

Complementary and Alternative Medicine: Evaluation of the Physicochemical and Thermal Properties of the Biofield Energy Treated Metronidazole



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Abstract

Metronidazole is an antibiotic and is useful for antibacterial and antiprotozoal medication. In this research work, the impact of the Trivedi Effect[®] (Consciousness Energy Healing Treatment) on the physicochemical properties of metronidazole was evaluated using the modern analytical technique. Metronidazole sample was divided into two parts, one part of metronidazole was considered as a control sample (no Biofield Energy Treatment was provided); however, the other part of metronidazole, was exposed to the Consciousness Energy Healing Treatment remotely by a well-known Biofield Energy Healer, Alice Branton and termed as a treated sample. The peak intensities, as well as crystallite sizes of the treated metronidazole were significantly altered ranging from -97.25% to 463% and -83.18% to 123.79%, respectively; however, the average crystallite size was significantly decreased by 14.91% compared with the control sample. The particle size values in the treated metronidazole were significantly decreased by 14.69% (d_{10}), 10.82% (d_{50}), 19.14% (d_{90}), and 16.88% {D (4,3)}; thus, the specific surface area was significantly increased by 24.7% compared to the control sample. The latent heat of fusion and latent heat of decomposition were decreased by 2.1% and 9.41%, respectively in the treated sample compared with the control sample. The total weight loss was increased by 2.56%; however, the residue amount was significantly decreased by 83.86% in the treated sample compared with the control sample.

The maximum thermal degradation temperature was decreased by 3.53% in the treated sample compared with the control sample. Thus, the Consciousness Energy Healing Treatment might have generated a new polymorphic form of metronidazole which may offer better solubility, dissolution, and good bioavailability compared with the control sample. The Consciousness Energy Treated metronidazole would be very useful to design more efficacious pharmaceutical formulations for the better therapeutic response against bacterial and protozoal infection in the vagina, stomach, liver, skin, joints, brain, and respiratory tract, aspiration pneumonia, rosacea, fungating wounds, intra-abdominal infections, lung abscess, periodontitis, amoebiasis, oral infections, etc.

Keywords: Complementary and Alternative Medicine; Metronidazole; The Trivedi Effect[®]; Consciousness Energy Healing Treatment; PXRD; Particle size; Surface area; DSC; TGA/DTG

Introduction

Metronidazole is the nitroimidazole class of antibiotic and useful for the antiprotozoal medication. It inhibits the microorganism by disrupting the DNA of microbial cells for the nucleic acid synthesis. It has the relatively little effect on human cells or aerobic bacteria, but this function only occurs when metronidazole is partially reduced, which usually happens only in anaerobic cells [1,2]. It is used to treat the bacterial infections of the vagina (bacterial vaginosis), stomach (giardiasis, pseudomembranous colitis), liver, skin, joints (pelvic inflammatory disease), brain, and respiratory tract, aspiration pneumonia, rosacea, fungating

wounds, intra-abdominal infections, lung abscess, periodontitis, amoebiasis, oral infections, and infections caused by susceptible anaerobic organisms such as Bacteroides, Clostridium, Fusobacterium, Dracunculus, Peptostreptococcus, *Helicobacter pylori*, and *Prevotella* species, etc. [2-5]. It is also used for the infections of *Giardia* in cats, dogs, horse, and other companion animals [2,6].

Common side effects associated with the metronidazole therapy are nausea, vomiting, headache, dizziness, diarrhoea, weight loss, abdominal pain, metallic taste in the mouth, thrombophlebitis, hypersensitivity reactions, stomatitis, glossitis, dark urine,

leucopenia, neutropenia, peripheral neuropathy, central nervous system toxicity, and paraesthesia etc. [2,7]. Metronidazole is bitter, and so in the liquid suspension, it contains in the form of metronidazole benzoate. Metronidazole has high oral bioavailability. It is also delivered in the form of the tablet, capsule, and intravenous injection also [7-9]. It is very harmful in case of skin contact (irritant, permeator), eye contact (irritant), inhalation, and ingestion. The solubility profile of metronidazole is very poor, where is slightly soluble in cold water, hot water, alcohol, chloroform, dilute acid, and dimethylformamide [10,11].

Many scientific communities throughout the globe doing the research work for the improvement of better physicochemical properties of the nutraceutical and pharmaceutical compounds, because the physicochemical properties of the pharmaceutical or nutraceutical compounds play a crucial role in its dissolution, absorption, and bioavailability profile in the body [12]. In this scenario, the Trivedi Effect®-Biofield Energy Healing Treatment has the significant impact on the physicochemical properties such as particle size, surface area, thermal behaviour, and bioavailability profile of nutraceutical and pharmaceutical compounds [13-17]. The Trivedi Effect® is a natural and only scientifically confirmed phenomenon in which a person can harness this inherently intelligent energy from the "Universe" and transmit it anywhere on the planet through the possible mediation of neutrinos [18].

This unique energy field exists surrounding the body of every living organism called the "Biofield", which is infinite and para-dimensional electromagnetic field. The Biofield Energy Healing Therapies have been testified with significantly beneficial outcomes against various disease conditions [19]. The National Institutes of Health (NIH) and National Center for Complementary and Alternative Medicine (NCCAM) recommend and included the Energy Therapy under the Complementary and Alternative Medicine (CAM) along with homeopathy, traditional Chinese herbs and medicines, aromatherapy, Qi Gong, Tai Chi, Reiki, hypnotherapy, Ayurvedic medicine, yoga, chiropractic/osteopathic manipulation, massage, relaxation techniques, meditation, etc., which has been accepted by most of the U.S. people [20,21].

The Trivedi Effect®-Consciousness Energy Healing Treatment has the significant potential for the transformation of the object(s), and the outcomes were published in numerous scientific journals. The Biofield Energy Treatment (the Trivedi Effect®) has the amazing capability to transform the physicochemical, structural, and behavioural properties of metals and ceramics [22,23], organic compounds [24,25], nutraceuticals [26,27], pharmaceuticals [28,29], microorganisms [30,31], various living cells [32,33], and improve the overall productivity of crops [34,35]. Therefore, the current study was designed and evaluated the impact of the Consciousness Energy Healing Treatment on the physicochemical and thermal properties of metronidazole using powder X-ray diffraction, particle size analysis, differential scanning calorimetry, and thermogravimetric analysis/ differential thermogravimetric analysis.

Materials and Methods

Chemicals and Reagents

Metronidazole (2-Methyl-5-nitroimidazole-1-ethanol) was purchased from Tokyo Chemical Industry Co., Ltd., Japan and other chemicals were purchased from India.

Consciousness Energy Healing Treatment Strategies

Metronidazole was the test sample for the experiment, which further divided into two equal parts. One part of metronidazole was treated with the Energy of Consciousness Healing Treatment (the Trivedi Effect®) remotely under standard laboratory conditions for 3 minutes by the well-known Biofield Energy Healer, Alice Branton, USA, and known as the Biofield Energy Treated metronidazole sample. However, the second part of metronidazole was considered as a control sample (no Biofield Energy Treatment was provided). Further, the control sample was treated with a "sham" healer, who did not have any knowledge about the Biofield Energy Treatment. After treatment, both the samples were kept in the sealed conditions and characterized using modern analytical techniques.

Characterization

The PXRD, PSA, DSC, and TGA analysis of metronidazole were performed. The PXRD analysis of metronidazole powder sample was performed with the help of Rigaku MiniFlex-II Desktop X-ray diffractometer (Japan) [36,37]. The average size of crystallites was calculated from PXRD data using the Scherrer's formula (1)

$$G = k\lambda/\beta\cos\theta \quad (1)$$

Where G is the crystallite size in nm, k is the equipment constant (0.94), λ is the radiation wavelength (0.154056 nm for $K\alpha_1$ emission), β is the full-width at half maximum, and θ is the Bragg angle [38].

The PSA was performed using Malvern Mastersizer 2000, from the UK with a detection range between 0.01 μm to 3000 μm using the wet method [39,40]. Similarly, the DSC analysis of metronidazole was performed with the help of DSC Q200, TA instruments. The TGA/DTG thermograms of metronidazole were obtained with the help of TGA Q50 TA instruments [39,40].

The % change in crystallite size, peak intensity, particle size, specific surface area (SSA), peak intensity, melting point, latent heat, weight loss and the maximum thermal degradation temperature (T_{max}) of the Biofield Energy Treated sample was calculated compared with the control sample using the following equation 2:

$$\% \text{ change} = \frac{[\text{Treated} - \text{Control}]}{\text{Control}} \times 100 \quad (2)$$

Results and Discussion

Powder X-ray Diffraction (PXRD) Analysis

The powder XRD diffractograms of both the sample metronidazole showed sharp and intense peaks (Figure 1) indicated that

both the samples were crystalline. Both the samples showed the highest peak intensity at 2θ equal to 12.6° (Table 1, entry 2). The peak intensities of the Biofield Energy Treated metronidazole were significantly altered compared to the control sample. Over-

all, the peak intensities of the Biofield Energy Treated metronidazole were significantly altered ranging from -97.25% to 463% compared to the control sample.

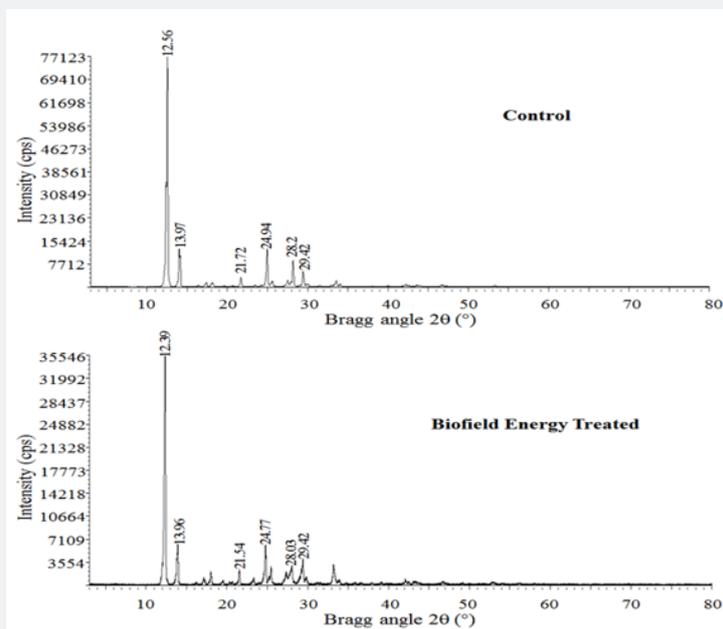


Figure 1: Powder XRD diffractograms of the control and the Biofield Energy Treated metronidazole.

Table 1: PXRD data for the control and the Biofield Energy Treated metronidazole.

Entry No.	Bragg angle (°2θ)		Peak Intensity (%)			Crystallite size (G, nm)		
	Control	Treated	Control	Treated	% change	Control	Treated	% change
1	6.49	6.42	79	28	-64.56	172	167	-2.91
2	12.56	12.39	9691	5372	-44.57	541	396	-26.8
3	13.97	13.96	1080	1010	-6.48	721	365	-49.38
4	16.4	16.28	90	41	-54.44	575	328	-42.96
5	17.4	17.24	262	165	-37.02	309	319	3.24
6	18.18	17.99	333	309	-7.21	240	502	109.17
7	19.57	19.57	63	99	57.14	163	331	103.07
8	20.52	20.67	102	78	-23.53	164	212	29.27
9	21.72	21.54	487	304	-37.58	386	627	62.44
10	23.49	23.34	125	140	12	516	338	-34.5
11	24.94	24.77	2056	933	-54.62	743	526	-29.21
12	25.43	25.48	208	365	75.48	501	633	26.35
13	25.63	25.61	232	28	-87.93	867	581	-32.99
14	27.48	27.36	448	351	-21.65	369	245	-33.6
15	28.2	28.03	1440	760	-47.22	648	189	-70.83
16	29.42	29.42	853	527	-38.22	428	505	17.99
17	30.07	29.85	292	226	-22.6	200	278	39
18	31.45	31.16	53	34	-35.85	380	240	-36.84
19	33.34	33.19	100	563	463	684	293	-57.16
20	33.54	33.94	361	139	-61.5	532	268	-49.62

21	34.05	34.9	182	5	-97.25	552	192	-65.22
22	36.04	35.93	20	34	70	274	429	56.57
23	36.83	36.62	25	29	16	216	365	68.98
24	42.05	42.08	79	94	18.99	227	508	123.79
25	42.6	42.47	63	43	-31.75	414	911	120.05
26	43.52	43.23	46	132	186.96	874	147	-83.18
27	46.67	46.67	215	113	-47.44	349	354	1.43
28	Average crystallite size					446.11	379.59	-14.91

Similarly, the crystallite sizes of the Biofield Energy Treated metronidazole sample were significantly altered ranging from -83.18% to 123.79% compared to the control sample. Overall, the average crystallite size of the Biofield Energy Treated metronidazole (379.59 nm) was significantly decreased by 14.91% compared with the control sample (446.11 nm).

The variations found in the crystallite sizes and peak intensities indicated the modification of the crystal morphology of the Biofield Energy Treated metronidazole compared to the control sample. The peak intensity of each diffraction face on the crystalline compound changes according to the crystal morphology [41] and alterations in the PXRD pattern provide the proof of polymorphic transitions [42,43]. The Consciousness Energy Healing Treatment (the Trivedi Effect[®]) probably produced the new polymorphic form of metronidazole through the Biofield Energy *via* neutrino oscillations [18]. Different polymorphic forms of pharmaceuticals have the significant effects on the drug performance, such as bioavailability, therapeutic efficacy, and toxicity, because

of their thermodynamic and physicochemical properties like melting point, energy, stability, and especially solubility, are different from the original form [44,45]. Thus, it can be assumed that the Consciousness Energy Healing Treated metronidazole would be better in designing pharmaceutical formulations containing metronidazole.

Particle Size Analysis (PSA)

The PSD analysis of both the control and the Biofield Energy Treated metronidazole were performed, and the data are presented in (Table 2). The particle size values of the control metronidazole at d_{10} , d_{50} , d_{90} , and D (4,3) were 146.78 μm , 307.35 μm , 624.32 μm , and 356.11 μm , respectively. Similarly, the particle sizes of the Biofield Energy Treated metronidazole at d_{10} , d_{50} , d_{90} , and D (4,3) were 125.21 μm , 274.09 μm , 504.82 μm , and 296.01 μm , respectively. Therefore, the particle size values in the Biofield Energy Treated metronidazole were significantly decreased at d_{10} , d_{50} , d_{90} , and D (4,3) by 14.69%, 10.82%, 19.14%, and 16.88%, respectively compared to the control sample.

Table 2: Particle size distribution of the control and the Biofield Energy Treated metronidazole.

Parameter	d_{10} (μm)	d_{50} (μm)	d_{90} (μm)	D (4,3) (μm)	SSA (m^2/g)
Control	146.78	307.35	624.32	356.11	0.0251
Biofield Energy Treated	125.21	274.09	504.82	296.01	0.0313
Percent change (%)	-14.69	-10.82	-19.14	-16.88	24.7

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.

The specific surface area of the Biofield Energy Treated metronidazole (0.0251 m^2/g) was significantly increased by 24.7% compared to the control sample (0.0313 m^2/g). Hence, it can be assumed that the Trivedi Effect[®]-Consciousness Energy Healing Treatment might act as an external force for breaking the larger particles to smaller particles in size of metronidazole sample, hence increased the surface area. It was reported that the particle size, shape, and surface area have their impact on the solubility, dissolution rate, absorption, bioavailability, and even the therapeutic efficacy if it is a drug [45,46]. The solubility profile of metronidazole is very poor, where is very slightly soluble in water, alcohol, dilute acid, chloroform, and dimethylformamide [10,11]. Thus, it is anticipated that the Biofield Energy Treated metronidazole might show the enhanced therapeutic properties of pharma-

ceutical formulations and would be better for the industry using it as a raw material for the manufacturing.

Differential Scanning Calorimetry (DSC) Analysis

The DSC thermograms of both control and the treated metronidazole are presented in (Figure 2). The DSC thermograms of the control and the treated metronidazole showed the sharp endothermic peak at 162.01°C and 161.55°C, respectively (Figure 2). Similarly, the control and the Biofield Energy Treated samples showed exothermic peaks at 288.01°C and 287.55°C, respectively (Figure 2). The thermogram pattern and melting point closely matched to the literature reported data [10]. The melting point and decomposition temperature of the Biofield Energy Treated metronidazole were decreased by 0.28% and 0.16%, respectively compared with the control sample (Table 3). The melting and

decomposition temperatures of the Biofield Energy Treated sample were decreased compared to the control sample. The melting point has been reported to decrease with decreasing particle size

[47]. The particle size results justified the decreased thermal behavior of the Biofield Energy Treated metronidazole compared to the control sample.

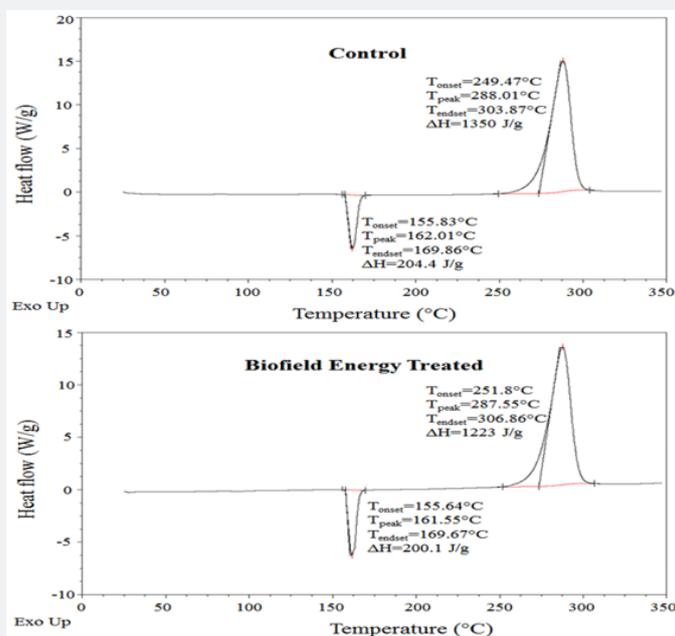


Figure 2: DSC thermograms of the control and the Biofield Energy Treated metronidazole.

Table 3: DSC data for both control and the Biofield Energy Treated samples of metronidazole.

Sample	Melting Temp (°C)	Decomposition Temp (°C)	ΔH (J/g)	
			Fusion	Decomposition
Control Sample	162.01	288.01	204.4	1350
Biofield Energy Treated	161.55	287.55	200.1	1223
% Change	-0.28	-0.16	-2.1	-9.41

ΔH: Latent heat of fusion/decomposition.

The latent heat of fusion (ΔH_{fusion}) of the Biofield Energy Treated metronidazole (161.55 J/g) was decreased by 2.1% compared with the control sample (200.1 J/g) (Table 3). Similarly, the latent heat of decomposition ($\Delta H_{\text{decomposition}}$) of the Biofield Energy Treated metronidazole (1223 J/g) was significantly decreased by 9.41% compared with the control sample (1350 J/g) (Table 3). The literature says that any change in the latent heat of fusion

can be attributed to the disrupted molecular chains and the crystal structure [48]. Thus, it can be predicted that the Trivedi Effect®-Consciousness Energy Healing Treatment might be responsible for the disruption the molecular chains and crystal structure of metronidazole which was the cause of declined thermal stability of the treated sample compared with the control sample.

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

Table 4: TGA/DTG data of the control and the Biofield Energy Treated samples of metronidazole.

Sample	TGA		DTG
	Total weight loss (%)	Residue %	T_{max} (°C)
Control	97.038	2.962	239.04
Biofield Energy Treated	99.522	0.478	230.61
% Change	2.56	-83.86	-3.53

T_{max} = the temperature at which maximum weight loss takes place in TG or peak temperature in DTG.

The TGA thermograms of the control and the Biofield Energy Treated metronidazole samples showed one step of thermal degradation (Figure 3). The Biofield Energy Treated metronidazole suffered a total weight loss of 2.56% more compared to the control sample (Table 4). Therefore, the residue amount was significantly decreased by 83.86% in the Biofield Energy Treated metronidazole compared to the control sample (Table 4). The

DTG of the control and the Biofield Energy Treated metronidazole also showed one peak in the thermograms (Figure 4). The T_{max} of the Biofield Energy Treated sample was decreased by 3.53% compared to the control sample (Table 4). Overall, TGA/DTG analysis of metronidazole samples revealed that the thermal stability of the Biofield Energy Treated sample was decreased compared with the control sample.

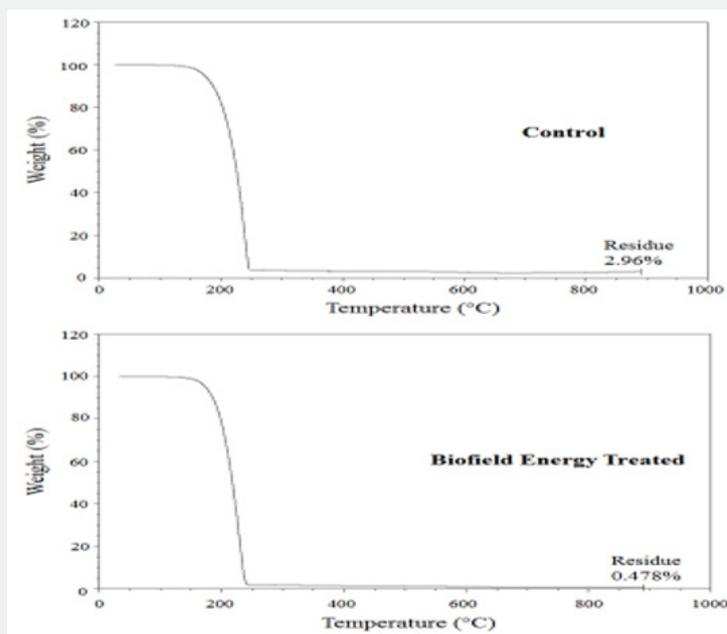


Figure 3: DSC thermograms of the control and the Biofield Energy Treated metronidazole.

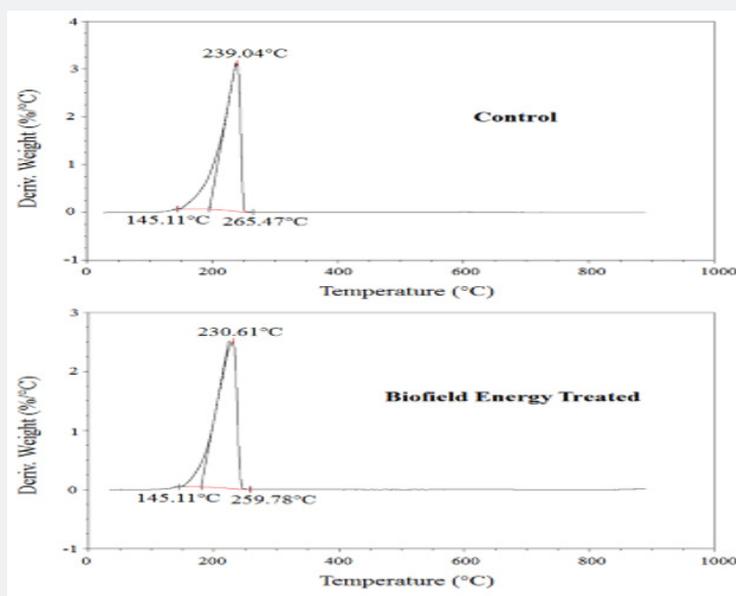


Figure 4: DTG thermograms of the control and the Biofield Energy Treated metronidazole.

Conclusion

The experimental results showed that the Trivedi Effect® (Consciousness Energy Healing Treatment) has a significant effect

on the particle size, surface area, and thermal properties of metronidazole. The peak intensities and crystallite sizes of the Biofield Energy Treated metronidazole were significantly altered ranging

from -97.25% to 463% and -83.18% to 123.79%, respectively; however, the average crystallite size was significantly decreased by 14.91% compared with the control sample. The particle size values in the Biofield Energy Treated metronidazole were significantly decreased by 14.69% (d_{10}), 10.82% (d_{50}), 19.14% (d_{90}), and 16.88% {D (4,3)}; thus, the specific surface area was significantly increased by 24.7% compared to the control sample. The latent heat of fusion and latent heat of decomposition were decreased by 2.1% and 9.41%, respectively in the Biofield Energy Treated sample compared with the control sample.

The total weight loss was increased by 2.56%; however, the residue amount was significantly decreased by 83.86% in the Biofield Energy Treated sample compared with the control sample. The maximum thermal degradation temperature was decreased by 3.53% in the treated sample compared with the control sample. From the results, it can be concluded that the Trivedi Effect®-Consciousness Energy Healing Treatment might have generated a new polymorphic form of metronidazole which may offer better solubility, dissolution, and good bioavailability compared with the control sample. The Trivedi Effect®-Consciousness Energy Healing Treated metronidazole would be very useful to design better pharmaceutical formulations that might offer better therapeutic response against bacterial and protozoal infections in the vagina (bacterial vaginosis), stomach (giardiasis, pseudomembranous colitis), liver, skin, joints (pelvic inflammatory disease), brain, and respiratory tract, aspiration pneumonia, rosacea, fungating wounds, intra-abdominal infections, lung abscess, periodontitis, amoebiasis, oral infections, and infections caused by susceptible anaerobic organisms such as *Bacteroides*, *Clostridium*, *Fusobacterium*, *Dracunculus*, *Peptostreptococcus*, *Helicobacter pylori*, and *Prevotella* species, etc.

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