International Journal of PharmTech Research
CODEN (USA): IJPRIF ISSN : 0974-4304
Vol.4, No.3, pp 889-899, July-Sept 2012

Formulation And Characterization Of Natural Biodegradable Chewing Gum

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Abstract: A big problem in use of chewing gum is the fact that after use, the chewing gum is often not disposed of in an environmentally compatible manner in waste bins or waste paper baskets,but is carelessly disposed of in the manner binds to dust on account of its stickness,become stained black and forms black spots.The syenthetic polymer based chewing gum do not decompose significantly under normal climatic condition and cannot be removed using street clearing methods.A long felt need has existed ,therefore either to modify chewing gum base,in such a manner that they become more easily removed or to modify chewing gum base in such a manner that they are chemically degradable. Corn zein as a gum base offers nonadhesive and biodegradable property.Various plastisizer are used for formulation of corn zein gum. The study shows corn zein is best suited to be used as biodegadable gum base which can be developed as acceptable product for consumers.
Key words: Corn zein, plastisizer, gumbase, chewing gum, biodegradable property.

1.INTRODUCTION

Zein was first discovered by Gorham in 1821. Endosperm of the corn kernel contain zein prolamine protein,which is found in maize. Osborne developed the first patented process for extraction of zein from corn gluten meal (CGM) using 95% ethanol. Swallen et al.(1) were granted a series of patents on zein production using different alcohols of varying concentrations and additives. Zein became commercially available in 1938 and quickly found application in coatings, fibers, films, plastics, adhesives and inks. Zein (often combined with vegetable oils and glycerin as plasticizers) is used as a waxing or glaze, to enhance shelf life of pharmaceutical tablets, nuts and candies by acting as a water and oxygen barrier. Zein fibers with the commercial name of Vicara was produced in 1948.

Zein reached a peak production of 7 million kg per year in 1956 but with the development of cheaper synthetic materials, the market for zein dropped significantly by 1960. Today there is one known manufacturer of zein in USA and one in Japan. The cost of purified zein is $20-70 per kg depending on the grade and purity. There are several hundred patents on applications of zein and renewed interest due to its biodegradability and potential nanotechnology applications, its current high price is still a limitation.

Assuming that "biodegradability" and being "renewable" and "green" can enhance the value of zein-based pharmaceutical applications.

In chewing gum formulation to promote primary texture characteristic like chewiness and juiciness, various plasticizers are used. Glycerol, PEG-4000, Stearic acid and Acetyl tributyl citrate were used as plasticizer for chewing gum formulations.

2) FORMULATION AND EXPERITATION

2.1) INGREDIENTS FOR PREPARATION OF GUM SAMPLE

Four different formulations of corn zein chewing gum sample were included in the study, which varied in the plasticizer used. The corn zein gum formulations used Glycerol, PEG-4000, Stearic acid and Acetyl tributyl citrate as plasticizer. Other than the plasticizer, all of the ingredients and the amounts of each ingredient were the same for each formulation.

The ingredients used in making each of the corn zein chewing gums consisted of 100 g corn zein (regular grade M P Biomedical,LLC), 500 mL of 60% ethanol (C.D.H. New Delhi), 5 g distilled monoglycerides (Estelle Pvt Limited), 16 g partially hydrogenated soybean oil (Krishna Oil extraction limited,pachor,Rajgarh,M.P.), 10 g artificial strawberry flavor (GLEE Gum kit U.S.A.), 100 g of 70% sorbitol solution (C.D.H. New Delhi), and 70 g each of plasticizer, either Stearic acid (C.D.H. New Delhi), PEG-4000 (C.D.H. New Delhi), Glycerol (C.D.H. New Delhi) and Acetyl tributyl citrate (Mulberry chemicals private limited, Mumbai).

Corn zein is a food-grade protein, and all the other ingredients used in the gum formulation for this study were also food-grade quality. Table 1 shows a summary of the corn zein gum formulation. Corn zein gum were made either with (A) Acetyl tributyl citrate , (B) Glycerol (C) PEG- 4000 and (D) contain Stearic acid as plastisizer.

2.2) FORMULATION METHOD FOR MAKING CORN ZEIN CHEWING GUM SAMPLES

Laboratory sigma blade mixer with front to rear speed ratio of 2:1 was used for formulation of Corn Zein chewing gum.Aqueous ethanolic solution of zein powder was poured in sigma blade mixer ,all the ingredients except hydrogenated soybean oil and flavor were added and mixed in sigma blade mixer for ten minutes.Sigma blade mixer had a temperature control device which maintains temperature intermittently until it reached 50 degree celsius. The special (z) shape of blade present in sigma blender helped in complete mixing and produce heat which evaporated the ethanol present in the solution.To prevent exposure of heat partially hydrogenated vegetable oil was added to sigma blender.(2)

The corn zein solution was poured into the container which had five liters of purified ice water having its temperature maintained at three degree Celsius.The cold water caused zein to precipitate from ethanol solution.A dough like consistency was formed and zein particles were able to aggregate together and entrap rest of the ingredients.The dough was kneaded and rinsed in containers of purified water for two times, 10 min each to form a flexible gum base. The kneading action by sigma blade blender further blended the ingredients and rinsed away any remaining ethanol. The gum base was then spread into a thin sheet with a roller and cut into strips of 5 g each. Each strip was approximately 4 cm long, 1 cm wide, and 2 mm thick. All the gum samples were stored at room temperature.

Coating of corn Zein gum was done by liquid coating solution of sorbitol & glycerin. This mixture was heated at 60 degree celsius for 15 min and allowed to mix uniformly. Gum piece was dipped in the solution, and after a specified time interval of 1 min, (to allow the liquid to spread evenly over the piece), a dry powder material (Sorbitol) was applied. This helps to dry the liquid coating; this is referred to as dry charging & is commonly used in soft panning operation.(3) The Corn Zein Gum was pre-blended with dry charge material & flavor. This was applied in about 3 to 12 dry charge application. After a dry charge 2 to 4 liquid application are made to cover dry charge material, than coating was dried in hot warm air from blower in temperature range 27 ^{0}C to 38 ^{0}C.

2.3) CHARACTERIZATION OF MEDICATED CHEWING GUM:

2.3.1) PHYSICAL EVALUATION OF MEDICATED CHEWING GUM: All Medicated Chewing Gum formulations were visually inspected; various physical properties of gum base were studied on basis of their solubility studies, relative humidity, color and moisture absorption. Following parameters were studied:

Table 1: **Formulation of various corn zein chewing gum.**

S.No	Ingredient	S-1	S-2	S-3	S-4
1.	Corn Zein	50g	50g	50g	50g
2.	Distilled Monoglyceride	2.5g	2.5g	2.5g	2.5g
3.	Vegetable Soyabean Oil Partially Hydrogenated	8g	8g	8g	8g
4.	Plasticizer	A 35g	B 35g	C 35g	D 35g
5.	Sorbitol solution	50g	50g	50g	50g
6.	Flavor	5g	5g	5g	5g

Table 2: Physiochemical properties of synthetic gum base after stability studies.

S.NO	Properties	Observations
1.	Color(before ageing)	Off white to yellow
2.	Color(after ageing)	Off white to dark pink
3.	Softening range(before ageing)	40 to 60^0C
4.	Softening range(after ageing)	42 to 58^0C
5.	Texture(before ageing)	Satisfactory
6.	Texture(after ageing)	Satisfactory

a) Weight variation: Weight variation of all formulation was done by method described in experimental work.
b) Physical evaluation of Corn Zein Gum: All formulation prepared by above procedure were physically evaluated for following parameters, Appearance, Color, Stickness,Hardness,Weight variation and texture analysis.
c) Hardness/Plasticity:. Texture analyser was used for determining strength and degree of deformation. Values obtained indicate flexibility of sample.
d) Weight variation: Weight of ten chewing gum was taken in one batch, then average weight is calculated ,from that standard deviation is calculated.
e) Stickiness: Texture analyzer from stable micro system model TA.XT-EXPRESS was used for determining Texture profile analysis (T.P.A). Values obtained indicate uniformity of sample.

2.3.2) STABILITY STUDY OF SYNTHETIC GUM : 5 gm of corn zein gum base was stored in container at 40°C ± 2°C at 75% RH ± 5% RH(According to ICH Q1A(R_2) (4) guidelines for stability for a period of six months. After six months the gum was examined for signs of ageing and physical deformalities.

2.3.3) TEXTURE ANALYSIS OF CORN ZEIN CHEWING GUM :
a) Comparison of the hardness of 2 types of coated chewing gum by penetration with a 2 mm cylinder probe.(5)

TA Settings
Sequence Title: Return to Start (Set Dist)
Test Mode: Compression
Pre-Test Speed: 0.5 mm/sec
Test Speed: 2.0 mm/sec
Post-Test Speed: 16.0 mm/sec
Distance: 2.0 mm
Trigger Type: Auto (Force)
Trigger Force: 5.0 g
Points per second: 250

Test Set-Up:
Place the Heavy Duty Platform onto the machine base. Position the sample on the platform, centrally under the probe, and commence the test. It is important that regular shaped samples are selected and it is advantageous for the pellets to have a flat under side.

Observations:
The probe approaches the sample and once the 5g trigger force is attained, a rapid rise in force is observed, as the probe penetrates through the coating of the chewing gum. A drop in force is observed when the probe enters the interior of the gum. The probe returns to its original starting position when a penetration distance of 3mm from the trigger point is reached. The peak force is measured as an indication of the coating hardness. The force value at the distance of 1.5mm is considered as the interior hardness.External coating hardness for S1 and S2 formulation was found to be 1498.252gm and 158.634gm (Table 3 and Fig 1).Glycerol was used as plastiscizer for S2

formulation which indicate softness for the formulation.

b) Testing of chewing gum by penetration with a 2mm cylinder probe

TA Settings
Sequence Title: Return to Start (Set Dist)
Test Mode: Compression
Pre-Test Speed: 0.8 mm/sec
Test Speed: 10.0 mm/sec
Post-Test Speed: 10.0 mm/sec
Target Mode: Distance
Distance: 2.0 mm
Trigger Type: Auto (Force)
Trigger Force: 5.0 g
Stop Plot At: Start Position
Points per second: 250

Table 3: Coating hardness force for formulation S1 and S2

Test ID	'Coating Hardness' Force 1	'Interior Hardness' Force 2
	gm	gm
chewing gum coating (S1)	1498.252	285.52
chewing gum coating (S2)	**158.634**	**287.312**

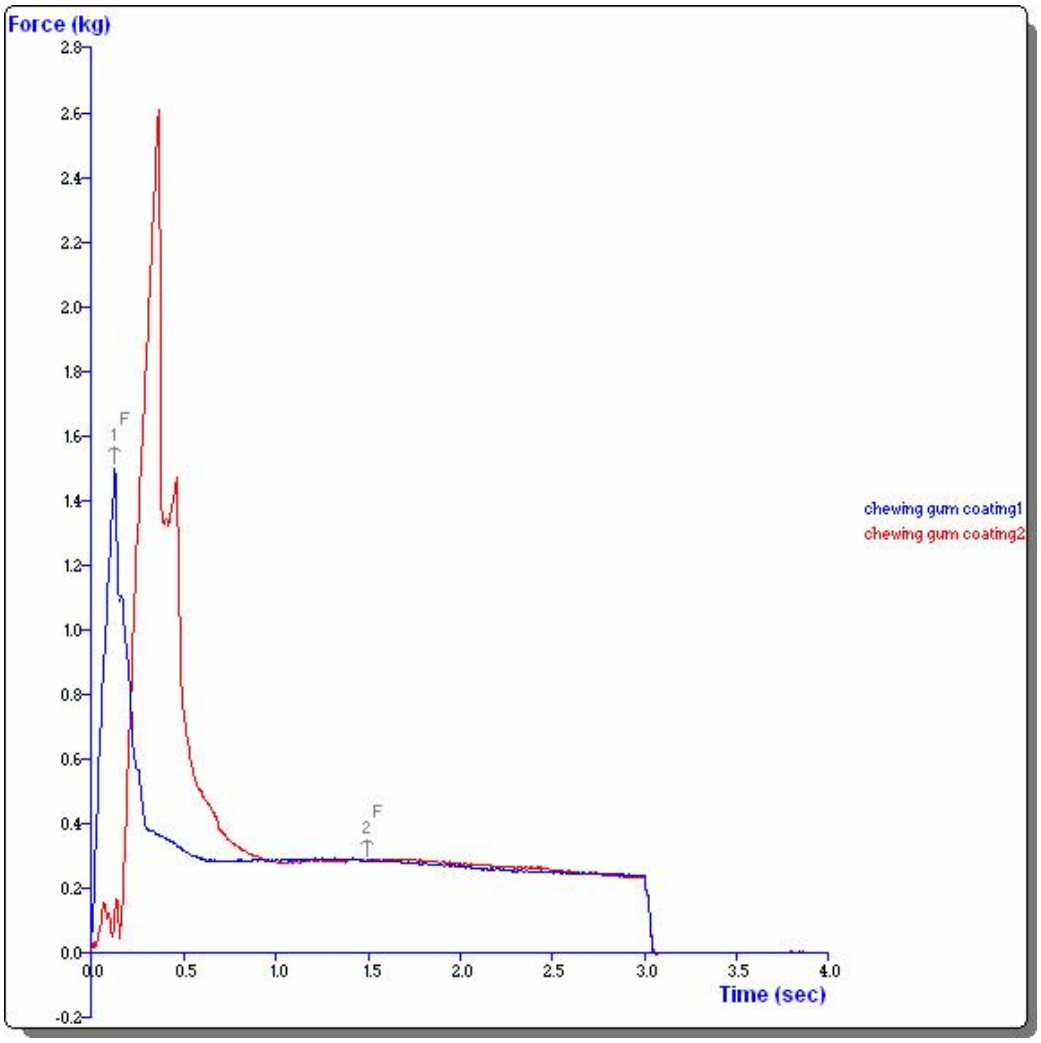

Fig1.Coating hardness of corn zein formulation S1 and S2.

Test Set-Up:
Place the Heavy Duty Platform onto the machine base. Position the sample on the platform, centrally under the probe, and commence the test. It is important that regular shaped samples are selected and it is advantageous for the pellets to have a flat under side

Observations:
The probe approaches the sample and once the 5g trigger force is attained, a rapid rise in force is observed, as the probe penetrates through the coating of the chewing gum. A drop in force is observed when the probe enters the interior of the gum. The probe returns to its original starting position when a penetration distance of 4mm from the trigger point is reached. The peak force is measured as an indication of the coating hardness. The force value at the distance of 3.5mm is considered as the interior hardness. Exterior and interior hardness for formulation S3 ,which utilizes PEG-4000 as plasticizer shows exterior and interior coating hardness force of 170.029gm and 43.272gm.(Table 4 and Fig 2).

Table 4: Coating hardness force for formulation S3

Test ID	Coating Hardness' Force 1	Interior Hardness' Force 2
	gm	gm
chewing gum coating (S3)	170.028	43.272

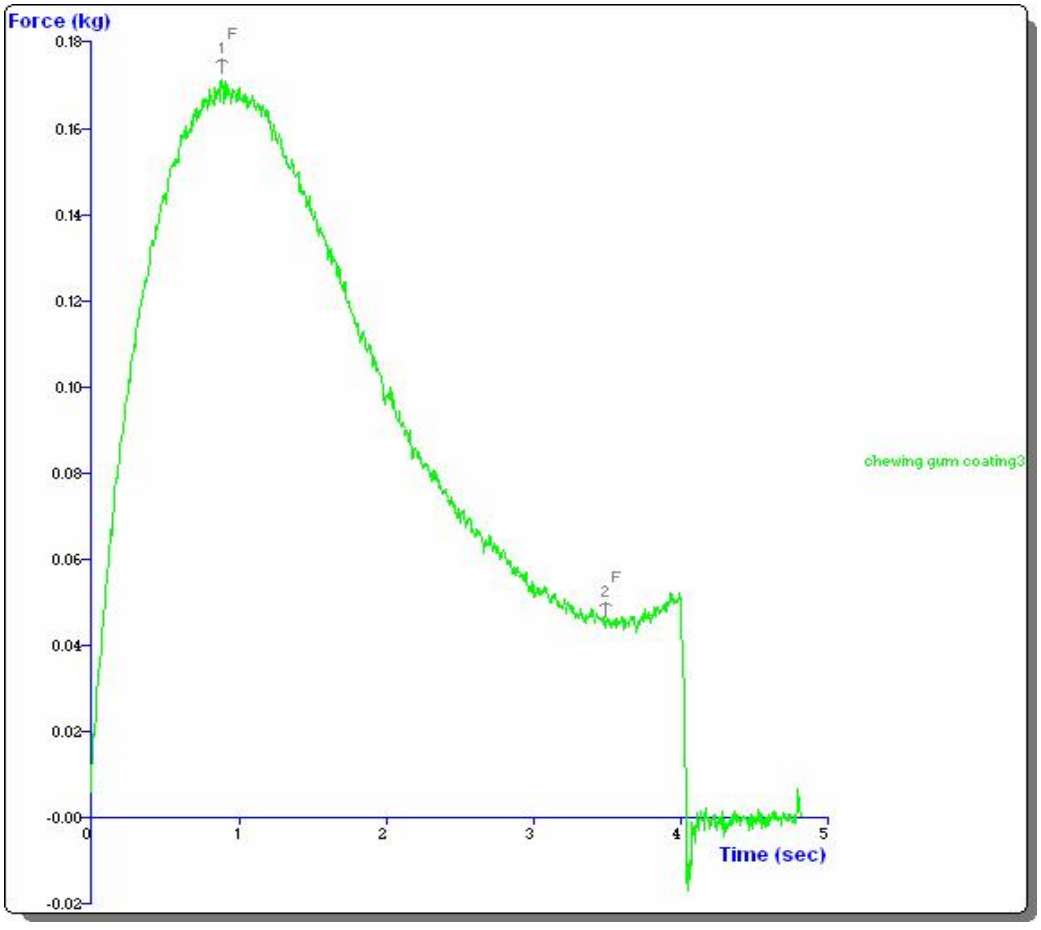

Fig2.Coating and interior hardness of zein chewing gum.

c).TPA Analysis (Texture Profile Analysis) for Corn Zein gum-

Probe Used: P/75; 75mm COMPRESSION PLATEN

Texture profile analysis (TPA) is an objective method of sensory analysis by compressing standard-sized samples of food twice. The test consists of compressing a bite-size piece of food two times in a reciprocating motion that imitates the action of the jaw and from the resulting force-time curve a number of textural parameters can be calculated, that correlate well with sensory evaluation.

Different chewing gum samples were tested by using a Compression platen of 75 mm diameter (P/75) with Texture Analyser and Texture profile analysis (TPA test) was performed for measurement of properties like Hardness, Fracturability, Springiness, Cohesiveness, Adhesiveness, Gumminess, Chewiness and Resilience.(6)

T.P.A (Texture Profile Analysis) Analysis curve for corn zein

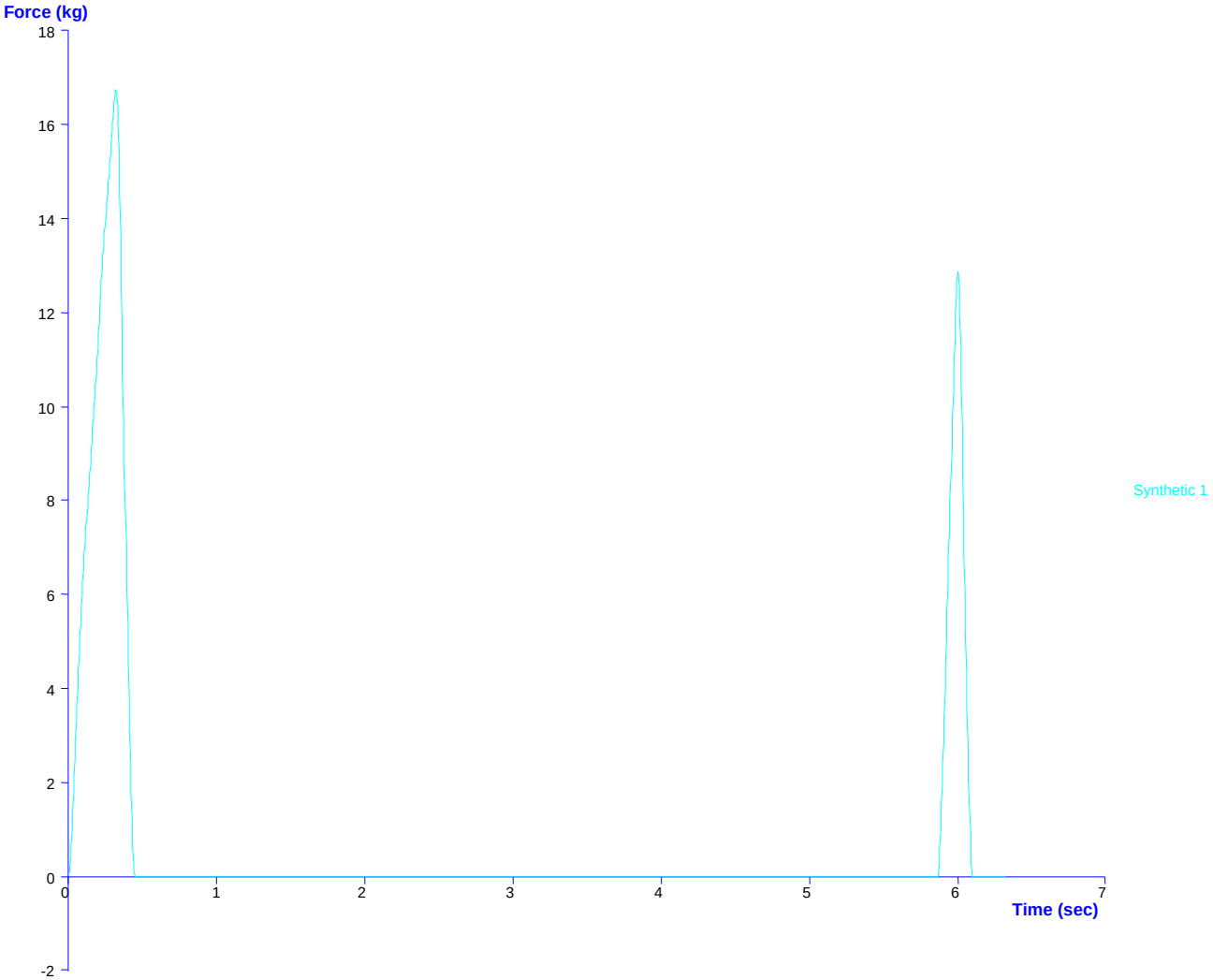

Fig 3:TPA Analysis curve for corn zein-1(S-1) formulation

Table 5: (TPA) Texture profile analysis of corn zein chewing gum

Test ID	Hardness	Fracturability	Adhesiveness	Springiness	Cohesiveness	Gumminess	Chewiness	Resilience
	g	g	g.sec					
Synthetic 4	15850.189		-0.831	0.413	0.373	5905.627	2437.243	0.327
Synthetic 1	16751.82		-6.579	0.403	0.366	6138.606	2473.767	0.318
Synthetic 2	17534.081		-1.512	0.409	0.408	7150.461	2925.189	0.367
Synthetic 3	14803.78		-0.102	0.429	0.402	5948.269	2549.258	0.351
Average:	16234.967		-2.256	0.413	0.387	6285.741	2596.364	0.34
S.D.	1176.32		2.939	0.011	0.021	585.31	224.124	0.022
Coef. of Variation	7.246		-130.271	2.642	5.34	9.312	8.632	6.568

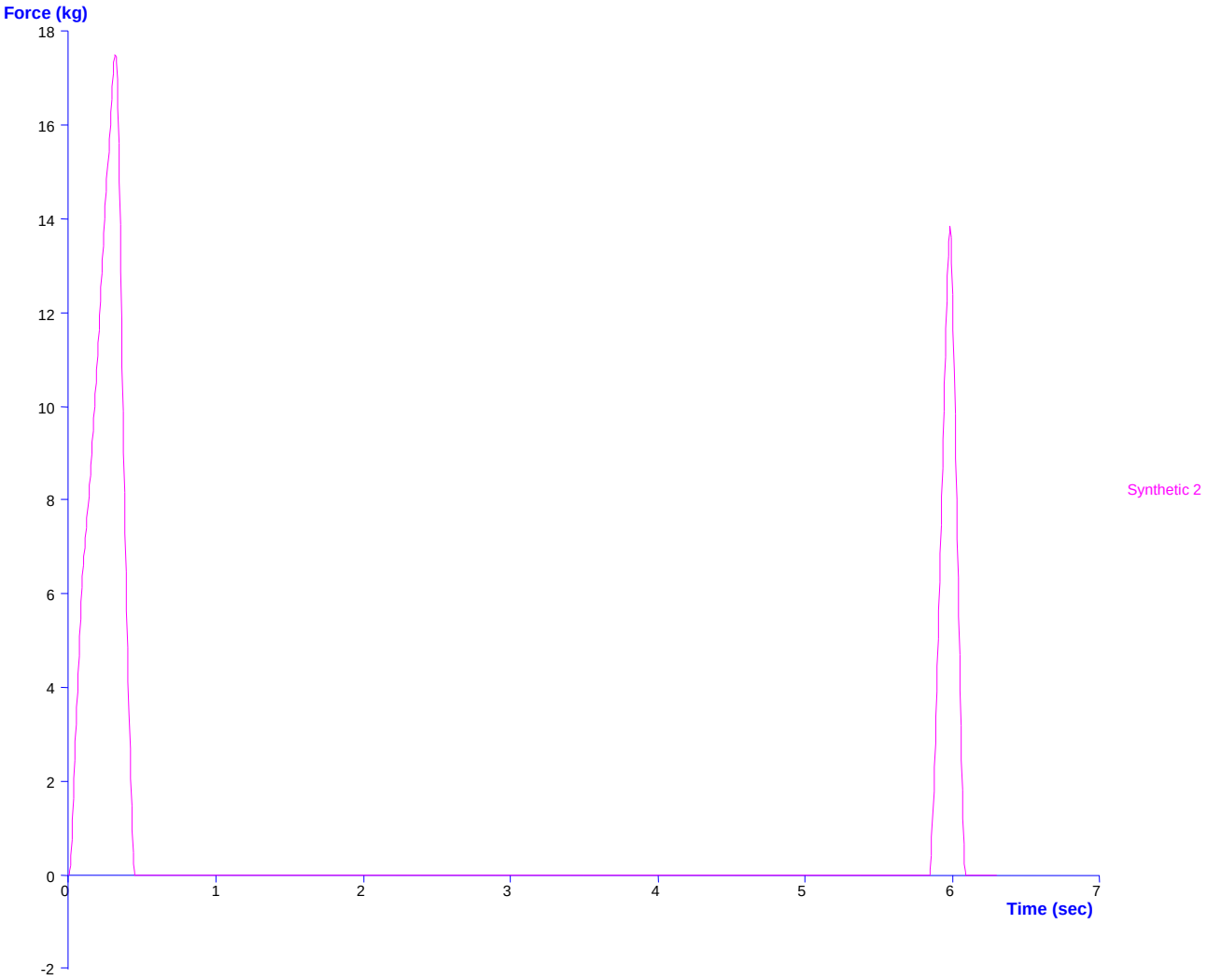

Fig 4: TPA Analysis curve for corn zein-2(S-2) formulation

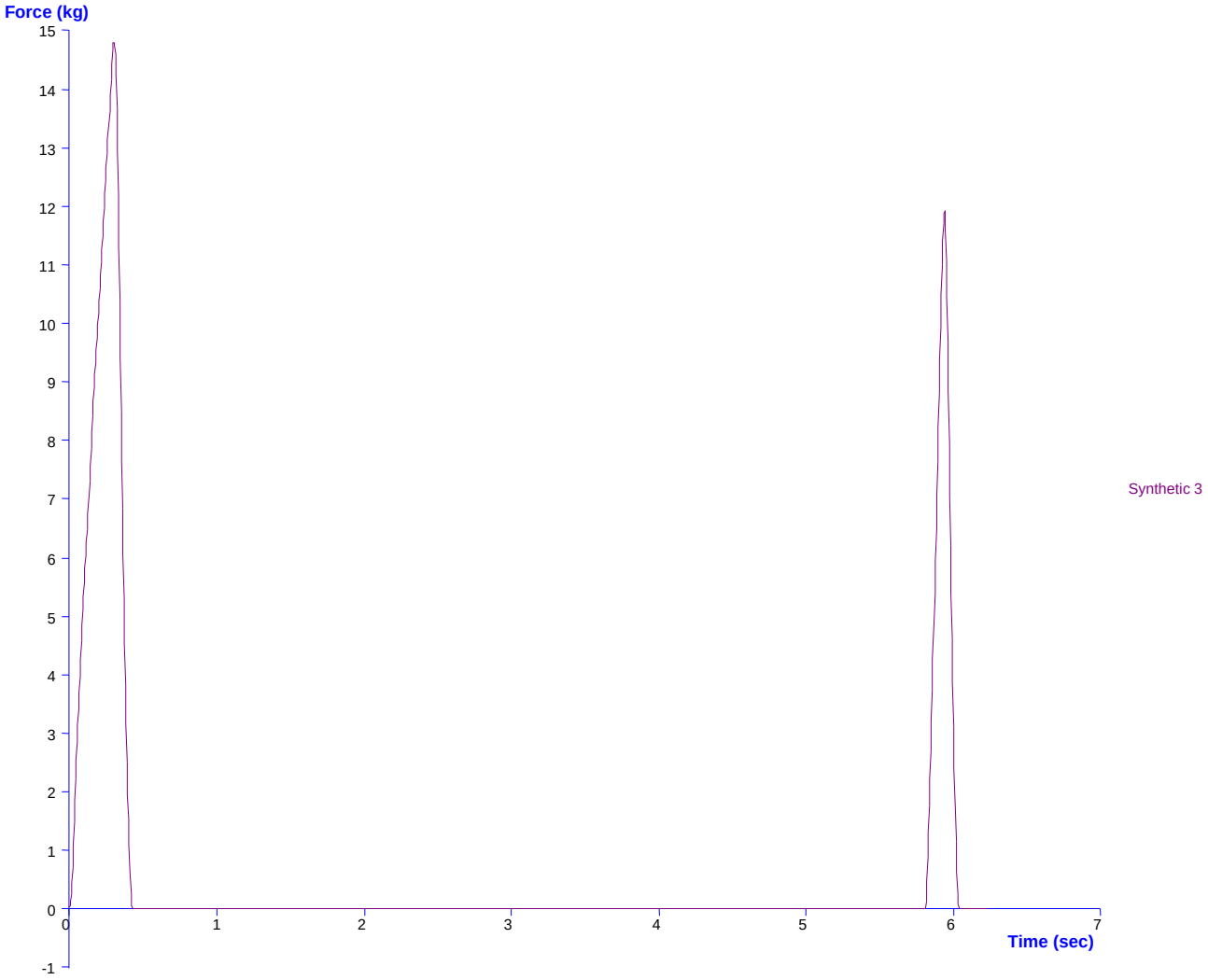

Fig 5: TPA Analysis curve for corn zein-3(S-3) formulation

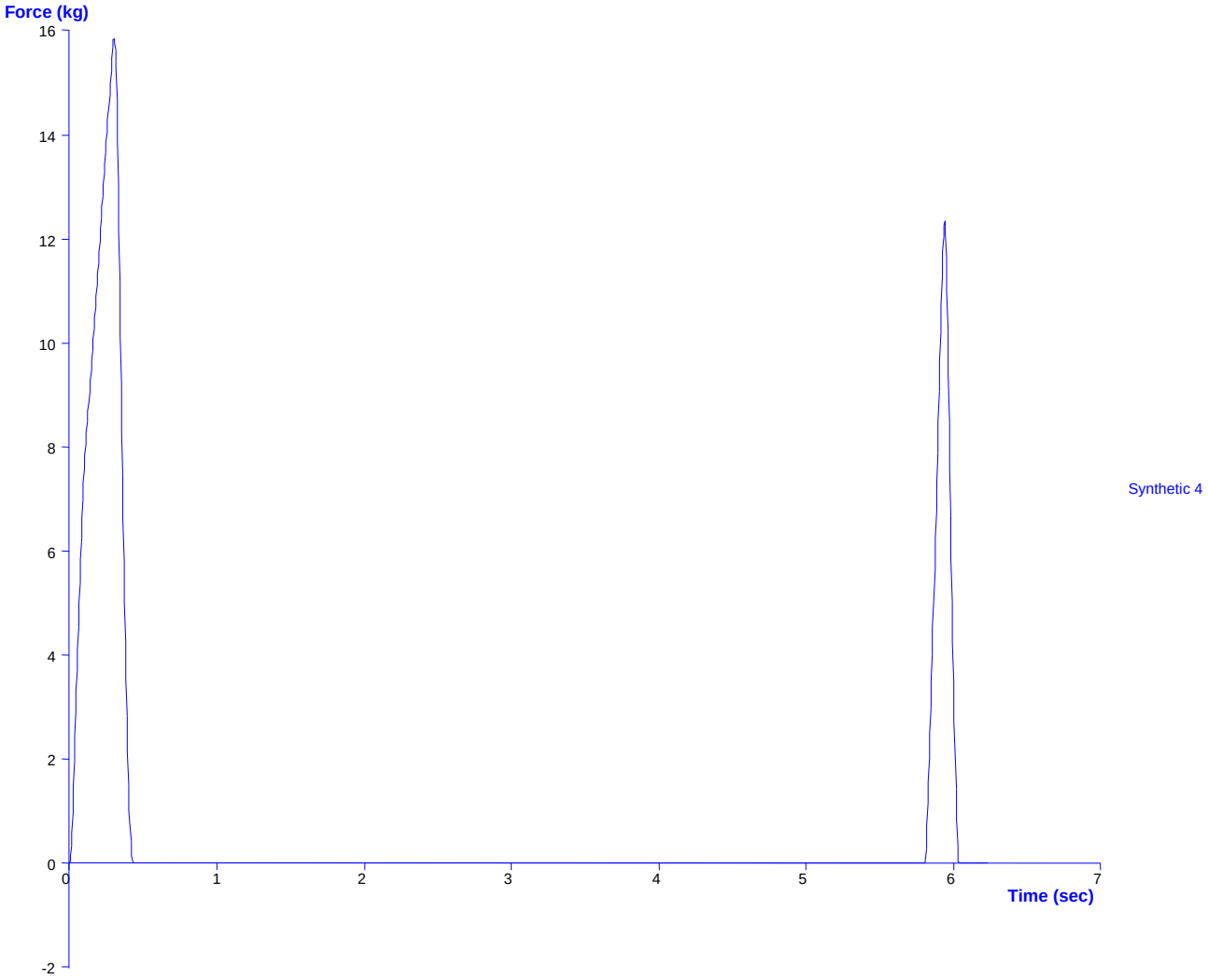

Fig 6 :TPA Analysis curve for corn zein-4(S-4) formulation

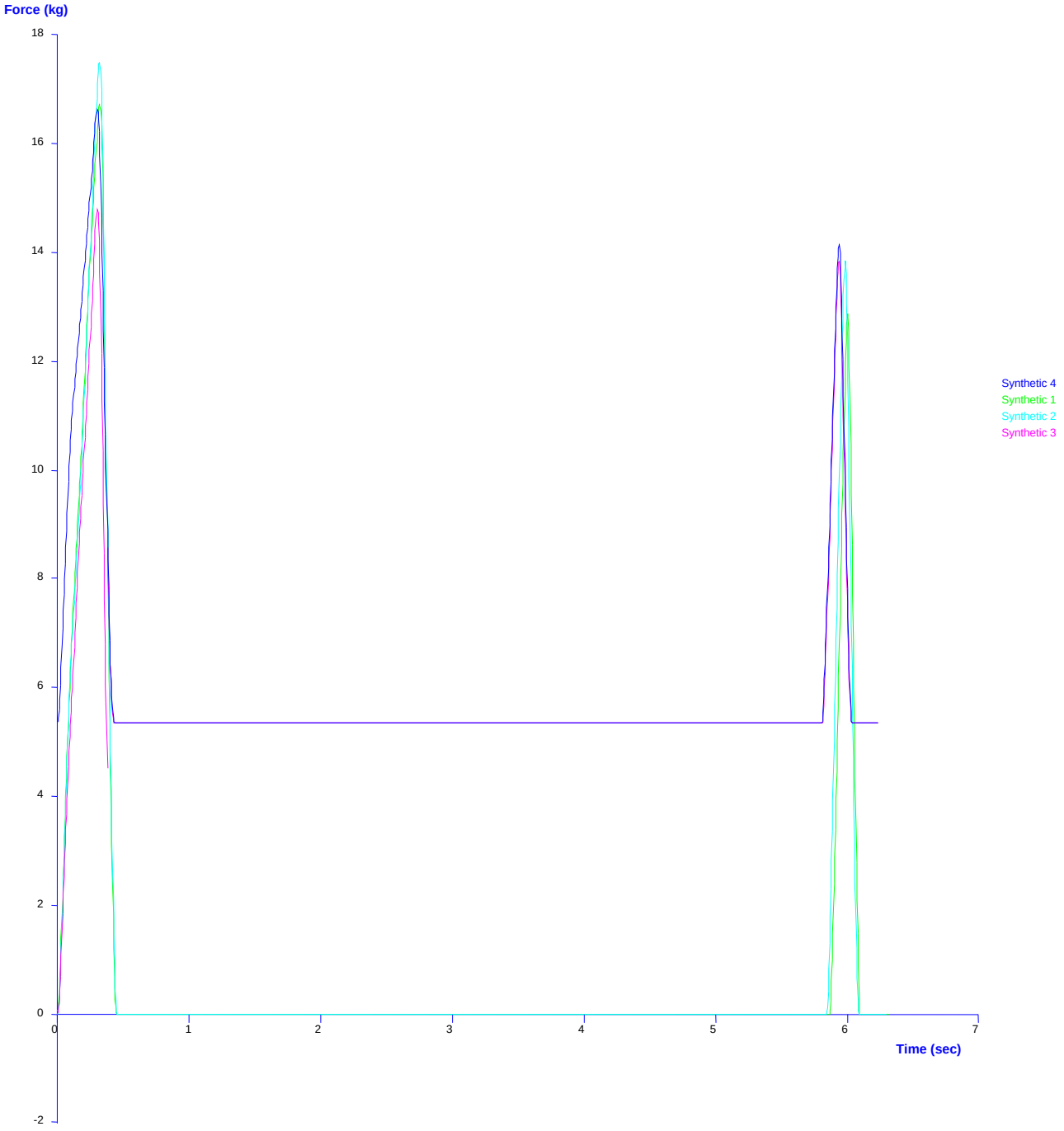
Force (kg)
18
16
14
12
10
8
6
4
2
0
-2
0
1
2
3
4
5
6
7
Time (sec)
Synthetic 4
Synthetic 1
Synthetic 2
Synthetic 3

Fig7: TPA analysis curve overlap of corn zein (S1-S4) chewing gum formulation

3) RESULTS AND DISCUSSION

Though chewing gum as a drug delivery system has gained wide acceptance only within smoking cessation and oral health care, clinical trials have proven that there are therapeutic advantages to be gained by using chewing gum as a drug delivery system through exploiting the effects achieved by chewing gum , the convenience of the delivery system, and the possibilities of having buccal absorption or local effect of an active substance. Furthermore, one of the trials has indicated that chewing gum as drug delivery systems are possibly safer for active substances that are susceptible to abuse. Chewing gum formulations may also be less prone to accidental overdose.

Effect of different formulations of chewing gum on final product's textural characteristics was successfully shown by Texture Analyser. The Texture Analyser does not require in-depth rheological training of the operator, either to run the test or interpret the results, which makes it very suitable for use in research & development. Using the same data results can be calculated repeatedly as per the convenience of operator without repetition of test. Testing with this instrument is ideally suited to product development or product standardization.Variation in significant TPA properties like springiness, cohesiveness, chewiness is also shown successfully by texture analyser.The Melting point of the corn zein chewing gum was found to be in the range of 45°C to 60°C.

Corn zein gum made up of glycerine,(S-2) as a plastisizer shows maximum gumminess value of 7150,chewiness of 2925 and hardness of 17534g,which is highest among all other formulations and most flexible.Values indicate glycerine as best plasticizer for corn zein chewing gum.

Corn zein gum made up of Acetyl tributyl citrate,(S-1) as a plasticizer shows gumminess value of 6138,chewiness of 2473 and hardness of 16751g,which indicate Acetyl tributyl citrate is less suitable to make Corn Zein chewing gum as its value are less than standard values. Corn zein gum made up of PEG-4000,(S-3) as a plasticizer shows gumminess value of 5948,chewiness of 2549,which is the lowest of all formulation and hardness of 14803g was reported.

Corn-zein chewing gum samples were coated and these coatings are brittle in nature and thus shown as fracturability in the results obtained. Different values of fracturability (of coatings) are observed in the graphs.

Above studies shows that all the parameters obtained by texture analysis by Texture Analyser can be complemented by the sensory evaluation data.

This study demonstrated the feasibility of using corn zein as a gum base and its potential for future optimization. Corn zein samples included in this study showed potential for future optimization. The formulation containing glycerol as plasticizer demonstrated its desirable textural characteristics.A possible way to further improve on sensory properties of zein gums is to incorporate lecithin in the formulation, which can improve flavor release, shelf life, and texture.

4). ACKNOWLEDGEMENT: Author wants to acknowledge CSIR for providing SRF fellowship and also wants to thank M.P.C.S.T, scientific and digital system to carry out texture analyses of chewing gum samples.

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