FINAL STUDY REPORT

STUDY TITLE

SKIN SENSITIZATION STUDY OF POLAR AND NON-POLAR EXTRACTS OF EXCALIBUR: VESSEL SEALER AND DISSECTION DEVICE USING GUINEA PIGS MAXIMIZATION TEST (GPMT)

TEST GUIDELINE: ISO 10993-10:2021

STUDY NO.: LBPL/G-2731 (TX)

STUDY CODE: GPMT

STUDY COMPLETION DATE: 22/04/2023

STUDY DIRECTOR

Ms. Rangalakshmi G. R.

SPONSOR

BLUE PHOENIX TECHNOLOGIES PVT.LTD.
(UNIT 301/302 A WING, SUNFLLOWER INDUSRIAL,
BLDG, OFF GOREGAON MULUND RD, SHIVNERI, MUMBAI,
MUMBAI CITY, MAHARASTRA,
INDIA, 400063)

TEST FACILITY

LIVEON BIOLABS PRIVATE LIMITED
PLOT NO.46 & 47, II PHASE, WATER TANK ROAD
KIADB INDUSTRIAL AREA, ANTHARASANAHALLI
TUMAKURU-572106, KARNATAKA
INDIA.

1. OBJECTIVE

The objective of this toxicity study was to assess the potential skin sensitization and biocompatibility of a polar extract (physiological saline) and non-polar extract (sesame oil) of "Excalibur: Vessel Sealer and Dissection Device" by injecting both polar extract and non-polar extract as a single intradermal injection to evaluate the possibility of hyperreactive skin (visible reactions i.e. erythema/oedema) followed by topical induction (erythema/oedema) and challenge Phase for skin reaction(erythema) in guinea pigs. This test also provides information on health hazards likely to be arise from acute exposure by the intended clinical route in humans.

2. STUDY DETAILS

Study Title	:	Skin Sensitization Study of Polar and Non-Polar Extracts of Excalibur: Vessel Sealer and Dissection Device using Guinea Pigs Maximization Test (GPMT).
Study Number	:	LBPL/G-2731 (TX)
Study Code	:	GPMT
ULR No.	:	TC-679423000000004F
Sponsor	:	BLUE PHOENIX TECHNOLOGIES PVT.LTD. (Unit 301/302 A Wing, Sunfllower Indusrial, Bldg, Off Goregaon Mulund Rd, Shivneri, Mumbai,Mumbai City, Maharastra, India, 400063)
Test Facility	:	LIVEON BIOLABS PRIVATE LIMITED Plot No. 46 & 47, Phase II Water Tank Road, KIADB Industrial Area Antharasanahalli, Tumakuru – 572106 Karnataka, India.

3. STUDY RESPONSIBILITIES

Study Director	:	Ms. Rangalakshmi. G. R.
Study Personnel I	:	Mr.Mariswamy. T.P
Study Personnel II	:	Ms. Bhavana S.B.
Study Personnel III	:	Ms. Supritha G.
Study Personnel IV	:	Ms.Navya.N
Study Personnel V	:	Ms. Chitashree.S R
Study Personnel VI	:	Ms.Swathi
Study Personnel VII	:	Ms.Bhavani.D B
Study Personnel VIII	:	Ms. Mamatha G.
Study Personnel IX	:	Ms.Syeda Iffath Unnisa
Study Personnel X	:	Mr. Vasantha Kumar B.S
Study Personnel XI	:	Mrs.Bhagyashree. M
Study Veterinarian	:	Dr. Sunkad Meghana
Sponsor Representative	:	Prashant Kavale
Monitoring Scientist	:	Dishant Dipen Shah

4. STUDY SCHEDULE

Study Initiation Date	: 27/01/2023
Experiment Start Date	: 30/01/2023
Acclimatization Period	: 30/01/2023 to 03/02/2023
Treatment Dates	: Intradermal induction phase: 04/02/2023 Topical induction phase : 11/02/2023 Challenge phase: 25/02/2023
Experiment End Date	: 28/02/2023
Draft Report to Sponsor	: 07/03/2023
Study Completion Date	: 22/04/2023

20. CONCLUSION

Based on the above results, the graded (Magnusson and Kligman grading scale) score was 0. The comparison of the skin reaction (at the challenge phase) of the test item treated animals with those of the Vehicle control group animals show that the test item "Excalibur: Vessel Sealer and Dissection Device" is classified as "Non-sensitizer" to Guinea Pigs under the stated experimental condition.

21. DATA COMPILATION

All individual animal data were presented in appendices and summarized and presented in tables. All findings were presented in the study report.

22. ANIMAL EUTHANASIA AND DISPOSAL

At the end of experiment period all the animals were sacrificed using carbon dioxide asphyxiation. The carcasses were stored in deep freezer and disposed through Medicare Environmental Management Pvt. Ltd.

23. STUDY REPORT DISTRIBUTION

The Final Study Report will be distributed as follows:
Copy No. 1/2 – Sponsor
Copy No. 2/2 – Archives, Liveon Biolabs Private Limited

24. ARCHIVING

All study-related records, Study Plan, Raw Data, Study Report, and the Test Item sample was maintained in the archives of Liveon Biolabs Private Limited for 9 years from the date of study completion. All the records and test item was handled according OECD Principles of GLP for testing of chemicals as specified by international [C(97)186/Final] legislation. After the completion of archiving period, the test facility management will coordinate with the sponsor for further course of action on archived material.

FINAL STUDY REPORT

STUDY TITLE

INTRACUTANEOUS REACTIVITY TEST OF POLAR AND NON-POLAR EXTRACTS OF EXCALIBUR: VESSEL SEALER AND DISSECTION DEVICE IN NEW ZEALAND WHITE RABBITS

TEST GUIDELINE: ISO 10993-23:2021

STUDY NO.: LBPL/G-2732 (TX)

STUDY CODE: IRTNZW

STUDY COMPLETION DATE: 20/04/2023

STUDY DIRECTOR

Mrs. Bhagyashree M.

SPONSOR

BLUE PHOENIX TECHNOLOGIES PVT.LTD.
(UNIT 301/302 A WING, SUNFLOWER INDUSTRIAL, BLDG,
OFF GOREGAON MULUND RD, SHIVNERI, MUMBAI,
MUMBAI CITY, MAHARASHTRA, INDIA, 400063)

TEST FACILITY

LIVEON BIOLABS PRIVATE LIMITED
PLOT NO. 46 & 47, II PHASE, WATER TANK ROAD
KIADB INDUSTRIAL AREA, ANTHARASANAHALLI
TUMAKURU-572106, KARNATAKA
INDIA

1. OBJECTIVE

The objective of this study is to assess the possible irritation likely to arise from Intracutaneous injection of the test item, "Excalibur: Vessel Sealer and Dissection Device" Following its single administration in New Zealand White Rabbits. This study will provide a rational basis of risk assessment in humans.

2. STUDY DETAILS

Study Title	:	Intracutaneous Reactivity Test of Polar and Non-Polar extracts of Excalibur: Vessel Sealer and Dissection Device in New Zealand White Rabbits.
Study Number	:	LBPL/G-2732 (TX)
Study Code	:	IRTNZW
ULR No	:	TC-679423000000005F
Sponsor	:	BLUE PHOENIX TECHNOLOGIES PVT.LTD. (Unit 301/302 A Wing, Sunflower Industrial, Bldg, Off Goregaon Mulund Rd, Shivneri, Mumbai,Mumbai City, Maharashtra, India, 400063)
Test Facility	:	LIVEON BIOLABS PRIVATE LIMITED Plot No.46 & 47, II Phase, Water Tank Road, KIADB Industrial Area, Antharasanahalli, Tumakuru – 572106. Karnataka, India.

3. STUDY RESPONSIBILITIES

Study Director	:	Mrs.Bhagyashrre M.
Study Personnel I	:	Ms. Supritha G.
Study Personnel II	:	Ms. Bhavana S.B.
Study Personnel III	:	Ms. Chitrashree S.R
Study Personnel IV	:	Ms. Mamatha G
Study Personnel V	:	Mr. Udayakumar V.G
Study Personnel VI	:	Mr. Ravikumara K.C
Study Personnel VII		Mr. Mariswamy T.P
Study Veterinarian	:	Dr. Sunkad Meghana
Sponsor Representative	:	Prashant Kavale
Monitoring Scientist	:	Dishant Dipen Shah

4. STUDY SCHEDULE

Study Initiation Date	:	23/01/2023
Experiment Start Date	:	27/01/2023
Acclimatization Period	:	27/01/2023 to 02/02/2023
Treatment Start Date	:	03/02/2023
Experiment End Date	:	06/02/2023
Draft Report to Sponsor	:	13/02/2023
Study Completion Date	:	20/04/2023

21. DATA COMPILATION

All individual animal data are presented in appendices and summarized and presented in tables.

22. CONCLUSION

Under the test conditions employed, no test item-related skin reaction was observed in all test animals. The difference between the polar test extract mean score and polar vehicle control mean score was '0.000'. The difference between the non-polar test extract mean score and non-polar vehicle control mean score was '0.000'. Hence, the test item, "Excalibur: Vessel Sealer and Dissection Device" meets the requirement of the test guideline ISO 10993 Part-23:2021 since the test item score was less than 1 and considered to be "Non-irritant".

23. ANIMAL EUTHANASIA AND DISPOSAL

At the end of experiment period all the animals were sacrificed using lethal dose of Sodium thiopental injection. The carcasses were stored in deep freezer until disposed of through Medicare Environmental Management Pvt. Ltd.

Details of Thiopental Injection IP: Batch No: 47373, Manufacture Date: July-2022, Expiry Date: June-2024, Manufactured by: NEON laboratories limited.

24. STUDY REPORT DISTRIBUTION

The Final Study Report will be distributed as follows:

Copy No. 1/2 – Sponsor

Copy No. 2/2 – Archives, Liveon Biolabs Private Limited

25. ARCHIVING

All study-related records, Study Plan, Raw Data, Study Report, and the Test Item samples was maintained in the archives of Liveon Biolabs Private Limited for 9 years from the date of study completion. All the records and test item was handled according to OECD Principles of GLP for testing of chemicals as specified by international [C (97)186/Final] legislation. After the completion of archiving period, the test facility management will coordinate with the sponsor for further course of action on archived material.

FINAL STUDY REPORT

STUDY TITLE

ACUTE SYSTEMIC TOXICITY TEST OF POLAR AND NON-POLAR EXTRACTS OF EXCALIBUR: VESSEL SEALER AND DISSECTION DEVICE IN SWISS ALBINO MICE

TEST GUIDELINE: ISO 10993-11:2017

STUDY NO.: LBPL/G-2733 (TX)

STUDY CODE: AST

STUDY COMPLETED ON: 20/04/2023

STUDY DIRECTOR

Mrs. Bhagyashree M

SPONSOR

BLUE PHOENIX TECHNOLOGIES PVT.LTD.
(UNIT 301/302 A WING, SUNFLOWER INDUSTRIAL, BLDG,
OFF GOREGAON MULUND RD, SHIVNERI, MUMBAI,
MUMBAI CITY, MAHARASHTRA, INDIA, 400063)

TEST FACILITY

LIVEON BIOLABS PRIVATE LIMITED
PLOT NO.46 & 47, II PHASE, WATER TANK ROAD
KIADB INDUSTRIAL AREA, ANTHARASANAHALLI
TUMAKURU-572106, KARNATAKA
INDIA.

1. OBJECTIVE

The objective of this toxicity study was to assess the potential acute systemic toxicity and biocompatibility of a polar extract (Physiological saline) and non-polar extract (Sesame oil) of "Excalibur: Vessel Sealer and Dissection Device" by injecting both polar extract (i.e., by slow bolus intravenous injection) and non-polar extract (i.e., by slow bolus intraperitoneal injection) as a single administration. Also, this test provides information on health hazards likely to arise from acute exposure by the intended clinical route in humans.

2. STUDY DETAILS

Study Title	:	Acute Systemic Toxicity Test of Polar and Non-Polar Extracts of "Excalibur: Vessel Sealerand Dissection Device" in Swiss Albino Mice.
Study Number	:	LBPL/G-2733 (TX)
Study Code	:	AST
ULR No.	:	TC-679423000000006F
Sponsor	:	BLUE PHOENIX TECHNOLOGIES PVT.LTD. (Unit 301/302 A Wing, Sunflower Industrial, Bldg, Off Goregaon Mulund Rd, Shivneri, Mumbai,Mumbai City, Maharashtra, India, 400063)
Test Facility	:	LIVEON BIOLABS PRIVATE LIMITED Plot No.46 & 47, II Phase, Water Tank Road, KIADB Industrial Area, Antharasanahalli, Tumakuru - 572106. Karnataka, India.

3. STUDY RESPONSIBILITIES

Study Director	:	Mrs. Bhagyashree M.
Study Personnel I	:	Ms. Supritha G
Study Personnel I	:	Ms. Bhavana S B
Study Personnel III	:	Ms. Mamatha G.
Study Personnel IV	:	Mr. Udaya Kumar V.G.
Study Personnel V	:	Ms. Chitrashree.S.R
Study Veterinarian	:	Dr. Sunkad Meghana.
Sponsor Representative	:	Prashant Kavale
Monitoring Scientist	:	Dishant Dipen Shah

4. STUDY SCHEDULE

Study Initiation Date	:	23/01/2023
Experiment Start Date	:	27/01/2023
Acclimatization Period	:	27/01/2023 to 02/02/2023
Treatment Start Date	:	03/02/2023
Experiment End Date	:	06/02/2023
Draft Report to Sponsor	:	13/02/2023
Study Completion Date	:	20/04/2023

18. OBSERVATIONS

18.1 Mortality, Morbidity and Clinical Signs

Animals were observed for clinical signs daily once, morbidity and mortality daily twice. There were no clinical signs observed hence, during holidays Animals were observed for clinical signs, morbidity and mortality once (i.e. morning). Animals were observed at time intervals of about 1 hour, 24 hour, 48 hour and 72 hour post administration.

18.2 Body Weight

Individual animal body weights were measured on the day of acclimatization, on Day 1 (before dosing), 2, 3 and at the end of the in-life / termination.

19. EVALUATION CRITERIA

As per the criteria, all animals observed and detailed as below:

None of the animals treated with the test sample/s did not showed any biological reactivity (i.e., normal behavior) when compared with respective control group animals. None of the animals treated with the test sample/s did not showed any mortalities/morbidity/no body weight loss when compared to respective control group's animals. Hence, test was not repeated.

20. ANIMAL EUTHANASIA AND DISPOSAL

After the completion of the experiment, the animals were sacrificed using carbon dioxide asphyxiation and the carcass was sent for disposal through Medicare Environmental Management Pvt. Ltd.

21. RESULTS

21.1 Mortality, Morbidity and Clinical signs

Refer to Table 1 and Appendix 1

There were no mortality/morbidity/no clinical signs observed in any of the tested animals throughout the experimental period.

21.2 Body Weight

Refer Table 2 to 3, Appendix 2

There were no body weight loss observed during the course of observation period.

22. DATA COMPILATION

All individual animal data was presented in Appendices and / summarized and presented in Tables.

23. CONCLUSION

Based on the above results and under the conditions of this study, the Polar and Non-polar test item extracts of "Excalibur: Vessel Sealer and Dissection Device" at volume of 50 mL/kg body weight did not showed any acute systemic toxicity in Swiss Albino Mice.

FINAL STUDY REPORT

STUDY TITLE

MATERIAL MEDIATED PYROGENICITY TEST OF POLAR EXTRACT OF EXCALIBUR: VESSEL SEALER AND DISSECTION DEVICE IN NEW ZEALAND WHITE RABBITS

TEST GUIDELINE(S): ISO 10993-11:2017 & USP GENERAL CHAPTER <151>

STUDY NO.: LBPL/G-2734 (TX)

STUDY CODE: PYR

STUDY COMPLETED ON: 26/04/2023

STUDY DIRECTOR

Ms. Rangalakshmi G R.

SPONSOR

BLUE PHOENIX TECHNOLOGIES PVT.LTD.
(UNIT 301/302 A WING, SUNFLLOWER INDUSRIAL,
BLDG, OFF GOREGAON MULUND RD, SHIVNERI, MUMBAI,
MUMBAI CITY, MAHARASTRA,
INDIA, 400063)

TEST FACILITY

LIVEON BIOLABS PRIVATE LIMITED
PLOT NO.46 & 47, II PHASE WATER TANK ROAD
KIADB INDUSTRIAL AREA, ANTHARASANAHALLI
TUMAKURU-572106, KARNATAKA
INDIA.

1. OBJECTIVE

The objective of this Material Mediated Pyrogenicity Test was to determine whether a polar extract of test item, "Excalibur: Vessel Sealer and Dissection Device" induces pyrogenic response following intravenous injection in New Zealand white rabbits.

2. STUDY DETAILS

Study Title	:	Material Mediated Pyrogenicity Test of Polar Extract of Excalibur: Vessel Sealer and Dissection Device in New Zealand White Rabbits.
Study Number	:	LBPL/G-2734 (TX)
Study Code	:	PYR
ULR No	:	TC-679423000000007F
Sponsor	:	BLUE PHOENIX TECHNOLOGIES PVT.LTD. (Unit 301/302 A Wing, Sunfllower Indusrial, Bldg, Off Goregaon Mulund Rd, Shivneri, Mumbai,Mumbai City, Maharastra, India, 400063)
Test Facility	:	LIVEON BIOLABS PRIVATE LIMITED Plot No.46 & 47, II Phase, Water Tank Road, KIADB Industrial Area, Antharasanahalli, Tumakuru – 572106, Karnataka, India.

3. STUDY RESPONSIBILITIES

Study Director	:	Ms. Rangalakshmi G R.
Study Personnel I	:	Ms. Bhavana S.B.
Study Personnel II	:	Mr. Mariswamy T P.
Study Personnel III	:	Ms. Supritha G.
Study Personnel IV	:	Mr. Vasantha Kumar B.S.
Study Personnel V	:	Mrs.Bhagyashree. M.
Study Veterinarian	:	Dr. Sunkad Meghana
Sponsor Representative	:	Prashanth Kavale
Monitoring Scientist	:	Dishant Dipen Shah

4. STUDY SCHEDULE

Study Initiation Date	:	27/01/2023
Experiment Start Date	:	31/01/2023
Acclimatization Date	:	31/01/2023 to 05/02/2023
Sham Test Date	:	06/02/2023
Main Test-I Date	:	07/02/2023
Experiment End Date	:	07/02/2023
Draft Report to Sponsor	:	16/02/2023
Study Completion Date	:	26/04/2023

21. CONCLUSION

Based on the results of the experiment under the test condition, it is concluded that the extract of test item "Excalibur: Vessel Sealer and Dissection Device." evaluated for pyrogen test in New Zealand White Rabbits was considered to be non-pyrogenic as it meets the requirements / criteria (≤0.5°C rectal temperature) of pyrogen test as per U.S.P General Chapters: <151> - Pyrogen Test.

22. STUDY REPORT DISTRIBUTION

The Final Study Report will be distributed as follows:

a) Copy No. 1/2 – Sponsor.
b) Copy No. 2/2 – Archives, Liveon Biolabs Private Limited

23. ARCHIVING

All study related records Study Plan, Raw Data, Study Report, Study Plan Amendment and Test Item will be maintained in the archives of Liveon Biolabs Private Limited for 9 years from the date of completion of the study. All the records and test item samples will be handled according to OECD Principles of GLP for the Testing of Chemicals as specified by International [C(97) 186/Final] legislation. After the completion of archiving period, the test facility management will co-ordinate with the sponsor for further course of action on archived material.

FINAL STUDY REPORT

STUDY TITLE

DETERMINATION OF *IN VITRO* CYTOTOXICITY EFFECT OF EXCALIBUR: VESSEL SEALER AND DISSECTION DEVICE EXTRACT OVER L929 CELL LINE BY EXTRACTION METHOD

TEST GUIDELINE: ISO 10993-5 :2009

STUDY NO.: LBPL/G-2537 (GT)

STUDY CODE: ICT

STUDY DIRECTOR

Ms. Amrutha N

STUDY COMPLETED ON: 01/12/2022

SPONSOR

BLUE PHOENIX TECHNOLOGIES PVT LTD.
(UNIT 301/302 A WING,
SUNFLOWER INDUSTRIAL,
BLDG. OFF GOREGAON MULUND RD,
SHIVNERI, MUMBAI, MUMBAI CITY, MAHARASHTRA
INDIA, 400063)

TEST FACILITY

LIVEON BIOLABS PRIVATE LIMITED
PLOT NO. 46 & 47, II PHASE, WATER TANK ROAD
KIADB INDUSTRIAL AREA, ANTHARASANAHALLI
TUMAKURU-572106, KARNATAKA
INDIA.

1. OBJECTIVE

The objective of this study was to assess the cytotoxic potential of the extract of test item, "Excalibur: Vessel Sealer and Dissection Device" using L929 mouse fibroblast cell line by Extraction Method.

2. STUDY DETAILS

Study Title	:	Determination of *In Vitro* Cytotoxicity Effect of Excalibur: Vessel Sealer and Dissection Device Extract over L929 Cell Line By Extraction Method.
Study Number	:	LBPL/G-2537 (GT)
Study Code	:	ICT
ULR Number	:	TC-679422000001150F
Sponsor	:	BLUE PHOENIX TECHNOLOGIES PVT LTD (Unit 301/302a Wing, Sunflower Industrial, Bldg. Off Goregaon Mulund Rd, Shivneri, Mumbai, Mumbai City, Maharashtra, India, 400063.
Test Facility	:	LIVEON BIOLABS PRIVATE LIMITED Plot No. 46 & 47, II Phase Water Tank Road, KIADB Industrial Area Antharasanahalli, Tumakuru – 572106 Karnataka, India

3. STUDY RESPONSIBILITIES

Study Director	:	Ms. Amrutha N
Study Personnel I	:	Mr.Satish.S
Study Personnel II	:	Ms.Komala.
Study Personnel III	:	Ms. Divya.T.H.
Sponsor Representative	:	Prashant Kavale
Monitoring Scientist	:	Dishant Dipen Shah

4. STUDY SCHEDULE

Study Initiation Date	:	15/11/2022
Experiment Start Date	:	17/11/2022
Seeding of Cell Line	:	17/11/2022
Extraction of Test Item	:	17/11/2022
Cytotoxicity Test Date	:	18/11/2022
Experiment End Date	:	19/11/2022
Draft Report to Sponsor	:	26/11/2022
Study Completion Date	:	01/12/2022

5. ABBREVIATIONS AND SYMBOLS

ATCC	:	American Type Culture Collection
cm^2	:	Square Centimeter
CO_2	:	Carbon dioxide
EDTA	:	Ethylene Diamine Tetra Acetic acid
FBS	:	Fetal Bovine Serum
g	:	Gram
GLP	:	Good Laboratory Practice
h/hr (s)	:	Hour (s)
ICT	:	*In Vitro* Cytotoxicity
IEC	:	International Electrotechnical Commission
ISO	:	International Organization for Standardization
MEM	:	Minimum Essential Medium
mL	:	Millilitre
No.	:	Number
OECD	:	Organization for Economic Co-operation and Development
rpm	:	Revolutions per minute
SD	:	Study Director
Sign.	:	Signature
TFM	:	Test Facility Management
TIIS	:	Test Item Information Sheet
%	:	Percentage
°C	:	Degree Celsius
>	:	Greater Than
±	:	Plus or Minus
&	:	and

18. ACCEPTANCE CRITERIA

The assay was considered valid since all the following criteria were met:

- Confluency of cell monolayer was greater than 80%.
- No marked differences in the test result for replicate culture vessels.
- The scoring for vehicle control and negative control showed no reactivity and positive control showed grade 4.

19. OBSERVATIONS AND RESULTS

- **Test Item**: There was no change in the color of the test item extract before keeping for extraction and after completion of extraction period when compared with vehicle control was observed.
- The pH of the test item extract was found to be 7, before keeping for extraction. There was no change in the pH of the test item extract after extraction period.
- **Subconfluency**: >80% of cell monolayer was observed.
- **Viability**: 95.83% of viability was observed.

19.1. Grading of Cytotoxicity

- **Vehicle control:** Grade 0, no reactivity, Discrete intracytoplasmatic granules, no cell lysis and no reduction of cell growth.
- **Test Item Treatment:** Grade 0, Discrete intracytoplasmatic granules, no cell lysis and no reduction of cell growth.
- **Negative Control:** Grade 0, Discrete intracytoplasmatic granules, no reactivity, no cell lysis and no reduction of cell growth.
- **Positive Control:** Grade 4, Discrete intracytoplasmatic granules, Severe reactivity, nearly complete destruction of the cell layers.

20. CONCLUSION

Based on the results obtained under the testing conditions employed, qualitative morphological grading of cytotoxicity of the test item extract was found to be Grade 0 which is not greater than 2. Hence, the test item " Excalibur: Vessel Sealer and Dissection Device" is considered as 'non-cytotoxic' to the subconfluent monolayer of L929 mouse fibroblast cells.