MTIC INTERCERT

CERTIFICATE

CERTIFICATE No. MTIC/1348/RC

WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

BRAHAD ELASTOMERS PVT LTD

534/A, 8th Main Road, Peenya 2nd Stage, Peenya Industrial Estate,
Bengaluru – 560 058, Karnataka, India.

IS IN COMPLIANCE WITH THE REQUIREMENTS OF STANDARD

ISO 9001:2015

THIS CERTIFICATE IS VALID FOR THE FOLLOWING ACTIVITIES

Manufacture and Supply of Silicon Rubber Components.

AUDIT REPORT No. MTIC/0480/RC

First issue date 24.01.2019 **Revision date 24.01.2025** **Expiry date 23.01.2028**

The validity of this certificate is subject to periodical audits and the complete re-assessment of the system every three years. For any further question with regard to this certificate please contact www.mtic-group.in

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Place : Bengaluru

Head of Certification

MTIC INTERCERT Certification Body

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APOLLO BIOSCIENCES

STUDY REPORT

STUDY TITLE

INTRACUTANEOUS REACTIVITY TEST OF POLAR AND NON-POLAR EXTRACTS OF NARI YARI MENTSTRUAL CUPIN NEW ZEALAND WHITE RABBITS

TEST GUIDELINE(S): ISO 10993-23:2021

STUDY NO.: ABS-MD-354

STUDY CODE: IRTNZW

Copy No.:1 of 2

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TEST FACILITY

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Devanahalli, Bengaluru-562110, Karnataka, India.

6. STUDY SUMMARY

The study was conducted to evaluate Intracutaneous reactivity of "Nari Yari Menstrual Cup" extracts when administered through intracutaneous route. The study was performed as per ISO 10993-23:2021, Biological Evaluation of Medical Devices Part 23: Tests for irritation.

The test item was extracted in polar i.e. 0.9% Sodium Chloride solution for injection and non-polar solvent i.e. Cottonseed oil.

Three male rabbits were administered with appropriate test item extract at a dose volume of 0.2 mL by an intracutaneous route into five separate sites on the left side of the back of three rabbits. Similarly, the control i.e. only polar and non-polar solvent was administered to the right side of the back of each rabbit.

Animals were observed immediately after injection. Observations for clinical signs of toxicity, erythema and oedema were conducted at (24±2)hrs, (48±2) hrs and (72±2) hours after injection.

Body weights were monitored on the day of dosing and at the end of the experimental period.

Animals exhibited reactions/signs of very slight erythema in the polar test extract sites at 24 hrs, 48 hrs and 72 hrs after test item administration and there were no signs of erythema and oedema in the respective control sites.

There were no signs of erythema and oedema in non-polar test sites and respective control sites.

None of the animals showed any change in body weights during the study period.

Conclusion:

Under the conditions of the study:

The difference between the polar test item extract and polar solvent control mean score is **'0.82'.**

The difference between the non-polar test item extract and non-polar solvent control mean score is **'00'.**

Since the test item score is less than 1. The test item **"Nari Yari Menstrual Cup"** can be considered as **non-irritant** and meets the requirement of the test guideline ISO 10993 Part-23:2021.

BIONEEDS

STUDY REPORT
Original: 1/2

STUDY TITLE

IN VITRO CYTOTOXICITY STUDY OF NARI YARI MENSTRUAL CUP BY ELUTION METHOD

[As per ISO 10993-5: 2009(E)]

STUDY No.: BIO-GNT 399

Study Completion Date: 03 October 2019

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2. SUMMARY

The test item Nari Yari Menstrual Cup obtained from Brahad Elastomers Pvt Ltd was evaluated for *In vitro* cytotoxicity in compliance with the International Standard ISO 10993-5, "Biological Evaluation of Medical Devices - Part 5 : 2009 : Tests for *In vitro* Cytotoxicity" and International Standard ISO 10993-12, "Biological Evaluation of Medical Devices"- Part 12:2012(E): Sample preparation and reference materials.

L-929 mouse fibroblast cells were seeded in 6 well plates and wells with subconfluent monolayer were selected for treatment. The growth medium supplemented with 10% Fetal Bovine Serum and antibiotics (1% Penicillin-Streptomycin) in each well was replaced with 1 mL extract of test item, negative control (High Density Polyethylene) and positive control (Polyurethane) in triplicates. Blank wells were treated with extraction medium maintained similar to test item extraction without any treatment. Post 24 hours of incubation, the treatment wells were examined microscopically for any abnormal cell morphology and cell lysis. L-929 mouse fibroblast cell lines treated with the test item extract resulted in discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth. Since there was no reactivity (Grade 0) and the reactivity grade was not greater than 2, the test item is considered as "non-cytotoxic". Cells in the blank wells and negative control showed discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth and no reactivity (Grade 0), whereas the positive control showed evidence of nearly complete or complete destruction of the cell layers with severe reactivity (Grade 4).

Conclusion

Based on the results obtained under laboratory testing conditions, the extract of test item, Nari Yari Menstrual Cup is considered as "non-cytotoxic" to the subconfluent monolayer of L-929 mouse fibroblast cells.

BIONEEDS

STUDY REPORT
Original: 1/2

STUDY TITLE

VAGINAL IRRITATION TEST OF NARI YARI MENSTRUAL CUP IN NEW ZEALAND WHITE RABBITS

[As per ISO 10993-10: 2010 (E)]

STUDY No.: BIO-ATX 843

Study Completion Date: 03 October 2019

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2. SUMMARY

The test item, Nari Yari Menstrual Cup obtained from Brahad Elastomers Pvt Ltd was evaluated for Vaginal Irritation in New Zealand White Rabbits as per the International Standard ISO 10993 Third edition: 2010-08-01, "Biological Evaluation of Medical Devices Part 10: Test for Irritation and Skin Sensitization". Reference Number: ISO 10993-10:2010(E).

The study was performed in twelve female rabbits, each group consisted of three animals [Polar Solvent Control (G1), Polar Test Item Extract (G2), Non-polar Solvent Control (G3) and Non-Polar Test Item Extract (G4)]. All the animals were observed for stages in oestrus cycle within 24 hours before initiating the treatment by vaginal smear examination and the animals revealed diestrus, proestrus and estrus stage. The Polar solvent control, polar test item extract, non-polar solvent control and non-polar test item extract was administered into vagina using soft catheter (6 cm) attached to the syringe for G1, G2, G3 and G4 group animals respectively at dose volume of 1 mL for five consecutive days.

All the animals were observed once daily for clinical signs of toxicity and twice daily for mortality and morbidity throughout the experimental period. At 24 (± 2) hours after the treatment and prior to the next treatment, the vaginal opening appearance and perineum for signs of discharge, erythema and oedema was observed. Body weight was recorded on the day of receipt, on the treatment Day 1 (prior to test item application) and on Day 6 prior to necropsy. All the animals were sacrificed by intravenous administration of sodium thiopentone at the end of the observation period. A complete gross pathological examination was carried out. Histopathological examination of vagina was conducted in G1, G2, G3 and G4 group animals at three sections, to include the cervical, central and caudal portions of each vagina.

No treatment related clinical signs of toxicity and mortality were noted in any of the treated animals during observation period. No treatment related changes were noted in body weight and percent change in body weight with respect to Day 1. All the animals revealed a physiologically normal increase in body weights during the observation period.

No treatment related gross pathological changes were observed in any of the group animals. All the collected vaginal tissues were microscopically evaluated and scored according to ISO 10993-10:2010 (E) Table B.3 and no treatment related adverse findings were observed in any of the tissues treated with the test item extracts.

The average group score of vaginal tissue reaction is 1.11 for polar solvent control (G1), 1.22 for polar test item extract (G2), 1.00 for non-polar solvent control (G3) and 1.11 for non-polar test item extract (G4). The average grade of irritation index is 0.11 for polar extract and 0.11 for non-polar extract.

Conclusion

Based on the observed results of the experiment and under the experimental conditions employed, the irritation index of both polar and non-polar extracts of Nari Yari Menstrual Cup was observed to be 0.11 for both polar and non-polar extract and hence the test item was considered as "non-irritant" to the vagina of New Zealand white rabbit when administered into the vagina for five consecutive days.

BIONEEDS

STUDY REPORT
Original: 1/2

STUDY TITLE

BACTERIAL REVERSE MUTATION TEST OF NARI YARI MENSTRUAL CUPS USING *SALMONELLA TYPHIMURIUM* AND *ESCHERICHIA COLI* TESTER STRAINS

(As per ISO 10993-3:2014, ISO 10993-33:2015)

STUDY No.: BIO-GNT 1512

Study Completion Date: 23 August 2021

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CONFIDENTIAL

2. SUMMARY

The test item, Nari Yari Menstrual Cups was evaluated for mutagenicity in Bacterial Reverse Mutation Test as per the International Standards (ISO) 10993-3, Third edition "Biological Evaluation of Medical Devices - Part 3: (2014-10-01) Tests for Genotoxicity, carcinogenicity and reproductive toxicity", "Biological Evaluation of Medical Devices - Part 12:2021 (E): Sample preparation and reference materials", International Standards (ISO) 10993-33, First edition (2015-03-01) "Biological Evaluation of Medical Devices - Part 33: Guidance on tests to evaluate genotoxicity - Supplement to ISO 10993-3".

The test item and blank extracts were prepared at the extraction ratio of 0.2 g/mL separately and kept in incubator shaker under agitation at 50±2°C for 70 hours and 1 minute for extraction.

Precipitation test was conducted for Polar and Non-polar 100% test item extracts and there was no precipitation observed.

Test item extract was assessed using *Salmonella typhimurium* tester strains TA98, TA100, TA1535, TA1537 and *Escherichia coli* WP2 uvrA (pKM101) which were exposed to polar and non-polar extract solution/plate was used in mutation assay for the identification of their mutagenic effects.

In the mutation assay, test item extracts (polar and non-polar) were tested at the limit concentration of 100% extract solution/plate. The study was conducted with and without metabolic activation. Solvent controls (Normal saline and DMSO) and appropriate positive controls (2-Nitrofluorene, Sodium azide, 9-Aminoacridine and 4-Nitroquinoline N-oxide for trials "without metabolic activation" and 2-Aminoanthracene for trials "with metabolic activation") were tested simultaneously. Two trials were carried out for this study in triplicates with the plate incorporation method (Trial I) and preincubation method (Trial II).

Based on experimental results obtained, the mean number of revertant colonies at the limit concentration was comparable to those of the solvent controls, in both the trials - plate incorporation method and preincubation method, in the presence and absence of metabolic activation. There was no appreciable increase in number of revertant colonies at the limit concentration of polar and non-polar extracts tested in both plate incorporation and preincubation method. The number of revertant colonies in the positive controls resulted in 3.7 to 15.0 fold increase under identical conditions.

Conclusion

Based on the results obtained, polar and non-polar extracts of the test item Nari Yari Menstrual Cups is considered as "non-mutagenic" at the limit concentration of 100% extract solution/plate in the Bacterial Reverse Mutation Test under the laboratory conditions when tested on *Salmonella typhimurium* TA98, TA100, TA1535, TA1537 and *Escherichia coli* WP2 uvrA (pKM101) tester strains.