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Unused and Expired Tablets as Emerging Contaminants and its Impact on Soil Quality: A Case Study of Paracetamol Tablet

Vasudha Ranjan*, Divya.J[1], Balamuralidhara.V[2], A.R. Akhila[3], Basavarajappa S.H.[4]

*Research Scholar, Department of Environmental Science, JSS Academy of Higher Educationand Research, Mysore

[1]Assistant Professor, Department of Environmental Science, JSS Academy of Higher Educationand Research, Mysore

[2]Associate Professor and Head of the Department, Department of Pharmaceutics, JSS College of Pharmacy, Mysore

[3]Lecturer, Department of Pharmaceutics, JSS College of Pharmacy, Mysore

[4]Assistant Professor, Department of Environmental Science, Shankaraghatta, Kuvempu University, Shimoga

Abstract

Problem: Acetaminophen, another name for paracetamol, is one of the over-the-counter medicines that is the most frequently used across the world. The frequent and unnecessary use of over-the-counter drugs contributes to the increased environmental pollution. The improper disposal of unused or expired tablets might reach to the landfills along with the household wastes. **Approach:** During the present research, a pilot study has been conducted in order to know the impacts of expired and non-expired paracip tablets on the soil quality. In order to analyse the quality and stability of the expired and non-expired tablets, the organoleptic and physical tests of both the paracip tablets were examined. For the experiment, the powdered expired and non-expired paracip tablets were added at the concentrations of 1g, 5g, and 10g to the landfill soil and kept for observations for 30 days. From all treatments, the soil samples were collected and subjected to extraction and used for the analysis of various physico-chemical parameters. **Findings:** From the results of the physical tests of both the paracip tablets, the rate of dissolution of expired paracip tablet was 0.26% at 120 minutes and the rate of dissolution of non-expired paracip tablet was 99.78% at 30minutes. From the experimental results, it was observed that, most of the parameter's values were found to be higher in comparison with the soil quality standards. **Conclusion:** From the study, it can be concluded that, the proper management of unused and expired tablets has to be taken care while disposing along with the household wastes in order to protect the overall environment.

Keywords: Paracetamol, Expired, Organoleptic, Soil Quality, Non-Expired, Disposal.

1. Introduction

Paracetamol, is one of the most consumed medications around the world. It is thefrequently used tablet, with the presence ofanalgesic (pain-relieving) and antipyretic (fever-reducing) properties. It is also called as acetaminophen. It is also present in the combination with other pharmaceuticals which accounts for more than 600 different prescription medicines. Paracetamol tablet is effective for mild to moderate pain relief, such as headaches, muscle aches and toothaches. Additionally, it can help to reduce the fever associated with various illnesses. Unlike other drugs such as ibuprofen, aspirin, and naproxen, which belongs to the class of nonsteroidal anti-inflammatory drugs (NSAIDs), paracetamol does not have significant anti-inflammatory properties. Despite the toughening environmental and waste management regulations in the pharmaceutical and agro-food industry, acetaminophen is frequently detected in water, sediments, sewage sludge and the soil [1].As the use of these drugs are unavoidable and these pharmaceutical compounds are excreted in the form of biological wastes as an active metabolite, either directly or indirectly in high fractions.

Paracetamol is listed as an essential medicine by the World Health Organization, highlighting its importance in a basic healthcare system. On the same way, the disposal of expired and unused tablets is one of the major responsibilities foroverall society. When these expired and unused tablets are directly disposed to the land, it can indeed have significant negative impacts on the environment [2]. Many research studies show that, when the expired paracetamol degrades in the soil, it can produce various metabolites. Some of the metabolites are p-Aminophenol and N-acetyl-p-benzoquinone imine.These are potentially toxic to the soil microorganisms.The soil enzymes are crucial for the breakdown of organic matter and nutrient cycling. Paracetamol and its degradation products can inhibit the enzyme activity, resulting in decline in the soil fertility [3]. The present research on the impacts of expired paracetamol on the soil is limited, and the actual effects can vary based on the factors such as soil type, climate, microbial community compositionand the concentration of the drug. The proper disposal of expired medications is essential to mitigate the potential environmental impacts [4]. Based on the above concept, the present study has been undertaken to know the effect of expired paracip tablet on the soil quality.

2. Materials and Methods:

Chemical composition of Paracetamol Tablets: Paracetamol is N-Acetyl-para-Aminophenol, synthetic chemical compound produced by acetylation of 4-aminophenol using acetic acid. Paracetamol includes calcium or magnesium stearate, cellulose, sodium benzoate, sodium lauryl sulphate, starch and sodium starch glycolate.Paracetamol is available in various trade names such as paracip, dolo, cetaponacetamol, anuphen, calpol, alvedon, 4-hydroxyacetanilide, N-(4-Hydroxyphenly)acetamide, 4-Acetamidophenol, panadol, tylenol, and so on. Paracetamol is soluble in water and solutions of alkali hydroxide but insoluble in

diethyl ether. The structural formula of paracetamol is $C_8H_9NO_2$. Paracip was the brand name of the tablet utilized in the present study.

Pharmaceutical analysis of expired and non-expired paracip tablets: In the current study, a survey was conducted in the Mysore city area. From the survey, it was found that, the expired paracip tablets are one among those commonly discarded medicines along with the household domestic wastes. To compare the effects and dissolution patterns of both expired and non-expired paracip tablet, the pharmaceutical analyses have been done. The general organoleptic properties and physical tests of both the expired and non-expired tablets were assessed. Organoleptic characterization includes the evaluation of the tablets' odour, taste and the colour. Each tablet's weight was measured individually to determine the average weight. The drug dosage and the content of both the tablets were also determined. The label of the tablet, indicatesthe active pharmaceutical ingredient, which aids in determining the therapeutic class. The physical tests included are hardness, friability, disintegration and 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 both the expired and non-expired paracip tablets was conducted under controlled laboratory conditions to evaluate the rate and extent of drug release with reference to time.

Collection of Soil Sample:A composite soil samples were collected from the nearby landfills. The collected soil sample was subjected to the soil quality characterization and the results were presented in Table 3. The soil samples were taken from a depth of 0-15 cmThe collected soil was air-dried, passed through a 2mm sieve and stored until further analysis being done. The analysis was conducted according to the standard manual [Standard Methodology of Soil Analysis by Arun Kumar Saha (2008), GKVK Manual (1999)]. From the results, it was observed that, all the soil quality parameters were found to be within the permissible limits.

Selection of Dose of Paracip Tablet: From the initial survey, about the type of various tablet that are disposed along with the domestic waste were recorded and quantified. Based on the quantification, the selection of concentration of paracip tablet was donefor the experiment.

Pilot study: In the current research, a pilot study was conducted. The expired and non-expired paracip tablets were powdered and mixed with landfill soil samples at the concentrations of 1g, 5g, and 10g, then transferred to polythene pots with 1 kg capacity. For 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

observationfor 30 days. The soil samples were collected at every 10 days intervalfrom all the treatments to assess theimpact on soil quality and comparison of the experimental results has been done by considering the soil quality standards.

3. Results and Discussions:

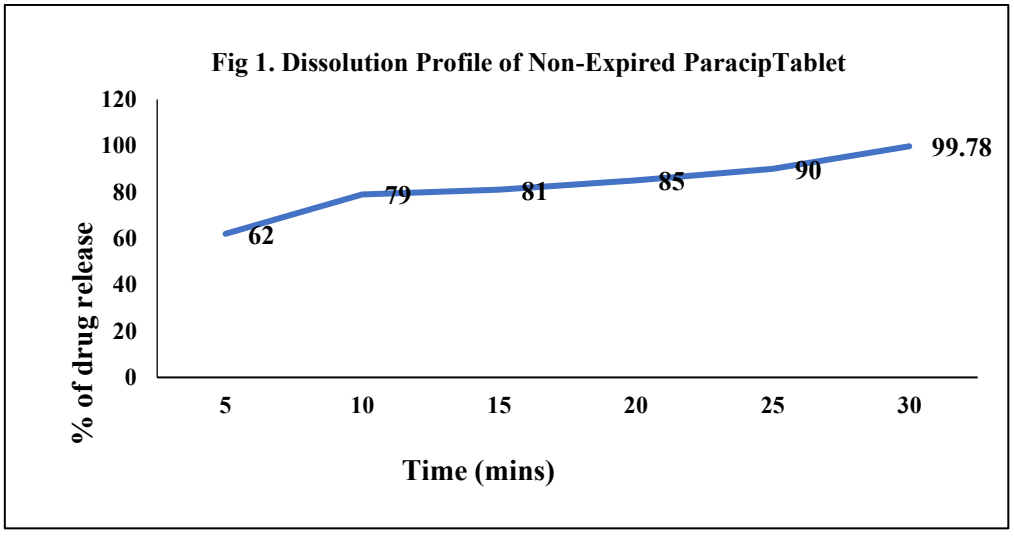
Table 1. Description of General Organoleptic Characteristics and Physical tests of Expired and Non-expired Paracip Tablets.

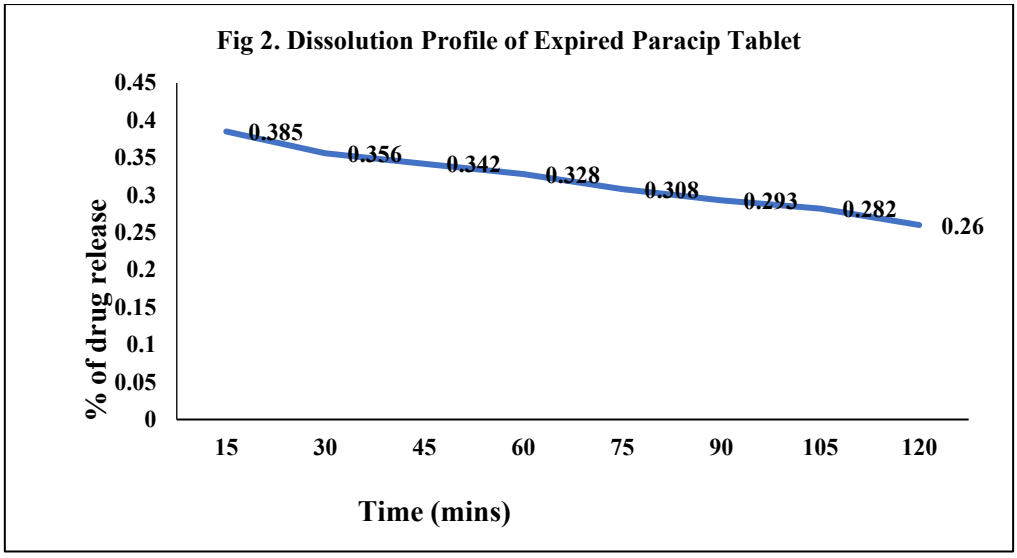
	Characteristics	Non-Expired tablet	Expired tablet
1	**Name of the tablet**	Paracip	Paracip
2	**Layer**	Uncoated single layer embossed tablet	Uncoated single layer embossed tablet
3	**Drug content**	Paracetamol IP	Paracetamol IP
4	**Dosage**	650mg	650mg
5	**Colour**	White	White
6	**Odour**	Kind of medicinal odour due to hydroxyl group in it	Kind of medicinal odour due to hydroxyl group in it
7	**Taste**	Bitter	Bitter
8	**Size**	10 mm in diameter	10 mm in diameter
9	**Shape**	Round	Round
10	**Weight**	Each tablet contains 0.827g	Each tablet contains 0.812g
11	**Therapeutic class**	Analgesics & antipyretics	Analgesics & antipyretics
12	**Hardness test**	8.06g	12.833g
13	**Friability**	0.007%	0.0061%
14	**Disintegration**	3 minutes	5minutes
15	**Dissolution**	Dissolution of drug is 99.78%at 30 mins	Dissolution of drug is 0.26%at 120 mins

Table 1 shows the organoleptic properties and physical tests of both the expired and non-expired paracip tablets. From the results, it was found that, both the paracip tablets are uncoated single layer with embossed type of tablet. The drug content present in the tablet is paracetamol. The dosage of the tablet was found to be 650mg per tablet. The colour of both the tablets were found to be white. There was akind of medicinal odour due to the presence of hydroxyl group in it. The tablets were found to be very bitter in taste. The shape of the non-expired tablet and expired paracip tablet was round in shape. Paracip tablets belongs to the therapeutic class of analgesics and antipyretics. Each non-expired paracip tablets weighs for about 0.827g whereas, the expired paracip weighs for about 0.812g

per tablet. This might be due to the loss of moisture content of the expired tablet when it is exposed to an open environment over the period of time.

The results observed from the physical tests of both the expired and non-expired paracip tablets are as follows: The hardness of the non-expired tablet was observed to be 8.06g, in case of expired paracip, the hardness was found to be 12.833g. The expired paracip tablet was harder than the non-expired paracip because of the moisture loss and due to the presence of hydroxyl group in it, which has water absorbing capacity after exposure to different environmental conditions. The friability of the non-expired paracip tablet observed was 0.007% and expired tablet was 0.0061%. The disintegration time of the non- expired paracip tablets was observed to be over 3 minutes;however, the expired paracip tablets took 5 minutes to dissolvecompletely in the normal water. Fig 1 and 2 shows the dissolution profile of non-expired and expired paracip tablet. From the dissolution study, it was observed that, 99.78% of non-expired paracip was released at 30 minutes and in case of expired tablet, the rate of dissolution of the drug observed was only 0.26% at 120 minutes. The dissolution rate of a drug is influenced by the size and arrangement of the drug particlesand the solubility of the drug in aqueous medium. A high dosage-tablet's hardness hinders the rapid dissolution of the drug component in water because, the water has to penetrate the solid matrix and break it down.





Based on the pharmaceutical analysis of expired and non-expired paracip tablets, it was observed that, the expired tablet disintegrates more slowly than the non-expired tablet. The expired tablet is less dissolved because of environmental factors like moisture loss, and it takes longer time to disintegrate compared to the non-expired tablet. Therefore, a pilot study and physico-chemical tests were carried out in order to determine the impact of expired and non-expired tablets on the soil environment. The experimental results are presented in the Tables 2 and 3.

Table 2. Physico-Chemical Characterization of Landfill Soil Sample Treated with Expired and Non-Expired Paracip Tablets																
Soil Physico-Chemical Parameters			**MC**	**WHC**	**BD**	**PD**	**Porosity**	**pH**	**EC**	**Ca^{2+}**	**Mg^{2+}**	**Cl^{-}**	**OC**	**AN**	**K^{+}**	**AP**	**SO_4^{2-}**
Normal Range			**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**
Days	**Soil Samples treated with different concentrations of expired & non-expired Paracip Tablet**																
10th Day	**Expired**	**1g**	**6.01**	47.57	1.18	1.99	40.39	**8.19**	**7.7**	**446**	**45.3**	**0.83**	**1.17**	**152.66**	**152.0**	**206.33**	**220.03**
		5g	**6.20**	47.68	1.19	2.08	42.51	**8.20**	**8.0**	**464.33**	**47**	**0.88**	**1.19**	**221.66**	**169.25**	**209.9**	**239.08**
		10g	**6.30**	47.84	1.20	2.15	43.67	**8.25**	**8.33**	**480.6**	**47.6**	**0.93**	**1.31**	**297.0**	**172.25**	**243.66**	**246.7**
	Non-Expired	**1g**	5.30	**57.25**	1.16	1.92	39.74	7.85	0.06	215	14.66	0.26	0.26	246.16	70.66	1.2	7.04
		5g	5.31	**57.62**	1.17	2.02	42.20	7.91	0.07	218	18	0.29	0.30	278.33	72.0	1.2	9.24
		10g	5.38	**57.93**	1.17	2.15	45.36	7.97	0.8	219.66	18.33	0.32	0.45	282.66	81.66	1.2	11.14
20th	**Expired**	**1g**	**6.35**	48.06	1.21	2.27	46.31	**8.33**	**8.8**	**480.7**	**49.3**	**0.99**	**1.55**	**343**	**176.37**	**554.90**	**250.51**
		5g	**6.43**	48.19	1.22	2.33	47.49	**8.37**	**8.83**	**487.33**	**50.0**	**1.05**	**1.57**	**359.66**	**184.98**	**613.60**	**257.17**

Day		**10 g**	**6.57**	48.31	1.23	2.40	48.84	**8.37**	**8.83**	**491.66**	**50.6**	**1.14**	**1.61**	**393.33**	**198.52**	**642.06**	**261.94**
	Non-Expired	**1g**	5.39	**58.24**	1.18	2.27	47.85	8.01	0.9	221.66	19.33	0.36	0.62	348	84	2.0	12.1
		5g	5.41	**58.36**	1.19	2.31	48.98	8.02	0.12	228	20.66	0.39	0.67	350.33	87.66	2.4	13.04
		10 g	5.46	**58.54**	1.21	2.39	49.28	8.05	0.15	230.66	21.33	0.42	0.75	370	95.66	2.4	15.24
30th Day	**Expired**	**1g**	**7.06**	48.41	1.25	2.47	49.58	**8.40**	**9.06**	**496.66**	**54.66**	**1.21**	**1.88**	**430.66**	**216.25**	**649.24**	**281.94**
		5g	**7.25**	48.52	1.26	2.54	50.52	**8.41**	**9.1**	**505.33**	**55**	**1.26**	**1.94**	**485**	**219.83**	**650.93**	**308.85**
		10 g	**7.41**	48.64	1.27	2.60	51.00	**8.49**	**9.30**	**533.0**	**57.6**	**1.34**	**2.03**	**525.0**	**236.90**	**650.96**	**343.85**
	Non-Expired	**1g**	5.61	**64.13**	1.22	2.44	50.1	8.06	0.17	234.0	23	0.46	0.96	379	120	3.6	17.05
		5g	5.63	**64.72**	1.24	2.51	50.62	8.12	0.18	237	24.66	0.49	1.00	385	141	4.8	22.76
		10 g	5.81	**65.12**	1.25	2.58	51.06	8.12	0.20	254.66	26	0.54	1.22	394	152	6.8	33.33

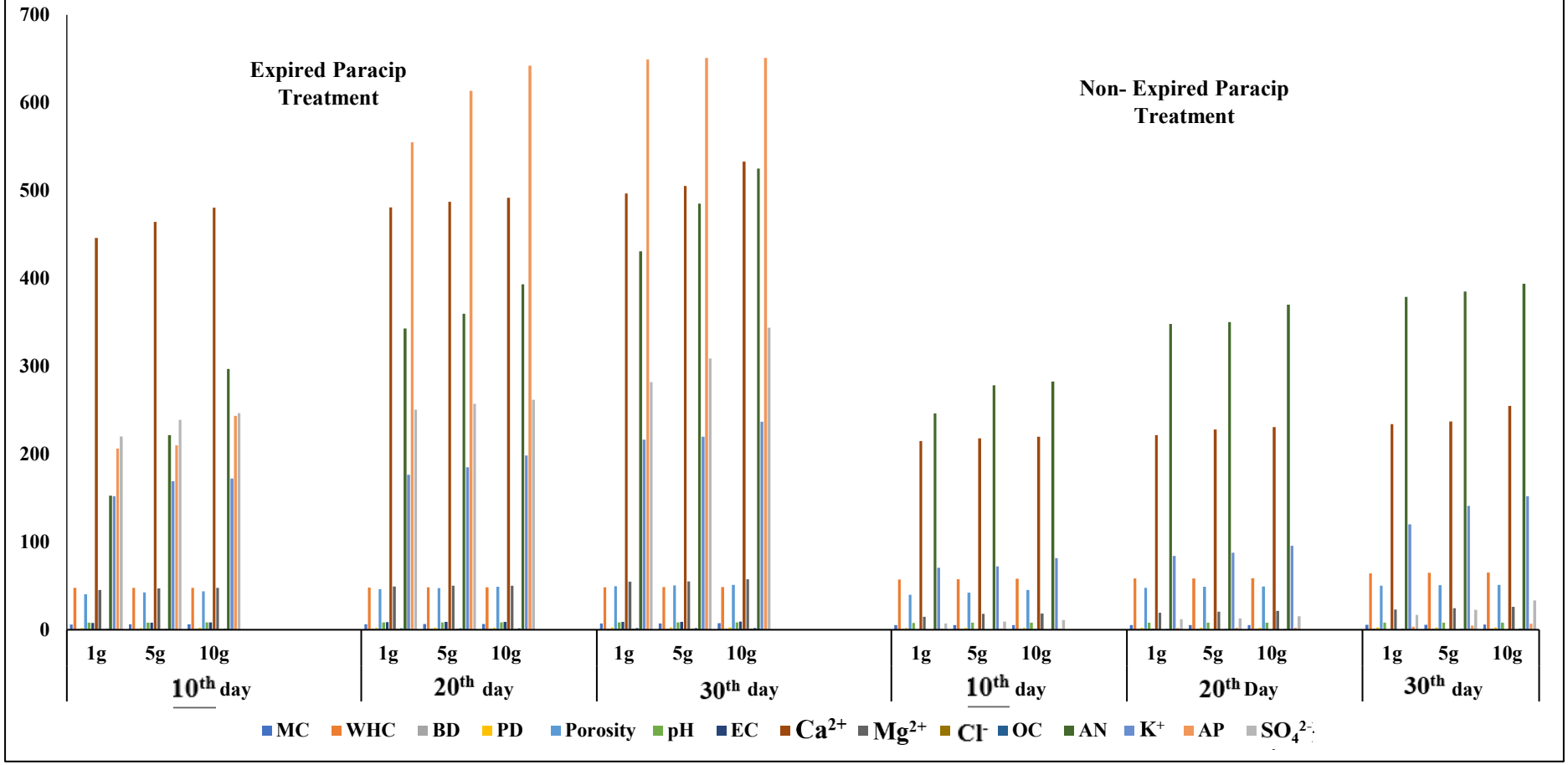
Note: The experiment results are the average values of three trails of each concentration

Table 3. Physico-chemical Characterization of Landfill Soil Before the Addition of Expired and Non- Expired Tablet (Control)

Parameter	MC	WHC	BD	PD	Porosity	pH	EC	Ca^{2+}	Mg^{2+}	Cl^-	OC	AN	K^+	AP	SO_4^{2-}
Values Obtained	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

[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]

Fig 3. Graphical Representation of Physico-chemical Parameters of Landfill Soil Sample Treated with Expired and Non expired Paracip Tablet with Different Concentrations at an Interval of 10th, 20th and 30th day



From the experimental results of an expired and non-expired paracip tablets, the following observations were made and presented as follows:

The Table 3 represents the physico-chemical parameters of the landfill soil before the addition of expired and non-expired tablet (Control). From the control result, it was found that,the physical parameters such as themoisture contentvalueswasfound to be 4.46% andthe waterholding capacity was foundto be 37.62%. The bulk densityvalues were observed to be1.182Mg/m^3,the values of particle densitywere found to be 1.876 Mg/m^3 andthe percentage of porosity value observed was 36.994%.The results of the chemical parametersin control are as follows:

ThepH value wasfound to be 7.35 and the electrical conductivity was observed to be 1.41 ds/m. The values of calcium and magnesiumwere found to be84.16 ppm and 19.45 ppm. The chloride valuewas found to be0.532% and around the percentage of organic carbon was found to be 0.66%. The available nitrogen value was observedto be 163 Kg/ha andthe potassium value was found to be251.40 Kg/ha. The available phosphorus was found to be 79.42 Kg/ha and the values of sulphate was observed to be 26.68ppm.

Moisture Content (MC): The moisture content in the soil is one among the major parameter needed for the degradation of any materials in the soil. During the present study, the moisture content values vary from 6.01 to 7.41% inan expired paracip treatment and 5.30 to 5. 81% in non-expired paracip treatment. The normal range for the moisture content varies from 1 to 1.65%. In comparison with the normal range, the higher value of the moisture content was observed in 10g concentration at 30th day interval.Many research shows that, the paracip tablets upon disintegration, can spike the moisture levels under various soil environmental conditions. Similar observation was recorded and itconfirms the findings in Juying Li st al., (2014).

Water Holding Capacity (WHC): The water holding capacity refers to the ability of a soil, to retain water within its pores or structure. The impact of an expired paracip tablet on soil's ability to retain water, depends on the specific compounds such as hydroxyl groupin the tablet. In the present study, the highest water holding capacity was observed in non-expired paracip treatment in comparison with an expired paracip. The maximum water holding capacity was found to be 65.12% in non-expired paracip and 48.64% in expired paracip treatment at 30th day interval.

Bulk Density (BD): The bulk density represents the compactness between the overall soil volume. From the experimental results, it was found that, the bulk density values were lower in 1g concentration of both the expired and non-expired paracip treatment at 10th day interval. As the day's increases, thebulk density values were found to be higher. The normal range of bulk densityvaries from 1-1.65 Mg/m^3. The highest bulk density values were found to be 1.27 Mg/m^3 in expired paracip and 1.25 Mg/m^3 in non-expired paracip treatment in 10g

concentration at 30th day interval. In comparison with the normal range, the bulk density values were found to be higher.

Particle Density (PD): 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 tablet increases, there was an increase in the particle density values in both the treatments. The normal range of the particle densityvariesfrom 2-2.65 Mg/m^3. The highest particle density values were observed in 10g concentration of expired paracip treatment at 30th day interval. In comparison with the normal range, in both the tablets, the particle density values were found to be within the limits.

Porosity (P): The porosity of the soil indicates the fraction of the soil volume that is occupied by pore or void spaces, which can contain air, water or other fluids. The normal range of the porosity varies from 30-65 %. In the present study, the porosity values were found to be within the normal range. The maximum porosity observed was 51.0% in the expired paracip treatment and 51.06 % in non-expired paracip treatment at 30th day interval.

pH: Thesoil pH is a measure of the concentration of hydrogen ions, indicating its acidity and alkalinity. The pH of the soil sample fluctuates in any location due to the impact of microbial activity under various environmental conditions. In the present study, the pH value ranges from 8.19 to 8.49 in an expired paracip treatment and 7.85 to 8.12 in non-expired paracip treatment. The normal range of the pH varies from 6.5 to 7.5. In comparison with the normal value, the pH values werefound to be higher. The maximum pH was found in 10g concentration at 30th day interval.

Electrical Conductivity (EC): In any type of soil, the electrical conductivity is a crucial measure of ionic concentration. The ability of the soil to conduct the electricity is measured by its electrical conductivity, which is influenced by its ionic composition and temperature. The normal range of the electrical conductivityvaries from 1-2 ds/m. In the present study, the highest electrical conductivity values observed was 9.30 ds/m in an expired paracip treatment and 0.20 ds/m in non-expired paracip in 10g concentration at 30th day interval. The electrical conductivity value was found to be higher in expired paracip treatment in comparison to normal range.

Calcium (Ca^{2+}) and Magnesium (Mg^{2+}): 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 30th day interval. The normal range of the calcium varies from 700-36000 ppm. The highest calcium values observed was 533.0 ppm in the expired paracip treatment and 254.66 ppm in non-expired paracip treatment. In comparison with the normal range, the calcium valueswas 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 normal range. The maximum magnesium content observed

was 57.6 ppm in the expired paracip treatment and 26 ppm in non-expired paracip treatment in 10g concentration at 30th day interval.

Organic carbon (OC) and Chloride(Cl^-): The organic carbon is a key component of organic matter that decomposes and releases nutrients to improve the soil fertility. From the experimental results, the organic carbonwas observed between the range 1.17 -2.03 % in the expired paracip treatment and 0.26 – 1.22 % in non-expired paracip treatment. The highest organic carbon was found to be 2.03% in expired paracip treatment at 30th day interval. The normal range of organic carbonvaries from 0.5-0.75%. In comparison with the normal range of organic carbon, the highest value was observed in expired paracip treatment at 30th day interval.

The chloride is one of the anions that influence the soil salinity and negatively affect the soil quality. The normal range of chloride in soil varies from 0.01-0.99%. In the present study, the chloride value was observed to be higher in expired paracip treatment in comparison with the normal range. The higher chloride value present in the soil was found to be 1.34% in the expired paracip treatment and 0.54% in non-expired paracip treatments at 30th day interval.

Available Nutrients: The addition of expired paracip tablets to the landfill soil, will influence on the availability of the essential nutrients such as potassium, sulphates, available phosphorus and available nitrogen. The paracip contains certain compounds and they can directly increase the amount of available nutrients in the soil once they get dissolve.

In the present study, the available nitrogen, available phosphorus and sulphates were found to be higher in expired paracip treatment. The normal range of available nitrogen in soil varies from 240-480 Kg/ha. The nitrogen is a part of the amide group (-NH-) in the structure of paracip tablet. . From the experimental results, the highest available nitrogen values observed was 525.0 Kg/ha in expired paracip treatment at 30th day interval. The degradation study of paracip showed that, the release of nitrogen from amide group results in the rise in the concentration of nitrogen on soil or water systems. Many research show that, when excess of nitrogen in soil leach into groundwater, it leads to the contamination with significant environmentand health impacts, it can cause methemoglobinemia disease in humans. Similar observation was recorded and confirms the findings in Marta Jewiak et al., (2014).

The normal range of the potassium in soil varies from 110-280 Kg/ha. From the experimental study, it was found that, the highest potassium value was observed to be 236.90 Kg/ha in expired paracip treatment at 30th day interval. In comparison with the normal range, the potassium values were found to be within the limits.

The soil's normal range of available phosphorus varies from 10-25 kg/ha. In the present study, the available phosphorus value was found to be higher in expired paracip treatment in comparison with the normal range. The maximum available

phosphorus observed was 650.96 Kg/ha in expired paracip treatment at 30th day interval.

From the experimental result, it was found that, the sulphate value was found to be higher in expired paracip treatment. The normal range of sulphates in soil varies from 8-30 Kg/ha. The highest sulphate value observed was 343.85 Kg/ha in expired paracip treatment at 30th day interval. In comparison with the normal range, the sulphates values were found to be higher.

4. Conclusion:

From the overall study, it can be concluded that, the improper disposal of an expired medicines directly on to the environment, it effects the whole ecosystem. The persistence and accumulation of unused, non-expired and expired paracetamol tablets can cause detrimental impact on the soil, water, air, aquatic animals and public health. The paracetamol and its metabolites can be toxic to the soil microorganisms, potentially disrupting soil ecosystems and nutrient cycles. Leaching of paracetamol into groundwater or surface water can lead to contamination.The paracetamol itself has limited bioaccumulation potential, its degradation products, such as p-aminophenol, can be toxic to aquatic organisms and soil fauna. The effective pharmaceutical waste management is crucial to mitigate the soil environmental impacts. Adopting the proper disposal practices protects ecosystems, human health and maintains the environmental sustainability.

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