

Research Article

Phytochemical and Toxicity Studies of Nadim Wellife Capsule: From Traditional Medicine to Scientific Exploration

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Abstract: **Aim:** Toxicity and phytochemical properties of Herbal Medicinal Products are of significant importance in the Medical studies. This current paper explored the phytochemical chemical and toxicity analysis of Nadim Well life Capsule formulated for general wellness. **Method:** Six (6) samples of the Nadim Wellife Capsules were sent to the Kwame Nkrumah University of Science and Technology, KNUST, Ashanti region, Ghana to the Department of Pharmacology to assessed the acute toxicity using fifteen (15) males, Sprague-Dawley rates in 3 groups (n=5). The Department of Pharmacognosy of the College of Health Sciences also assessed the Phytochemical and Physicochemical properties of the product. **Result:** With the toxicity studies: None of the animals died during the study period and no signs of toxicity attributable to test product treatment were observed. The lethal dose (LD₅₀) of the extract was estimated to be above 13.79g/kg. The phytochemical analysis also proved significant phytochemical constituents. **Conclusion:** The LD₅₀ of the extract from Nadim Wellife Capsules was greater than 13.79g/kg body weight in rats, which can be regarded as low toxicity in the rats. The product is also safe with positive phytochemical constituents.

Keywords: Nadim Wellife Capsules, Toxicity, Phytochemicals, herbal product, constituents.

INTRODUCTION

In Ghana, the Herbal Medical industry has received a huge boost with the introduction of the degree program in Herbal Medicine at the Kwame Nkrumah University of Science and Technology, Ashanti region, Ghana. The Traditional Medicine Practice Council (TMPC) of the Ministry of Health has also played an integral role in the development of the industry based on the Traditional Medicine ACT 575. The ACT 575 is undergoing an amendment to formally also include Alternative System of Medicine. The ACT 575 fully backed Traditional Medicine leaving alternative medicine behind. The new Traditional and Alternative Medicine Bill 2018 would repeal the ACT 575. According to the new document, alternative system of healing is defined as medical practice that is outside the jurisdiction of traditional and allopathic medicine in Ghana.

Alternative Medicine has also received a major boost with the introduction of the Professional program in Naturopathic Medicine at the Nyarkotey College of Holistic Medicine, Tema community, 7, Post Office, Ghana. The college offers the Professional four year

Doctor of Naturopathic Medicine similar to the Doctor of Naturopathic Medicine in the US and Canada accredited by the Council of Naturopathic Medicine. The Nyarkotey college of Holistic Medicine is also fully recognized by the Traditional Medicine Practice Council.

Though, there is acceptance of Herbal Medicine in Ghana, much of the concerns had to do with the safety of these products on the market. Trained Herbal Medical practitioners from the Kwame Nkrumah University of Science and Technology (KNUST), Centre for Research into Plant Medicine and Tetteh Quarshie Memorial Hospital in Ghana are licensed to consult and prescribe Herbal Medicine for clients both in the government and private hospitals in Ghana. Although the acceptance level of herbal medicines continues to increase, the fact still remains, that there is paucity of data on the acceptability and concurrent application of HM in Ghana (Agyei-Baffour, P. *et al.*, 2017).

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According to Martins Ekor (2013) herbal medicines have shown promising potential with the efficacy, however, many of them remain untested and their use are either poorly monitored or not even monitored at all. The consequence of this is an inadequate knowledge of their mode of action, potential adverse reactions, contraindications, and interactions with existing orthodox pharmaceuticals and functional foods to promote both safe and rational use of these agents. Since safety continues to be a major issue with the use of herbal remedies, it becomes imperative, therefore, that relevant regulatory authorities put in place appropriate measures to protect public health by ensuring that all herbal medicines are safe and of suitable quality.

In Ghana, the FDA has put in place mechanism for all herbal products to meet some requirement before registration. Herbal products are to

be tested at some recognized institutions such as: Kwame Nkrumah University of Science and Technology, Kumasi, The Centre for Research into Plant Medicine, Mampong *et al.*, These institutions issue certificate or report on toxicity and microbiology to be sent to the FDA if the said product meet the requirements.

METHODOLOGY

Six (6) samples of the Nadim Wellife Capsules were sent to the Kwame Nkrumah University of Science and Technology, KNUST, Ashanti region, Ghana to the Department of Pharmacology to assessed the acute toxicity using fifteen (15) males, Sprague-Dawley rates in 3 groups (n=5). The Department of Pharmacognosy of the College of Health Sciences also assessed the Phytochemical and Physicochemical properties of the product. Below are the findings:

A. DEPARTMENT OF PHARMACOGNOSY COLLEGE OF HEALTH SCIENCES

PRODUCT: NADIM WELIFE CAPSULES

1. ORGANOLEPTIC PROPERTIES

Form	-	Capsules
Colour	-	Shells – Cyan
	-	Content – Brown
Taste	-	Slightly bitter
Odour	-	Characteristic

2. PHYSICOCHEMICAL PROPERTIES

pH (1% cold aqueous ext.)	-	5.6
Total alcohol soluble extractives	-	5.1
Total water soluble extractives	-	5.0
Moisture content	-	5.1

3. PHYTOCHEMICAL PROPERTIES

Reducing sugars	-	Positive
Saponins	-	Positive
Tannins	-	Positive
Alkaloid	-	Positive
Flavonoid	-	Positive
Sterols	-	Negative
Coumarins	-	Negative

3. CHROMATOGRAPHIC PROFILE

Stationary phase	-	Silica gel
Detecting reagent	-	Anisaldehyde in sulphuric acid
Sample used	-	Chloroformic extract
Mobile phase	-	Chloroform : Pet ether
		9 : 1

RESULTS

- Six (6) spots were observed after spraying with the detecting reagent
- Three (3) purple spots (Rfs – 0.88, 0.46 & 0.16)
- Three (3) blue spots (Rfs – 0.56, 0.82 & 0.90)

B

**DEPARTMENT OF PHARMACOLOGY
TOXICOLOGICAL REPORT**

Table 1 Acute Toxicity

Animal Species	No. of animals/ group	Route of administration	Doses administered	No. of death Recorded	Approx. lethal dose	Duration of study
Sprague-Dawley Rats	15 males, 3 groups (n=5)	Oral	0, 6.90 13.79 g/kg	No deaths recorded	above 13.79 g/kg	48 h

REMARKS

Contents of capsules were reconstituted by dissolving in distilled water at a concentration of 2 g/kg. Rats were treated with 0, 6.90 and 13.79g/kg of the reconstituted extract and observed over 48 hours for signs of toxicity. None of the animals died during the study period and no signs of toxicity attributable to test product treatment were observed. The lethal dose (LD₅₀) of the extract was estimated to be above 13.79g/kg (Table 1)

TEST RESULTS**Level of microbial contamination**

1. The total aerobic viable count of sample (BP 2015 Specification - $\leq 1 \times 10^5$ cfu/mL)	3.42x10 ² cfu/mL
2. Test for <i>Escherichia coli</i> -MAC /37°C/48hrs (BP 2015 Specification - Nil/mL)	None detected
3. Test for <i>Staphylococcus aureus</i> – MSA/37°C/48hrs (BP 2015 Specification - Nil/mL)	None detected
4. Test for <i>Salmonella spp.</i> BSA/37°C/48hrs (BP 2015 Specification - Nil/mL)	None detected
5. Test for <i>Pseudomonas aeruginosa</i> PCA/37°C/48hrs (BP 2015 Specification - Nil/mL)	None detected
6. Test for Yeast and Moulds - SB/25°C/5days (BP 2015 Specification - $\leq 1.0 \times 10^5$ cfu/mL)	3.16 x 10 ² cfu/mL

REMARKS

- The bacterial load obtained for aerobic viable count was within the acceptable limit.
- The fungal load was also within the acceptable limit (BP 2015). No harmful microorganisms were detected.

DISCUSSION

The product Nadim Wellife Capsules is well formulated, contains important phytochemicals such as: Saponins, Tannins, Alkaloid and Flavonoid (Fig 1) and backed by science for wellness, it is safe to be used and has successfully passed the toxicologically analysis.

CONCLUSION

The results indicate that the LD₅₀ of the extract from *Nadim Wellife Capsules* was greater than 13.79g/kg body weight in rats, which can be regarded as *low toxicity* in the rats.

DEPARTMENT OF PHARMACEUTICS**MICROBIAL TEST PROTOCOL – (BP Level of Microbial Contamination)**

- Assessment of total viable count of aerobic bacteria and fungi.
- Test for specific harmful organisms.

None of the laboratory rats died in the process (Table 1). Toxicity of Herbal products are a subject of both local and international interest in the health sector as more patients turned to these remedies for their health. Proponents of herbal medicines claimed their products are safe and hence patients' attentions are diverted to these remedies. But are these remedies really safe compared to pharmaceutical drugs?

The field of Pharmacovigilance is under researched in the herbal industry in Ghana. Most Herbal companies in Ghana have no pharmacovigilance unit to monitor the progress of their products on the market.

Toxicity of herbal products Pharmacovigilance for complementary medicines is in its infancy (Barnes, J. 2003). Data are lacking in several areas relevant to safety. Standard pharmacovigilance tools have additional limitations when applied to investigating safety concerns with complementary medicines.

Another area of concern is adulterated herbal product with allopathic ingredients. For example, in one research article (Khan, M.A. *et al.*, 2016) titled pharmaceutical evaluation and toxicological quantification of heavy metals and adulterated allopathic contents in raw and finished dosage form of antihypertensive herbal products. The study authors concluded that the antihypertensive herbal products contained different kind of adulterants. Their findings suggest that effective regulatory measures should be put in place to address this problem. This will help to decrease the toxic effects of these remedies and increase the commercialization, internationalization and harmonization of antihypertensive herbal products.

Another area of interest in toxicity concerned is the heavy metal content in raw materials. For instance (Kulhari, A. *et al.*, 2013) Investigation of heavy metals in frequently utilized medicinal plants collected from environmentally diverse locations of north western India concluded that, cultivation of medicinal plants and other dietary herbs should be curtailed near environmentally polluted especially industrial areas for avoidance of health hazards.

Another research (Sadhu, A. *et al.*, 2015) indicates geographical regions in India suitable for procuring raw materials to develop and manufacture phytopharmaceutical products. The increasing information over the recent years on the occurrence of pyrrolizidine alkaloids (PAs) in honey, herbal food and tea products has raised concerns about the safety of herbal medicines with respect to contamination. To this day, little is known on the occurrence of toxic PAs in herbal medicines, especially in tropical West Africa. A 2017 study in Ghana (Letsyo, E. *et al.*, 2017) results show that a total of 60% of the analyzed herbal products were PA positive, indicating an average PA-concentration of 25.0µg/kg. The maximum PA level (1290.0µg/kg) was attributed to a regulatory-approved herbal medicine not known, according to the list of declared ingredients, to contain PA-plant parts. Interestingly, higher PA content (average, 30.2µg/kg) was detected in regulatory-approved herbal medicines, in contrast to lower amount (average, 8.0µg/kg) detected in non-regulatory-approved products.

A 2018 (Ahmad, L. *et al.*, 2018) study which underscores two major aspects about herbal medicine in Neelum Valley, Azad Kashmir to determine the presence or absence of hepatotoxic pyrrolizidine alkaloids and if they are within the suggested limit for the use of herbs in excess report for the first time

advised government regulatory authorities and non-governmental organizations that use of this plant as herbal medicine should be excluded before more accurate quality control tests.

CONCLUSION

Nadim Wellife Capsule is safe and has successfully passed the toxicological analysis conducted at the Kwame Nkrumah University of Science and Technology.

Conflict of Interest

The author of this paper report no conflict of interest

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