Final Pathology Report

A 7-Day Exploratory Oral Toxicity Study of QRX-111 in Female Sprague Dawley Rats

Nova Pathology Study Number: NP-12-S-001

Sponsor Study Number: QRX-12-S-111

Testing Facility Study Number: NPC-12-S-101

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Regulatory Compliance and Quality Assurance

This study was conducted for research and development purposes and was not regulated by FDA Good Laboratory Practices regulations (21 CFR 58). The portion of the study conducted by Nova Pathology was done in accordance with the study protocol and Nova Pathology Standard Operating Procedures (SOPs). Quality assurance support was not included for this non-regulated study.

Pathologist’s Signature

Study Title: A 7-Day Exploratory Oral Toxicity Study of QRX-111 in Female Sprague Dawley Rats

Nova Pathology Study Number: NP-12-S-001

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Testing Facility Study Number: NPC-12-S-101

Study Pathologist

Signature: ___________________________  Date: ___________________________

Michael J Tomlinson, DVM, PhD
Diplomate, ACVP
Nova Pathology, PC
1. Summary of Test Article-Related Findings

The objective of this study was to determine the toxicity associated with oral administration of QRX-111 to female Sprague-Dawley rats for seven consecutive days. This pathology report by Nova Pathology discusses the mortality, clinical pathology, organ weight, necropsy and histologic data in this study. Twenty-five female Sprague Dawley [CD (SD): (CRL)] rats were assigned to one of five treatment groups, as outlined in the Summary of Experimental Design.

<table>
<thead>
<tr>
<th>Group</th>
<th>Treatment</th>
<th>Dose Level (mg/kg)</th>
<th>Number of Animals</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Vehicle</td>
<td>0</td>
<td>5 ♀</td>
</tr>
<tr>
<td>2</td>
<td>QRX-111</td>
<td>10</td>
<td>5 ♀</td>
</tr>
<tr>
<td>3</td>
<td>QRX-111</td>
<td>30</td>
<td>5 ♀</td>
</tr>
<tr>
<td>4</td>
<td>QRX-111</td>
<td>100</td>
<td>5 ♀</td>
</tr>
</tbody>
</table>

Test article-related findings are summarized by group as follows:

**Group 4: QRX-111, 100 mg/kg**
1. Small thymus and spleen and red discoloration in the lung on Day 8.
2. Decreased total leukocytes and lymphocytes and increased neutrophils on Day 8.
3. Decreased mean group weights (absolute, relative to terminal body weight and relative to brain weight) in thymus and spleen on Day 8.
5. Subacute inflammation in lung and liver; hemorrhage in the lung on Day 8.

**Group 3: QRX-111, 30 mg/kg**
1. Small thymus and spleen and red discoloration in the lung on Day 8.
2. Decreased mean group weights (absolute, relative to terminal body weight and relative to brain weight) in thymus and spleen.
3. Cytoplasmic vacuolation in pancreatic acinar cells and duodenal enterocytes on Day 8.
4. Subacute inflammation and hemorrhage in the lung on Day 8.
5. Lymphoid hypocellularity in thymus and spleen on Day 8.

**Group 2: QRX-111, 10 mg/kg**
1. Decreased mean group weights (absolute, relative to terminal body weight and relative to brain weight) in thymus on Day 8.
2. Cytoplasmic vacuolation in pancreatic acinar cells on Day 8.
3. Lymphoid hypocellularity in thymus on Day 8.
2. Pathology Narrative

2.1 Introduction
The objective of this study was to determine the toxicity associated with oral administration of QRX-111 to female Sprague-Dawley rats for seven consecutive days. This pathology report by Nova Pathology discusses the mortality, clinical pathology, organ weight, necropsy and histologic data in this study.

2.2 Experimental Design
Twenty female Sprague Dawley [CD (SD): (CRL)] rats were assigned to one of four treatment groups, as outlined in the Summary of Experimental Design.

<table>
<thead>
<tr>
<th>Group</th>
<th>Treatment</th>
<th>Dose Level (mg/kg)</th>
<th>Number of Animals</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Vehicle</td>
<td>0</td>
<td>5 ♀</td>
</tr>
<tr>
<td>2</td>
<td>QRX-111</td>
<td>10</td>
<td>5 ♀</td>
</tr>
<tr>
<td>3</td>
<td>QRX-111</td>
<td>30</td>
<td>5 ♀</td>
</tr>
<tr>
<td>4</td>
<td>QRX-111</td>
<td>100</td>
<td>5 ♀</td>
</tr>
</tbody>
</table>

The study was conducted by NPC Laboratories, Inc. personnel, including the dosing and necropsy phases of the study. Slides were prepared from selected formalin-fixed tissues (see table below) by NPC Laboratories and submitted to Nova Pathology for evaluation by light microscopy. Necropsy findings, clinical pathology data and organ weight data are included in appendices in the study report but were also submitted to Nova Pathology for interpretation in this report. Gross lesions observed at the terminal necropsy and histopathology findings were entered in a validated data management program (StarTox™, Version 3.0) and are presented in the data tables.

<table>
<thead>
<tr>
<th>Tissues Evaluated by Light Microscopy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone marrow (sternum)</td>
</tr>
<tr>
<td>Bone, Sternum</td>
</tr>
<tr>
<td>Brain</td>
</tr>
<tr>
<td>Cecum</td>
</tr>
<tr>
<td>Colon</td>
</tr>
<tr>
<td>Duodenum</td>
</tr>
<tr>
<td>Heart</td>
</tr>
</tbody>
</table>

2.3 Results/Discussion

2.3.1 Mortality and Necropsy Findings
All animals survived until the scheduled terminal necropsy on Day 8. Gross lesions for the scheduled terminal necropsy animals presented in an appendix in the study report. These data are summarized in Table 1 and are presented for individual animals in Table 3 in this pathology report.

The spleen was small in none of five, none of five, one of five and four of five animals in Groups 1, 2, 3 and 4, respectively, on Day 8. This change correlated with splenic lymphoid depletion and was considered to be related to QRX-111 at 30 and 100 mg/kg. The thymus was small in none of five, none of five, one of five and one of five animals in Groups 1, 2, 3 and 4, respectively on Day
8. Because it correlated with decreased thymic weights and histologic thymic lymphoid hypopcellularity and did not occur in the control group, small thymus was attributed to QRX-111 at 30 and 100 mg/kg.

Red discoloration was present in the lung in none of five, none of five, one of five and one of five animals in Groups 1, 2, 3 and 4, respectively, on Day 8. This finding, which correlated with hemorrhage, was attributed to QRX-111 at 30 and 100 mg/kg but was considered to most likely be a secondary rather than a direct effect. Red discoloration was present in mandibular and mesenteric lymph nodes and correlated with sinus erythrocytosis. Because sinus erythrocytosis was not considered to be related to QRX-111 and its incidence was not clearly dose-related, red discoloration in mandibular and mesenteric lymph nodes was considered incidental and unrelated to QRX-111.

2.3.2 Clinical Pathology
Hematology and serum chemistry data are presented in appendices in the study report. Specimens for hematology and clinical chemistry were collected at necropsy on Day 8.

**Hematology**
On Day 8, there was a trend toward decreasing total leukocytes and lymphocytes with these values in Group 4 (100 mg/kg) being statistically significantly decreased relative to the control group. Relative to Group 1 (control group), total neutrophils were increased in Group 4 (100 mg/kg) but were slightly decreased in Group 3 (30 mg/kg). Mean group values and percent change relative to controls for these parameters are summarized in the following table.

<table>
<thead>
<tr>
<th>Group</th>
<th>QRX-111 (mg/kg)</th>
<th>Total Leukocytes (10^9/\mu L)</th>
<th>Total Neutrophils (10^9/\mu L)</th>
<th>Total Lymphocytes (10^9/\mu L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0</td>
<td>9.8 NA</td>
<td>0.8 NA</td>
<td>8.2 NA</td>
</tr>
<tr>
<td>2</td>
<td>10</td>
<td>8.3 -14</td>
<td>0.7 -13</td>
<td>7.2 -12</td>
</tr>
<tr>
<td>3</td>
<td>30</td>
<td>7.6 -21</td>
<td>0.5 -36</td>
<td>6.3 -23</td>
</tr>
<tr>
<td>4</td>
<td>100</td>
<td>6.2 -35</td>
<td>1.8 +125</td>
<td>3.0 -52</td>
</tr>
</tbody>
</table>

Values in **BOLD** are statistically significantly different from controls; \(p < 0.05\)

Based on these data, decreased total leukocytes and lymphocytes and increased total neutrophils were attributed to QRX-111 at 100 mg/kg on Day 8. Mean group values for these parameters at 10 and 30 mg/kg were considered to be incidental due to the magnitude of the changes relative to the control group and to the small number of animals per group. Increased total neutrophils on Day 8 were attributed to QRX-111 at 100 mg/kg due to the magnitude of the increase and the presence of inflammation in the lung and liver at this dose. However, the significance of this finding was considered to be uncertain in light of the decreases in total neutrophils at 10 and 30 mg/kg. There were no dose-related trends or statistically significant changes in mean group values for parameters of the erythron or for platelets and none of these values was attributed to QRX-111 on Day 8.

**Serum Chemistry**
On Day 8, mean group serum triglyceride values in animals dosed with QRX-111 at 10, 30 and 1000 mg/kg were decreased relative to the control group. However, the decreases were not dose-related, none were statistically different from controls and there was no histologic correlate in the liver for this finding. For these reasons, decreased triglycerides were considered to be incidental and unrelated to QRX-111.
Some other mean group values for some serum chemistry parameters were statistically significantly different from comparable values in the control group (Group 1). These values included aspartate aminotransferase at 30 mg/kg, calcium at 30 mg/kg and total bilirubin at 30 mg/kg. However, these changes were not dose-related and did not have a histologic correlate. For these reasons, no changes in data for these serum or other chemistry parameters measured were attributed to QRX-111 at 10, 30 or 100 mg/kg.

2.3.3 Body and Organ Weight

Body Weights
Group mean and individual animal body and organ weights are presented in an appendix in the study report. Mean group terminal body weights are summarized in the following table.

<table>
<thead>
<tr>
<th>Group 1(Control)</th>
<th>QRX-111, 10 mg/kg</th>
<th>QRX-111, 10 mg/kg</th>
<th>QRX-111, 10 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>248.76 ±11.69</td>
<td>238.82 ±8.20</td>
<td>231.40 ±13.80</td>
<td>220.42 ±12.65</td>
</tr>
</tbody>
</table>

There was a slight trend toward decreasing mean group body weights with increasing dose of QRX-111 at 10, 30 and 100 mg/kg but the differences between mean group values were not statistically different from the mean group control value and were considered to be related to QRX-111.

Organ Weights
Changes in mean group weights, weight to brain weight ratios and weight to terminal body weight ratios for spleen and thymus on Day 8 are summarized in the following table.

<table>
<thead>
<tr>
<th>Organ</th>
<th>QRX, mg/kg</th>
<th>Weight (g)</th>
<th>% Change</th>
<th>% BW</th>
<th>% Change</th>
<th>% BrW</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spleen</td>
<td>0</td>
<td>0.503</td>
<td>NA</td>
<td>0.201</td>
<td>NA</td>
<td>25.197</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>0.382</td>
<td>-24</td>
<td>0.159</td>
<td>-21</td>
<td>19.499</td>
<td>-23</td>
</tr>
<tr>
<td></td>
<td>30</td>
<td>0.405</td>
<td>-19</td>
<td>0.177</td>
<td>-12</td>
<td>21.994</td>
<td>-13</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>0.370</td>
<td>-26</td>
<td>0.168</td>
<td>-16</td>
<td>19.270</td>
<td>-24</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>0.523</td>
<td>NA</td>
<td>0.212</td>
<td>NA</td>
<td>26.276</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>0.334</td>
<td>-36</td>
<td>0.139</td>
<td>-34</td>
<td>17.069</td>
<td>-35</td>
</tr>
<tr>
<td></td>
<td>30</td>
<td>0.249</td>
<td>-52</td>
<td>0.107</td>
<td>-49</td>
<td>13.538</td>
<td>-48</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>0.0259</td>
<td>-50</td>
<td>0.117</td>
<td>-45</td>
<td>13.452</td>
<td>-49</td>
</tr>
</tbody>
</table>

Values in **BOLD** are statistically significantly different from controls; p <0.05
% BW = % Terminal Body Weight; % BrW = % Brain Weight

Mean group spleen weights (absolute, relative to terminal body weight and relative to brain weight) in animals dosed with QRX-111 at 10, 30 and 100 mg/kg were decreased relative to comparable values in the vehicle control group (Group 1) on Day 8 but the decreases were not dose-related or statistically significantly different form the control group. Lymphoid hypocellularity in the spleen was attributed to QRX-111 at 30 and 100 mg/kg and is a histologic correlate to decreased spleen weights. For these reasons, the decreased mean group spleen weights (absolute, relative to terminal body weight and relative to brain weight) were attributed to QRX-111 in animals dosed at 30 and 100 mg/kg but were most likely secondary to systemic toxicity rather than a direct effect of QRX-111. Mean group thymus weights (absolute, relative to terminal body weight and relative to brain weight) in animals dosed with QRX-111 at 10, 30 and
100 mg/kg were decreased relative to comparable values in the control group (Group 1). The decreases in animals dosed with QRX-111 at 30 and 100 mg/kg were similar and were greater than the decreases at 10 mg/kg. Lymphoid hypocellularity in the thymus was attributed to QRX-111 at 10, 30 and 100 mg/kg and is commonly associated with systemic toxicity in rodents. For these reasons, mean group thymus weights, thymus to brain weight ratios and thymus to terminal body weight ratios were attributed to QRX-111 at 10, 30 and 100 mg/kg on Day 8.

No test article-related changes in organ weights, organ weight to brain weight ratios and organ weight to terminal body weight ratios were present in brain, liver, kidney, heart or lung.

2.3.4 Histopathology

Histologic findings that were attributed to QRX-111 were present in the pancreas, small intestine, lung, liver, spleen and thymus. Hypocellularity in bone marrow at 100 mg/kg was of uncertain relationship to QRX-111. Histologic findings are presented in the following tables:

Table 2: Summary of Histologic Findings: Day 8
Table 3: Individual Animal Data

The presence of an entry in the histopathology data for each tissue is summarized in Table 4: Tabulated Summary of Tissues Evaluated. A plus (+) in this table indicates that the tissue was present and evaluated or that it was unavailable after required attempts to obtain sections by cutting deeper into the paraffin block or by obtaining and processing additional sections from wet tissue.

2.3.5 Diagnostic Terms

Hypocellularity: Relative to the vehicle control animals, decreased hematopoietic cells in the bone marrow

Hypocellular, Lymphoid: Relative to vehicle control animals, decreased lymphocytes in the thymic cortex, PALS and marginal zone in the spleen and follicles in the mesenteric lymph node.

Inflammation, Subacute: Infiltrates of variable numbers of macrophages, lymphocytes and granulocytes in the interstitium and alveoli in the lung; sometimes with a distinct perivascular distribution.

Vacuolation, Cytoplasm: Clear cytoplasmic vacuoles in pancreatic acinar cells and in mucosal epithelium in the small intestine (duodenum).

Other histologic terms were considered self-explanatory and did not require description. Each histologic finding was assigned a severity grade based on the following scheme:

Minimal = 1; Mild = 2; Moderate = 3; Marked = 4
2.3.6 Histologic Findings

Histologic findings that were considered to be direct effects of QRX-111 were present in the duodenum, pancreas, lung and liver. Findings considered to most likely be secondary to QRX-111 induced systemic stress were present in thymus and spleen.

Pancreas and Duodenum

Clear cytoplasmic vacuoles were present in pancreatic acinar cells and in enterocytes in the duodenum. In the pancreas, this finding was present in none of five, two of five (minimal), five of five (minimal to mild) and five of five (minimal to mild) animals dosed with QRX-111 at 0, 10, 30 and 100 mg/kg, respectively. Cytoplasmic vacuolation of duodenal enterocytes was present in none of five, none of five, two of five (minimal) and five of five (minimal) animals dosed with QRX-111 at 0, 10, 30 and 100 mg/kg, respectively. Based on these data, on Day 8, cytoplasmic vacuolation in pancreatic acinar cells was attributed to QRX-111 at 10, 30 and 100 mg/kg and in duodenal enterocytes at 30 and 100 mg/kg.

Lung

Subacute inflammation and hemorrhage both occurred with dose-related incidence and severity in animals dosed with QRX-111 at 30 and 100 mg/kg. Subacute inflammation was present in none of five, none of five, two of five (minimal to mild) and five of five (minimal to moderate) animals dosed with QRX-111 at 0, 10, 30 and 100 mg/kg, respectively. Hemorrhage was not present in animals dosed with QRX-111 at 0 or 10 mg/kg. This finding was minimal in two of five and minimal to mild in four of five animals dosed with QRX-111 at 30 and 100 mg/kg, respectively. Based on the incidence and severity data, subacute inflammation and hemorrhage in the lung were attributed to QRX-111 at 30 and 100 mg/kg on Day 8.

Liver

Subacute inflammation, morphologically similar to that observed in the lung was minimal to mild in three of five animals dosed with QRX-111 at 100 mg/kg but did not occur in animals dosed at 0, 10, or 30 mg/kg. Based on this data and its similarity to subacute inflammation in the lung, subacute inflammation in the liver was attributed to QRX-111 at 100 mg/kg on Day 8.

Thymus and Spleen

Lymphoid hypocellularity was mainly cortical in the thymus and in the PALS and marginal zone in the spleen. This finding is commonly associated with systemic stress due to any cause in rodents. Thymic lymphoid hypocellularity was present in none of five, three of five (minimal), four of five (minimal to mild) and five of five (minimal to marked) animals dosed with QRX-111 at 0, 10, 30 and 100 mg/kg, respectively. In the spleen, this finding was present in none of five, none of five, two of five (minimal to mild) and five of five (minimal to moderate) animals dosed with QRX-111 at 0, 10, 30 and 100 mg/kg, respectively. In both thymus and spleen, the severity of lymphoid hypocellularity was dose-related. Based on these data, lymphoid hypocellularity was attributed to QRX-111 at 10, 30 and 100 mg/kg in the thymus and at 30 and 100 mg/kg in the spleen.

Other Tissues

Minimal hypocellularity was noted in one of five animals dosed with QRX-111 at 100 mg/kg. This finding can occur due to direct toxicity but because it occurred in only one animal, the possible relationship to QRX-111 and significance of this finding in this study were considered to be uncertain. Other histologic findings which were present in other tissues did not have dose-
related incidence or severity, are common findings in naïve rats and were considered to be incidental and unrelated to QRX-111.

2.4 Conclusions

Under the conditions of this study, all animals survived until the scheduled terminal necropsy on Day 8. Small thymus and spleen were attributed to QRX-111 at 30 and 100 mg/kg. Decreased mean group weights (absolute, relative to terminal body weight and relative to brain weight) in thymus (10, 30 and 100 mg/kg) and splenic (30 and 100 mg/kg) were attributed to QRX-111 at on Day 8. Decreased total leukocytes and lymphocytes and increased total neutrophils at 100 mg/kg were the only clinical pathology parameters that were attributed to QRX-111 on Day 8. Histologic findings considered to be directly related to QRX-111 on Day 8 included cytoplasmic vacuolation in pancreatic acinar cells at 10, 30 and 100 mg/kg and in duodenal enterocytes at 30 and 100 mg/kg. Subacute inflammation in lung at 30 and 100 mg/kg and in the liver at 100 mg/kg was related to QRX-111 while hemorrhage in lung was also attributed to QRX-111 at 30 and 100 mg/kg. Lymphoid hypocellularity in the thymus at 10, 30 and 100 mg/kg and in spleen at 30 and 100 mg/kg was attributed to QRX-111 and was most likely secondary to systemic stress. Based on these data, a no-effect level was not determined in this 7-day repeat-dose oral toxicity study.
TABLE 1

Summary of Necropsy Findings: Day 8
<table>
<thead>
<tr>
<th>Organs</th>
<th>Group:</th>
<th>Group 01</th>
<th>Group 02</th>
<th>Group 03</th>
<th>Group 04</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Diagnoses</td>
<td>TN</td>
<td>TN</td>
<td>TN</td>
<td>TN</td>
</tr>
<tr>
<td></td>
<td>Sacrifice:</td>
<td>TN</td>
<td>TN</td>
<td>TN</td>
<td>TN</td>
</tr>
<tr>
<td></td>
<td>Sex:</td>
<td>F</td>
<td>F</td>
<td>F</td>
<td>F</td>
</tr>
<tr>
<td><strong>Lung</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Discoloration, Red</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td><strong>Lymph Node, Mandibular</strong></td>
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<td>(3)</td>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
</tr>
<tr>
<td></td>
<td>Discoloration, Red</td>
<td>3</td>
<td>5</td>
<td>4</td>
<td>3</td>
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<tr>
<td></td>
<td>Enlarged</td>
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<td>2</td>
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<td>0</td>
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<td><strong>Lymph Node, Mesenteric</strong></td>
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<td>(0)</td>
<td>(1)</td>
<td>(1)</td>
</tr>
<tr>
<td></td>
<td>Discoloration, Red</td>
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<td>0</td>
<td>1</td>
<td>1</td>
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<tr>
<td><strong>Spleen</strong></td>
<td></td>
<td>(0)</td>
<td>(0)</td>
<td>(1)</td>
<td>(4)</td>
</tr>
<tr>
<td></td>
<td>Small</td>
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<td>0</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td><strong>Thymus</strong></td>
<td></td>
<td>(0)</td>
<td>(0)</td>
<td>(1)</td>
<td>(1)</td>
</tr>
<tr>
<td></td>
<td>Small</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
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</tbody>
</table>

Group 01 = Control - 0 mg/kg
Group 02 = QRX-111, 10 mg/kg
Group 03 = QRX-111, 30 mg/kg
Group 04 = QRX-111, 100 mg/kg
TABLE 2:

Summary of Histologic Findings, Day 8
Table Number: 2  
Summary of Histologic Findings: Day 8  
Study Number: QRX-12-S-111  
QRX Pharmaceuticals, Inc.  
Anytown, WA 9800X

<table>
<thead>
<tr>
<th>Organs</th>
<th>Group:</th>
<th>Group 01</th>
<th>Group 02</th>
<th>Group 03</th>
<th>Group 04</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sacrifice:</td>
<td>TN</td>
<td>TN</td>
<td>TN</td>
<td>TN</td>
</tr>
<tr>
<td>Diagnoses</td>
<td>Sex:</td>
<td>F</td>
<td>F</td>
<td>F</td>
<td>F</td>
</tr>
<tr>
<td>Bone Marrow, Sternum</td>
<td></td>
<td>(5)</td>
<td>(5)</td>
<td>(5)</td>
<td>(5)</td>
</tr>
<tr>
<td></td>
<td>Within Normal Limits</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Hypocellular</td>
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<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>minimal</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Bone, Sternum</td>
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Group 1=Control - 0 mg/kg  
Group 2=QRX-111, 10 mg/kg  
Group 3=QRX-111, 30 mg/kg  
Group 4=QRX-111, 100 mg/kg
### Summary of Histologic Findings: Day 8

**Study Number:** QRX-12-S-111  
**QRX Pharmaceuticals, Inc.**  
**Anytown, WA 9800X**

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<thead>
<tr>
<th>Organs</th>
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Group 01=Control - 0 mg/kg  
Group 02=QRX-111, 10 mg/kg  
Group 03=QRX-111, 30 mg/kg  
Group 04=QRX-111, 100 mg/kg
# Table Number: 2
Summary of Histologic Findings: Day 8
Study Number: QRX-12-S-111
QRX Pharmaceuticals, Inc.
Anytown, WA 9800X

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<th>Organs</th>
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**Lymph Node, Mandibular (continued)**

Hypercellular, Lymphocyte (continued)
- marked: 0 0 1 0
- Sinus Erythrocytosis
  - minimal: 3 3 1 3
  - mild: 1 2 3 0

**Lymph Node, Mesenteric**

- (5) (5) (5) (5) (5)
  - Within Normal Limits: 4 2 0 2
  - Hypercellular, Lymphocyte
    - minimal: 0 0 2 0
    - Hypocellular, Lymphocyte
      - minimal: 0 0 1 1
      - mild: 0 0 0 1
      - Infiltrate, Macrophage
        - mild: 0 0 1 1
      - Sinus Erythrocytosis
        - minimal: 1 3 3 1
        - mild: 0 2 0 0

**Mammary Gland**

- (5) (5) (5) (5) (5)
  - Within Normal Limits: 5 5 5 5

**Pancreas**

- (5) (5) (5) (5) (5)
  - Within Normal Limits: 5 3 0 0
  - Vacuolation, Cytoplasm
    - minimal: 0 2 5 5
    - mild: 0 0 3 2

**Rectum**

- (5) (5) (5) (5) (5)
  - Within Normal Limits: 5 5 5 5

**Skin**

- (5) (5) (5) (5) (5)
  - Within Normal Limits: 5 5 5 5

**Spleen**

- (5) (5) (5) (5) (5)
  - Within Normal Limits: 5 5 3 0
  - Hypocellular, Lymphocyte
    - minimal: 0 0 2 5
    - mild: 0 0 1 2

Group 01=Control - 0 mg/kg
Group 02=QRX-111, 10 mg/kg
Group 03=QRX-111, 30 mg/kg
Group 04=QRX-111, 100 mg/kg
Table Number: 2
Summary of Histologic Findings: Day 8
Study Number: QRX-12-S-111
QRX Pharmaceuticals, Inc.
Anytown, WA 9800X

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<th>Organs</th>
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**Spleen (continued)**
- Hypocellular, Lymphocyte (continued)
  - moderate: 0 0 0 2

**Stomach**
- Within Normal Limits: (5) (5) (5) (5)
  - Within Normal Limits: 5 5 5 5

**Thymus**
- Within Normal Limits: (5) (5) (5) (5)
  - Hemorrhage
    - minimal: 0 0 0 1
    - minimal: 0 3 4 5
  - Hypocellular, Lymphocyte
    - minimal: 0 3 3 1
    - mild: 0 0 1 2
    - moderate: 0 0 0 1
    - marked: 0 0 0 1

Group 01=Control - 0 mg/kg
Group 02=QRX-111, 10 mg/kg
Group 03=QRX-111, 30 mg/kg
Group 04=QRX-111, 100 mg/kg
TABLE 3:

Individual Animal Data
Table Number: 3
Individual Animal Data
Study Number: QRX-12-S-111
QRX Pharmaceuticals, Inc.
Anytown, WA 9800X

Species: CD (SD): (CRL)  Animal Number: 101  Sex: Female
Gp: (01) Control - 0 mg/kg  Fate: (TN) Terminal Necropsy  Days on Study: 8

**Macroscopic Results**
- Lymph Node, Mandibular  Discoloration, Red, right

**Microscopic Results**
- Heart  Infiltrate, Cellular, Myocardium, focal, minimal
- Kidney  Mineralization, minimal
- Liver  Infiltrate, Mononuclear Cell, minimal
- Vacuolation, Cytoplasm, Hepatocyte, focal, minimal
- Lymph Node, Mandibular  Sinus Erythrocytosis, minimal
- Hypercellular, Lymphocyte, minimal

*The following organs were found to be Within Normal Limits:*
- Bone Marrow, Sternum:  Bone, Sternum:  Brain:  Cecum:  Colon:  Duodenum:  Ileum:  Jejunum:  Lung:

**Macroscopic/Microscopic Correlations**
- Lymph Node, Mandibular-Discoloration, Red, right  Lymph Node, Mandibular-Sinus Erythrocytosis, minimal
Table Number: 3
Individual Animal Data
Study Number: QRX-12-S-111
QRX Pharmaceuticals, Inc.
Anytown, WA 9800X

Species: CD (SD): (CRL)  Animal Number: 102  Sex: Female  
Gp: (01) Control - 0 mg/kg  Fate: (TN) Terminal Necropsy  Days on Study: 8

Macroscopic Results
No macroscopic findings on file.

Microscopic Results
- Kidney: Mineralization, mild
- Liver: Infiltrate, Mononuclear Cell, minimal
- Lymph Node, Mandibular: Sinus Erythrocytosis, minimal

The following organs were found to be Within Normal Limits:
- Bone Marrow, Sternum: Bone, Sternum: Brain: Cecum: Colon: Duodenum: Heart: Ileum: Jejunum:
- Thymus

Macroscopic/Microscopic Correlations
No correlations are currently entered.
Table Number: 3
Individual Animal Data
Study Number: QRX-12-S-111
QRX Pharmaceuticals, Inc.
Anytown, WA 9800X

Species: CD (SD): (CRL)  Animal Number: 103  Sex: Female
Gp: (01) Control - 0 mg/kg  Fate: (TN) Terminal Necropsy  Days on Study: 8

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<td>Lymph Node, Mandibular Enlarged, right</td>
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The following organs were found to be Within Normal Limits:

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**Macroscopic Results**
- Lymph Node, Mandibular - Discoloration, Red, right

**Microscopic Results**
- Kidney - Mineralization, minimal
- Liver - Infiltrate, Mononuclear Cell, minimal
- Lymph Node, Mandibular - Sinus Erythrocytosis, mild
  - Hypercellular, Lymphocyte, mild
- Lymph Node, Mesenteric - Sinus Erythrocytosis, minimal

*The following organs were found to be Within Normal Limits:*

**Macroscopic/Microscopic Correlations**
- Lymph Node, Mandibular-Discoloration, Red, right :: Lymph Node, Mandibular-Sinus Erythrocytosis, mild
Species: CD (SD): (CRL)    Animal Number: 105    Sex: Female
Gp: (01) Control - 0 mg/kg    Fate: (TN) Terminal Necropsy    Days on Study: 8

Macroscopic Results
   No macroscopic findings on file.

Microscopic Results
   Heart             Infiltrate, Cellular, Myocardium, focal, minimal
   Kidney            Basophilia, Tubular Epithelium, focal, minimal

The following organs were found to be Within Normal Limits:

Macroscopic/Microscopic Correlations
   No correlations are currently entered.
Table Number: 3  
Individual Animal Data  
Study Number: QRX-12-S-111  
QRX Pharmaceuticals, Inc.  
Anytown, WA 9800X  

Species: CD (SD): (CRL)  
Animal Number: 201  
Sex: Female  
Gp: (02) QRX-111, 10 mg/kg  
Fate: (TN) Terminal Necropsy  
Days on Study: 8  

Macroscopic Results  
Lymph Node, Mandibular  
Discoloration, Red, right  
Enlarged, right  

Microscopic Results  
Kidney  
Basophilia, Tubular Epithelium, focal, unilateral, minimal  
Cast, Proteinic, Renal Tubule, focal, unilateral, minimal  
Liver  
Infiltrate, Mononuclear Cell, minimal  
Lymph Node, Mandibular  
Sinus Erythrocytosis, minimal  
Hypercellular, Lymphocyte, minimal  
Lymph Node, Mesenteric  
Sinus Erythrocytosis, minimal  
Thymus  
Hypocellular, Lymphocyte, minimal  

The following organs were found to be Within Normal Limits:  
Bone Marrow, Sternum:  
Bone, Sternum:  
Brain:  
Cecum:  
Colon:  
Duodenum:  
Heart:  
Ileum:  
Jejunum:  
Lung:  
Mammary Gland:  
Pancreas:  
Rectum:  
Skin:  
Spleen:  
Stomach:  

Macroscopic/Microscopic Correlations  
Lymph Node, Mandibular-Discoloration, Red, right :: Lymph Node, Mandibular-Sinus Erythrocytosis, minimal  
Lymph Node, Mandibular-Enlarged, right :: Lymph Node, Mandibular-Sinus Erythrocytosis, minimal
Species: CD(SD): (CRL)  Animal Number: 202  Sex: Female  
Gp: (02) QRX-111, 10 mg/kg  Fate: (TN) Terminal Necropsy  Days on Study: 8

<table>
<thead>
<tr>
<th>Macroscopic Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymph Node, Mandibular</td>
</tr>
<tr>
<td>Enlarged, right</td>
</tr>
<tr>
<td>Discoloration, Red, right</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Microscopic Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney</td>
</tr>
<tr>
<td>Basophilia, Tubular Epithelium, focal, minimal</td>
</tr>
<tr>
<td>Liver</td>
</tr>
<tr>
<td>Infiltrate, Mononuclear Cell, minimal</td>
</tr>
<tr>
<td>Lymph Node, Mandibular</td>
</tr>
<tr>
<td>Sinus Erythrocytosis, minimal</td>
</tr>
<tr>
<td>Hypercellular, Lymphocyte, mild</td>
</tr>
<tr>
<td>Lymph Node, Mesenteric</td>
</tr>
<tr>
<td>Sinus Erythrocytosis, mild</td>
</tr>
</tbody>
</table>

The following organs were found to be Within Normal Limits:

<table>
<thead>
<tr>
<th>Macroscopic/Microscopic Correlations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymph Node, Mandibular-Discoloration, Red, right :::: Lymph Node, Mandibular-Sinus Erythrocytosis, minimal</td>
</tr>
<tr>
<td>Lymph Node, Mandibular-Enlarged, right :::: Lymph Node, Mandibular-Hypercellular, Lymphocyte, mild</td>
</tr>
</tbody>
</table>
Table Number: 3
Individual Animal Data
Study Number: QRX-12-S-111
QRX Pharmaceuticals, Inc.
Anytown, WA 9800X

Species: CD (SD): (CRL) Animal Number: 203 Sex: Female
Gp: (02) QRX-111, 10 mg/kg Fate: (TN) Terminal Necropsy Days on Study: 8

Macroscopic Results
Lymph Node, Mandibular Discoloration, Red, right

Microscopic Results
Kidney Mineralization, minimal
Lung Infiltrate, Macrophage, Alveolus, focal, minimal
Lymph Node, Mandibular Sinus Erythrocytosis, mild
Thymus Hypocellular, Lymphocyte, minimal

The following organs were found to be Within Normal Limits:

Macroscopic/Microscopic Correlations
Lymph Node, Mandibular-Discoloration, Red, right ::: Lymph Node, Mandibular-Sinus Erythrocytosis, mild
Table Number: 3
Individual Animal Data
Study Number: QRX-12-S-111
QRX Pharmaceuticals, Inc.
Anytown, WA 9800X

Species: CD (SD): (CRL)    Animal Number: 204    Sex: Female
Gp: (02) QRX-111, 10 mg/kg    Fate: (TN) Terminal Necropsy    Days on Study: 8

Macroscopic Results
  Lymph Node, Mandibular    Discoloration, Red, right

Microscopic Results
  Liver    Vacuolation, Cytoplasm, Hepatocyte, minimal
  Lymph Node, Mandibular    Sinus Erythrocytosis, mild
  Hypercellular, Lymphocyte, mild
  Lymph Node, Mesenteric    Sinus Erythrocytosis, mild
  Pancreas    Vacuolation, Cytoplasm, acinar cell, minimal

The following organs were found to be Within Normal Limits:
  Bone Marrow, Sternum: Bone, Sternum: Brain: Cecum: Colon: Duodenum: Heart: Ileum: Jejunum:

Macroscopic/Microscopic Correlations
  Lymph Node, Mandibular-Discoloration, Red, right :: Lymph Node, Mandibular-Sinus
  Erythrocytosis, mild
Table Number: 3  
Individual Animal Data  
Study Number: QRX-12-S-111  
QRX Pharmaceuticals, Inc.  
Anytown, WA 9800X  

Species: CD (SD): (CRL)  
Animal Number: 205  
Sex: Female  
Gp: (02) QRX-111, 10 mg/kg  
Fate: (TN) Terminal Necropsy  
Days on Study: 8  

Macroscopic Results  
Lymph Node, Mandibular Discoloration, Red, right  

Microscopic Results  
Kidney  
Mineralization, mild  
Basophilia, Tubular Epithelium, minimal  
Liver  
Infiltrate, Mononuclear Cell, minimal  
Lung  
Infiltrate, Macrophage, Alveolus, focal, mild  
Lymph Node, Mandibular Sinus Erythrocytosis, minimal  
Liver  
Infiltrate, Mononuclear Cell, minimal  
Pancreas  
Vacuolation, Cytoplasm, acinar cell, focal, minimal  
Thymus  
Hypocellular, Lymphocyte, minimal  

The following organs were found to be Within Normal Limits:  
Bone Marrow, Sternum:  
Bone, Sternum:  
Brain:  
Cecum:  
Colon:  
Duodenum:  
Heart:  
Ileum:  
Jejunum:  
Lymph Node, Mesenteric:  
Mammary Gland:  
Rectum:  
Skin:  
Spleen:  
Stomach  

Macroscopic/Microscopic Correlations  
Lymph Node, Mandibular-Discoloration, Red, right :::: Lymph Node, Mandibular-Sinus Erythrocytosis, minimal
Table Number: 3
Individual Animal Data
Study Number: QRX-12-S-111
QRX Pharmaceuticals, Inc.
Anytown, WA 9800X

Species: CD (SD): (CRL)    Animal Number: 301    Sex: Female
Gp: (03) QRX-111, 30 mg/kg    Fate: (TN) Terminal Necropsy    Days on Study: 8

Macroscopic Results
- Lymph Node, Mandibular Enlarged, right
  Discoloration, Red, right
- Lymph Node, Mesenteric Discoloration, Red

Microscopic Results
- Liver Infiltrate, Mononuclear Cell, minimal
- Lung Infiltrate, Macrophage, Alveolus, minimal
  Hemorrhage, minimal
- Lymph Node, Mandibular Sinus Erythrocytosis, minimal
- Lymph Node, Mandibular Hypercellular, Lymphocyte, mild
- Lymph Node, Mesenteric Hypercellular, Lymphocyte, minimal
- Pancreas Vacuolation, Cytoplasm, acinar cell, minimal
- Thymus Hypocellular, Lymphocyte, minimal

The following organs were found to be Within Normal Limits:
- Bone Marrow, Sternum:  Bone, Sternum:  Brain:  Cecum:  Colon:  Duodenum:  Heart:  Ileum:  Jejunum:
  Kidney:  Mammary Gland:  Rectum:  Skin:  Spleen:  Stomach

Macroscopic/Microscopic Correlations
- Lymph Node, Mandibular-Discoloration, Red, right ::: Lymph Node, Mandibular-Sinus Erythrocytosis, minimal
- Lymph Node, Mandibular-Enlarged, right ::: Lymph Node, Mandibular-Hypercellular, Lymphocyte, mild
- Lymph Node, Mesenteric-Discoloration, Red :::: Lymph Node, Mesenteric-No Histologic Correlate
Individual Animal Data
Study Number: QRX-12-S-111
QRX Pharmaceuticals, Inc.
Anytown, WA 9800X

Species: CD(SD): (CRL)  Animal Number: 302  Sex: Female
Gp: (03) QRX-111, 30 mg/kg  Fate: (TN) Terminal Necropsy  Days on Study: 8

**Macroscopic Results**
No macroscopic findings on file.

**Microscopic Results**
- Colon: Inflammation, Subacute, submucosa, focal, minimal
- Lung: Infiltrate, Macrophage, Alveolus, focal, minimal
- Lymph Node, Mesenteric: Infiltrate, Macrophage, sinusoid, mild
  Hypocellular, Lymphocyte, minimal
- Pancreas: Vacuolation, Cytoplasm, acinar cell, minimal
- Thymus: Hypocellular, Lymphocyte, minimal

*The following organs were found to be Within Normal Limits:*

**Macroscopic/Microscopic Correlations**
No correlations are currently entered.
Table Number: 3  
Individual Animal Data  
Study Number: QRX-12-S-111  
QRX Pharmaceuticals, Inc.  
Anytown, WA 9800X

<table>
<thead>
<tr>
<th>Species: CD (SD): (CRL)</th>
<th>Animal Number: 303</th>
<th>Sex: Female</th>
<th>Study Number: QRX-12-S-111</th>
<th>Fate: (TN) Terminal Necropsy</th>
<th>Days on Study: 8</th>
</tr>
</thead>
</table>

### Macroscopic Results
- Lymph Node, Mandibular Enlarged, right
- Discoloration, Red, right

### Microscopic Results
- Duodenum Vacuolation, Cytoplasm, epithelium, columnar, mucosa, minimal
- Lung Hemorrhage, multifocal, minimal
- Inflammation, Subacute, unilateral, multifocal, mild
  *Present in one of two lobes evaluated.*
- Infiltrate, Macrophage, Alveolus, minimal
- Lymph Node, Mandibular Sinus Erythrocytosis, mild
- Hypercellular, Lymphocyte, marked
- Lymph Node, Mesenteric Sinus Erythrocytosis, minimal
- Pancreas Vacuolation, Cytoplasm, acinar cell, mild

*The following organs were found to be Within Normal Limits:*
- Bone Marrow, Sternum:  
- Bone, Sternum:  
- Brain:  
- Cecum:  
- Colon:  
- Heart:  
- Ileum:  
- Jejunum:  
- Kidney:  
- Liver:  
- Mammary Gland:  
- Rectum:  
- Skin:  
- Spleen:  
- Stomach:  
- Thymus:

### Macroscopic/Microscopic Correlations
- Lymph Node, Mandibular-Discoloration, Red, right ::: Lymph Node, Mandibular-Sinus Erythrocytosis, mild
- Lymph Node, Mandibular-Enlarged, right ::: Lymph Node, Mandibular-Hypercellular, Lymphocyte, marked
Species: CD(SD): (CRL)  Animal Number: 304  Sex: Female  Gp: (03) QRX-111, 30 mg/kg  Fate: (TN) Terminal Necropsy  Days on Study: 8

**Macroscopic Results**
- Lymph Node, Mandibular Discoloration, Red, right
- Spleen Small
- Thymus Small

**Microscopic Results**
- Duodenum Vacuolation, Cytoplasm, epithelium, columnar, mucosa, minimal
- Kidney Dilatation, Renal Tubule, focal, minimal
  - *Subcapsular.*
- Kidney Fibrosis, Interstitium, focal, minimal
  - *Consistent with a small subcapsular infarct.*
- Kidney Infiltrate, Mononuclear Cell, Interstitium, focal, minimal
  - *Subcapsular.*
- Lung Inflammation, Subacute, bilateral, multifocal, minimal
- Lymph Node, Mandibular Sinus Erythrocytosis, mild
- Lymph Node, Mesenteric Sinus Erythrocytosis, minimal
- Pancreas Vacuolation, Cytoplasm, acinar cell, mild
- Spleen Hypocellular, Lymphocyte, mild
- Thymus Hypocellular, Lymphocyte, mild

The following organs were found to be Within Normal Limits:

**Macroscopic/Microscopic Correlations**
- Lymph Node, Mandibular-Discoloration, Red, right :: Lymph Node, Mandibular-Sinus Erythrocytosis, mild
- Spleen-Small :: Spleen-Hypocellular, Lymphocyte, mild
- Thymus-Small :: Thymus-Hypocellular, Lymphocyte, mild
Table Number: 3  
Individual Animal Data  
Study Number: QRX-12-S-111  
QRX Pharmaceuticals, Inc.  
Anytown, WA 9800X  

Species: Crl: CD(SD)  
Animal Number: 305  
Sex: Female  
Gp: (03) QRX-111, 30 mg/kg  
Fate: (TN) Terminal Necropsy  
Days on Study: 8  

<table>
<thead>
<tr>
<th>Macroscopic Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymph Node, Mandibular</td>
</tr>
<tr>
<td>Discoloration, Red, right</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Microscopic Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart</td>
</tr>
<tr>
<td>Infiltrate, Cellular, Myocardium, focal, minimal</td>
</tr>
<tr>
<td>Kidney</td>
</tr>
<tr>
<td>Basophilia, Tubular Epithelium, focal, unilateral, minimal</td>
</tr>
<tr>
<td>Fibrosis, Interstitium, unilateral, focal, minimal</td>
</tr>
<tr>
<td>Infiltrate, Mononuclear Cell, Interstitium, focal, unilateral, minimal</td>
</tr>
<tr>
<td>These findings are consistent with a small infarct involving one nephron.</td>
</tr>
<tr>
<td>Liver</td>
</tr>
<tr>
<td>Infiltrate, Mononuclear Cell, minimal</td>
</tr>
<tr>
<td>Vacuolation, Cytoplasm, Hepatocyte, minimal</td>
</tr>
<tr>
<td>Lymph Node, Mandibular</td>
</tr>
<tr>
<td>Sinus Erythrocytosis, mild</td>
</tr>
<tr>
<td>Hypercellular, Lymphocyte, mild</td>
</tr>
<tr>
<td>Lymph Node, Mesenteric</td>
</tr>
<tr>
<td>Sinus Erythrocytosis, minimal</td>
</tr>
<tr>
<td>Hypercellular, Lymphocyte, minimal</td>
</tr>
<tr>
<td>Pancreas</td>
</tr>
<tr>
<td>Vacuolation, Cytoplasm, acinar cell, mild</td>
</tr>
<tr>
<td>Spleen</td>
</tr>
<tr>
<td>Hypocellular, Lymphocyte, minimal</td>
</tr>
<tr>
<td>Thymus</td>
</tr>
<tr>
<td>Hypocellular, Lymphocyte, minimal</td>
</tr>
</tbody>
</table>

The following organs were found to be Within Normal Limits:  
Bone Marrow, Sternum:  
Bone, Sternum:  
Brain:  
Cecum:  
Colon:  
Duodenum:  
Ileum:  
Jejunum:  
Lung:  
Mammary Gland:  
Rectum:  
Skin:  
Stomach  

Macroscopic/Microscopic Correlations  
Lymph Node, Mandibular-Discoloration, Red, right ::: Lymph Node, Mandibular-Sinus Erythrocytosis, mild
Table Number: 3
Individual Animal Data
Study Number: QRX-12-S-111
QRX Pharmaceuticals, Inc.
Anytown, WA 9800X

Species: CD(SD): (CRL) Animal Number: 401 Sex: Female
Gp: (04) QRX-111, 100 mg/kg Fate: (TN) Terminal Necropsy Days on Study: 8

<table>
<thead>
<tr>
<th>Macroscopic Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymph Node, Mesenteric</td>
</tr>
<tr>
<td>Discoloration, Red</td>
</tr>
<tr>
<td>Spleen</td>
</tr>
<tr>
<td>Small</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Microscopic Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duodenum</td>
</tr>
<tr>
<td>Vacuolation, Cytoplasm, epithelium, columnar, mucosa, minimal</td>
</tr>
<tr>
<td>Very small vacuoles on the apical side of the nucleus.</td>
</tr>
<tr>
<td>Kidney</td>
</tr>
<tr>
<td>Mineralization, minimal</td>
</tr>
<tr>
<td>Liver</td>
</tr>
<tr>
<td>Infiltrate, Mononuclear Cell, minimal</td>
</tr>
<tr>
<td>Lung</td>
</tr>
<tr>
<td>Inflammation, Subacute, perivascular, bilateral, multifocal, minimal</td>
</tr>
<tr>
<td>Lymph Node, Mesenteric</td>
</tr>
<tr>
<td>Hypocellular, Lymphocyte, minimal</td>
</tr>
<tr>
<td>Sinus Erythrocytosis, minimal</td>
</tr>
<tr>
<td>Pancreas</td>
</tr>
<tr>
<td>Vacuolation, Cytoplasm, acinar cell, mild</td>
</tr>
<tr>
<td>Spleen</td>
</tr>
<tr>
<td>Hypocellular, Lymphocyte, moderate</td>
</tr>
<tr>
<td>Thymus</td>
</tr>
<tr>
<td>Hypocellular, Lymphocyte, mild</td>
</tr>
<tr>
<td>Hemorrhage, focal, minimal</td>
</tr>
</tbody>
</table>

The following organs were found to be Within Normal Limits:

Macroscopic/Microscopic Correlations
 Lymph Node, Mesenteric-Discoloration, Red :: Lymph Node, Mesenteric-Sinus Erythrocytosis, minimal
 Spleen-Small :: Spleen-Hypocellular, Lymphocyte, moderate
Table Number: 3
Individual Animal Data
Study Number: QRX-12-S-111
QRX Pharmaceuticals, Inc.
Anytown, WA 9800X

Species: CD (SD): (CRL) Animal Number: 402 Sex: Female
Gp: (04) QRX-111, 100 mg/kg Fate: (TN) Terminal Necropsy Days on Study: 8

Macroscopic Results
- Lymph Node, Mandibular: Discoloration, Red, right
- Spleen: Small

Microscopic Results
- Duodenum: Vacuolation, Cytoplasm, epithelium, columnar, mucosa, minimal
- Kidney: Infiltrate, Mononuclear Cell, Interstitium, focal, minimal
- Liver: Inflammation, Subacute, portal, multifocal, mild
- Lung: Hemorrhage, multifocal, minimal
- Lymph Node, Mandibular: Sinus Erythrocytosis, minimal
- Pancreas: Vacuolation, Cytoplasm, acinar cell, minimal
- Spleen: Hypocellular, Lymphocyte, minimal
- Thymus: Hypocellular, Lymphocyte, minimal

The following organs were found to be Within Normal Limits:

Macroscopic/Microscopic Correlations
- Lymph Node, Mandibular-Discoloration, Red, right ::: Lymph Node, Mandibular-Sinus Erythrocytosis, minimal
- Spleen-Small ::: Spleen-Hypocellular, Lymphocyte, minimal
Table Number: 3
Individual Animal Data
Study Number: QRX-12-S-111
QRX Pharmaceuticals, Inc.
Anytown, WA 9800X

Species: CD (SD): (CRL)  Animal Number: 403  Sex: Female
Gp: (04) QRX-111, 100 mg/kg  Fate: (TN) Terminal Necropsy  Days on Study: 8

Macroscopic Results
- Lung: Discoloration, Red, all lobes
- Lymph Node, Mandibular: Discoloration, Red, right
- Spleen: Small

Microscopic Results
- Bone Marrow, Sternum: Hypocellular, minimal
- Duodenum: Vacuolation, Cytoplasm, epithelium, columnar, mucosa, minimal
- Heart: Inflammation, Lymphoplasmacytic, myocardium, ventricle, right, diffuse, mild
- Lung: Hemorrhage, alveolus, multifocal, mild
- Inflammation, Subacute, perivascular, bilateral, multifocal, moderate
- Lymph Node, Mandibular: Sinus Erythrocytosis, minimal
- Lymph Node, Mesenteric: Hypocellular, Lymphocyte, mild
- Pancreas: Vacuolation, Cytoplasm, acinar cell, mild
- Spleen: Hypocellular, Lymphocyte, moderate
- Thymus: Hypocellular, Lymphocyte, marked

The following organs were found to be Within Normal Limits:
- Skin:  Stomach

Macroscopic/Microscopic Correlations
- Lung-Discoloration, Red, all lobes ::: Lung-Hemorrhage, alveolus, multifocal, mild
- Lymph Node, Mandibular-Discoloration, Red, right ::: Lymph Node, Mandibular-Sinus
- Erythrocytosis, minimal
- Spleen-Small ::: Spleen-Hypocellular, Lymphocyte, moderate
<table>
<thead>
<tr>
<th>Macroscopic Results</th>
<th>Microscopic Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thymus Small</td>
<td>Thymus Hypocellular, Lymphocyte, moderate</td>
</tr>
<tr>
<td>Duodenum</td>
<td>Vacuolation, Cytoplasm, epithelium, columnar, mucosa, minimal</td>
</tr>
<tr>
<td>Kidney</td>
<td>Mineralization, minimal</td>
</tr>
<tr>
<td>Liver</td>
<td>Inflammation, Subacute, portal, multifocal, mild</td>
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<tr>
<td>Lung</td>
<td>Infiltrate, Mononuclear Cell, minimal</td>
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<tr>
<td>Lymph Node, Mesenteric</td>
<td>Infiltrate, Macrophage, sinusoid, mild</td>
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<tr>
<td>Pancreas</td>
<td>Vacuolation, Cytoplasm, acinar cell, minimal</td>
</tr>
<tr>
<td>Spleen</td>
<td>Hypocellular, Lymphocyte, mild</td>
</tr>
<tr>
<td>Thymus</td>
<td>Hypocellular, Lymphocyte, moderate</td>
</tr>
</tbody>
</table>

The following organs were found to be Within Normal Limits:
- Bone Marrow, Sternum
- Brain: Cecum
- Colon: Heart
- Ileum: Jejunum
- Lymph Node, Mandibular
- Mammary Gland: Rectum
- Skin: Stomach

Macroscopic/Microscopic Correlations
- Thymus-Small:::Thymus-Hypocellular, Lymphocyte, moderate
Table Number: 3  
Individual Animal Data  
Study Number: QRX-12-S-111  
QRX Pharmaceuticals, Inc.  
Anytown, WA 9800X

Species: CD(SD): (CRL)  
Animal Number: 405  
Sex: Female  
Gp: (04) QRX-111, 100 mg/kg  
Fate: (TN) Terminal Necropsy  
Days on Study: 8

**Macroscopic Results**  
Lymph Node, Mandibular: Discoloration, Red, right  
Spleen: Small

**Microscopic Results**  
Duodenum: Vacuolation, Cytoplasm, epithelium, columnar, mucosa, minimal  
Kidney: Mineralization, minimal  
Liver: Inflammation, Subacute, portal, minimal  
Lung: Hemorrhage, multifocal, minimal  
Lymph Node, Mandibular: Sinus Erythrocytosis, minimal  
Pancreas: Vacuolation, Cytoplasm, acinar cell, minimal  
Spleen: Hypocellular, Lymphocyte, minimal  
Thymus: Hypocellular, Lymphocyte, mild

*The following organs were found to be Within Normal Limits:*  
Bone Marrow, Sternum: Bone, Sternum: Brain: Cecum: Colon: Heart: Ileum: Jejunum:  
Lymph Node, Mesenteric: Mammary Gland: Rectum: Skin: Stomach

**Macroscopic/Microscopic Correlations**  
Lymph Node, Mandibular-Discoloration, Red, right :: Lymph Node, Mandibular-Sinus Erythrocytosis, minimal  
Spleen-Small :: Spleen-Hypocellular, Lymphocyte, minimal
TABLE 4:

Tabulated Summary of Tissues Evaluated
### Tabulated Summary of Tissues Evaluated

**Study Number:** QRX-12-S-111  
**QRX Pharmaceuticals, Inc.**  
**Anytown, WA 9800X**

<table>
<thead>
<tr>
<th>Group</th>
<th>Sex</th>
<th>Animal Number</th>
<th>Organ Names</th>
<th>Sacrifice Type</th>
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**Nova Pathology Study Number NP-12-S-001**  
**Page 40 of 41**
<table>
<thead>
<tr>
<th>Group</th>
<th>Sex</th>
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<th>Organ Names Sacrifice Type</th>
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<td>Cecum</td>
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<td>F</td>
<td>3 4 5 1 2 3</td>
<td>Colon</td>
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<td>Duodenum</td>
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<td></td>
<td>0 0 0 0 0 0</td>
<td>Heart</td>
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