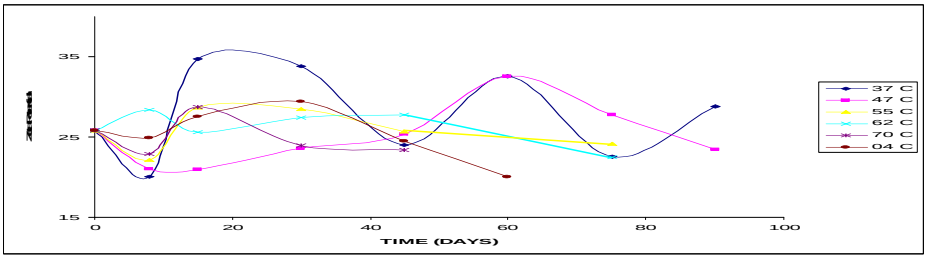

Fig. 28: *Change in Zeta Potential of B.B.APPLICATION at different storage temperatures*

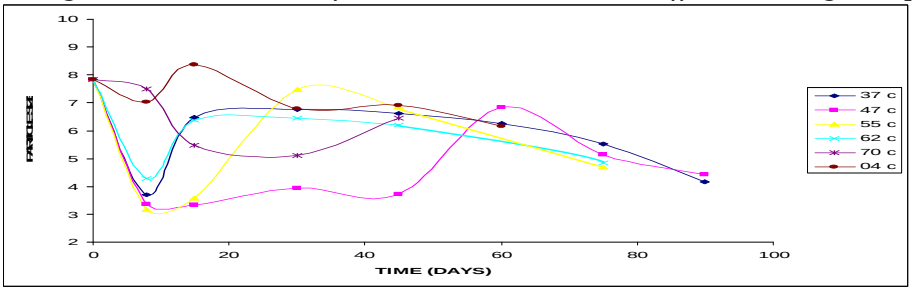

Fig.29: *Change in Particle Size of B.B.APPLICATION at different storage temperatures*

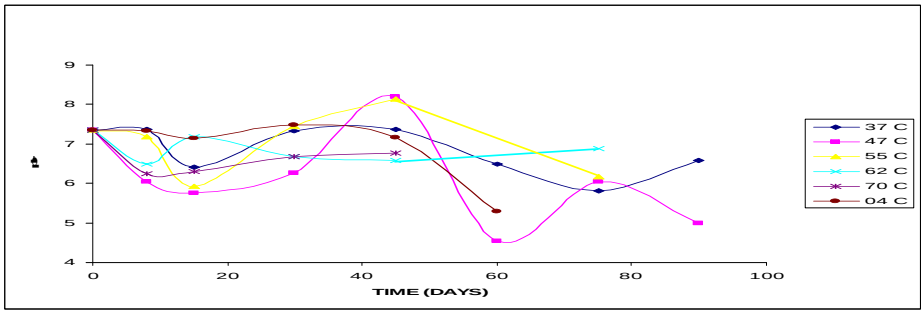

Fig. 30: *Change in pH of B.B.APPLICATION at different storage temperatures*

Conclusion

In respect of oral emulsions containing light liquid paraffin, Cremaffin exhibited low initial zeta potential value (-11.70±5.63mv) whereas Agarol was associated with quite greater charge (-27.55±10.5mv). Also, Cremaffin had low particle size (about 3-4 µm) than that of Agarol (about 8-13 µm). However, it was much basic (pH about 10 units) than the latter (pH 4.76 units). Cremaffin having pH of 10.11 evinced the progressive drop in pH whereas Agarol with initial acid character having pH 4.76 hardly underwent pH changes before breaking. It is however striking to note that in case of Cremaffin rise in storage temperature led to relatively faster decrease in pH whereas in case of Cremaffin at low temperature, the product was relatively more stable and the initial rise in pH may be observed.

Topical emulsions on comparison for different properties may be arranged as:

Zeta Potential (mv): Ascabiol (70.5±22.3) > Bioscab (42.95±10.6) > B. B. Application (25.8±12.5).
Particle size (nm): B. B. Application (7835±.260) > Bioscab (4500±1.0)>Ascabiol (2930±.690) and pH(units): Ascabiol (8-9)>B. B. Application (7-8)>Bioscab(4-8).

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