

TEST ARTICLE NAME

Analytica AutoStart 150mL Burette

TEST ARTICLE IDENTIFICATION

Lot: 20080909

TEST ARTICLE RECEIVED

September 15, 2008

SPONSOR

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STUDY TITLE

Chemical Testing per ISO 8536-5 for Burette Infusion Sets

RESULTS

Test	Result	Limit	Met/Did Not Meet Limit
Reducing (oxidizable matter)	Total amount of potassium permanganate used was 0.080 mL	Total amount of potassium permanganate used shall not exceed 2.0 mL	Met
Titration acidity or alkalinity	0.1 mL of 0.01 M hydrochloric acid was used change the indicator color to gray	≤ 1 mL of 0.01M hydrochloric acid is used to change the indicator color to gray	Met
Residue on evaporation	<1 mg	≤5 mg	Met
UV absorption of extract solution	<0.025 absorbance for S1	<0.1 absorbance for S1	Met
Metal Ions			
Barium	<0.050 µg/mL	≤1 µg/mL	Met
Chromium	<0.050 µg/mL	≤1 µg/mL	Met
Copper	<0.050 µg/mL	≤1 µg/mL	Met
Lead	<0.050 µg/mL	≤1 µg/mL	Met
Tin	<0.050 µg/mL	≤1 µg/mL	Met
Cadmium	<0.050 µg/mL	≤0.1 µg/mL	Met
Heavy Metals	Test solution did not exceed that of the standard matching solution	Test solution does not exceed that of the standard matching solution	Met

CONCLUSION


The test material met the limits for ISO 8536-5 for Burette Infusion Sets.

METHOD

The standard procedure for ISO 8536-5 for Burette Infusion Sets was followed.

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other samples is the sponsor's responsibility. All procedures were conducted in conformance with good manufacturing practices and certified to ISO 13485:2003.

APPROVAL


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11-14-08
Date