

## 8. Conclusion

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Under the conditions of this study, there was no erythema and no edema from the SC test extract injected intracutaneously into rabbits. There was very slight erythema and very slight edema from the SO test extract injected intracutaneously into rabbits. Each test article extract met the requirements of the test since the difference between the test extracts and corresponding control mean score was 1.0 or less.

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other samples is the sponsor's responsibility. All procedures were conducted in conformance with good manufacturing practices and certified to ISO 13485:2003.

## 9. Records

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All raw data pertaining to this study and a copy of the final report are to be retained in designated NAMSA archive files.

## 10. References

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