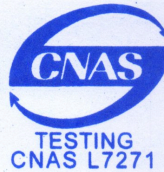




2012270492R号  
有效期至2015年10月27日



## TEST REPORT

№ UNQDA20143065

Sample Name : SplashLight® Reload Tablet

Application Name: Prolume LTD & BioToy LLC

Test Category: Consumer Safety Tests

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Sample Name	Coelenterazine Tablets	Brand Name	SplashLight® Reload Tablets CTZ
Specification	Yellow Tablets Rx#141014-CTZ	Sample Grade	Rx#: 141014CTZ
Test Category	Consumer Safety Test	Production Date	November 5,2014
Sample Provider	Bruce Bryan, MD	Sampling Date	November 5,2014
Application Name	Prolume LTD & BioToy LLC	Receive Date	November 18, 2014
Manufacturer	Prolume LTD & BioToy LLC	Sample Quantity	200g
Sent By	Tian Hui	Lot Size	6000 grams
Sampling Site	Sample presentation	Sample Description	In bulk Sample in good condition
Testing Date	November 20,2014	Test Item	Skin test , Eye irritation Test , Oral LD50 Test
Regulation	GB/T 21604-2008,GB/T 21609-2008,customer specified		
Conclusion			
Not assessed,only specific results in the report.			
			
Issue Date: December 31, 2014			
Remarks	1.Sample information is provided by application, no confirmed by our laboratory, which we are only responsible for the samples that we received on November18, 2014.		

Approved: *Apple*      Audit: *Jance wang*      Plait: *Eiko*

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Sequence number	Inspection item	Test Result	Test method
1	Skin irritation test	Please see the next page	GB/T 21604-2008
2	Eye irritation test	Please see the next page	GB/T 21609-2008
3	LD50	Please see the next page	Customer specified (OECD 425)

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**TEST REPORT**

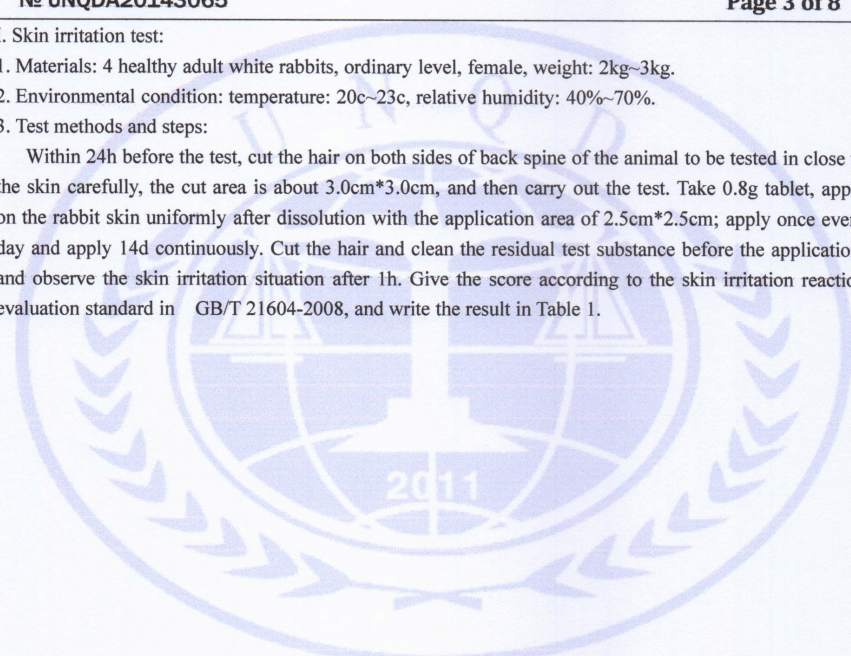
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**I. Skin irritation test:**

1. Materials: 4 healthy adult white rabbits, ordinary level, female, weight: 2kg~3kg.
2. Environmental condition: temperature: 20c~23c, relative humidity: 40%~70%.
3. Test methods and steps:

Within 24h before the test, cut the hair on both sides of back spine of the animal to be tested in close to the skin carefully, the cut area is about 3.0cm\*3.0cm, and then carry out the test. Take 0.8g tablet, apply on the rabbit skin uniformly after dissolution with the application area of 2.5cm\*2.5cm; apply once every day and apply 14d continuously. Cut the hair and clean the residual test substance before the application, and observe the skin irritation situation after 1h. Give the score according to the skin irritation reaction evaluation standard in GB/T 21604-2008, and write the result in Table 1.



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Inspection item		Table 1 Many Skin Irritation Tests					
Number of application day	Number of animals (piece)	Skin irritation reaction score					
		Sample			Comparison		
		Erythema	Edema	Total score	Erythema	Edema	Total score
1	4	1	0	0	0	0	1
2	4	0	0	0	0	0	0
3	4	0	0	0	0	0	0
4	4	0	0	0	0	0	0
5	4	0	0	0	0	0	0
6	4	0	0	0	0	0	0
7	4	0	0	0	0	0	0
8	4	0	0	0	0	0	0
9	4	0	0	0	0	0	0
10	4	0	0	0	0	0	0
11	4	0	0	0	0	0	0
12	4	0	0	0	0	0	0
13	4	0	0	0	0	0	0
14	4	0	0	0	0	0	0
Average of every animal score in 14 days		0.063			0		
Average of every animal score in one day		0.018			0		
Inspection conclusion		<p><b>There is no skin irritation reaction after the test substance contacts the animal daily for 14 days. The average highest total score is 0.063, so the test substance is non-irritating according to the skin irritation intensity grading standard.</b></p>					

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**II. Eye irritation test:**

1. Materials: 3 healthy adult white rabbits, ordinary level, male, weight: 2kg~3kg.

2. Environmental condition: temperature: 20c~23c, relative humidity: 40%~70%.

3. Test methods and steps:

1) One-tablet test method: pull the lower eyelid of rabbit one eye open slightly, using one tablet dissolved in 10mL of tap water instill 0.1ml test solution into the conjunctival sac, close the eye passively for 1s, the other eye is not treated for comparison; do not rinse the eye with any solution, examine the eye 1h, 24h, 48h, 72h, the fourth day and the seventh day after instilling the solution. If eye inflammation does not occur, the test may be terminated. If any irritation or inflammation occurs and does not spontaneously resolve within 7 days, the observation time shall be extended, but not more than 21 days. Observation items include conjunctiva, iris, cornea and other damage is noted. Report inflammation intensity according to the standard scoring and grading methods and record results in Table 2.

2) Four-tablet test method: pull the lower eyelid of rabbit one eye open slightly, using four tablets, dissolved in 10mL tap water, instill 0.1ml test solution into the conjunctival sac. Close the eye passively for 1s, the other eye is not treated for comparison; do not rinse the eye with any solution, and examine the eye 1h, 24h, 48h, 72h, the fourth day and the seventh day after dripping the solution, if eye irritation does not occur, the test can be terminated. If any eye irritation occurs and does not spontaneously resolve within 7 days, the observation time shall be extended, generally not more than 21 days. Observation items include conjunctiva, iris, cornea and other any other damage is noted. Report inflammation intensity scoring using grading standards and record the result into Table 3.

4. Results:

**10X Concentration Result:**

**Eyes became red and swollen at 1h, and 24h with excess tearing, eyes returned to normal at 72h.**

**40X Concentration Result:**

**Eyes became red and swollen at 1h, 24h and 72h with excess tearing, eyes returned to normal at 4 days.**

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Inspection item		Table 2: Single Tablet Eye Irritation Test											
Number of animals (pieces)	Part	Eye irritation reaction score											
		1h		24h		48h		72h		4d		7d	
		Sample	Comparison	Sample	Comparison	Sample	Comparison	Sample	Comparison	Sample	Comparison	Sample	Comparison
1	Conjunctiva	0	0	0	0	1	0	0	0	0	0	0	0
	Iris	0	0	0	0	0	0	0	0	0	0	0	0
	Cornea	0	0	0	0	0	0	0	0	0	0	0	0
2	Conjunctiva	0	0	1	0	2	0	0	0	0	0	0	0
	Iris	0	0	0	0	0	0	0	0	0	0	0	0
	Cornea	0	0	0	0	0	0	0	0	0	0	0	0
3	Conjunctiva	1	0	0	0	1	0	0	0	0	0	0	0
	Iris	0	0	0	0	0	0	0	0	0	0	0	0
	Cornea	0	0	0	0	0	0	0	0	0	0	0	0
<b>Inspection conclusion</b>		<b>According to GB/T 21609-2008, the test substance is a slight irritant in accordance with the eye irritation intensity grading standard.</b>											

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Inspection item		Table 3 Four Tablet Eye Irritation Test											
Number of animals (piece)	Part	Eye irritation reaction score											
		1h		24h		48h		72h		4d		7d	
		Sample	Comparison	Sample	Comparison	Sample	Comparison	Sample	Comparison	Sample	Comparison	Sample	Comparison
1	Conjunctiva	0	0	0	0	1	0	0	0	0	0	0	0
	Iris	0	0	0	0	0	0	1	0	0	0	0	0
	Cornea	0	0	0	0	0	0	0	0	0	0	0	0
2	Conjunctiva	0	0	1	0	2	0	0	0	0	0	0	0
	Iris	0	0	0	0	0	0	0	0	0	0	0	0
	Cornea	0	0	0	0	0	0	0	0	0	0	0	0
3	Conjunctiva	1	0	0	0	1	0	0	0	0	0	0	0
	Iris	0	0	0	0	0	0	0	0	0	0	0	0
	Cornea	0	0	0	0	0	0	0	0	0	0	0	0
<b>Inspection conclusion</b>		<b>According to GB/T 21609-2008, the test substance is moderately irritant in accordance with the eye irritation intensity grading standard.</b>											

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III. Oral Safety:

1. Test animal: SD rat, SPF grade, male, weight: 200g~230g, 5 rats with roughly the same mass.
2. Animal test environment: shielded environment, relative humidity: 50%
3. Feed: full-nutrition rat feed.
4. Test methods and steps  
 Sample treatment method: no treatment.  
 Test method: make the tablet into powder, take 2120mg, dissolve into 50mL running water, let one rat drink 10mL solution after completely dissolved, observe 24h, the first one survive, and let the following 4 rats drink 10ml solution in turn. If the 4 rats survive after 24h, stop and observe the subsequent changes of 5 rats until the 14<sup>th</sup> day.
5. **Result**  
 Observe until the 14<sup>th</sup> day after intoxication, the animals do not suffer from poison and death, and the autopsy is normal, and the results are shown in the following Table 4.

**Table 4**

Gender	Dose group (mg/kg)	Number of animals (piece)	Weight ( $\bar{x} \pm S$ )/g		Number of dead animals (piece)	Death rate (%)
			Initial weight	Final weight		
Male	2000	5	227.2±1.5	230.6±3.4	0	0

6. Conclusion:  
**Acute oral toxicity test, LD50>2000mg/kg, nontoxic.**

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