

**A 4- Week Repeated Dose Inhalation Toxicity Study
of LuvA UPI(Ultra Plasma Ion) in Sprague-Dawley
Rats**

Study Number: 15-RR-593N

Sponsor: Gwellkorea Co., Ltd

Nonclinical Research Institute, Chemon Inc.



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Study Overview

Title	A 4- Week Repeated Dose Inhalation Toxicity Study of LuvA UPI(Ultra Plasma Ion) in Sprague-Dawley Rats	
Objectives	The present study was carried out to investigate the toxicity of the ions generated by ion generator LuvA UPI(Ultra Plasma Ion) after a 4-week repeated inhalation exposure in Sprague-Dawley rats.	
Regulatory guidelines	This study was performed based on the methodologies consulted with the sponsor.	
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Schedule	Sep 09, 2015 Sep 11, 2015 Sep 23, 2015 Oct 20, 2015 Oct 21, 2015 Dec 11, 2015 Dec 16, 2015 Dec 22, 2015	Approval of protocol (study initiation) Animal acquisition (experimental initiation) Starting of inhalation Completion of inhalation Necropsy Completion of histopathological examination (experimental completion) Submission of draft report Submission of final report (study completion)

Archives

The protocol, protocol amendment, final report, raw data, sample of test article, specimens and other relevant evidential documents will be retained and stored in the Archives of Nonclinical Research Institute, Chemon Inc. for three years after the experimental completion of the study.

The samples for clinical pathology (serum) will be retained for one year after the completion of analysis.

Further storage of above materials shall be consulted with the sponsor.

Summary

The present study was carried out to investigate the toxicity of the ions generated by the ion generator LuvA UPI (Ultra Plasma Ion) after a 4-week repeated inhalation exposure in Sprague-Dawley rats.

Study groups consisted of a treatment group exposed to the ion generator LuvA UPI (Ultra Plasma Ion) and control group exposed to the non-ion generator LuvA UPI (Ultra Plasma Ion). Twelve animals (6 animals/sex) were allocated to each group and exposed by inhalation for 4 weeks. The following parameters were examined and the results of the treatment group were compared with those of control group: general clinical observations, body weight, food consumption, ophthalmological examination, urinalysis, hematological test, clinical biochemistry test, organ weight, necropsy finding and histopathological test. The study results are as follows.

1. In general clinical observation, there were no treatment-related changes.
2. In body weight, there were no treatment-related changes.
3. In food consumption, there were no treatment-related changes.
4. No ions were generated in the control group. The data of generated ions were provided by the sponsor, and the density of cation was 1999900/cc and that of anion were 1999900/cc.
5. In urinalysis, there were no treatment-related changes.
6. In hematological test, there were no treatment-related changes.
7. In clinical biochemistry test, there were no treatment-related changes.
8. In organ weight, there were no treatment-related changes.
9. In necropsy findings, there were no treatment-related changes.
10. In histopathological test, there were no treatment-related changes.

Based on the above results, a 4-week repeated inhalation exposure to the ions generated by the ion generator LuvA UPI (Ultra Plasma Ion) did not induce any change compared to the control group in Sprague-Dawley rats. Therefore, there was no toxicity by the ions generated by LuvA UPI (Ultra Plasma Ion).