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Evaluation of Impact of Expired and Non-Expired Albendazole Tablet on Soil Quality

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Abstract

Problem: Albendazole tablet is one among the antiparasitic drug widely used for the animals and humans, in order to treat the parasitic infections due to its broad-spectrum of anthelmintic activity. These tablets can be released into the soil from the households wastes and healthcare facilities. The release of the active pharmaceutical substances from the albendazole will result in the soil and water pollution due to the process of surface run-off and leaching. **Approach:** During the present research, a pilot study has been conducted in order to know the impacts of expired and non-expired albendazole tablets on the soil quality. In order to know the various properties and characteristics of both the tablets, few pharmaceutical evaluation tests were done. For the study, the expired and non-expired albendazole tablets were collected, powdered and added at the rate of 1g, 5g and 10g to the landfill soil sample. In order to maintain the moisture level, a tracer amount of water was added and it was kept for observations for a period of 30 days. After 30 days, the soil samples were collected, subjected to extraction and used for the analysis of various physico-chemical parameters. **Findings:** From the experimental result, it was found that, the expired albendazole tablet has greater potential to cause the negative impact on the soil quality. It was observed that, the parameters such as moisture content, (7.44%), pH (8.98), electrical conductivity (7.06 ds/m), potassium (2100.6 Kg/ha), available phosphorus (3588.8 Kg/ha) and sulphate values (421.96 ppm) were found to be higher in expired albendazole treatments, in comparison with the normal range of the soil quality standards. **Conclusion:** From the study, it was concluded that, the expired albendazole tablets in the soil can persist for longer periods, altering the soil chemical composition.

Key Words: Soil Parameters, Domestic Wastes, Unused and Expired Drugs.

Introduction:

Pharmaceuticals play a crucial role in the well-being of all living organisms. However, their persistence in the environment can have harmful effects. Numerous studies have identified the presence of various pharmaceutical compounds under the different environmental conditions. Consequently, the current environmental research is focused on the understanding of how the pharmaceutically active substances contribute to the contamination of the natural resources. Due to the widespread of human usage, the large quantities of pharmaceuticals are being discharged into the environment [1]. Among the major contributors, the municipal solid wastes play a crucial role in the accumulation of contaminants, including pharmaceutical residues. Many pharmaceuticals will have negative effects due to its chemical composition. For instance, certain drugs may result in the microbial resistance, which shows acute toxic effect or physiological functions of humans [2]. During the present research, it was observed that, the frequent disposal of expired and unused albendazole tablet was observed in the study area along with the household wastes. The albendazole is one among the antiparasitic medicine having a broad-spectrum of anthelmintic drug, used to treat the parasitic infections in humans and animals. Its primary mechanism involves inhibiting the tubulin polymerization in parasites, which disrupts their microtubule structure, impairing their cellular functions and ultimately leading to their death [3]. The antiparasitic drugs are broadly classified based on the type of parasite they target. The various types of helminthic medicines are Mebendazole, Albendazole, Diethylcarbamazine, Pyrantel Pamoate, Niclosamide and Levamisole. These drugs are used to treat many diseases such as, *Trichuris trichiura*, *Ancylostoma duodenale*, *Necator americanus* and so on.

Numerous studies have investigated the potential of albendazole in controlling the plant-parasitic nematodes. However, when albendazole expires, its active chemical components may degrade over a period of time, reducing its effectiveness in eliminating the nematodes or other soil-dwelling pests [4]. The expired albendazole has the potential to disrupt the soil microbial communities, posing a threat to the beneficial bacteria and fungi. If the degraded components of the expired drug produce toxic byproducts, they can interfere with the microbial activity and disrupt the nutrient cycle of the soil [5]. Additionally, the improper disposal of large quantities of the expired albendazole tablet can lead to its leaching into the soil and water systems, potentially harming the plant roots and altering the soil chemistry [6]. Based on the above concept, the present study has been undertaken in order to know the effect of albendazole tablet on the soil quality.

Materials and Methodology:

Chemical Composition of Albendazole Tablet: The albendazole is a broad spectrum anthelmintic. It is used for the treatment of Threadworm, Hookworm and Tape- worm. Albendazole is chemically known as methyl [5-(propylthio)-1H-

benzimidazol-2-yl] carbamate. Albendazole binds to the colchicines -sensitive site of β -tubulin inhibiting their polymerization into microtubules. The molecular formula of albendazole is $C_{12}H_{15}N_3O_2S$.

Pharmaceutical Study of Expired and Non-Expired Albendazole Tablet: A survey was carried out in the Mysore area for the present study. According to the survey, the expired albendazole medicines are among those often-disposed medicines along with the household trash. The pharmaceutical analyses have been conducted to assess the effects and the dissolution patterns of both the expired and non-expired albendazole tablets. For both the tablets' physical characteristics and the general organoleptic characteristics were evaluated. The assessment of taste, colour and the odour of both the tablets were carried out. To get the average weight, the weight of each tablet was measured separately. Additionally, the drug dosage and the content of both the tablets were also determined. The label of the tablet, indicates the active pharmaceutical ingredient, which aids in determining the therapeutic class. The physical tests included are hardness, friability, disintegration and the dissolution tests. The hardness test assessed the mechanical strength of the tablets, while the disintegration test evaluates, how quickly the tablets break down in the normal water. The dissolution of the tablets was conducted under the controlled laboratory conditions in order to evaluate the rate and extent of drug release with reference to time.

Collection of Soil Sample: From the nearby landfills, a composite soil samples were collected. The soil samples were taken from a depth of 0-15 cm. The collected soil was air dried, passed through 2mm sieve and stored for further analysis. The collected soil samples were subjected to the soil quality characterization. The analysis was conducted according to the standard manual [Standard Methodology of Soil Analysis by Arun Kumar Saha (2008), GKVK Manual (1999)]. The soil samples were subjected to physico-chemical characterisation and from the results it was observed that, all the parameters were found to be within the normal range.

Selection of Dosage of Albendazole Tablet: Based on the survey, the kinds of tablets that are disposed along with the domestic wastes were noted and quantified. The concentration of the albendazole was chosen for the experiment based on the quantification.

Pilot Study: In the current research, a pilot study was conducted. The expired and non-expired albendazole tablets were powdered and mixed with landfill soil sample at the concentrations of 1g, 5g, and 10g, then transferred to polythene pots with 1kg capacity. For the accurate results, three trials with one control (without any addition of tablets) were maintained for each concentration. The

moisture levels were maintained during the experimental study. All the treatments were kept for observation for 30 days. The soil samples were collected at every 10 days interval from all the treatments to assess the impact on the soil quality and the comparison of the experimental results has been done by considering the soil quality standards.

Results and Discussion:

Table 1. Description of General Organoleptic Characteristics and Physical tests of Expired and Non-expired Albendazole Tablets			
	Characteristics	Non-Expired tablet	Expired tablet
1	Name of the tablet	Albendazole	Albendazole
2	Layer	Uncoated, unlayered, slight embossed	Uncoated, unlayered, slight embossed
3	Drug content	Albendazole	Albendazole
4	Dosage	400mg	400mg
5	Colour	Sunset Yellow FCF	Sunset Yellow FCF
6	Odour	Faint fruity smell	Faint fruity smell
7	Taste	Sweet and chewable	Sweet and chewable
8	Size	1.9cm	1.8cm
9	Shape	Caplet shape	Caplet shape
10	Weight	Each tablet contains 0.653g	Each tablet contains 0.642g
11	Therapeutic class	Anthelmintics	Anthelmintics
12	Hardness test	6.9g	7.83g
13	Friability	0.0061 %	0.0013%
14	Disintegration	6 mins	7mins
15	Dissolution	Dissolution of a drug is 95.1 % in 30minutes	Dissolution of a drug is 2.505% in 120mins

The interpretation of the obtained experimental results were presented as follows. Table 1 shows the organoleptic properties and the physical tests of both the expired and non-expired albendazole tablets. From the results, it was found that, both the Albendazole tablets are uncoated, single layer with slight embossed type of tablet. The drugcontent present in the both the tablet is albendazole. The dosage of the tablet was found to be 400mg per tablet. The colour of both the tablets were found to be sunset yellow FCF. The odour of the tablet was faint fruity. The tablets were found to be sweet and chewable. The shape of the non-expired tablet and expired albendazole tablet was caplet in shape. Albendazole tablets belongs to the therapeutic class of anthelmintics.

The results observed from the physical tests of both the expired and non-expired albendazole tablets are as follows:

Weight: The non-expired albendazole tablets weigh approximately 0.653g, while the expired ones weigh about 0.642g. The slight reduction in the weight for the expired tablets is likely due to the moisture loss over the period of time.

Hardness: The non-expired albendazole tablets have the hardness of 6.9g, whereas expired tablets are harder, measuring 7.83g. The moisture penetration into the tablet matrix becomes more difficult when the tablets are harder, which might slow down the dissolution process.

Friability: The non-expired albendazole tablets exhibit a friability of 0.0061%, compared to expired tablets. Lower the friability indicates that, the expired tablets are less liable to crumbling, which may be attributed to their increased hardness.

Disintegration Time: Both the albendazole tablet disintegrate within 6-7 minutes in water.

Dissolution Rate: A significant difference was observed in the dissolution pattern of the tablets. The non-expired tablets release 95.1% of albendazole within 30 minutes [7], whereas the expired tablets release only 2.505% even after 120 minutes. This drastic reduction in the dissolution rate for the expired albendazole tablets suggests that, the increased hardness and the potential changes in the tablet matrix over a period of time adversely affect the drug release pattern in the soil systems.

Based on the above physical tests of both the expired and non-expired albendazole tablet, it was observed that, the expired tablet's quality and stability of the tablet was shown lesser dissolution rate in comparison with the non-expired tablet. In order to study its effectiveness in the soil environment, the setablets were further used for pilot study.

The results of the physico-chemical parameters of the landfill soil samples treated with different concentrations of expired and non-expired albendazole tablets are presented in Table 2. The experimental results were compared with the soil quality standards and the control values. The interpretation of the obtained experimental results are presented as follows.

In the present study, it was observed that, as the number of days increased, with the concentration of expired and non-expired albendazole tablet, the percentage of moisture content in the soil sample were also found to increase. In both the treatments, the moisture content values were found to be higher in comparison with the normal range of the soil quality standard. The higher moisture content observed was 7.44% in 10g concentration of expired albendazole at 30th day interval. In non-expired albendazole treatments, the highest moisture content was found to be 7.20% in 10g concentration at 30th day interval. The expired medicines may undergo degradation when exposed to the moisture, which could

affect the soil's composition and potentially lead to the leaching of harmful substances into the surrounding environment [8].

The water holding capacity refers to the ability of a soil, to retain water within its pores or structure. From the experiment, it was observed that, in comparison with the control, the highest water holding capacity was found in non-expired albendazole treatment. The maximum water holding capacity was found to be 46.3% in non-expired albendazole and 46.2% in expired tablet treatment at 30th day interval.

The bulk density represents the compactness between the overall soil volume. From the study, it was observed that, in both the tablet treatments, the bulk density values were found to increase as the number of days increases. The normal range of bulk density varies from 1-1.65 Mg/m³. In comparison with the normal range of the soil quality standard, the bulk density values were found to be within the range and higher than the control value. From the results, it was observed that, the higher bulk density values observed was 1.37 Mg/m³ in 10g concentration at 30th day interval in expired albendazole treatment.

The particle density of the soil indicates the mass of a particle per unit volume. In the present study, it was observed that, as the concentration of the albendazole tablet increases, there was an increase in the particle density values in both the tablet treatments. In comparison with the normal range of the soil and the control, the particle density values were found to be within the soil quality standards. The highest particle density was found to be 2.68 Mg/m³ in 10g of expired albendazole concentration at 30th day interval.

The porosity of the soil indicates the fraction of the soil volume that is occupied by the pore or the void spaces, which can contain air, water or other fluids. The normal range of the porosity in the soil varies from 30-65 %. In the present study, the porosity values were found to be within the soil quality standards.

The maximum porosity observed was 50.2% in the expired albendazole treatment and 52.22 % in non-expired tablet treatment at 30th day interval.

The pH of the soil sample in any geographical condition varies due to the influence of microbial activity under the various environmental conditions. Particularly, in waste dumping sites, various categories of waste and its disintegration in various environmental conditions will influence over the variation of pH. In the present study, the pH value ranges from 8.34 to 8.98 in an expired albendazole treatment and 6.98 to 7.49 in non-expired tablet treatment. The normal range of the pH in the soil varies from 6.5 to 7.5. In comparison with the soil quality standards and the control, the pH values were found to be higher. The maximum pH was found in 10g concentration at 20th day interval in expired albendazole treatment.

The electrical conductivity is a vital indicator of the ionic concentration in any type of the soil. The normal range of the electrical conductivity in the soil varies from 1-2 ds/m. In the present study, the highest electrical conductivity values observed was 7.06 ds/m in an expired albendazole treatment and 0.26 ds/m in non-expired tablet treatment in 10g concentration at 20th day interval. The electrical conductivity value was found to be higher in expired albendazole treatment in comparison to the soil quality standards. This indicates even though non-expired albendazole tablet has an impact on the electrical conductivity values, the expired tablet with increase concentration will have greater impact on the overall soil quality.

In general, the calcium is one of the main elements that helps in controlling the pH level of the soil. From the experimental results, the calcium content was gradually increased from 10th day to 20th day interval. The normal range of the calcium in the soil varies from 700-36000 ppm. The highest calcium values observed was 445 ppm in the non-expired albendazole treatment in 10g concentration at 20th day and 325.6 ppm in 1g concentration of expired tablet treatment at 30th day interval. In comparison with the soil quality standard, the calcium values were found to be lesser. The normal range of magnesium varies from 1200 – 15000 ppm. In the present study, the magnesium values in both the treatments were found to be lesser in comparison with the soil standard. The maximum magnesium content observed was 42.6 ppm in the expired albendazole treatment in 10g concentration at 10th day interval and 52.3 ppm in non-expired tablet treatment in 5g concentration at 30th day interval.

The chloride is one among the anions that is responsible for the increase in the soil salinity and has negative impacts on the soil quality. From the study, it was found that, the chloride values observed was lesser at 10th day expired albendazole

treatment in comparison with the soil quality standard and the control. The higher chloride values were found to be 1.43% in expired albendazole treatment and 1.25% in non-expired tablet treatment in 10g concentration at 30th day interval.

The organic carbon is a major component of organic matter, which decomposes to release the essential nutrients in order to enhance the soil fertility. From the experimental results, the organic carbon was observed between the range 0.62-1.56 % in the expired albendazole treatment and 0.27-1.23% in non-expired tablet treatment. The highest organic carbon was found to be 1.56% in 10g concentration of expired albendazole treatment at 30th day interval. The normal range of the organic carbon in the soil varies from 0.5-0.75%. In comparison with the soil quality standard of organic carbon, the highest value was observed in the expired albendazole treatment.

The addition of the expired albendazole tablets to the landfill soil, can influence on the availability of the essential nutrients such as available nitrogen, potassium, sulphates and available phosphorus due to its chemical composition. In the present study, in comparison with the normal range, the nitrogen values were found to be within the range in both the treatments. The highest available nitrogen value observed was 167 Kg/ha in expired albendazole treatment in 1g concentration at 10th day interval and 123 Kg/ha in 1g concentration of non-expired tablet treatment at 10th day interval.

From the experimental analysis, the potassium levels in the expired albendazole treatments were observed in the range of 8610.6kg/ha to 21100.6Kg/ha. In comparison with the soil quality standard and the control values, the potassium values were found to be very much higher in expired albendazole treatment. The maximum potassium value observed was 21100.6 Kg/ha in 10g concentration at 20th day interval. Generally, organic materials in landfills can contribute to higher levels of potassium due to the decomposition of plant and food waste, which release the high potassium content.

The soil's normal range of the available phosphorus varies from 10-25 kg/ha. In the present study, the available phosphorus value was found to be higher in both the albendazole tablet treatment in comparison with the normal range. The maximum available phosphorus observed was 3588.8 Kg/ha in expired albendazole treatment and 649.3 Kg/ha in non-expired in 10g concentration at 20th day interval. The experimental results show that, among all the treatments, the highest sulphate value observed was 421.96 ppm in 10g concentration at 20th day interval in the expired albendazole treatment. In comparison with the soil quality standards and the control, the higher sulphate values were observed in the expired albendazole treatment.

In relation to the study of effect of unused and expired albendazole tablets on the soil quality, much of the research work is focused on the sorption and kinetic studies with limited focus on soil quality parameters. Based on the few references, the present experimental results were correlated as follows. In case of the physical parameters, many research reviews states that,

the pharmaceuticals that are disposed were bind to the soil particles and influence over the soil physical properties. This was observed by few researchers like Oluwatoyin et al., 2021, In case of the pH and electrical conductivity, the dissolution of the albendazole tablet will influence the rise in pH level that intern has influence over the major cationic and anionic concentrations in the soil. The similar observations were documented from Pavlovic et al., 2018 and other researchers from their studies on the pharmaceutical's absorption and its behaviour in the soil matrix. In case of other cations and anions like calcium, magnesium, chloride mainly influence the electrical conductivity and its value will increase with the increase in the albendazole tablet concentration (9). The present study, also highlights the need of in-depth research pertaining to the unused and expired albendazole tablets disposal along with domestic waste impact on the overall the soil health

Conclusion:

Based on the experiment conducted with the amendment of expired and non-expired albendazole tablets into the landfill soil sample, it was found that, the soil's physico-chemical properties were found to be altered. The major alteration in soil parameters were found in expired albendazole treatments. This might be due to the effect of expired albendazole medicine on the soil depends on the chemical composition of the tablet with their degradation of active pharmaceutical ingredients. From the experimental results, it was found that, the expired albendazole tablet has shown greater potential to cause negative impact on the soil quality. The parameters such as moisture content, pH, electrical conductivity, potassium, available phosphorus and sulphate values were found to be higher in expired albendazole treatments, in comparison with the normal range of the soil. From the organoleptic characterization of expired albendazole tablet showed the influence over the soil property when its accumulation reaches to higher level. Due to this, the soil near the landfills may get contaminated, which might cause leachate to seep through the soil profile and cause damage to the upper part of the soil, reducing the soil quality. From the overall study, it can be concluded that, the persistence and accumulation of unused and expired albendazole tablets can get into surface waters or groundwater directly. This will have an impact on the aquatic ecosystem. Additionally, the substances have the potential to enter the human food chain and harm people indifferent ways. This can be minimized by implementing the medicine disposal policy, specialized pharmaceutical waste treatment facilities, guidelines and improving the awareness of the public on the appropriate medicine disposal methods and practices will help to prevent the environmental contamination.

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Table 2. Physico-Chemical Characterization of Landfill Soil Sample Treated with Expired and Non-Expired Albendazole Tablets																	
Soil Physico-Chemical Parameters		M C (%)	WH C (%)	BD (Mg /m³)	PD (Mg/ m³)	Poro sity (%)	pH	EC (ds/ m)	Ca ² + (ppm)	Mg ²⁺ (ppm)	Cl ⁻ (%)	OC (%)	AN (Kg/h a)	K ⁺ (Kg/h a)	AP (Kg/h a)	SO ₄ ²⁻ (pp m)	
Normal Range of Soil		1-1.65	-	1-1.65	2-2.65	30-65	6.5 - 7.5	1-2	700-36000	1200-15000	0.01 - 0.99	0.5-0.75	240-480	110-280	10-25	8-30	
Control		4.46	37.62	1.182	1.876	36.994	7.35	1.41	84.16	19.45	0.532	0.66	163	251.4	79.42	26.68	
Days																	
10 th Day	Expired	1g	6.11	43.7	1.19	2.16	44.7	8.35	4.0	311.3	41.33	0.89	0.76	<u>167</u>	9466.3	2521.5	148.1
		5g	6.24	44.1	1.21	2.28	46.4	<u>8.34</u>	3.9	318.6	35	0.96	0.9	154.6	<u>8610.6</u>	2409.9	171.4
		10g	6.29	44.3	1.23	2.31	47.0	8.91	6.56	312.6	<u>42.6</u>	1.02	1.52	161.3	18315.3	2975.5	350.0
	Non-Expired	1g	4.94	41.6	1.16	1.95	40.5	7.10	0.16	390.3	42	0.47	0.53	123	134	600.7	25.24
		5g	5.22	42.0	1.17	1.97	40.4	7.14	0.2	398.3	46	0.53	0.72	106.6	135.3	207.2	20.95
		10g	5.55	42.4	1.18	1.98	40.4	7.09	0.2	366	49.3	0.62	0.75	121.3	135.3	490.7	9.04

20 th Day	Expired	1g	6.4 7	44. 7	1.25	2.39	46.3	8.4 0	4.16	319.3	30.3	1.09	<u>0.62</u>	144.3	8613	2665. 1	144. 7
		5g	6.6 2	44. 9	1.26	2.45	48.3	8.3 9	3.96	311	37.3	1.17	0.84	117	10797	3134. 9	133. 8
		10 g	7.0	45. 2	1.27	2.51	48.9	<u>8.9</u> <u>8</u>	<u>7.06</u>	321	41.3	1.24	1.46	130.6	<u>21100</u> <u>.6</u>	<u>3588.</u> <u>8</u>	<u>421.</u> <u>96</u>
	Non-Expired	1g	5.9 5	43. 7	1.18	2.02	41.2	7.1 1	0.17	375.6	37.6	0.73	0.51	112.6	119.6	425.4	20.6 6
		5g	6.2 3	44. 2	1.19	2.13	43.9	6.9 8	0.19	392.3	41.0	0.87	0.56	117	128	460.1	21.0 4
		10 g	6.5 1	44. 5	1.20	2.26	46.6	7.3 7	0.26	445	50.38	0.93	1.23	113	136.3	649.3	50.3 8
30 th Day	Expired	1g	7.1 7	45. 5	1.28	2.57	49.1	8.6 2	4.86	<u>325.6</u>	38.3	1.31	0.81	129.6	9159	2429. 8	137. 16
		5g	7.3 8	45. 9	1.30	2.60	49.9	8.4 0	4.30	316.6	41.0	1.37	1.12	131.3	10659 .6	2035. 5	139. 06
		10 g	<u>7.4</u> <u>4</u>	<u>46.</u> <u>2</u>	<u>1.37</u>	<u>2.68</u>	<u>50.2</u>	8.8 1	5.93	318.3	36.6	<u>1.43</u>	<u>1.56</u>	138	18887 .6	1489. 8	298. 60
	Non-Expired	1g	6.8 3	45. 6	1.22	2.39	48.8	7.4 9	0.12	379.6	37.6	1.09	0.27	111	132	621	37.6 2
		5g	7.0 8	45. 8	1.24	2.53	50.4	7.4 3	0.15	427.0	52.3	1.17	0.6	102.3	135.3	523	42.5 7
		10 g	7.2 0	46. 3	1.25	2.63	52.2 2	7.4 4	0.19	413.3	44.3	1.25	0.77	113	133	648.8	49.2 4

Note: The experimental results are the average values of three trails of each concentration[MC-Moisture content, WHC- Water Holding Capacity, BD-Bulk Density, PD-Particle Density, EC-Electrical Conductivity, Ca^{2+} - Calcium, Mg^{2+} Magnesium, Cl^- - Chloride, OC-Organic Carbon, AN-Available Nitrogen, K^+ -Potassium, AP-Available Phosphorus, SO_4^{2-} -Sulphates]