Whitehouse Laboratories
A Division of AMRI

Report of Analysis (Revised)

Client: Domino Amjet
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Lab Tracking #: 45291
Received On: 2/10/2017
Analysis Dates: 2/21/2017; 3/21/2017
Report Date: 2/23/2017
Revised Date: 3/24/2017
P.O. Number: 21897

Sample ID: Bottles with four ink types – 2BK106 Black Ink, 2BK124 Black Ink for Plastics, 1BK111 Black Ethanol Blend Ink, and 2CL158 Clear Fluorescent Low Transfer Fast Dry Ink

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Test Method: USP 39 / NF 34 Supplement 2 <661.2> Plastic Packaging Systems for Pharmaceutical Use – Physicochemical Tests

Reference Standard: Not Applicable

Test Result: See pages 2 – 7

Attachments: None

Comments: The sample meets USP 39 / NF 34 Supplement 2 requirements for the tests conducted. Report revised to include test results for Bottles 2 – 6. All additional samples meet USP 39 / NF 34 Supplement 2 requirements.

Laboratory Management Approval,

Date: 3/29/2017

Justine Young
Associate Director of Container Qualification

Quality Assurance Data Review,

Christine Paisker Date: 3/24/2017

Christine Paisker
Quality Assurance Manager

TEST RESULTS

USP <661.2> PHYSICOCHEMICAL TESTS

Bottle # 1:

Appearance

Result: *Solution C1* was clear and colorless.

Specification: *Solution C1* is clear and colorless.

Absorbance

Result: The maximum absorbance was 0.01.

Specification: The absorbance is NMT 0.20.

Total Organic Carbon

Result: The difference in TOC concentrations between *Solution C1* and a *suitable blank* was 1 mg/L.

Specification: The difference in TOC concentrations between *Solution C1* and a *suitable blank* is NMT 8 mg/L.

Acidity or Alkalinity

Result: The solution was *colorless* after the addition of phenolphthalein solution, *pink* after the addition of 0.01 N sodium hydroxide, and *orange-red* after the addition of 0.01 N hydrochloric acid and 0.1 mL of methyl red solution.

Specification: The solution is *colorless* after the addition of phenolphthalein solution, *pink* after the addition of 0.01 N sodium hydroxide, and *orange-red or red* after the addition of 0.01 N hydrochloric acid and 0.1 mL of methyl red solution.

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Test Results Continued onto Page 3...

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Test Results Continued from Page 2...

TEST RESULTS

USP <661.2> PHYSICOCHEMICAL TESTS

Bottle # 2:

Appearance

Result: *Solution C1* was clear and colorless.

Specification: *Solution C1* is clear and colorless.

Absorbance

Result: The maximum absorbance was 0.07.

Specification: The absorbance is NMT 0.20.

Total Organic Carbon

Result: The difference in TOC concentrations between *Solution C1* and a *suitable blank* was 1 mg/L.

Specification: The difference in TOC concentrations between *Solution C1* and a *suitable blank* is NMT 8 mg/L.

Acidity or Alkalinity

Result: The solution was *colorless* after the addition of phenolphthalein solution, *pink* after the addition of 0.01 N sodium hydroxide, and *orange-red* after the addition of 0.01 N hydrochloric acid and 0.1 mL of methyl red solution.

Specification: The solution is *colorless* after the addition of phenolphthalein solution, *pink* after the addition of 0.01 N sodium hydroxide, and *orange-red or red* after the addition of 0.01 N hydrochloric acid and 0.1 mL of methyl red solution.

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Test Results Continued onto Page 4...

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Test Results Continued from Page 3...

TEST RESULTS

USP <661.2> PHYSICOCHEMICAL TESTS

Bottle # 3:

Appearance

Result: *Solution C1* was clear and colorless.

Specification: *Solution C1* is clear and colorless.

Absorbance

Result: The maximum absorbance was 0.00.

Specification: The absorbance is NMT 0.20.

Total Organic Carbon

Result: The difference in TOC concentrations between *Solution C1* and a *suitable blank* was 1 mg/L.

Specification: The difference in TOC concentrations between *Solution C1* and a *suitable blank* is NMT 8 mg/L.

Acidity or Alkalinity

Result: The solution was *colorless* after the addition of phenolphthalein solution, *pink* after the addition of 0.01 N sodium hydroxide, and *orange-red* after the addition of 0.01 N hydrochloric acid and 0.1 mL of methyl red solution.

Specification: The solution is *colorless* after the addition of phenolphthalein solution, *pink* after the addition of 0.01 N sodium hydroxide, and *orange-red or red* after the addition of 0.01 N hydrochloric acid and 0.1 mL of methyl red solution.

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Test Results Continued onto Page 5...

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Test Results Continued from Page 4...

TEST RESULTS

USP <661.2> PHYSICOCHEMICAL TESTS

Bottle # 4:

Appearance

Result: *Solution C1* was clear and colorless.

Specification: *Solution C1* is clear and colorless.

Absorbance

Result: The maximum absorbance was 0.01.

Specification: The absorbance is NMT 0.20.

Total Organic Carbon

Result: The difference in TOC concentrations between *Solution C1* and a *suitable blank* was 1 mg/L.

Specification: The difference in TOC concentrations between *Solution C1* and a *suitable blank* is NMT 8 mg/L.

Acidity or Alkalinity

Result: The solution was *colorless* after the addition of phenolphthalein solution, *pink* after the addition of 0.01 N sodium hydroxide, and *orange-red* after the addition of 0.01 N hydrochloric acid and 0.1 mL of methyl red solution.

Specification: The solution is *colorless* after the addition of phenolphthalein solution, *pink* after the addition of 0.01 N sodium hydroxide, and *orange-red or red* after the addition of 0.01 N hydrochloric acid and 0.1 mL of methyl red solution.

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Test Results Continued onto Page 6...

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Test Results Continued from Page 5...

TEST RESULTS

USP <661.2> PHYSICOCHEMICAL TESTS

Bottle # 5:

Appearance

Result: *Solution C1* was clear and colorless.

Specification: *Solution C1* is clear and colorless.

Absorbance

Result: The maximum absorbance was 0.01.

Specification: The absorbance is NMT 0.20.

Total Organic Carbon

Result: The difference in TOC concentrations between *Solution C1* and a *suitable blank* was 1 mg/L.

Specification: The difference in TOC concentrations between *Solution C1* and a *suitable blank* is NMT 8 mg/L.

Acidity or Alkalinity

Result: The solution was *colorless* after the addition of phenolphthalein solution, *pink* after the addition of 0.01 N sodium hydroxide, and *orange-red* after the addition of 0.01 N hydrochloric acid and 0.1 mL of methyl red solution.

Specification: The solution is *colorless* after the addition of phenolphthalein solution, *pink* after the addition of 0.01 N sodium hydroxide, and *orange-red or red* after the addition of 0.01 N hydrochloric acid and 0.1 mL of methyl red solution.

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Test Results Continued onto Page 7...

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Test Results Continued from Page 6...

TEST RESULTS

USP <661.2> PHYSICOCHEMICAL TESTS

Bottle # 6:

Appearance

Result: *Solution C1* was clear and colorless.

Specification: *Solution C1* is clear and colorless.

Absorbance

Result: The maximum absorbance was 0.01.

Specification: The absorbance is NMT 0.20.

Total Organic Carbon

Result: The difference in TOC concentrations between *Solution C1* and a *suitable blank* was 1 mg/L.

Specification: The difference in TOC concentrations between *Solution C1* and a *suitable blank* is NMT 8 mg/L.

Acidity or Alkalinity

Result: The solution was *colorless* after the addition of phenolphthalein solution, *pink* after the addition of 0.01 N sodium hydroxide, and *orange-red* after the addition of 0.01 N hydrochloric acid and 0.1 mL of methyl red solution.

Specification: The solution is *colorless* after the addition of phenolphthalein solution, *pink* after the addition of 0.01 N sodium hydroxide, and *orange-red or red* after the addition of 0.01 N hydrochloric acid and 0.1 mL of methyl red solution.

******End of Report******

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