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THE STUDY OF
TOXICOLOGICAL EVALUATION OF HERBAL & MINERAL BASED FORMULATIONS

Study Center

NIRMA UNIVERSITY

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Study Report

Toxicological evaluation of Cardo 600 tablet on mice.

Sponsor:
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Dhanwantary Prasad, Station Road,
Unjha - 384170,
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Study Center:
Department of Pharmacology,
Institute of Pharmacy,
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Summary

The acute toxicity study indicates potential target organs, spectrum of toxic effect and will aid to establish maximum tolerable dose. Single dose toxicity studies in rodents are prerequisite for treatment of new drug in human. The purpose of this study was to assess the possible health hazards likely to arise when single dose of Cardo 600 tablet was administered by oral route to mice. The acute toxicity was evaluated in female mice after an oral administration at a dose level of 2000 mg/kg with concentration of 200mg/ml. Animals were observed at least twice daily for any clinical signs and mortality throughout the 15 days of observation period. No abnormalities were detected in clinical signs like appearance, respiration, motor activity, tremors, convulsions, corneal reflexes, lacrimation, miosis, mydriasis, salivation, diarrhea and other discharge. Individual body weights of all animals were recorded at the start of treatment, day 8 and day 15. No significant change in body weight in all animals was observed. No macroscopic abnormalities were obtained at termination. The Cardo 600 tablet is safe up to 2000mg/kg dose in mice.

Study Objective:

The purpose of this study was to assess the possible hazards likely to arise when single dose of Cardo 600 tablet administered by oral route to mice. This study provides a rational basis for the assessment of toxicological risk to human at higher dose.

Materials and Methods:

1. Test Item: Cardo 600 tablet
2. Vehicle: 0.5% CMC

   Cardo 600 tablet was received by sponsor and stored at recommended storage condition. Characterization of Cardo 600 tablet was performed by the sponsor.
3. Test Facility: Department of Pharmacology

   Institute of Pharmacy

   Nirma University
4. Test System:

   Species: Mice

   Strain: C57BL/6

   Sex: Female

   No of animals: 12

   Weight: 20-30 gm (6-8 week)
5. Identification: Tail marking
6. Housing: Temperature 22$\pm$ 3

   Humidity: 30-70%

   12 hr light/dark cycle
7. Food: Rodent feed manufactured by M/s Pranav Agro Pvt. Ltd., Baroda.
8. Water: Clean purified water
9. Acclimatization and randomization: Animals were acclimatized for the minimum period of one week. All animals assigned to study were subjected to pre-treatment veterinary health examination.

Experimental design:

1. **Animal allocation to groups:** Prior to start of treatment, all the animals were subjected to randomization (body weight basis). All 12 female mice were allocated to two groups.

Group	Dose Level (mg/kg)	Animal Numbers
1	Vehicle Control (10ml/kg)	12
2	Cardo 600 tablet (2000 mg/kg)	12

2. **Treatment Procedure:** The Cardo 600 tablet was administered at a dose level of 2000 mg/kg dose level along with a vehicle control group.
3. **Route of administration:** The Cardo 600 tablet was administered by oral route to 3-4 hour fasted animals using graduated syringe at an approximately constant dose volume of 10ml/kg.
4. **Observation during Experimental Period:** Animals were observed at 15, 30 minute, 1 hr, 2hr, 3hr, and 4hr post dosing followed by one evening observation. From day two, all mice were observed at least twice daily for any clinical signs and mortality throughout the 15 days the observation period. Cage side observations were carried out including changes in skin, hair coat, eyes, mucous membranes, respiratory, circulatory, autonomic and central nervous system, somatomotor activity and behavior pattern. Particular attention was directed to observation of tremors, convulsions, salivation, diarrhea, lethargy, sleep and coma. Individual body weight were recorded at the start of treatment (day 0), day 8 and day 15.
5. **Terminal studies:** At termination all the surviving mice were subjected for description of all macroscopic abnormalities. All mice at the end of observation period were euthanized.
6. **Statistical Analysis:** All the data were presented in Mean$\pm$SD. Statistical analysis was carried out using the individual animal data.

Results:

Table 1: Summary of survival in mice.

Group	**Vehicle Control (10ml/kg)**	**Cardo 600 tablet (2000 mg/kg)**
Day	**No. of surviving rat/Initial No. of mice**	
1	12/12	12/12
2	12/12	12/12
3	12/12	12/12
4	12/12	12/12
5	12/12	12/12
6	12/12	12/12
7	12/12	12/12
8	12/12	12/12
9	12/12	12/12
10	12/12	12/12
11	12/12	12/12
12	12/12	12/12
13	12/12	12/12
14	12/12	12/12
15	12/12	12/12

No mortality was observed up to 15th day

Table 2: Summary of clinical signs

Group	**Dose Level (mg/kg)**	**Clinical signs***	**No. of mice without signs/ No. of mice treated**
1	Vehicle Control (10ml/kg)	No abnormality detected	12/12
2	Cardo 600 tablet (2000 mg/kg)	No abnormality detected	12/12

- Clinical signs included changes in skin, hair coat, eyes, mucous membranes, respiratory, somatomotor activity and behavior pattern, tremors, convulsions, salivation, diarrhea, lethargy, sleep and coma.
- No sign of intoxication detected in all animals. No macroscopic abnormalities were obtained at termination.

Table 3: Summary of body weight of mice

Group	Dose Level (mg/kg)	Days		
		0	8	15
1	Vehicle Control (10ml/kg)	26.00±0.50	25.50±0.64	26.5±0.37
2	Cardo 600 tablet (2000 mg/kg)	27.80± 1.20	27.80± 1.30	28.30±1.03

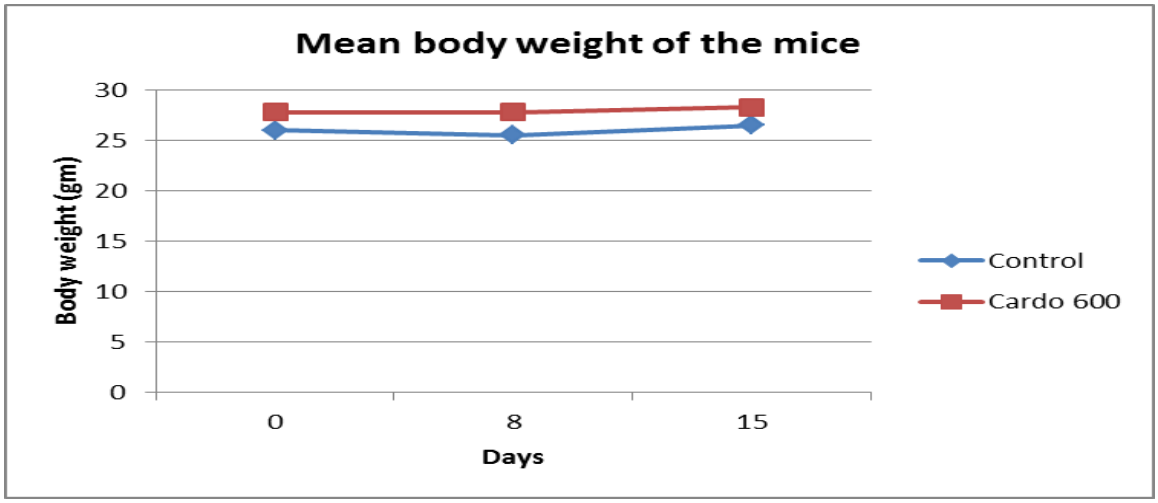

Figure 1: Increase in body weight of mice over 15 days.

No significant change in body weight in all animals was observed.

Conclusion:

The acute toxicity of Cardo 600 tablet was evaluated in female mice after oral administration of at the dose of 2000 mg/kg. Animals were observed at least twice daily for any clinical signs and mortality throughout the 15 days of observation period. No abnormalities were detected in clinical signs like appearance, respiration, motor activity, tremors, convulsions, corneal reflexes, lacrimation, miosis, mydriasis, salivation, diarrhea and other discharge. Individual body weights of all animals were recorded at the start of treatment, day 7 and day 15. No significant change in body weight in all animals was observed. No macroscopic abnormalities were obtained at termination. The Cardo 600 tablet is safe up to 2000mg/kg dose in mice.

Dr. Snehal Patel
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Study Report

Toxicological evaluation of Cruel Capsule on mice.

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Study Center:
Department of Pharmacology,
Institute of Pharmacy,
Nirma University.S.G. Highway,
Ahmedabad-382481
Gujarat, INDIA

Summary

The acute toxicity study indicates potential target organs, spectrum of toxic effect and will aid to establish maximum tolerable dose. Single dose toxicity studies in rodents are prerequisite for treatment of new drug in human. The purpose of this study was to assess the possible health hazards likely to arise when single dose of Cruel Capsule was administered by oral route to albino mice. The acute toxicity was evaluated in female mice after an oral administration at a dose level of 2000 mg/kg with concentration of 200mg/ml. Animals were observed at least twice daily for any clinical signs and mortality throughout the 15 days of observation period. No abnormalities were detected in clinical signs like appearance, respiration, motor activity, tremors, convulsions, corneal reflexes, lacrimation, miosis, mydriasis, salivation, diarrhea and other discharge. Individual body weights of all animals were recorded at the start of treatment, day 8 and day 15. No significant change in body weight in all animals was observed. No macroscopic abnormalities were obtained at termination. The Cruel Capsule is safe up to 2000mg/kg dose in mice.

Study Objective:

The purpose of this study was to assess the possible hazards likely to arise when single dose of Cruel Capsule administered by oral route to mice. This study provides a rational basis for the assessment of toxicological risk to human at higher dose.

Materials and Methods:

1. Test Item: Cruel Capsule
2. Vehicle: 0.5% CMC

   Cruel Capsule was received by sponsor and stored at recommended storage condition. Characterization of Cruel Capsule was performed by the sponsor.
3. Test Facility: Department of Pharmacology

   Institute of Pharmacy

   Nirma University
4. Test System:

   Species: Mice

   Strain: C57BL/6

   Sex: Female

   No of animals: 12

   Weight: 20-30 gm (6-8 week)
5. Identification: Tail marking
6. Housing: Temperature 22$\pm$ 3

   Humidity: 30-70%

   12 hr light/dark cycle
7. Food: Rodent feed manufactured by M/s Pranav Agro Pvt. Ltd., Baroda.
8. Water: Clean purified water
9. Acclimatization and randomization: Animals were acclimatized for the minimum period of one week. All animals assigned to study were subjected to pre-treatment veterinary health examination.

Experimental design:

1. **Animal allocation to groups:** Prior to start of treatment, all the animals were subjected to randomization (body weight basis). All 12 female mice were allocated to two groups.

Group	Dose Level (mg/kg)	Animal Numbers
1	Vehicle Control (10ml/kg)	12
2	Cruel Capsule (2000 mg/kg)	12

2. **Treatment Procedure:** The Cruel Capsule was administered at a dose level of 2000 mg/kg dose level along with a vehicle control group.

3. **Route of administration:** The Cruel Capsule was administered by oral route to 3-4 hour fasted animals using graduated syringe at an approximately constant dose volume of 10ml/kg.

4. **Observation during Experimental Period:** Animals were observed at 15, 30 minute, 1 hr, 2hr, 3hr, and 4hr post dosing followed by one evening observation. From day two, all mice were observed at least twice daily for any clinical signs and mortality throughout the 15 days the observation period. Cage side observations were carried out including changes in skin, hair coat, eyes, mucous membranes, respiratory, circulatory, autonomic and central nervous system, somatomotor activity and behavior pattern. Particular attention was directed to observation of tremors, convulsions, salivation, diarrhea, lethargy, sleep and coma. Individual body weights were recorded at the start of treatment day 0, day 8 and day 15.

5. **Terminal studies:** At termination all the surviving mice were subjected for description of all macroscopic abnormalities. All mice at the end of observation period were euthanized.

6. **Statistical Analysis:** All the data were presented in Mean$\pm$SD. Statistical analysis was carried out using the individual animal data.

Results:

Table 1: Summary of survival in mice.

Group	**Vehicle Control (10ml/kg)**	**Cruel Capsule (2000 mg/kg)**
Day	**No. of surviving rat/Initial No. of mice**	
1	12/12	12/12
2	12/12	12/12
3	12/12	12/12
4	12/12	12/12
5	12/12	12/12
6	12/12	12/12
7	12/12	12/12
8	12/12	12/12
9	12/12	12/12
10	12/12	12/12
11	12/12	12/12
12	12/12	12/12
13	12/12	12/12
14	12/12	12/12
15	12/12	12/12

No mortality was observed up to 15th day

Table 2: Summary of clinical signs

Group	**Dose Level (mg/kg)**	**Clinical signs***	**No. of mice without signs/ No. of mice treated**
1	Vehicle Control (10ml/kg)	No abnormality detected	12/12
2	Cruel Capsule (2000 mg/kg)	No abnormality detected	12/12

- Clinical signs included changes in skin, hair coat, eyes, mucous membranes, respiratory, somatomotor activity and behavior pattern, tremors, convulsions, salivation, diarrhea, lethargy, sleep and coma.
- No sign of intoxication detected in all animals. No macroscopic abnormalities were obtained at termination.

Table 3: Summary of body weight in female mice

Group	Dose Level (mg/kg)	Days		
		0	8	15
1	Vehicle Control (10ml/kg)	26.00±0.50	25.50±0.64	26.50±0.37
2	Cruel Capsule (2000 mg/kg)	25.50±2.16	25.08±2.65	22.75±3.11

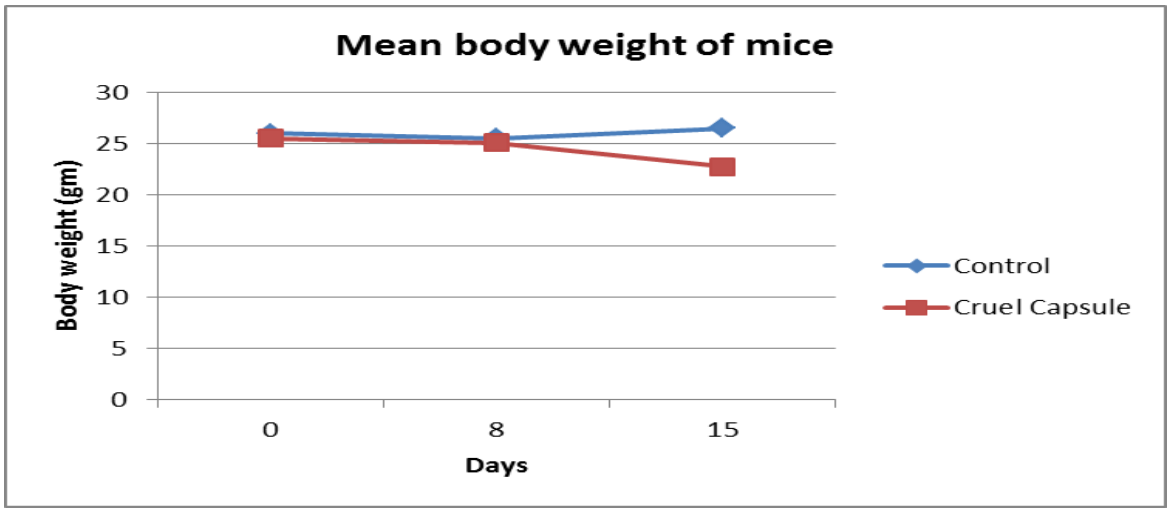

Figure 1: Decrease in body weight of female mice over 15 days.

No significant change in body weight in all animals treated with cruel capsule was observed.

Conclusion:

The acute toxicity of Cruel Capsule was evaluated in female mice after oral administration of at the dose of 2000 mg/kg. Animals were observed at least twice daily for any clinical signs and mortality throughout the 15 days of observation period. No abnormalities were detected in clinical signs like appearance, respiration, motor activity, tremors, convulsions, corneal reflexes, lacrimation, miosis, mydriasis, salivation, diarrhea and other discharge. Individual body weight of all animals was recorded at the start of treatment, day 7 and day 15. No significant change in body weight of all animals was observed. No macroscopic abnormalities were obtained at termination. The Cruel Capsule is safe up to 2000mg/kg dose in mice.

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Study Report

Toxicological evaluation of Jambruyog Tablet on mice.

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Study Center:
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Summary

The acute toxicity study indicates potential target organs, spectrum of toxic effect and will aid to establish maximum tolerable dose. Single dose toxicity studies in rodents are prerequisite for treatment of new drug in human. The purpose of this study was to assess the possible health hazards likely to arise when single dose of Jambruyog tablet was administered by oral route to albino mice. The acute toxicity was evaluated in female mice after an oral administration at a dose level of 2000 mg/kg with concentration of 200mg/ml. Animals were observed at least twice daily for any clinical signs and mortality throughout the 15 days of observation period. No abnormalities were detected in clinical signs like appearance, respiration, motor activity, tremors, convulsions, corneal reflexes, lacrimation, miosis, mydriasis, salivation, diarrhea and other discharge. Individual body weight of all animals was recorded at the start of treatment, day 8 and day 15. No significant change in body weight in all animals was observed. No macroscopic abnormalities were obtained at termination. The Jambruyog tablet is safe up to 2000mg/kg dose in mice.

Study Objective:

The purpose of this study was to assess the possible hazards likely to arise when single dose of Jambruyog tablet administered by oral route to mice. This study provides a rational basis for the assessment of toxicological risk to human at higher dose.

Materials and Methods:

1. Test Item: Jambruyog tablet
2. Vehicle: 0.5% CMC

   Jambruyog tablet was received by sponsor and stored at recommended storage condition. Characterization of Jambruyog tablet was performed by the sponsor.
3. Test Facility: Department of Pharmacology

   Institute of Pharmacy

   Nirma University
4. Test System:

   Species: Mice

   Strain: C57BL/6

   Sex: female

   No of animals: 12

   Weight: 20-30 gm (6-8 week)
5. Identification: Tail marking
6. Housing: Temperature 22$\pm$ 3

   Humidity: 30-70%

   12 hr light/dark cycle
7. Food: Rodent feed manufactured by M/s Pranav Agro Pvt. Ltd., Baroda.
8. Water: Clean purified water
9. Acclimatization and randomization: Animals were acclimatized for the minimum period of one week. All animals assigned to study were subjected to pre-treatment veterinary health examination.

Experimental design:

1. **Animal allocation to groups:** Prior to start of treatment, all the animals were subjected to randomization (body weight basis). All 12 female mice were allocated to two groups.

Group	Dose Level (mg/kg)	Animal Numbers
1	Vehicle Control (10ml/kg)	12/12
2	Jambruyog tablet (2000 mg/kg)	12/12

2. **Treatment Procedure:** The Jambruyog tablet was administered at a dose level of 2000 mg/kg dose level along with a vehicle control group.
3. **Route of administration:** The Jambruyog tablet was administered by oral route to 3-4 hour fasted animals using graduated syringe at an approximately constant dose volume of 10ml/kg.
4. **Observation during Experimental Period:** Animals were observed at 15, 30 minute, 1 hr, 2hr, 3hr, and 4hr post dosing followed by one evening observation. From day two, all mice were observed at least twice daily for any clinical signs and mortality throughout the 15 days the observation period. Cage side observations were carried out including changes in skin, hair coat, eyes, mucous membranes, respiratory, circulatory, autonomic and central nervous system, somatomotor activity and behavior pattern. Particular attention was directed to observation of tremors, convulsions, salivation, diarrhea, lethargy, sleep and coma. Individual body weight were recorded at the start of treatment (day 0), day 8 and day 15.
5. **Terminal studies:** At termination all the surviving mice were subjected for description of all macroscopic abnormalities. All mice at the end of observation period were euthanized.
6. **Statistical Analysis:** All the data were presented in Mean$\pm$SD. Statistical analysis was carried out using the individual animal data.

Results:

Table 1: Summary of survival in mice.

Group	**Vehicle Control (10ml/kg)**	**Jambruyog tablet (2000 mg/kg)**
Day	**No. of surviving rat/Initial No. of mice**	
1	12/12	12/12
2	12/12	12/12
3	12/12	12/12
4	12/12	12/12
5	12/12	12/12
6	12/12	12/12
7	12/12	12/12
8	12/12	12/12
9	12/12	12/12
10	12/12	12/12
11	12/12	12/12
12	12/12	12/12
13	12/12	12/12
14	12/12	12/12
15	12/12	12/12

No mortality was observed up to 15th day

Table 2: Summary of clinical signs

Group	**Dose Level (mg/kg)**	**Clinical signs***	**No. of mice without signs/ No. of mice treated**
1	Vehicle Control (10ml/kg)	No abnormality detected	12/12
2	Jambruyog tablet (2000 mg/kg)	No abnormality detected	12/12

- Clinical signs included changes in skin, hair coat, eyes, mucous membranes, respiratory, somatomotor activity and behavior pattern, tremors, convulsions, salivation, diarrhea, lethargy, sleep and coma.
- No sign of intoxication detected in all animals. No macroscopic abnormalities were obtained at termination.

Table 3: Summary of body weight in mice

Group	Dose Level (mg/kg)	Days		
		0	8	15
1	Vehicle Control (10ml/kg)	26.00±0.50	25.50±0.64	26.50±0.37
2	Jambruyog tablet (2000 mg/kg)	25.12±2.21	25.12±2.49	26.12± 2.56

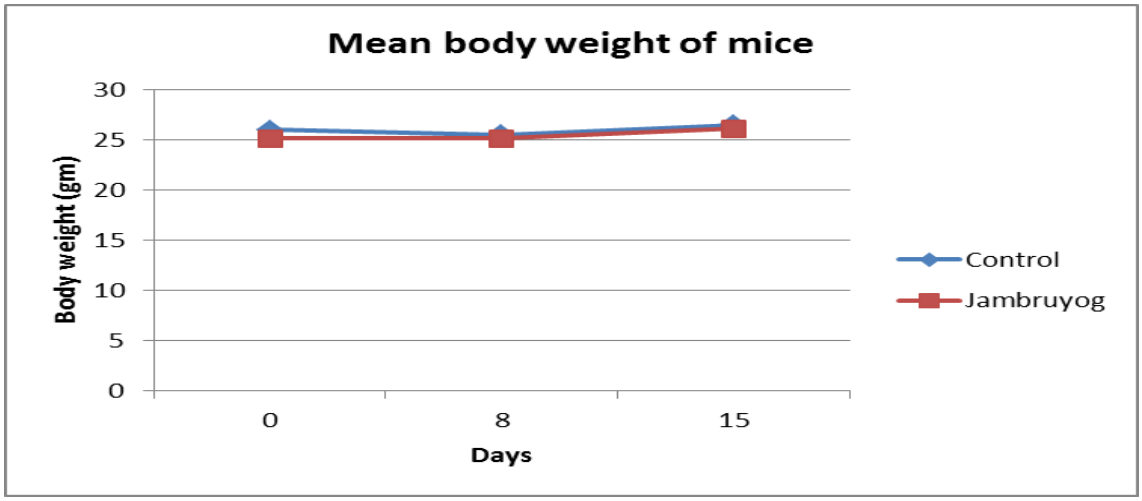

Figure 1: Increase in body weight of female mice over 15 days

No significant change in body weight of all animals was observed.

Conclusion:

The acute toxicity of Jambruyog tablet was evaluated in female mice after oral administration of at the dose of 2000 mg/kg. Animals were observed at least twice daily for any clinical signs and mortality throughout the 15 days of observation period. No abnormalities were detected in clinical signs like appearance, respiration, motor activity, tremors, convulsions, corneal reflexes, lacrimation, miosis, mydriasis, salivation, diarrhea and other discharge. Individual body weight of all animals was recorded at the start of treatment, day 7 and day 15. No significant change in body weight in all animals was observed. No macroscopic abnormalities were obtained at termination. The Jambruyog tablet is safe up to 2000 mg/kg dose in mice.

Dr. Snehal Patel
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Study Report

Toxicological evaluation of Navratna Rasa tablet on mice.

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Study Center:
Department of Pharmacology,
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Gujarat, INDIA

Summary

The acute toxicity study indicates potential target organs, spectrum of toxic effect and will aid to establish maximum tolerable dose. Single dose toxicity studies in rodents are prerequisite for treatment of new drug in human. The purpose of this study was to assess the possible health hazards likely to arise when single dose of Navratna Rasa tablet was administered by oral route to albino mice. The acute toxicity was evaluated in female mice after an oral administration at a dose level of 2000 mg/kg with concentration of 200mg/ml. Animals were observed at least twice daily for any clinical signs and mortality throughout the 15 days of observation period. No abnormalities were detected in clinical signs like appearance, respiration, motor activity, tremors, convulsions, corneal reflexes, lacrimation, miosis, mydriasis, salivation, diarrhea and other discharge. Individual body weights of all animals were recorded at the start of treatment, day 8 and day 15. No significant change in body weight in all animals was observed. No macroscopic abnormalities were obtained at termination. The Navratna Rasa tablet is safe up to 2000mg/kg dose in mice.

Study Objective:

The purpose of this study was to assess the possible hazards likely to arise when single dose of Navratna Rasa tablet administered by oral route to mice. This study provides a rational basis for the assessment of toxicological risk to human at higher dose.

Materials and Methods:

1. Test Item: Navratna Rasa tablet
2. Vehicle: 0.5% CMC

   Navratna Rasa tablet was received by sponsor and stored at recommended storage condition. Characterization of Navratna Rasa tablet was performed by the sponsor.
3. Test Facility: Department of Pharmacology

   Institute of Pharmacy

   Nirma University
4. Test System:

   Species: Mice

   Strain: C57BL/6

   Sex: Female

   No of animals: 12 Weight: 20-30 gm (6-8 week)
5. Identification: Tail marking
6. Housing: Temperature 22$\pm$ 3

   Humidity: 30-70%

   12 hr light/dark cycle
7. Food: Rodent feed manufactured by M/s Pranav Agro Pvt. Ltd., Baroda.
8. Water: Clean purified water
9. Acclimatization and randomization: Animals were acclimatized for the minimum period of one week. All animals assigned to study were subjected to pre-treatment veterinary health examination.

Experimental design:

1. **Animal allocation to groups:** Prior to start of treatment, all the animals were subjected to randomization (body weight basis). All 12 female mice were allocated to two groups.

Group	Dose Level (mg/kg)	Animal Numbers
1	Vehicle Control (10ml/kg)	12
2	Navratna Rasa tablet (2000 mg/kg)	12

2. **Treatment Procedure:** The Navratna Rasa tablet was administered at a dose level of 2000 mg/kg dose level along with a vehicle control group.
3. **Route of administration:** The Navratna Rasa tablet was administered by oral route to 3-4 hour fasted animals using graduated syringe at an approximately constant dose volume of 10ml/kg.
4. **Observation during Experimental Period:** Animals were observed at 15, 30 minute, 1 hr, 2hr, 3hr, and 4hr post dosing followed by one evening observation. From day two, all mice were observed at least twice daily for any clinical signs and mortality throughout the 15 days the observation period. Cage side observations were carried out including changes in skin, hair coat, eyes, mucous membranes, respiratory, circulatory, autonomic and central nervous system, somatomotor activity and behavior pattern. Particular attention was directed to observation of tremors, convulsions, salivation, diarrhea, lethargy, sleep and coma. Individual body weight were recorded at the start of treatment (day 0), day 8 and day 15.
5. **Terminal studies:** At termination all the surviving mice were subjected for description of all macroscopic abnormalities. All mice at the end of observation period were euthanized.
6. **Statistical Analysis:** All the data were presented in Mean$\pm$SD. Statistical analysis was carried out using the individual animal data.

Results:

Table 1: Summary of survival in mice.

Group	**Vehicle Control (10ml/kg)**	**Navratna Rasa tablet (2000 mg/kg)**
Day	**No. of surviving rat/Initial No. of mice**	
1	12/12	12/12
2	12/12	12/12
3	12/12	12/12
4	12/12	12/12
5	12/12	12/12
6	12/12	12/12
7	12/12	12/12
8	12/12	12/12
9	12/12	12/12
10	12/12	12/12
11	12/12	12/12
12	12/12	12/12
13	12/12	12/12
14	12/12	12/12
15	12/12	12/12

No mortality was observed up to 15th day

Table 2: Summary of clinical signs

Group	**Dose Level (mg/kg)**	**Clinical signs***	**No. of mice without signs/ No. of mice treated**
1	Vehicle Control (10ml/kg)	No abnormality detected	12/12
2	Navratna Rasa tablet (2000 mg/kg)	No abnormality detected	12/12

- Clinical signs included changes in skin, hair coat, eyes, mucous membranes, respiratory, somatomotor activity and behavior pattern, tremors, convulsions, salivation, diarrhea, lethargy, sleep and coma.
- No sign of intoxication detected in all animals. No macroscopic abnormalities were obtained at termination.

Table 3: Summary of body weight in female mice

Group	Dose Level (mg/kg)	Days		
		0	8	15
1	Vehicle Control (10ml/kg)	26.00±0.50	25.50±0.64	26.50±0.37
2	Navratna Rasa tablet (2000 mg/kg)	26.75 ± 3.30	25.25 ± 3.22	27.50 ± 2.67

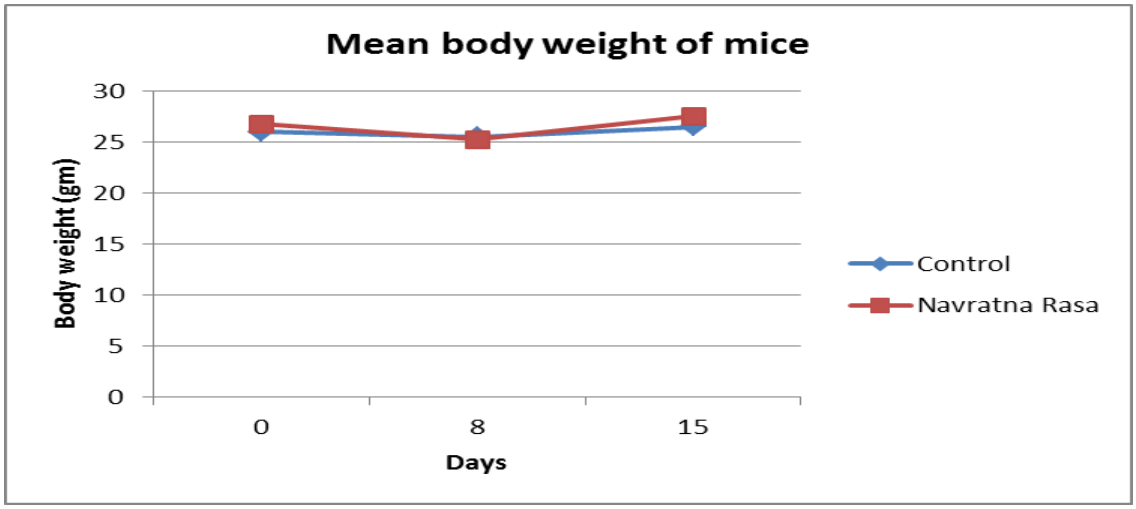

Figure 1: Increase in body weight of female mice over 15 days

No significant change in body weight of all animals was observed at the end of 15 days.

Conclusion:

The acute toxicity of Navratna Rasa tablet was evaluated in female mice after oral administration of at the dose of 2000 mg/kg. Animals were observed at least twice daily for any clinical signs and mortality throughout the 15 days of observation period. No abnormalities were detected in clinical signs like appearance, respiration, motor activity, tremors, convulsions, corneal reflexes, lacrimation, miosis, mydriasis, salivation, diarrhea and other discharge. Individual body weights of all animals were recorded at the start of treatment, day 7 and day 15. Increase of body weight in all animals at day 15 was observed. No macroscopic abnormalities were obtained at termination. The Navratna Rasa tablet is safe up to 2000mg/kg dose in mice.

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Study Report

Toxicological evaluation of Vigorise Gold Capsule on mice.

Sponsor:
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Study Center:
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Institute of Pharmacy,
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Ahmedabad-382481
Gujarat, INDIA

Summary

The acute toxicity study indicates potential target organs, spectrum of toxic effect and will aid to establish maximum tolerable dose. Single dose toxicity studies in rodents are prerequisite for treatment of new drug in human. The purpose of this study was to assess the possible health hazards likely to arise when single dose of Vigorise Gold Capsule was administered by oral route to albino mice. The acute toxicity was evaluated in female mice after an oral administration at a dose level of 2000 mg/kg with concentration of 200mg/ml. Animals were observed at least twice daily for any clinical signs and mortality throughout the 15 days of observation period. No abnormalities were detected in clinical signs like appearance, respiration, motor activity, tremors, convulsions, corneal reflexes, lacrimation, miosis, mydriasis, salivation, diarrhea and other discharge. Individual body weights of all animals were recorded at the start of treatment, day 8 and day 15. No significant change in body weight in all animals was observed. No macroscopic abnormalities were obtained at termination. The Vigorise Gold Capsule is safe up to 2000mg/kg dose in mice.

Study Objective:

The purpose of this study was to assess the possible hazards likely to arise when single dose of Vigorise Gold Capsule administered by oral route to mice. This study provides a rational basis for the assessment of toxicological risk to human at higher dose.

Materials and Methods:

1. Test Item: Vigorise Gold Capsule
2. Vehicle: 0.5% CMC

   Vigorise Gold Capsule tablet was received by sponsor and stored at recommended storage condition. Characterization of Navaratna Yogamrit tablet was performed by the sponsor.
3. Test Facility: Department of Pharmacology

   Institute of Pharmacy

   Nirma University
4. Test System:

   Species: Mice

   Strain: C57BL/6

   Sex: Female

   No of animals: 12

   Weight: 20-30 gm (6-8 week)
5. Identification: Tail marking
6. Housing: Temperature 22$\pm$ 3

   Humidity: 30-70%

   12 hr light/dark cycle
7. Food: Rodent feed manufactured by M/s Pranav Agro Pvt. Ltd., Baroda.
8. Water: Clean purified water
9. Acclimatization and randomization: Animals were acclimatized for the minimum period of one week. All animals assigned to study were subjected to pre-treatment veterinary health examination.

Experimental design:

1. **Animal allocation to groups:** Prior to start of treatment, all the animals were subjected to randomization (body weight basis). All 12 mice were allocated into two groups.

Group	Dose Level (mg/kg)	Animal Numbers
1	Vehicle Control (10ml/kg)	12
2	Vigorise Gold Capsule (2000 mg/kg)	12

2. **Treatment Procedure:** The Vigorise Gold Capsule was administered at a dose level of 2000 mg/kg dose level along with a vehicle control group.
3. **Route of administration:** The Vigorise Gold Capsule was administered by oral route to 3-4 hour fasted animals using graduated syringe at an approximately constant dose volume of 10ml/kg.
4. **Observation during Experimental Period:** Animals were observed at 15, 30 minute, 1hr, 2hr, 3hr, and 4hr post dosing followed by one evening observation. From day two, all mice were observed at least twice daily for any clinical signs and mortality throughout the 15 days the observation period. Cage side observations were carried out including changes in skin, hair coat, eyes, mucous membranes, respiratory, circulatory, autonomic and central nervous system, somatomotor activity and behavior pattern. Particular attention was directed to observation of tremors, convulsions, salivation, diarrhea, lethargy, sleep and coma. Individual body weight were recorded at the start of treatment (day 0), day 8 and day 15.
5. **Terminal studies:** At termination all the surviving mice were subjected for description of all macroscopic abnormalities. All mice at the end of observation period were euthanized.
6. **Statistical Analysis:** All the data were presented in Mean$\pm$SD. Statistical analysis was carried out using the individual animal data.

Results:

Table 1: Summary of survival in mice.

Group	**Vehicle Control (10ml/kg)**	**Vigorise Gold Capsule (2000 mg/kg)**
Day	**No. of surviving rat/Initial No. of mice**	
1	12/12	12/12
2	12/12	12/12
3	12/12	12/12
4	12/12	12/12
5	12/12	12/12
6	12/12	12/12
7	12/12	12/12
8	12/12	12/12
9	12/12	12/12
10	12/12	12/12
11	12/12	12/12
12	12/12	12/12
13	12/12	12/12
14	12/12	12/12
15	12/12	12/12

No mortality was observed up to 15th day

Table 2: Summary of clinical signs

Group	**Dose Level (mg/kg)**	**Clinical signs***	**No. of mice without signs/ No. of mice treated**
1	Vehicle Control (10ml/kg)	No abnormality detected	12/12
2	Vigorise Gold Capsule (2000 mg/kg)	No abnormality detected	12/12

- Clinical signs included changes in skin, hair coat, eyes, mucous membranes, respiratory, somatomotor activity and behavior pattern, tremors, convulsions, salivation, diarrhea, lethargy, sleep and coma.
- No sign of intoxication detected in all animals. No macroscopic abnormalities were obtained at termination.

Table 3: Summary of body weight in female mice

Group	Dose Level (mg/kg)	Days		
		0	8	15
1	Vehicle Control (10ml/kg)	26.00±0.50	25.50±0.64	27.50±0.37
2	Vigorise Gold Capsule (2000 mg/kg)	28.50±1.73	27.50±1.5	27.60±1.89

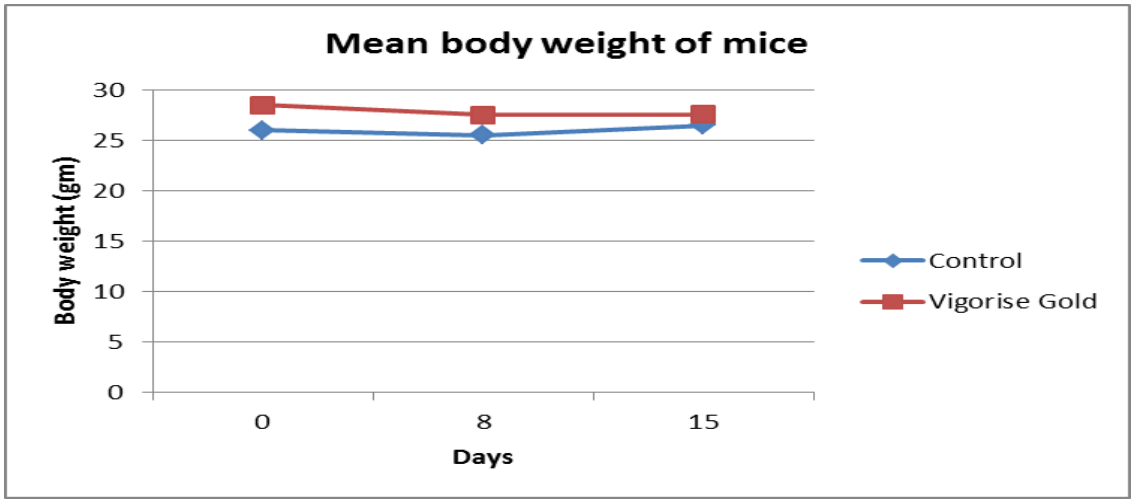

Figure 1: Slight decrease in body weight of female mice over 15 days

No significant change in body weight of animals was observed.

Conclusion:

The acute toxicity of Vigorise Gold Capsule was evaluated in female mice after oral administration of at the dose of 2000 mg/kg. Animals were observed at least twice daily for any clinical signs and mortality throughout the 15 days of observation period. No abnormalities were detected in clinical signs like appearance, respiration, motor activity, tremors, convulsions, corneal reflexes, lacrimation, miosis, mydriasis, salivation, diarrhea and other discharge. Individual body weights of all animals were recorded at the start of treatment, day 7 and day 15. No significant change in body weight of all animals was observed. No macroscopic abnormalities were obtained at termination. The Vigorise Gold Capsule is safe up to 2000mg/kg dose in mice.

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