



**Water-based basic lubricant  
White Rabbit Vaginal Irritation Study  
STUDY REPORT**

**Client : InnoveMed Bio-tech Co., Ltd.**

**Testing Institution : Master Laboratory Co., Ltd.**

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## RESULTS

The study was performed in compliance with ISO 10993-10:2010 to investigate the response of Vaginal irritation of 「Water-based basic lubricant」 extract on New Zealand White Rabbits. The individual animal vaginas in 3 segments (UV: anterior to the cystic urethral opening vagina; MV: middle vagina; CV: posterior to cervix vagina) were examined microscopically and the histopathology findings were analyzed semiquantitatively and listed in Appendix 3. The observations were listed and tabulated for severities, graded for scores of 0 to 4 following the grading system as listed in Appendix 4. And the microscopic observations were illustrated in Fig 1 and Fig 2. The observations were categorized into 4 groups, namely (1) Epithelium necrosis/crosion, (2) Leucocyte infiltration, (3) Vascular congestion and (4) Edema. The observations were averaged per group (average grade) for comparison and all observations for individual animals were counted for description of response to irritation index as defined in Appendix 5. All slides were examined microscopically and evaluated. In the three vagina segments of rabbits implanted of control articles or test articles, there were no noticeable differences in the average grade of histopathology findings in both polarity and non-polarity treatment groups.

## CONCLUSION

The characteristics of evaluation by histological examination, the results revealed that the test article was considered minimal irritation (average grades were 3.89 and 3.78) in polarity and non-polarity treatment groups, both were same status with control (average grades were 3.33 and 3.55). According to the histological evaluation and grading score, the UV, MV and CV of irritation score was (i) polar : 0.6 (ii) non-polar : 0.2 . Therefore, the test article extracts cause non-irritation in this study.