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Full Length Research

Evaluation of the Physicochemical and Thermal Properties of Consciousness Energy Healing Treated Polylactic-co-glycolic Acid (PLGA)

Gopal Nayak[1], Mahendra Kumar Trivedi[1], Alice Branton[1], Dahryn Trivedi[1], Snehasis Jana[2,*]

[1]Trivedi Global, Inc., Henderson, USA
[2]Trivedi Science Research Laboratory Pvt. Ltd., Bhopal, India

*****Corresponding Author: Snehasis Jana, Trivedi Science Research Laboratory Pvt. Ltd., Bhopal, India. Tel: +91-022-25811234; Email: publication@trivedieffect.com

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Poly(lactic-co-glycolic acid) (PLGA) is an FDA approved popular biodegradable copolymer, which has several applications in the pharmaceuticals and biomedical industries. But the degradation and stability of PLGA is a major problem. The objective of this research work was to evaluate the effect of the Trivedi Effect®-Consciousness Energy Healing Treatment on the physicochemical and thermal properties of PLGA using modern analytical techniques. The test sample was divided into control and treated parts. The control part of the test sample did not receive the Biofield Energy Treatment; whereas the other part of the sample received the Biofield Energy Treatment remotely by a famous Biofield Energy Healer, Gopal Nayak and was known as a treated sample. The particle size values were significantly increased by 15.76% (d_{10}), 15.73% (d_{50}), 12.04% (d_{90}), and 13.81% {D(4,3)}; hence, the specific surface area was significantly decreased by 12.45% in the treated sample compared to the control sample. The latent heat of evaporation and latent heat of fusion were altered by 1.05% and -55.13%, respectively in the treated PLGA compared with the control sample. The total weight loss was significantly increased by 10.34%; however, the residue amount was 95.77% less in the treated PLGA sample compared to the control sample. From these results, it can be concluded that the Trivedi Effect®-Consciousness Energy Healing Treated PLGA may show better flowability, shape, and appearance compared with the control PLGA. The Biofield Energy Treated PLGA can provide better benefits for designing the pharmaceutical/nutraceutical formulations and manufacturing of biomedical devices, *i.e.*, sutures, grafts, surgical sealant films, prosthetic devices, implants, micro, and nanoparticles.

Keywords: PLGA, The Trivedi Effect®, Consciousness Energy Healing Treatment, Complementary and Alternative Medicine, Particle size, Surface area, DSC, TGA/DTG

1. INTRODUCTION

Poly(lactic-co-glycolic acid) (PLGA) is a Food and Drug Administration (FDA) approved copolymer, which is popular among the several available biodegradable polymers with long clinical experience (Makadia *et al.*, 2011). This copolymer is a synthesized from the polylactic acid and glycolic acid. On hydrolysis of its ester linkages releases the monomers. The two monomers are the by-products of various metabolic pathways, therefore exhibit minimum systemic toxicity in the body. Higher the content of glycolide units in the PLGA unit, lower the time required for degradation. Thus, it has a great deal of attention in research and development due to its mechanical resistance, constant biodegradation rate, and regular individual chain geometry (Erbettan *et al.*, 2012). The PLGA is used for the manufacturing of biomedical devices, *i.e.*, prosthetic devices, grafts, sutures, surgical sealant films, implants, micro, and nanoparticles (Pavot *et al.*, 2014). It is amongst the FDA-approved polymers as a delivery vehicle for drugs, proteins, and other macromolecules such as peptides, RNA, and DNA (Makadia *et al.*, 2011). Explicitly, PLGA is useful

for the designing of better pharmaceuticals formulations, *i.e.*, the drug like simvastatin, amoxicillin, vancomycin, and minocycline loaded PLGA nanoparticles could be effective in sustain drug release (Shinde *et al.*, 2011; Tseng *et al.*, 2013; Kashi *et al.*, 2012). The PLGA which contains less than 50% glycolic acid units is freely soluble in most common organic solvents. However, PLGA rich in glycolyl units ≥50% is insoluble in most organic solvents (Samadi *et al.*, 2013; Jain *et al.*, 2000). Anhydride form of PLGA has satisfactory heat stability (Gilding *et al.*, 1979). The stability of it is a major concern, which is completely depends upon the monomer (poly lactic acid and glycolic acid) distribution pattern, chain-ends chemical composition, size, shape, porosity, and presence of additives (*i.e.*, acidic/ basic compounds, plasticizers, or drugs), moisture, and temperature (Anderson *et al.*, 1997; Alexis *et al.*, 2005; Hyon *et al.*, 2011).

The Biofield Energy Healing Treatment (the Trivedi Effect®-Consciousness Energy Healing treatment) has been scientifically proved to have the significant effects on altering the particle size, surface area, crystallite size, solubility, melting point, latent heat, *etc.* of the objects (Nayak *et al.*, 2011a; b; Branton *et al.*, 2017). The Trivedi Effect® is natural and only scientifically proven phenomenon in which an expert can harness this inherently intelligent energy from the Universe and transmit it anywhere on the planet through the possible mediation of neutrinos (Trivedi *et al.*, 2016b). Inside our body, due to the continuous movement of the blood, heart, charged particles, *i.e.*, ions, cells, etc.; a unique para-dimensional electromagnetic field generated inside the body is called a “Biofield”. The Biofield Energy Healing therapy has been recognized as a Complementary and Alternative Medicine (CAM) health care approach by the National Center of Complementary and Integrative Health (NCCIH) with other therapies (i.e., homeopathy, Ayurvedic medicine, Qi Gong, Tai Chi, yoga, chiropractic/osteopathic manipulation, massage, acupuncture, acupressure, hypnotherapy, Reiki, Rolfing, aromatherapy, cranial sacral therapy, etc.). This type of CAM has been accepted by most of the world population (Barnes *et al.*, 2008; Koithan *et al.*, 2009). The Biofield Energy Healing Therapies have been accepted worldwide and reported many significant outcomes in international journals (Rubik *et al.*, 2015; Oschman *et al.*, 2003). Similarly, the Trivedi Effect®-Consciousness Energy Healing Treatment also adopted by many people around the world and also reported the significant outcomes in the different field of sciences, *i.e.*, organic chemistry, material science, nutraceutical/pharmaceutical sciences, microbiology, agriculture, biotechnology, and medical science (Trivedi *et al.*, 2016a; Trivedi *et al.*, 2017; Trivedi *et al.*, 2015a-f). In this study the effect of the Trivedi Effect®-Consciousness Energy Healing Treatment on PLGA was evaluated using particle size analysis (PSA), powder X-ray diffraction (PXRD), differential scanning calorimetry (DSC) analytical techniques, and thermogravimetric analysis (TGA)/ Differential thermogravimetric analysis (DTG).

2. MATERIALS AND METHODS

2.1. Chemicals and Reagents

The polylactic-co-glycolic acid (PLGA, 70:30) powder sample was purchased from Changchun Hang Gai Biological Technology Co., Ltd., China. Other chemicals utilized during the experiments were of analytical grade available in India.

2.2. Consciousness Energy Healing Treatment Strategies

The test sample PLGA powder sample was divided into two parts. One part of the test sample was treated with the Trivedi Effect®-Consciousness Energy Healing Treatment remotely under standard laboratory conditions for 3 minutes by a famous Biofield Energy Healer, Gopal Nayak, India and the sample was called as a Biofield Energy Treated sample. The other part of the test sample was called as a control sample. But, the control sample was treated with a “sham” healer. The “sham” healer unaware about the Biofield Energy Treatment. After the treatment, the treated and untreated PLGA powder samples were kept in the sealed conditions and characterized using modern analytical techniques.

2.3. Characterization

2.3.1. Particle Size Analysis (PSA)

The particle size of PLGA was determined with the help of Malvern Mastersizer 2000, from the UK using the wet method (Nayak *et al.*, 2011a; b). The calculations were done by using software Mastersizer Ver. 5.54.
The % change in particle size (d) for PLGA at below 10% level (d_{10}), 50% level (d_{50}), 90% level (d_{90}), and D(4,3) was calculated using the following equation 1:

$$\% \text{ change in particle size} = \frac{[d_{Treated} - d_{Control}]}{d_{Control}} \times 100 \quad (1)$$

Where $d_{Control}$ and $d_{Treated}$ are the particle size (µm) for at below 10% level (d_{10}), 50% level (d_{50}), and 90% level (d_{90}) of the control and the treated PLGA samples, respectively.
The % change in surface area (S) was calculated using the following equation 2:

$$\% \text{ change in surface area} = \frac{[S_{Treated} - S_{control}]}{S_{control}} \times 100 \quad (2)$$

Where $S_{Control}$ and $S_{Treated}$ are the surface area of the control and the treated PLGA, respectively.

2.3.2. Powder X-ray Diffraction (PXRD) Analysis

The PXRD analysis of PLGA was done with the help of Rigaku MiniFlex-II Desktop X-ray diffractometer (Japan) (Rigaku, 1997; Zhang *et al.,* 2015). The average crystallite sizes are generally calculated using the Scherrer's formula (3):

$$G = k\lambda/\beta\cos\theta \quad (3)$$

Where k is the equipment constant (0.94), G is the crystallite size in nm, λ is the radiation wavelength (0.154056 nm for Kα1 emission), *β* is the full-width at half maximum (FWHM), and θ is the Bragg angle (Langford *et al.,* 2017).

2.3.3. Differential Scanning Calorimetry (DSC)

The DSC analysis of PLGA was done with the help of DSC Q200, TA instruments. The sample of ~1-2 mg was loaded into the aluminium sample pan at a heating rate of 10ºC/min from 30°C to 350°C (Nayak *et al.*, 2011a; b). The % change in melting point (T) was calculated using the following equation 4:

$$\% \text{ change in melting point} = \frac{[T_{Treated} - T_{Control}]}{T_{Control}} \times 100 \quad (4)$$

Where $T_{Control}$ and $T_{Treated}$ are the melting point of the control and the treated PLGA samples, respectively.
The % change in the latent heat of fusion (ΔH) was calculated using the following equation 5:

$$\% \text{ change in latent heat of fusion} = \frac{[\Delta H_{Treated} - \Delta H_{Control}]}{\Delta H_{Control}} \times 100 \quad (5)$$

Where $\Delta H_{Control}$ and $\Delta H_{Treated}$ are the latent heat of fusion of the control and the treated PLGA samples, respectively.

2.3.4. Thermal Gravimetric Analysis (TGA) / Differential Thermogravimetric Analysis (DTG)

TGA/DTG analysis of PLGA was done with the help of TGA Q50 TA instruments. The sample of ~4-6 mg was loaded to the platinum crucible at a heating rate of 10ºC/min from 25°C to 1000°C with the recent literature (Nayak *et al.*, 2011a; b). The % change in weight loss (W) was calculated using the following equation 6:

$$\% \text{ change in weight loss} = \frac{[W_{Treated} - W_{control}]}{W_{control}} \times 100 \quad (6)$$

Where $W_{Control}$ and $W_{Treated}$ are the weight loss of the control and the treated PLGA, respectively.
The % change in maximum thermal degradation temperature (T_{max}) (M) was calculated using the following equation 7:

$$\% \text{ change in Tmax (M)} = \frac{[M_{Treated} - M_{control}]}{M_{control}} \times 100 \quad (7)$$

Where $M_{Control}$ and $M_{Treated}$ are the T_{max} values of the control and the treated PLGA, respectively.

3. RESULTS AND DISCUSSION

3.1. Particle Size Analysis (PSA)

The particle size distribution analysis of the control and the Biofield Energy Treated PLGA were performed, and the results are presented in Table 1. The particle size values of the control sample at d_{10}, d_{50}, d_{90}, and D(4,3) were 118.238 µm, 379.347 µm, 824.198 µm, and 432.263 µm, respectively. Similarly, the particle sizes of the treated PLGA at d_{10}, d_{50}, d_{90}, and D(4,3) were 136.873 µm, 439.018 µm, 923.415 µm, and 491.98 µm, respectively. The particle size values in the Biofield Energy Treated sample were significantly increased by 15.76%, 15.73%, 12.04%, and 13.81% at d_{10}, d_{50}, d_{90}, and D(4,3), respectively compared to the control sample (Table 1). The specific surface area (SSA) of the

Biofield Energy Treated sample (0.0239 m^2/g) was significantly decreased by 12.45% compared with the control sample (0.0273 m^2/g). The Consciousness Energy Healing Treatment might have influenced the intermolecular force, hence increased the particle sizes and increased surface area of PLGA. The particle size and surface area of a compound have the significant effect on the solubility, dissolution, absorption, and bioavailability of it. The increase in the particle size enhanced the flowability, shape, and appearance of the compound (Mosharrof *et al.,* 1995; Buckton *et al.,* 1992). The Trivedi Effect®-Consciousness Energy Healing Treated PLGA might improve the powder flowability in the pharmaceutical and nutraceutical formulations.

Table 1: *Particle size distribution of the control and the Biofield Energy Treated PLGA.*

Parameter	d_{10} (µm)	d_{50} (µm)	d_{90} (µm)	D(4,3) (µm)	SSA (m^2/g)
Control	118.238	379.347	824.198	432.263	0.0273
Biofield Treated	136.873	439.018	923.415	491.98	0.0239
Percent change* (%)	15.76	15.73	12.04	13.81	-12.45

d_{10}, d_{50}, and d_{90}: particle diameter corresponding to 10%, 50%, and 90% of the cumulative distribution, D(4,3): the average mass-volume diameter, and SSA: the specific surface area. *denotes the percentage change in the particle size distribution of the Biofield Energy Treated sample with respect to the control sample.

3.2. Powder X-ray Diffraction (PXRD) Analysis

The diffractograms of the control and the Biofield Energy Treated PLGA did not show clear and intense peaks (Figure 1), which indicated that both samples were amorphous in nature. The Biofield Energy Treated diffractograms did not conclude any crystallinity pattern compared to the control PLGA sample.

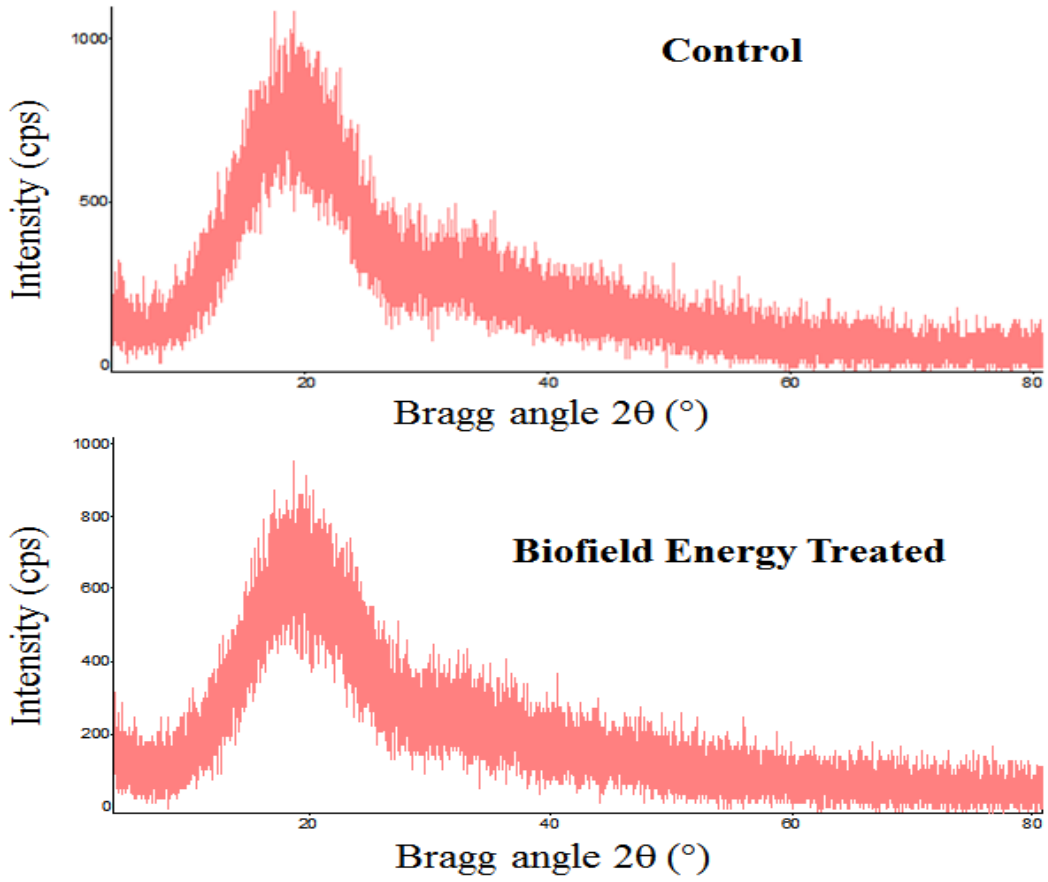

Figure 1: *PXRD diffractograms of the control and the Biofield Energy Treated PLGA.*

3.3. Differential Scanning Calorimetry (DSC) Analysis

The thermograms of the control and the Biofield Energy Treated PLGA showed two endothermic peaks. The control sample showed the sharp endothermic peaks at 61.2°C and 326.04°C in the thermogram (Figure 2). Similarly, the treated PLGA showed the sharp endothermic peaks at 61.2°C and 331.13°C in the thermogram (Figure 2). The 1st endothermic peak was due to the evaporation of engrossed water molecule from the sample, whereas the 2nd large endothermic pick was due to the melting of PLGA. The experimental results were well coordinated with the reported data (Makadia *et al.*, 2011). The evaporation temperature did not alter at all, but the melting point slightly increased by the 1.56% of the Biofield Energy Treated sample compared to the control sample (Table 2). Similarly, the latent heat of evaporation ($\Delta H_{evaporation}$) and latent heat of fusion (ΔH_{fusion}) were altered by 1.05% and -55.13%, respectively in the Biofield Energy Treated PLGA compared with the control sample (Table 2). The thermal behavior of the Biofield Energy Treated sample was altered compared to the control sample. Any change in the molecular chains, and the crystal structure influence the thermal stability (Zhao et al., 2015). Hence, Gopal Nayak's Biofield Energy Treatment might have disturbed the molecular chains and crystal structure of PLGA which lead to altered thermal stability of the treated PLGA sample compared to the control sample.

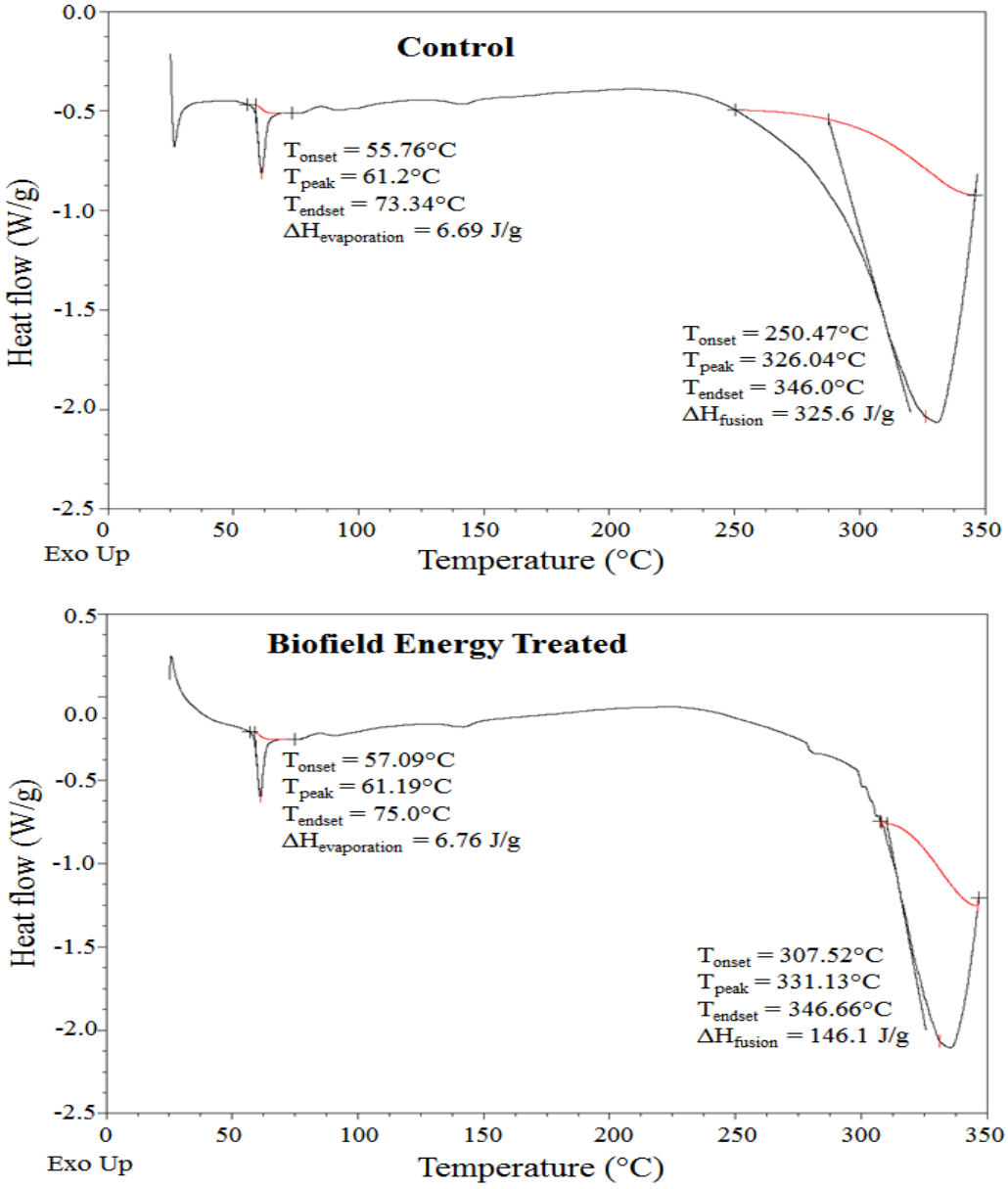

Figure 2: *DSC thermograms of the control and the Biofield Energy Treated PLGA.*

Table 2: *DSC data for both control and Biofield Energy Treated PLGA.*

Sample	Melting point (°C)		ΔH (J/g)	
	1st Peak	2nd Peak	Evaporation	Melting
Control	61.2	326.04	6.69	325.6
Biofield EnergyTreated	61.2	331.13	6.76	146.1
% Change*	0.00	1.56	1.05	-55.13

ΔH: Latent heat of evaporation/fusion, *denotes the percentage change of the Biofield Energy Treated PLGA with respect to the control sample.

3.4. Thermal Gravimetric Analysis (TGA) / Differential Thermogravimetric Analysis (DTG)

The TGA/DTG thermograms of the control and the treated PLGA showed one step of thermal degradation process (Figures 3 and 4). The total weight loss in the treated PLGA (99.59%) was significantly increased by 10.34% compared with the control sample (90.26%). However, the residual amount was 95.77% less in the case of the treated PLGA compared to the control sample (Table 3).

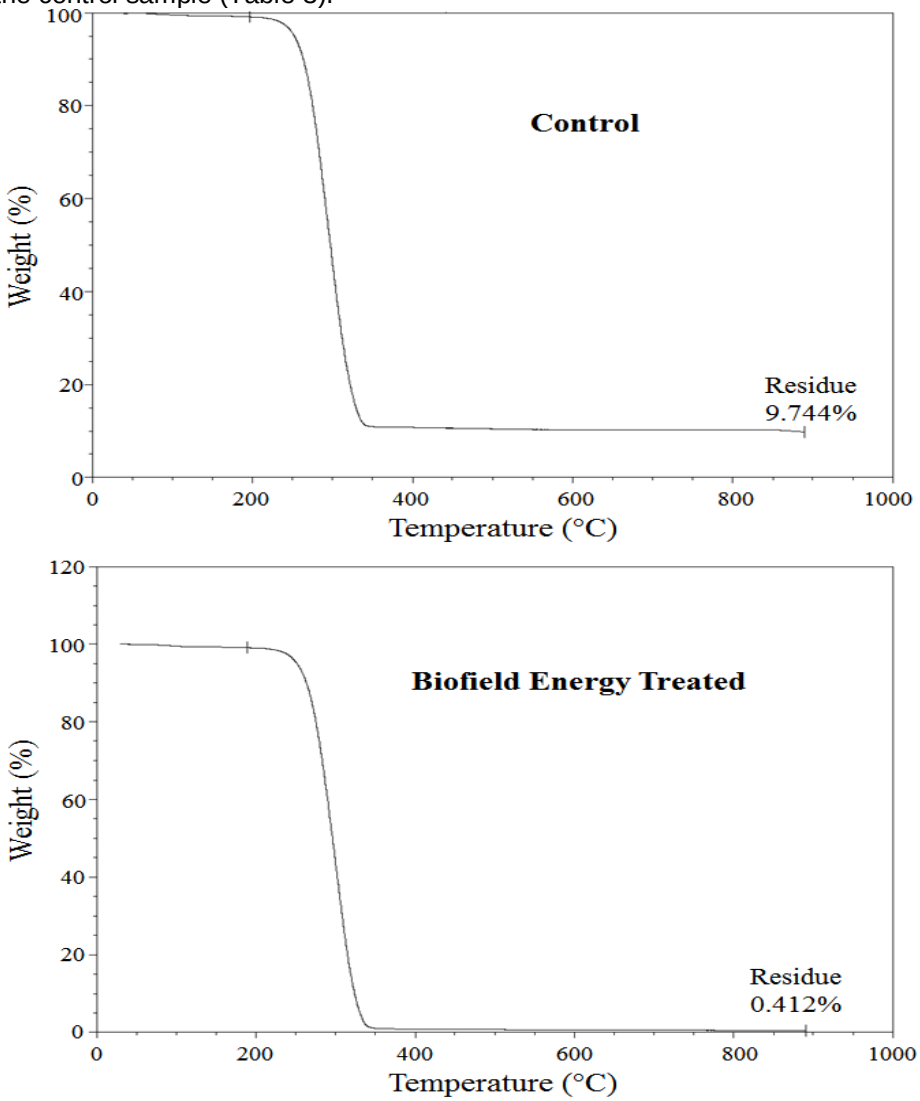

Figure 3: *TGA thermograms of the control and the Biofield Energy Treated PLGA.*

Table 3: *TGA/DTG data of the control and Biofield Energy Treated samples of PLGA.*

Sample	TGA		DTG
	Total weight loss (%)	Residue %	T_{max} (°C)
Control	90.26	9.74	298.41
Biofield Energy Treated	99.59	0.41	300.71
% Change*	10.34	-95.77	0.77

*denotes the percentage change of the Biofield Energy Treated sample with respect to the control sample, T_{max} = the temperature at which maximum weight loss takes place in TG or peak temperature in DTG.

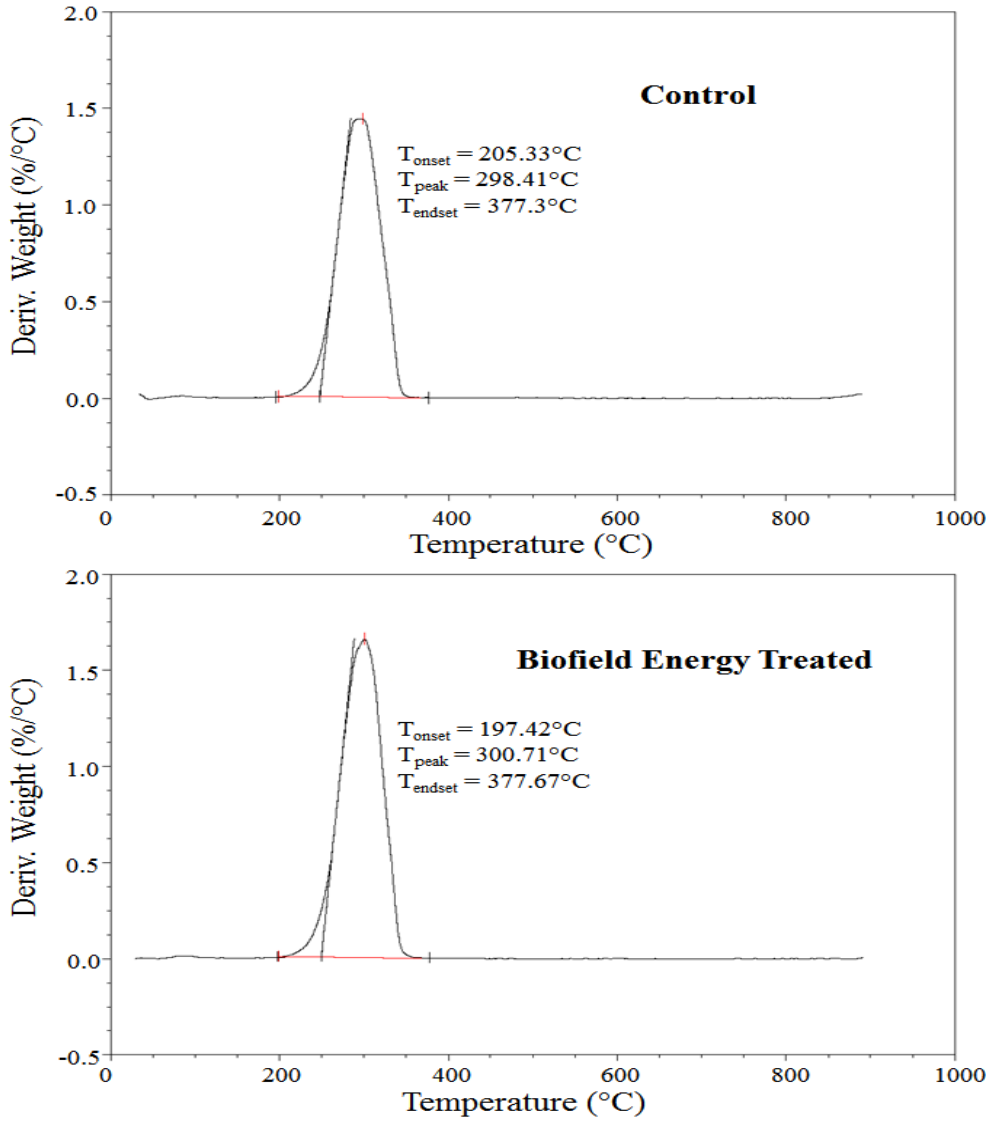

Figure 4: *DTG thermograms of the control and Biofield Energy Treated PLGA.*

The maximum thermal degradation temperature (T_{max}) of the Biofield Energy Treated sample was slightly increased by 0.77% compared to the control sample. Overall, TGA/DTG thermal analytical results concluded that the thermal stability of the Biofield Energy Treated PLGA sample was altered compared with the control sample.

4. CONCLUSIONS

The experimental results showed a significant impact of the Trivedi Effect®-Consciousness Energy Healing

Treatment on the particle size, surface area, and thermal behaviors of the PLGA powder sample. The particle size values were significantly increased by 15.76% (d_{10}), 15.73% (d_{50}), 12.04% (d_{90}), and 13.81% {D(4,3)}; hence, the specific surface area was significantly decreased by 12.45% in the Biofield Energy Treated sample compared to the control sample. The $\Delta H_{evaporation}$ and ΔH_{fusion} were altered by 1.05% and -55.13%, respectively in the Biofield Energy Treated PLGA compared with the control sample. The total weight loss was significantly increased by 10.34%; however, the residue amount was 95.77% less in the Biofield Energy Treated PLGA sample compared to the control sample. From the results, it can be concluded that the Trivedi Effect®-Consciousness Energy Healing Treated PLGA may show better flowability, shape, and appearance compared with the control PLGA. Therefore, the Biofield Energy Treated PLGA can provide better benefits for designing the pharmaceutical/nutraceutical formulations and manufacturing of biomedical devices, *i.e.*, sutures, grafts, surgical sealant films, prosthetic devices, implants, micro, and nanoparticles.

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