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检测
TESTING
CNAS L0317

Ningbo Customs District Technology Center

TEST REPORT

REPORT NUMBER	232300010004
SAMPLE NAME	AO3 ozone water flosser
CUSTOMER	Shanghai Xiyun Ozonetek Co.,Ltd.

TEST REPORT

CUSTOMER:	Shanghai Xiyun Ozonetek Co.,Ltd.
ADDRESS of CUSTOMER:	Building5,No.5,Lane 208,Rongle East Road,Songjiang Distric, Shanghai
MANUFACTURE:	Shanghai Xiyun Ozonetek Co.,Ltd.
ADDRESS of MANUFACTURE:	Building5,No.5,Lane 208,Rongle East Road,Songjiang Distric, Shanghai
SAMPLE NAME:	AO3 ozone water flosser
SAMPLE STATUS:	Ozone water dental flusher generates water
SAMPLE QUANTITY:	1 machine and a bottle of liquid
SAMPLE BRAND:	AO-III
SAMPLE SIZE:	XY-AO3200
SAMPLE PREDUCT DATE:	2023.06.12
SAMPLE EXP. DATE:	2 years

The above information and samples are provided and confirmed by the consignor, and the Center does not assume any responsibility to verify the accuracy, appropriateness and/or completeness of the information provided by the consignor.

SAMPLE RECEIVED DATE:	2023.10.11
TEST PERIOD:	2023.10.11 ~ 2023.11.14
TESTING ADDRESS:	Block C, Meigang Building, Meishan Subdistrict, Beilun District, Ningbo, Zhejiang, China

TEST RESULTS:

A. Test Item: Acute systemic toxicity test

Test Standard: *ISO 10993-11:2017 "Biological evaluation of medical devices — Part 11: Tests for systemic toxicity"*

Conclusion: Under the conditions of this experiment, the test sample did not cause acute systemic toxicity in mice, and the test sample had no acute systemic toxicity.

B. Test Item: Oral mucosa irritation test

Test Standard: *ISO 10993-23:2021 "Biological evaluation of medical devices -- Part 23: Tests for irritation"*

Conclusion: Under the conditions of this test, the test sample has no irritation effect on the oral mucosa tissue.

Ningbo Customs District Technology Center

检验检测专用章

Authorized Officer Signature:

Report release date: 2023.11.14

Ningbo Customs District Technology Center Contact address: No. 66, Qingyi Road, High-Tech District, Ningbo, Zhejiang, China/315048.

Complaints Hotline: 0574-87022702 Complaint email: zlk@nbyjg.com

A. Acute systemic toxicity test

1. Materials and methods

1.1. Preparation of test product: Inject the water provided by the customer into the machine water tank, conduct experiments using the water generated by the machine.

1.2. Vehicle: sterile water for injection (Manufacturers: Huaxia Shengsheng Pharmaceutical (Beijing) Co.,Ltd; Approval No.: GYZZ H20163266; Lot No.: 220713103; Production date: July. 13, 2022, Expiration date: July. 12, 2024)

1.3. Experimental animals and environmental Conditions:

1.3.1. Experimental animal information

Species: Mice

Strain: ICR

Microbial grade: SPF

Receipt animal date: 2023.10.07

Acclimatization: 5 days

Number and sex: 10 females were nulliparous and non-pregnant

Weight range at the beginning of the test: 19.7g～21.4g

Animal source: Zhejiang Vital River Laboratory Animal Technology Co. ,LTD

Certificate No.: SCXK（ZHE）2019-0001

Qualification certificate number: 20230928Abzz0619999543

1.3.2. Environmental Conditions

Breeding room: Animal house in barrier environment.

Laboratory animal use license No. SYXK(ZHE)2021-0032.

Illumination: Use an automatic timer to control 12 hours of light and 12 hours of darkness.

Temperature: 21.8℃ ~ 22.5℃.

Relative humidity: 50.5% ~ 55.8%.

1.3.3. Feed

Name: Co 60-irradiated standard commercial pelleted rat feed

Production unit: Jiangsu Xietong Pharmaceutical Bio-engineering Co., Ltd

Production License Number: Jiangsu Feed Certificate (2019) 01008

Quality Certificate No.: 20-SM230809015

Specification: 2kg / bag, 10 bags / box

Production date: 2023.08.01

Batch No.: 23080101

Shelf life: 6 months under normal temperature

1.3.4. Water

First-grade RO ultra-filtered water (add sodium hypochlorite to control the free chlorine content in the water to 2~3ppm sterilization). Water intake ad libitum through automatic water supply system.

1.4. Methods

1.4.1. Test Preparations: 10 mice were selected, randomly divided into control group and test group, 5 animals per set. The animals were marked and weighed. Fasting for 4 hours before the test.

1.4.2. Test Procedure:

The test group was given a single administration of original sample by gavage, and the control group was given a single administration of sterile water for injection correspondingly in the same way (dose volume 20mL/kg). Observation of the animals was individually after dosing at least once during the first 1h. Signs of toxicity including mortality,time course of onset, severity and duration of effects were recorded 4h, 24h, 48h and 72h after test. The individual weights of animals should be determined shortly before the test and recorded as well as within 0 day,1 day,2 day and 3 day .Gross autopsies were performed on all animals that died during the observation period and on all survivors after 3 days observation.

2. Results

2.1. Mortality: No animal died during the experiment in experiment period. The mortality data was given in Table 2.

2.2. Signs of toxicity: No signs of toxicity were observed till scheduled termination. All animals feeding and activity are normal. The Signs of toxicity data was given in Table 1.

2.3. Body Weight: All the surviving animals exhibited a progressive increase in body weight throughout the study period, and the body weight was normal after administration. The body weight was given in Table 2.

2.4. Necropsy and Gross Pathology: For no abnormal signs of toxicity was observed, Gross pathological examination was not performed on all the treated animals.

1. Conclusion

Under the conditions of this experiment, the test sample did not cause acute systemic toxicity in mice, and the test sample had no acute systemic toxicity.

Table 1 mortality and Signs of toxicity

Group	Deaths / Total number of animals	Observation				
		1h	4h	24h	48h	72h
Control group	0/5	normal	normal	normal	normal	normal
Test group	0/5	normal	normal	normal	normal	normal

Table 2 Body Weight(g)

Group	Sex	Number of animals	Body Weight（ $\bar{X}$±SD）（g）				
			0 day	1 day	2 day	3 day	3 day Body Weight gain
Control group	♀	5	20.5±0.63	21.8±0.71	23.2±0.80	24.7±0.88	4.2±0.27
Test group	♀	5	20.3±0.55	21.7±0.58	23.1±0.61	24.6±0.66	4.3±0.19

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B. Oral mucosa irritation test

1. Materials and Methods

1.1. Preparation of test sample

Inject the water provided by the customer into the machine water tank, conduct experiments using the water generated by the machine.

1.2. Experimental animals and feeding environment

1.2.1. Experimental animal information

Species: hamster

Strain: golden hamster

Microbial grade: SPF

Number of animals: 3

Animal sex: Female, animals are nulliparous and non-pregnant

Weight range at the beginning of the test: 138.7g ~ 160.3g

Animal source: Beijing Vital River Laboratory Animal Technology Co., Ltd.

Animal Production License No.: SCXK (Beijing) 2021-0011

Animal Quality Certificate No.: ♂:No.110011231109343943, ♀:No.110011231109344074.

1.2.2. Feeding environment

Feeding Room: ordinary animal room

Temperature: 22.0℃ ~ 22.8℃

Relative humidity: 48.5% ~ 59.6%

Experimental animal use license No.: SYXK (Zhe) 2021-0032.

1.2.3. Feed information

Type: Co60 irradiated experimental mouse feed

Manufacturers: Jiangsu Xietong Pharmaceutical Bio-engineering Co., Ltd.

Production License No.: Jiangsu Feed Certificate (2019) 01008

Production date: 2023.08.14

Quality Certificate No.: 20-SM230913115

Batch No.: 23080115.

1.2.4. Drinking water

First-grade RO ultra-filtered water (add sodium hypochlorite to control the free chlorine content in the water to 2-3ppm sterilization). Directly for animals to drink freely through the drinking spout.

2. Test Method

Choose a suitable collar of width 3.6 mm, placed around the neck so that it permits normal feeding and respiration but prevents the animal from removing the cotton-wool pellet. Weigh each animal daily for two days during the test period. A cotton ball soaked with the test sample was placed in the left pouch capsule with forceps and exposed for 1 h, the right control group was treated with a cotton-wool pellet impregnated with the sodium chloride injection. The cheek pouch were

observed visually after contact by removing the collars and cotton balls and were examined before each contact. These steps were repeated every hour for 4h. At 24 h after the final treatment, examine the cheek pouches macroscopically, and humanely sacrifice the hamsters and remove tissue samples from representative areas of the pouches. Fix with 10% formalin, embed in conventional paraffin, semi-serial section, take 5 slices at intervals, H.E staining, and examine under microscope.

3. Assessment of results

3.1. Macroscopic evaluation

Visually observe the mucosa of the place where the sample is placed, and check whether the buccal mucosa has hyperemia, swelling, erosion and ulcer reaction. Compare the mucosa of the test side and the control side, and observe and score the oral mucosa with naked eyes;

The observation scores of each animal were added together and divided by the total number of animals observed to obtain the average score for each animal.

3.2. Histological evaluation

According to the results of histopathological examination, the tissue irritation reaction of oral mucosa was scored.

The grades for microscopic evaluation for all the animals in the test group are added and the sum is divided by the number of observations to obtain a test group average. Repeat for the control group(s).

Subtract the control group average from the test group average to obtain the irritation index

4. Results

The results of the visual observation of the test samples 24h after the last exposure are shown in Table 1 and the oral mucosal tissue reaction irritation index is shown in Table 2.

5. Conclusions

Under the test conditions, the sample has no irritation effect on the oral mucosa tissue.

Attached Tables 1 Visual observation and evaluation form of oral mucosal irritation

No.	Experimental group score	Control group score	Experimental group average score	Control group average score	Irritation index
1	0	0			
2	0	0	0	0	0
3	0	0			

Attached Tables 2 Summary table of oral tissue reaction score results

Group	No.	Irritation response score					Average score	Irritation index
		Epithelial tissue	Leukocyte infiltration	Congestion of blood vessel	Oedema	Summation		
Test group	1	0	0	1	0	1	1.00	0.33
	2	0	0	1	0	1		
	3	0	0	1	0	1		
Control group	1	0	0	1	0	1	0.67	
	2	0	0	0	0	0		
	3	0	0	1	0	1		

Note: 1) Average score = the addition of stimulus response scores of 3 animals/total number of animals; 2) stimulus index = average score of the test group-average score of the negative control group.

* * * *The End * * * *

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Address of each testing site of the center:

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Address (Huikang Road): No.8, Huikang Road, Yinzhou District, Ningbo, Zhejiang, China/315100
Address (Beilun): No. 219 Changjiang South Road, Beilun District, Ningbo, Zhejiang, China/315800
Address (Meishan): Block C, Meigang Building, Meishan Subdistrict, Beilun District, Ningbo, Zhejiang, China China/315832
Address (Free Trade Zone): Ningbo Free Trade Zone, 4/F, Building 1, No.6, Gangdong Avenue, East Free Trade Zone,Ningbo, Zhejiang, China/315800
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Address (Yuyao science and Innovation Center): Building 2, science and innovation center, Shuanghe Road, Yuyao，Zhejiang, China/315400
Address (Yuyao Nanlei South Road): No.399, Nanlei South Road, Yuyao, Zhejiang, China/315400
Address (Ninghai): No. 183, Renmin Road, Ninghai, Zhejiang, China/315600
Address (Xiangshan): Xiangshan Branch, No.228, Xingsheng Road, Dandong Subdistrict, Xiangshan, Zhejiang, China/315700