Acute toxicity studies of polyherbal formulation (Methiorep Premix)

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Abstract

An experimental study with the objective to evaluate the acute toxicity of polyherbal formulation Methiorep Premix (supplied by Ayurvet Ltd., Baddi, India), was done as per OECD guidelines 423. Methiorep is a scientifically developed combination of herbs that contains herbal ingredients rich in Methionine in free form as well as conjugated form. The study was done on 3 males and 3 female Wistar Albino rats which were administered an initial dose of 500 mg/kg body weight followed by 2000 mg/kg & 5000 mg/kg body weight. The animals were observed for signs of convulsions, tremors, circling, depression, excitement and mortality. Body weight was recorded at 0,7th and 14th day and plasma total protein, albumin; AST and ALT were measured to evaluate the toxicity of the preparation. No abnormal sign of symptoms were observed in any of the animal fed with Methiorep Premix at the dose rate of 500 mg/kg body weight, 2000 mg/kg body weight & 5000mg/kgbody weight. No mortality was observed in any of the animals indicating its safety. **Keywords:** Toxicity, Polyherbal, Broiler, Premix, Wistar Albino Rat, Animal.

Introduction

Methionine is an essential amino acid needed for healthy and productive poultry. It is generally the first limiting amino acid in poultry diets. Methionine has main role in energy production, protein synthesis, it also help in enhancing egg production with optimum egg size, overall growth performance, FCR and livability in broilers and layers (Aerni et al., 2005 and Binder, 2003). Methiorep Premix is a new product by Ayurvet Ltd Baddi, India. Methiorep is a combination of herbs viz. Cicer arientinum, Phaseolus mungo, Mucuna pruriens, Triticum sativum, allium cepa & many more rich source of protein with highly bioavailable methionine. As per the guidelines from Government when any new product is to be put in the market, it is necessary to generate the data regarding its safety. The present investigation is planned with the objective to evaluate the acute toxicity of Methiorep Premix.

Materials and Methods

The present study work was conducted in Department of Pharmacology and Toxicology, College of Veterinary and Animal Sciences Parbhani, Maharashtra, India. The new herbal preparation Methiorep (supplied by Ayurvet Ltd. Baddi India) were administered orally following OECD 423 guidelines to 3 Wistar male (M1-M3) and 3 female rats (F1-F3) using limit dose in three steps (viz; exposing 3 female rats in

1st step & 3 male rats in the 2nd step to a dose of 500. 2000 and 5000 mg/kg body weight) (ASTM, 1987). Further three male rats were taken up and weighed and marked for identification and same procedure was repeated. Following administration of single dose of herbal preparation animals were observed for the clinical symptoms for 30 minutes, at hourly intervals for next 24 hours and thereafter for total 14 days. The animals were observed for signs of convulsions, tremors, circling, depression, excitement and mortality. No mortality was observed in any of the rats. Body weight was recorded at 0,7th and 14th day and plasma total protein, albumin, Aspartate Amino transferase & Alkaline Phosphatase (SGOT & SGPT) were measured to evaluate the toxicity of the preparation. All the animals are terminally sacrificed for gross necropsy findings.

Results and Discussion

All the animals were carefully observed for development of any toxic signs or symptoms at different time intervals of 0, 30 minutes, 1, 2, 4, 6, 8, 12 hrs and then daily for period of 14 days. No abnormal sign of symptoms were observed in any of the animal fed with Methiorep Premix at the dose rate of 500 mg/kg body weight, 2000 mg/kg body weight and 5000mg/kgbody weight. No mortality was observed in any animal indicating its safety. Hence, from the present study it can be concluded that the Methiorep Premix is nontoxic

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Table-1. Blood parameters of rats fed Methiorep Premix (5000 mg/kg b.wt.) after 7 days

Animal	Total protein(g/dl)	Albumin (g/dl)	Total Cholesterol (mg/dl)	SGOT(U/L)	SGPT (U/L)
F1	3.25	1.95	39.8	37.75	28.38
F2	6.18	2.96	27.75	65.30	36.37
F3	7.61	3.65	41.13	71.01	25.45
M1	5.25	3.20	33.77	66.75	27.48
M2	5.42	2.23	35.05	56.68	22.5
M3	4.60	2.78	46.14	56.39	39.15

at the limit dose of 5000 mg/kg body weight. No adverse effect was seen on the body weight gain and no significant changes in the biochemical parameters from those of normal values of these parameters were observed as compared to control, indicating no adverse effect on the liver at experimental dose rate (table1). No adverse effect, was seen even at a higher limit dose of 5000 mg/kg. Clinical examination of all the rats were normal and necropsy findings does not showed any remarkable findings (Table:2).

Summary and Conclusion

Therefore, it is concluded that the administration of Methiorep Premix is safest & has no adverse effect on growth related and biochemical parameters. It is also inferred that 'Methiorep Premix' being safe at a higher limit dose, belongs to class 5 or unclassified substances as per Globally Harmonized Classified System (GHC) for chemical substances and mixture indicative of very high LD_{50} value. Hence, it can be

recommended as a safe product to replace synthetic methionine in poultry ration and for supplementation in basal diet for regular usage.

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Table-2. Record of Clinical Examination of rats fed Methiorep Premix (5000 mg/kg b.wt.)

Animal ID	Sex	Clinical Symptoms	Duration (Days)
F1-F3	F	NAD-ALL	1-14
M1-M3	М	NAD-ALL	1-14
