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STUDY REPORT

Study Number

ARL/G/19/PT0054

Study Title

Acute Oral Toxicity Study of "Permaglu Tablet" in Wistar Rats

Sponsor copy (1 of 2)

Study Director

Mr. Kalpesh Nagar

Test Facility

Accuprec Research Labs Pvt Ltd.

(FDCA, ISO 9001:2015, GLP, CPCSEA, NABL, ISO/IEC 17025 & AYUSH approved Lab)

Opp. Zydus Pharmez,

Changodar - Bavla Highway,

Nr. Matoda Patia, Post: Matoda,

Ahmedabad - 382213, Gujarat, India

Sponsor

Pigmed Life Science

Cellar- 2, Hari Darshan Complex,

Hari Darshan Char Rasta, Maninagar,

Ahmedabad-380023, Gujarat.

Study Completion Date

05/07/2019

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Statement of Compliance with Good Laboratory Practice

Study No.: ARL/G/19/PT0054

Study Title: Acute Oral Toxicity Study of "Permaglu Tablet" in Wistar Rats

I, the undersigned hereby declare that this study, was conducted in compliance with the Organization of Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice (GLP) for the Testing of Chemicals as specified by International [C(97) 186/Final] Legislation and in accordance with the approved study plan and by following all relevant in-house SOPs. The study also meets the requirements of CFR 21 – Part 58 (April, 2018), (United States Food and Drugs Administration Principles of Good Laboratory Practice for the Testing of Chemicals).

All the documents pertaining to the study, including raw data, material, original study plan and final study report will be retained at Archives of Accuprec Research Labs, Ahmedabad, India.

No unforeseen circumstances which might have affected the quality of study were observed. This Final study report is a complete, true and accurate representation of the study conducted and results obtained. I accept the responsibility for the validity of data.

Study Director

Name : **Mr. Kalpesh Nagar**

Signature :

Date : 05/07/2019

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Statement by Test Facility Management

Study No.: ARL/G/19/PT0054

Study Title: Acute Oral Toxicity Study of "Permaglu Tablet" in Wistar Rats

The Test Facility Management has made available all the resources to the Study Director necessary for conduct of present study in compliance with agreed study plan between the Test Facility and the Sponsor.

The Test Facility Management hereby approves this study report for issuance

Test Facility Management

Name : **Dr. Rina Gokani**

Signature :

Date : 05/07/2019

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Statement by Quality Assurance Unit

Study No.: ARL/G/19/PT0054

Study Title: Acute Oral Toxicity Study of "Permaglu Tablet" in Wistar Rats

The study has been inspected by Quality Assurance Department of Accuprec Research Labs Pvt Ltd., Matoda, Ahmedabad, 382213, Gujarat, India and the findings have been reported to the Study Director and to the Management. The dates of inspection, phases inspected and the dates of reporting have been listed below:

S. No.	Date of Inspection	Phase	Date of Reporting	
			SD	Management
Initiation Phase				
1	16/04/2019	Review of Study Plan	16/04/2019	16/04/2019
2	17/04/2019	Review of Final Study Plan	17/04/2019	17/04/2019
In-Life Phase				
1	24/04/2019	Body weight, Dosing & Clinical Observation	24/04/2019	24/04/2019
2	30/04/2019	Body weight & Detailed Clinical Observation	30/04/2019	30/04/2019
3	07/05/2019	Body weight, Dosing & Detailed Clinical Observation	07/05/2019	07/05/2019
4	08/05/2019	Gross necropsy	08/05/2019	08/05/2019
Reporting Phase				
1	13/06/2019	Review of Draft Report	13/06/2019	13/06/2019
2	03/07/2019	Review of Final Report	03/07/2019	03/07/2019

The report was audited against the pertinent data generated and it accurately reflects the raw data.

Quality Assurance Unit

Name : Mr. Bhushan Amrutkar

Signature :

Date : 05/07/2019

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Abbreviations

CPCSEA	Committee for the Purpose of Control and Supervision of Experiments on Animals
g	gram
GLP	Good Laboratory Practice
h	Hour
IAEC	Institutional Animal Ethics Committee
°C	Degree Centigrade
OECD	Organization for Economic Co-operation and Development
PPE	Personnel Protective Equipment
QA	Quality Assurance
SOP	Standard Operating Procedure
TFM	Test Facility Management

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Study Information

Study number	ARL/G/19/PT0054
Study title	Acute Oral Toxicity Study of "Permaglu Tablet" in Wistar Rats
Test item name	Permaglu Tablet
Test item code	ARL/PIG/0762/2019
Study director	Mr. Kalpesh Nagar
TFM	Dr. Rina Goakni Email Id: Rina.gokani@accuprec.com
Test facility	Accuprec Research Labs Pvt Ltd Opp. Zydus Pharmez, Changodar - Bavla Highway, Nr. Matoda Patia, Post: Matoda Ahmedabad - 382213, Gujarat, India.
Sponsor	Pigmed Life Science Cellar- 2, Hari Darshan Complex, Hari Darshan Char Rasta, Maninagar, Ahmedabad-380023, Gujarat.
Sponsor Representative	Mr. Vijay Patel pigmedlifescience@gmail.com

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Study Schedule

Study Initiation Date (Date on which Study Director signs Study Plan)	18/04/2019
Experiment Start Date (Date on which first study specific data is Collected)	19/04/2019
Experiment Completion Date (Date on which last study specific data is Collected)	10/05/2019
Study Completion Date (Date on which Study Director signs the Final Report)	05/07/2019

List of Study Personnel

Research Associate	Ms. Neha lavle
Research Assistant	Mr. Mehul Hudda
Research Assistant	Mr. Jainik Khamar
Research Assistant	Ms. Monika Thesiya

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1. INTRODUCTION

In principle, the method is not intended to allow the calculation of a precise LD50, but does allow for the determination of defined exposure ranges where lethality is expected since death of a proportion of the animals is still the major endpoint of this test.

The study is to evaluate adverse effects and lethal dose 50 (LD_{50}) of a Permaglu Tablet after single oral administration in wistar rats. It is necessary to evaluate the general toxicity potential to meet requirement specified in regulatory guideline. The test item will be used in the treatment of diabetes.

1.1. Objective

The objective of this study is to determine the possible health hazards likely to arise in Wistar rats following single oral exposure of permaglu tablet followed by a 14-day observation period.

1.2. GLP Compliance

This study was performed in accordance with the OECD Principles of Good Laboratory Practice ENV/MC/CHEM (98) 17, Environment Directorate, Organization for Economic Co-operation and Development, Paris, 1998. The study also meet the requirements of United States Food and Drug Administration Principles of Good Laboratory Practice for the testing of chemicals as specified by CFR 21 - Part 58 as revised on April 1, 2018

1.3. Study Guideline

The study was performed in accordance with the mutually agreed study plan (Study Protocol) between the Sponsor and Accuprec Research Labs and by following applicable in-house standard operating procedures (SOPs).

The study was performed based on the following standard:

- OECD 423 Acute Oral Toxicity – Acute Toxic Class Method

1.4. Certifications

The test facility is certified for compliance to below mentioned national and international standards:

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- **Food and Drugs Control Administration (FDCA):** Approval for carrying out test on drugs / cosmetics and raw materials used in their manufacture on behalf of licensees for manufacture for sale of drugs / cosmetics.

  Certificate for **Good Laboratory Practices** as prescribed under Drugs and Cosmetics Act 1940.

- **BS Certification Services Limited, UK, ISO 9001:2015:**Service Provider for Regulatory Testing and Research & Development Services, such as, Analytical Testing of Pharmaceuticals & Cosmetics, Biotechnological, Microbiological, Bio - Compatibility Studies of Medical Devices, Preclinical & Toxicological, Phytochemical, Food Testing, Formulation & Development Services, Dyes & Pigment Testing, Herbal Formulation Development, Stability Testing, Clinical Services, Regulatory Dossier Preparation, Intellectual Property Management Services.
- **CPCSEA, Government of India, Ministry of Environment and Forests, New Delhi:** Certification for the purpose of 'Research'.
- **ISO/IEC 17025:2017. National Accreditation Board for Testing and Calibration Laboratories (NABL):** Biological and chemical testing.

1.5. Quality Assurance Unit

The Quality Assurance department was review the study plan and, audit the critical phases of study, raw data, draft and final report. All findings were reported to the study director and management. A Quality Assurance statement was incorporated in the final report indicating the dates of inspection, phases inspected and the dates of reporting.

1.6. Animal Welfare

The study is designed to use minimum number of animals to meet the scientific objectives, the goal of sponsor and in consideration of applicable regulatory requirements.

Protocol for general procedures and use of animals for conducting this study in rats has been reviewed and approved by the Institutional Animal Ethics committee(IAEC vide protocol number ARL/PT/477/2018, dated 28th July, 2018). All procedures related to animal experiment will be performed as per the recommendations of the Guide for the Care and Use of Laboratory Animals and Committee for the Purpose of Control and

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Supervision of Experiments on Animals (CPCSEA) guidelines following all the ethical practices as laid down in the CPCSEA guidelines for animal care.

1.7. Safety Precautions

Personnel working with animals, test item and its formulation were wearing personal protection such as gloves, head cap, face mask, protective body garments and goggles . In case of an accidental contact with test item, eye / skin were washed thoroughly and appropriate medical treatment was soughted .

2. MATERIALS AND METHODS

Details of the methods mentioned in the subsequent sections of the Study Plan are as per applicable Standard Operating Procedures (SOPs) of Accuprec Research Labs, Matoda, Gujarat, India.

2.1. Test Item (Test Article) Details

Sponsor has been provided the test item along with product details form. Sponsor is responsible for the identity, composition, stability, characterization of test item. Relevant information received from sponsor is summarized below:

Name of the Test Item	Permaglu Tablet
Sponsor name and Address	Pigmed Life Science Cellar- 2, Hari Darshan Complex, Hari Darshan Char Rasta, Maninagar, Ahmedabad-380023, Gujarat.
Batch No.	TAG565
Manufacturing Date	02/01/2019
Expiry Date	31/12/2023
Physical State	Solid
Colour	Light green coloured circular biconvex coated tablet
Dimension Size	Thickness-4.41 mm, Dia.- 9.52mm
Solubility	Water Soluble
Storage Conditions	Store in cool, dry place
Date of Receipt at TICO	08/02/2019

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2.1.1. Identification of Test Item

Upon receipt of test item from the sponsor along with Product details form, the test facility has allotted test item code and the same was documented.

2.2. Test System

Species	:	Rat (*Rattusnorvegicus*)
Strain	:	Wistar
Sex	:	Female (nulliparous and non-pregnant)
Age	:	8-12 Weeks at the start of treatment
No. of Animals	:	12 (Remaining animals were returned to Animal House.)
Source	:	Accuprec Research Labs. (CPCSEA Registration No.:1709/PO/Rc/S/13/CPCSEA)

2.2.1. Justification for Selection of Test System and Number of Animals

Historically, rat is found to be a suitable model for pre-clinical safety evaluation studies and is recommended by regulatory agencies. The Wistar rat has been shown to be sensitive to toxic effects of a variety of drugs and chemicals. Therefore, the species and strain is a reasonable alternative to larger mammals for toxicity testing with respect to human safety assessment. This study is designed to use the fewest number of animals possible, consistent with the objectives of the study, contemporary scientific needs and standards, and in consideration of regulatory requirements.

2.2.2. Environmental Conditions

Animals were maintained under the following environmental conditions:

Temperature	: 19 - 25°C
Relative humidity	: 30 - 70%
Light/dark cycle (photoperiod)	: 12 h light & 12 h dark cycle

2.2.3. Housing of Animals

Animals were housed in groups (maximum of three animals) in clean, sterilized Polypropylene cages having provision for holding pelleted food and drinking water in bottle throughout the study period. Cages and water bottles were cleaned and changed as per internal SOP.

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2.2.4. Feed and Drinking Water

Animals were fed *ad libitum* with standard pelleted laboratory animal diet (Keval sales corporation).Every batch of feed is analyzed for microbial contamination and proximate analysis. Bedding material were changed on regular basis.

Fresh potable drinking water processed through a reverse osmosis system was provided *ad libitum* to animals in water bottles via sipper tube. Analysis of water for specific microbiological load and chemical contaminants are carried out on a regular basis.

The results of feed and water analyses were retained with the records of the test facility. No contaminants are expected to be present in the feed and water in sufficient quantities to affect the conduct or results of the study.

2.2.5. Sanitation

During the conduct of the study, the floor of the experimental room was cleaned daily. All worktops and floor were mopped with disinfectant solution on a day-to-day basis.

2.2.6. Acclimatization

All animals were acclimatized for minimum 5 days. During acclimatization all animals were observed once for clinical signs and twice for mortality/morbidity. Body weights were recorded on day of receipt.

Animals were identified by a unique number provided by animal facility marking on tail. Each cage was identified by cage label.

2.2.7. Selection of Animals

At the commencement of treatment, animals were selected in such a way that the body weight of each animal was fall in an interval within ± 20 % of the mean initial body weight of previously dosed animal. Animals were identified as per in-house SOP. Each cage was identified by cage label having details like Study No., Cage No., Dose, Species, Strain, Sex, Animal ID, Treatment Start date and Date of Necropsy.

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2.2.8. Preparation of Test System

The animals were fasted overnight prior to dosing and further 3-4 hours after dosing.

3. EXPERIMENTAL DESIGN

3.1. Preparation of Test Item

The required amount of test item was crushed in mortar and pestle. A small amount of water added to triturate the tablet. Once the tablet is crushed entirely forming a suspension, it was transferred to a volumetric flask. The required volume of water added to make up the volume and was used for dose administration. For volume of formulation exceeding the designated volume of volumetric flask, micropipette was used for making the final volume.

3.2. Treatment procedure

The test item was administered orally. Animals were dosed in sequence at 48 h intervals. The dose volume was maintained at 10 mL/kg of body weight for all animals. Dose volume was calculated on the basis of overnight-fasted body weight on the day of dosing for each animal. The test item was administered by oral gavage, with a cannula fitted to a graduated syringe. Fasting was continued until 3-4 hours after dosing

Limit Test:

A limit test at one dose level of 2000mg/kg body weight was carried out with six animals (three animals per step with gap of 48 hours). five or more animals were survive, the limit test was concluded by giving LD_{50} of test item as more than 2000 mg/kg.

Class Method.

A minimum gap of 48 hours were kept before switching over to the next dose.

3.3. Route of Administration and Rationale

Test items were administered by oral route as specified in OECD 423 Acute Oral Toxicity – Acute Toxic Class Method.

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4. OBSERVATIONS

Following observations were made during the course of the study.

4.1. Clinical Observations

Throughout the study period, all animals were observed for mortality and morbidity twice daily. Animals were observed for general clinical signs for at 30mins, 1 hr, 2 hr and 4 hr post dose on Day 1 and thereafter daily once for 14 days.

4.2. Body Weight

Individual animal body weight was recorded on Day 1 (prior to treatment) and on Day 7 and Day 14. Fasting body weights were recorded on Day 15. The body weight data was expressed as Mean ± S.D.

4.3. Detailed Clinical Examination

All animals were examined for detailed clinical observation at weekly interval.

4.4. Gross Pathology

At the end of the observation period, on Day 15, all animals were euthanized by CO_2 asphyxiation followed by exsanguination and subjected to gross necropsy, including examination of external surfaces, orifices and thoracic/abdominal cavities.

5. RESULTS

5.1. Clinical and Mortality Observation

(Appendix 1)

No any clinical sign or mortality was observed in any of the treated animal of throughout the study period. All animals treated with test item and were found to be normal throughout study period.

5.2. Body Weight

(Appendix 2)

No significant change in body weight was observed in any of the treated animal throughout the study period.

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5.3. Detailed Clinical Examination

(Appendix 3)

All animals were found to be normal and no abnormality was detected in any of the treated animals.

5.4. Gross Necropsy

(Appendix 4)

No gross pathological changes were recorded in any of the treated animals.

6. CONCLUSION

Single administration of test item, 'Permaglu Tablet in Wistar rats by oral route, respectively, resulted in no toxicity. The test item was found to be non-toxic and meeting the requirement of OECD 423 Acute Oral Toxicity – Acute Toxic Class Method.

7. AMENDMENTS AND DEVIATIONS

No Amendments and deviations have been made in this study.

8. ARCHIVAL DETAILS

Raw data and other documents generated during the course of this study together with a copy of the study plan, amendments (if any) and final report will be archived, for a period of 9 years from the date of study completion in the Archives of Accuprec Research Labs, Matoda, INDIA. The archival period can be extended, if requested by the sponsor based on mutual agreement.

9. STUDY PLAN DISTRIBUTION

Hard copies of final study plan will be distributed as follows

Sponsor Copy	: 1 signed original (1 of 2)
Test Facility Copy	: 1 signed original (2 of 2)
Others	: Photocopy to QA

10. STUDY REPORT DISTRIBUTION

Hard copies of the study report will be distributed as follows:

Sponsor Copy	: 1 signed original (1 of 2)
Test Facility Copy	: 1 signed original (2 of 2)

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11. REFERENCES

- CPCSEA Guideline for Laboratory Animal Facility, 2015. By the Committee for the Purpose of Control and Supervision of Experiments on Animals, Chennai.
- Food and Drug Administration, Good Laboratory Practice (GLP) regulations as set forth in Title 21 of the United States Federal Regulations, Part 58, 2018.
- OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE MONITORING Number 1 OECD Principles on Good Laboratory Practice (as revised in 1997), ENV/MC/CHEM (98)17.
- OECD guideline 423 - Acute Oral Toxicity – Acute Toxic Class Method.

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12. APPENDIX

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Appendix 1: Individual Animal Clinical Signs and mortality

Groups	Sex	Anima l No.	Day								
			30 min.	1 hr	2 hr	4 hr	2	3	4	5	6
G1	F	001	1	1	1	1	1	1	1	1	1
	F	002	1	1	1	1	1	1	1	1	1
	F	003	1	1	1	1	1	1	1	1	1
G2	F	004	1	1	1	1	1	1	1	1	1
	F	005	1	1	1	1	1	1	1	1	1
	F	006	1	1	1	1	1	1	1	1	1

1 = normal or no mortality

Appendix 1 continued: Individual Animal Clinical Signs and mortality

Groups	Sex	Animal No.	Day								
			7	8	9	10	11	12	13	14	15
G1	F	001	1	1	1	1	1	1	1	1	1
	F	002	1	1	1	1	1	1	1	1	1
	F	003	1	1	1	1	1	1	1	1	1
G2	F	004	1	1	1	1	1	1	1	1	1
	F	005	1	1	1	1	1	1	1	1	1
	F	006	1	1	1	1	1	1	1	1	1

1 = normal or no mortality

Appendix 2: Individual Animal Body Weight

Groups	Animal No.	Sex	Day 1	Day 7	Day 14	Day 15
G1	001	F	218	218	222	218
	002	F	208	211	219	214
	003	F	218	221	229	225
		Mean	214.67	216.67	223.33	219.00
		SEM	3.33	2.96	2.96	3.21
G2	004	F	229	230	234	228
	005	F	213	214	220	217
	006	F	225	229	236	229
		Mean	222.33	224.33	230.00	224.67
		SEM	4.81	5.17	5.03	3.84

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Appendix 3: Individual Animal Detailed Clinical Observation

Groups	Sex	Animal No.	Day	
			7	14
G1	F	001	NAD	NAD
	F	002	NAD	NAD
	F	003	NAD	NAD
G2	F	004	NAD	NAD
	F	005	NAD	NAD
	F	006	NAD	NAD

NAD: No abnormality detected

Appendix 4: Individual Animal Gross Pathology Data

Groups	Sex	Animal No.	Day 15
G1	F	001	No Gross lesions observed
	F	002	No Gross lesions observed
	F	003	No Gross lesions observed
G2	F	004	No Gross lesions observed
	F	005	No Gross lesions observed
	F	006	No Gross lesions observed

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Appendix 5: Certificate

This is to certify that the test material "Permaglu Tablet", supplied by Pigmed Life Science Cellar-2, Hari Darshan Complex, Hari Darshan Char Rasta, Maninagar, Ahmedabad-380023, Gujarat. (India) was tested for Acute Oral Toxicity Study in Wistar rats according to OECD guideline 423; compliance with the requirements of GLP.

Permaglu Tablet was found to be non-toxic when administered via oral route, respectively in rats for 14 days.

The present report of the Acute Oral Toxicity Study of "Permaglu Tablet" in Wistar Rats', performed according to OECD guideline 423, has been submitted through IAEC Study Protocol No. "ARL/PT/477/2018".

Accuprec Research Labs Pvt. Ltd., is approved for experiment on laboratory animals by Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA, New Delhi).

Accuprec Research Labs Pvt. Ltd., is approved by the Food & Drug Administration, Gujarat State, Gandhinagar, through License No. GTL/37/31.

Date: 05/07/2019

05/07/2019

Mr. Kalpesh Nagar

Study Director

05/07/2019

Mr. Bhushan Amrutkar

QAU

05/07/19

Dr. Rina Gokani

TFM

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