East African Scholars Journal of Medical Sciences
Abbreviated Key Title: East African Scholars J Med Sci
ISSN: 2617-4421 (Print) & ISSN: 2617-7188 (Online)
Published By East African Scholars Publisher, Kenya

Volume-3 | Issue-4 | Apr-2020 | DOI: 10.36349/EASMS.2020.v03i04.002

OPEN ACCESS

Short Article

Safety Profile of an Herbal Product Prostalinic for Prostatic Health

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Article History
Received: 18.03.2020
Accepted: 12.04.2020
Published: 15.04.2020

Journal homepage:
https://www.easpublisher.com/easjms

Quick Response Code

Abstract: ***Aim*:**This paper addresses the toxicity, microbial and phytochemical and physicochemical studies of Prostalinic, an herbal prostate product formulated by one student studying Naturopathic and Holistic Medicine at Nyarkotey College of Holistic Medicine, Tema community, 7, Ghana for Prostate health. ***Method*:** Six (6) samples of the Product, Prostalinic were sent to the Kwame Nkrumah University of Science and Technology, KNUST, Ashanti region, Ghana to the Department of Herbal Medicine for analysis. ***Result:*** The toxicological findings revealed that the product have been established for quality control purposes ***Conclusion*:** None of the animals died in the course of the toxicity studies.
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Keywords: Prostate, Health, Toxicity, Herbal, Product.

METHODOLOGY & FINDINGS

Tab 1- *Phytochemical and Physicochemical Studies*

PROSTALINIC		
Name	-	Prostalinic
Indication	-	Not stated
Active Ingredients	-	Not stated
Date Of Manufacture	-	Not stated
Date Of Expiry	-	Not stated
Batch Number	-	Not stated
Produced By	-	Redeemer Herbal Clinic And Research Centre Ltd.
1.ORGANOLEPTIC PROPERTIES		
Form	-	Liquid
Colour	-	Brown
Taste	-	Bitter
Odour	-	Characteristic
2. PHYSICOCHEMICAL PROPERTIES		
Ph	-	5.37
Dry weight per Ml	-	0.1547g
Specific gravity/Ml	-	1.0010
3. PHYOCHEMICAL PROPERTIES		
Reducing sugars	-	Positive
Saponins	-	Positive
Alkaloids	-	Not detected
Flavonoids	-	Positive

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Phytosterols	-	Positive
Terpenoids	-	Positive
Tannins	-	Positive

Tab 2.
4. FOURIER-TRANSFORM INRARED FINGERPRINT OF PROSTALINIC

Sample preparation: About 20Ml of the herbal mixture was evaporated to dryness.

Instrumentation: A small amount of the dried mixture was placed on the sample area of the Bruker Fourier transform infrared (FT-IR) spectrometer and scanned between 4000-400cm-^{1} with a resolving power of 4cm-^{1} and a cumulative scanning limitation of 24times.

Results: Principal peaks appeared at wavenumbers 3307.03, 2954.13, 1558.36 and 1045.21cm-^{1}

Comments: Fourier-Transform Infrared (FT-IR) Fingerprint of Prostalinic has been established for reference.

TABLE 3: 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	18 males, 3 groups (n=6)	oral	0, 6.25 and 12.5g/kg	No deaths recorded	Above 12.5 g/kg	48h

Remarks
On Toxicity Test, a volume of 750ml of the mixture was evaporated to dryness to obtain a semi-solid mass (Yield=2.73%w/v) this was reconstituted by dissolving in distilled water (2g/ml). Rats were treated with 0, 6.25 and 12.5g/kg of the test product and observed over 48hours for signs of toxicity.
None of the animals died during the study period and no signs of toxicity attributable to the test product treatment were observed. The lethal dose (LD50) of the product was estimated to be above 12.5g/kg (Table 3).
For Phytochemical and physiochemical properties analysis, the properties of Prostalinic have been established for quality control purposes(**Tab 3**)

iii.

TEST RESULTS

Level of Microbial Contamination

1. The total aerobic viable count of sample (BP 2018 Specification- - ≤ 1 x 10^5 cfu/mL — $2.71x10^2$ cfu/mL
2. Test for Escherichia coli- MAC /37°C/48hrs (BP 2018 Specification- Nil/ML) — Detected
3. Test for Staphylococcus aureus-MSA/37°C/48hrs (BP 2018 Specification-Nil/ML) — None detected
4. Test for Salmonella spp. BSA/37°C/48hrs (BP 2015 Specification - Nil/mL) — Detected
5. Test for Pseudomonas aeruginosa PCA/37°C/48hrs (BP 2015 Specification - Nil/mL) — None detected
6. Test for Yeast and Moulds - SB/25°C/5days

CONCLUSION

The results indicate that the LD50_of the extract from PROSTALINIC was greater than 12.5g/kg body weight in rats. Which can be regarded as of low toxicity in the rats.

Tab 4
Microbial Analysis of R-Mixture
Microbial Test Protocol-(BP Level of Microbial Contamination)

i. Assessment of total viable count of aerobic bacteria and fungi)
ii. Test for specific harmful organisms.

(BP 2015 Specification - ≤ $1.0x10^5$ cfu/mL) 2.34×10^2 cfu/mL

Remarks.

I. The bacterial load obtained for aerobic viable count was within the acceptable limit.
II. The fungal load was also within the acceptable limit (BP 2015).
III. However, two harmful microorganisms such as Escherichia coli and salmonella species were detected.

DISCUSSION

The product Prostalinic contains important phytochemicals such as: saponins, Flavonoids, Tannins and Alkaloid is the only phytochemical absent in the product (**Tab 1**). None of the laboratory rats died in the process (**Table 3**). However, two harmful microorganisms such as Escherichia coli and Salmonella species were detected (**Tab 4**).

Harmful microorganism is an issue of health concern in the herbal industry. However, Toxicity of herbal products Pharmacovigilance for complementary medicines is at the gestational stage (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. It is therefore paramount for all herbal medicinal products to get tested and approved by the FDA in Ghana before commercialization.

CONCLUSION

The Product, has successfully passed the toxicological analysis conducted at the Kwame Nkrumah University of Science and Technology, KNUST, Ashanti Region, Ghana.

Conflict of Interest: None

Acknowledgement

The author thanks his staff, Mr. George Nartey and student, Philip Opey of Redeemer Herbal Clinic & Research Center for producing the product for the research.

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