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Determination of the ED50 of Diarrhea Stop Capsule in Rats

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ABSTRACT

Introduction: Diarrhea remains a significant cause of morbidity and mortality globally, particularly in developing countries. The ED50 represents the dose at which 50% of the treated population exhibits a therapeutic response in case cessation of diarrhea.

Objective: The aim of this study was to determine the median effective dose (ED50) of Diarrhea Stop Capsule in albino rats.

Methods: A total of 70 rats were divided into seven groups (n=10/group) and administered increasing oral doses: 25, 50, 75, 100, 125, and 150 mg/kg, with one group as control. Diarrhea was induced by administered 2ml castor oil orally for each rat.

Results: Responses were observed and recorded over 6 hours. The ED50 was calculated using the Probit method. The results show a dose-dependent effect, with an estimated ED50 of 83.4 mg/kg.

Conclusion: The Diarrhea Stop Capsule demonstrated dose-dependent antidiarrheal activity in rat, with an ED₅₀ of approximately 83.4 mg/kg. These results support further pharmacological and clinical studies to standardize dosing protocols for human use.

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Introduction

Diarrhea is a significant global health concern, responsible for one in ten deaths among children under five years old, totaling approximately 800,000 annually. Additionally, it affects over 2.8 billion adolescents, adults, and older children each year. Diarrhea remains a significant cause of morbidity and mortality globally, particularly in developing countries [1]. As a common gastrointestinal ailment, diarrhea can cause severe dehydration and other serious health complications. Herbal medicines have been employed for centuries as effective remedies for various illnesses due to their natural origin, accessibility, and favorable safety profiles [2]. According to the World Health Organization (WHO), nearly 80% of the global population depends on traditional medicine to address primary healthcare needs [3,4]. Despite advancements in healthcare, diarrhea continues to impose a substantial burden worldwide, particularly in developing nations where it remains a leading cause of morbidity and mortality [5].

While synthetic antidiarrheal drugs have proven effectiveness, concerns regarding their side effects and restrictions for certain

demographic groups, such as children and the elderly, have encouraged exploration into herbal alternatives [6,7]. Medicinal plants have long been utilized for diarrhea treatment owing to their antimicrobial, anti-inflammatory, and astringent properties [8]. Unlike single-agent pharmaceuticals, herbal remedies often offer a multi-target therapeutic approach by combining the effects of diverse active phytochemicals to deliver broader health benefits [9].

Notable anti-diarrheal plants include *Vernonia amygdaloides*, cinnamon bark, ginger, and ginseng, which manifest impressive efficacy through mechanisms such as gut microbiota modulation, enhancement of gut barrier function, and anti-inflammatory actions [10]. Many herbal treatments feature synergistic combinations of active compounds that work harmoniously to alleviate symptoms. Research has substantiated the traditional use of medicinal plants by analyzing the bioactive properties within their extracts, further validating their role in managing diarrhea effectively [11]. Determination of the effective dose is essential to define the therapeutic window and optimize usage [12].

The ED50 is the dose at which 50% of the test subjects exhibit a defined effect and is a critical pharmacological parameter [13]. The name of new herbal product is Diarrhea Stop Capsule which composed of seven herbs: Punica granatum, Psidium guajava, Matricaria chamomilla, Ceratonia siliqua, Camellia sinensis, Zingiber officinale, and Mentha spp. The new formulation of this product was done by Prof. Dr. Hussien O. Kadi and Ismail Hamoud Ali Al-geobri (Patent). This study aims to determine the ED50 of Diarrhea Stop Capsule in rats.

Materials and Methods

Quantal dose response curve study was conducted at Yemen University 21/3/2025 to determine the ED50 of Diarrhea Stop capsule (herbal product) in rats. The Ethics Committee of Yemen University, Faculty of medical Sciences approved the protocol and have been performed in accordance with the ethical standards. A total of 70 healthy adult albino rats (150-250 g) were used in this study. Animals were housed under standard laboratory conditions with free access to food and water. The animals were fasted overnight before the experiment. Diarrhea was induced using castor oil at 2 mL/rat [14].

One hour post-induction, rats were orally administered Diarrhea Stop was dissolved in distilled water in at doses of 25, 50, 75, 100, 125, and 150 mg/kg. Control group received distilled water. Therapeutic response was defined as complete cessation of diarrhea within 6 hours. Percentage of responders per group was calculated. Dose response curve and Probit analysis were used to estimate ED50.

Results

Adult rats were administered escalating oral doses of Diarrhea Stop at the following doses: 25, 50, 75, 100, 125, and 150 mg/kg. The corresponding response percentages were recorded as 10%, 30%, 50%, 60%, 80%, and 90%, respectively. Data were analyzed using graphical dose-response analysis and Probit regression, as recommended in pharmacological studies. The median effective dose (ED50) represents the dose at which 50% of the experimental subjects exhibit the expected pharmacological response. In this study, the ED50 of Diarrhea Stop Capsule was determined in rats using two approaches: (1) graphical analysis of the dose-response curve, and (2) Probit regression analysis.

The following table shows the response rate of rats treated with increasing doses of Diarrhea Stop.

Table 1: Response Rate of Rats that Had Diarrhea Induced with Castor Oil Treated with Increasing Doses of Diarrhea Stop

Groups	Dose (mg/kg)	Number of Responders	Response Rate (%)
Group 1	25	1	10
Group 2	50	3	30
Group 3	75	5	50
Group 4	100	6	60
Group 5	125	8	80
Group 6	150	9	90
Control group	0	0	0

From the dose-response curve, the ED50 was graphically interpolated at approximately 83.4 mg/kg, where the response reached 50%. Using Probit regression analysis, the calculated

ED50 was consistent with the graphical estimate, confirming the median effective dose in rats.

Discussion

The ED50 value determined in this study reflects the potency of Diarrhea Stop Capsule in managing experimentally induced diarrhea in rats. The dose-response curve demonstrated a strong correlation between dose and therapeutic effect. These findings are consistent with previous studies evaluating the efficacy of herbal anti-diarrheal formulations [15]. Establishing the ED50 is a critical step in progressing to clinical dosage studies [16].

The results suggest that Diarrhea Stop Capsule has a potent effect even at relatively low doses. Herbal formulations such as Diarrhea Stop Capsule offer promising therapeutic benefits as antidiarrhea. Gazala and Dheeraj, 2023, reported that Phyto-preparations from traditionally utilized plants, proven effective in managing diarrhea via the anti-diarrheal effects of these herbs are attributed to their antisecretory, antiperistaltic, antimicrobial, and antispasmodic properties as well as antimotility [17].

The dose-response relationship observed aligns with previous findings in herbal antidiarrheal studies. Extracts from plants such as Psidium guajava, Punica granatum, and Terminalia chebula have shown similar dose-dependent efficacy [18]. This validates the traditional claims regarding the Diarrhea Stop Capsule. Moreover, the ED₅₀ value falls within a therapeutically safe range, making it suitable for clinical development.

The ED50 value determined in this study reflects the potency of Diarrhea Stop Capsule in managing experimentally induced diarrhea in rats. The dose-response curve demonstrated a strong correlation between dose and therapeutic effect. These findings are consistent with previous studies evaluating the efficacy of herbal anti-diarrheal formulations [19]. Establishing the ED50 is a critical step in progressing to clinical dosage studies [20]. The results indicate that Diarrhea Stop Capsule has a potent effect even at relatively low doses.

Conclusion

The Diarrhea Stop Capsule demonstrated dose-dependent anti-diarrheal activity in rat, with an ED₅₀ of approximately 83.4 mg/kg. These results support further pharmacological and clinical studies to standardize dosing protocols for human use [21].

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