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Confidential report for:

Campden BRI

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Report on:

Examination of a Capsule Reported from Elderflower water

Work performed by Campden BRI (Chipping Campden) Limited

Report number: EM/REP/181302-06635/3 ♦ Issue date: 1st February 2018

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Our ref: Capsule Report

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SAMPLE DETAILS

Purchase Order No.: 12345678910

SAMPLE INFORMATION

Date sample(s) received : 20th February 2018
Packaging : In original bottle
Storage conditions : Ambient Temperature
Date(s) sample(s) examined : 22nd-23rd February 2018

METHODS AND REFERENCES

Analyst reference : GED, RJL
Method reference(s) : TES-AC-192 : Light Stereomicroscopy
TES-AC-193 : Compound Light Microscopy
TES-AC-385 : Fourier Transform Infrared Spectroscopy
N/A : Perkin Elmer Axion Direct Sample Analysis (DSA) System and Perkin Elmer Axion 2 Time of Flight Mass Spectrometry (TOF-MS).
Deviations from the method reference(s) : None

RESULTS

The complaint sample consisted of a pre-opened bottle of elderflower water, which was reported to contain a capsule. The capsule was removed from the bottle, decanted into a glass beaker and photographed which can be referred to in Plate 1.

On visual inspection it was possible to see numerous light brown/cream coloured spansules and the remains of a bright yellow coloured capsule casing settled at the bottom of the bottle (refer to Plate 1). The liquid itself had a green/yellow tinge, considered most likely to have resulted from the colouring of the capsule casing leaching out. Approximately 200ml of the liquid remained in the bottle.

The remains of the capsule were removed from the liquid for examination under the stereo microscope (Plate 2). Here the capsule casing was seen to have softened considerably and the spansules were of variable sizes and shapes (some had a deflated appearance). No markings were present on the capsule casing to assist in identification.

A section of the capsule casing was examined under the compound microscope. Here it was seen to have a speckled appearance and stained positively for the presence of protein following the addition of eosin solution (Plate 3). A couple of the spansules were also examined under the compound microscope. Here they were seen to contain maize starch, a commonly used excipient/bulking agent in tablets and capsules (Plate 4).

FT-IR spectroscopy was performed on both the capsule casing and the spansules. A good match in the reference libraries was found with gelatine for the capsule casing (Figure 1), however a match to an active ingredient could not be obtained for the spansules.

The sample was analysed using Perkin Elmer Axion Direct Sample Analysis (DSA) System and Perkin Elmer Axion 2 Time of Flight Mass Spectrometer (TOF-MS). Analysis of the complaint sample found a number of groups of peaks of potential interest present. It was possible to identify one of these groups as an intermediate of Omeprazole.

Following this analysis, a sample of a known omeprazole was analysed in a similar manner to the complaint sample. Very similar results to those of the complaint sample were achieved for the Omeprazole capsule contents and at similar relative levels.

CONCLUSIONS

It was concluded that the complaint sample was the remains of an Omeprazole capsule. Omeprazole is prescribed to treat reflux oesophagitis, stomach ulcers and to relieve heartburn and indigestion. It works by reducing the amount of acid in the stomach and can also fight against infection by *Helicobacter pylori*, which can cause stomach ulcers.

PLATE 1 Shows the remains of the capsule settled at the bottom of the bottle of elderflower water (top and middle) and decanted into a glass beaker (bottom). Note the yellow/green tinge of the liquid

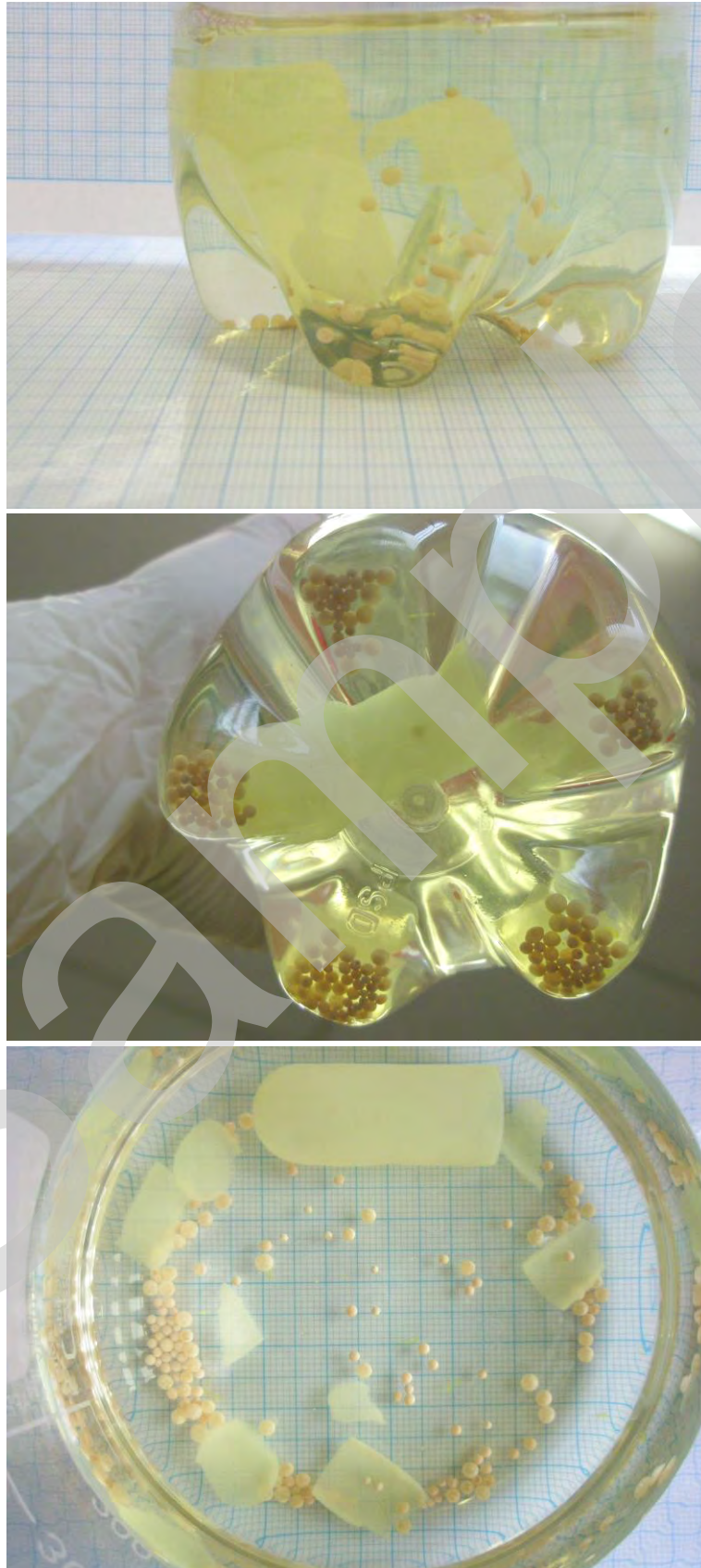
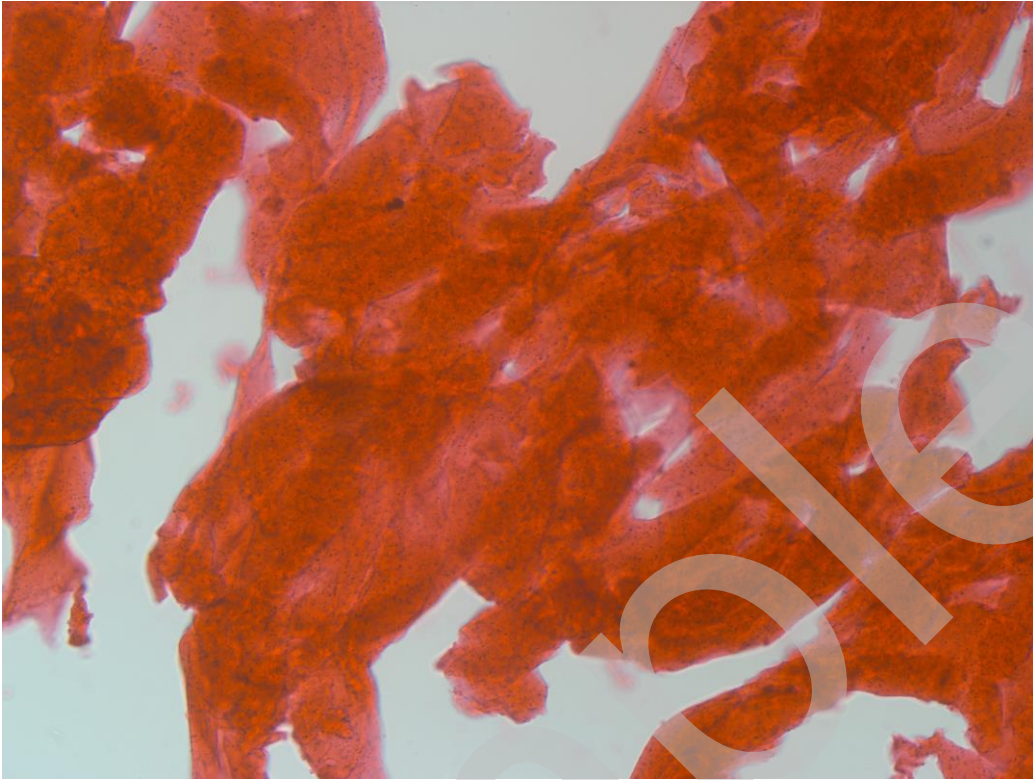


PLATE 2 Shows the remains of the capsule on a glass Petri dish (top) and the variable sizes and shapes of the spansules (bottom), both photographed against a millimetre-squared background



PLATE 3 Shows a section of the capsule casing stained positively for the presence of protein with eosin solution. Magnification x 220



Sample

PLATE 4 Shows some of the maize starch granules present in the spansules, as viewed under bright field light (top) and under polarised light (bottom). Magnification x 220

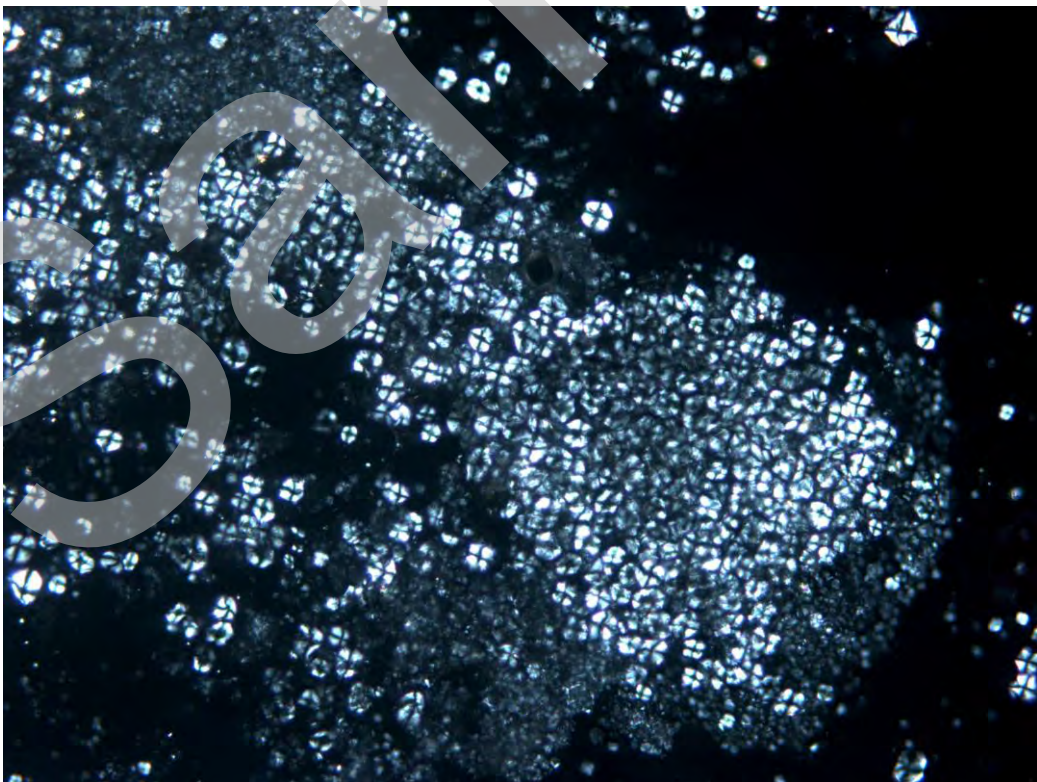
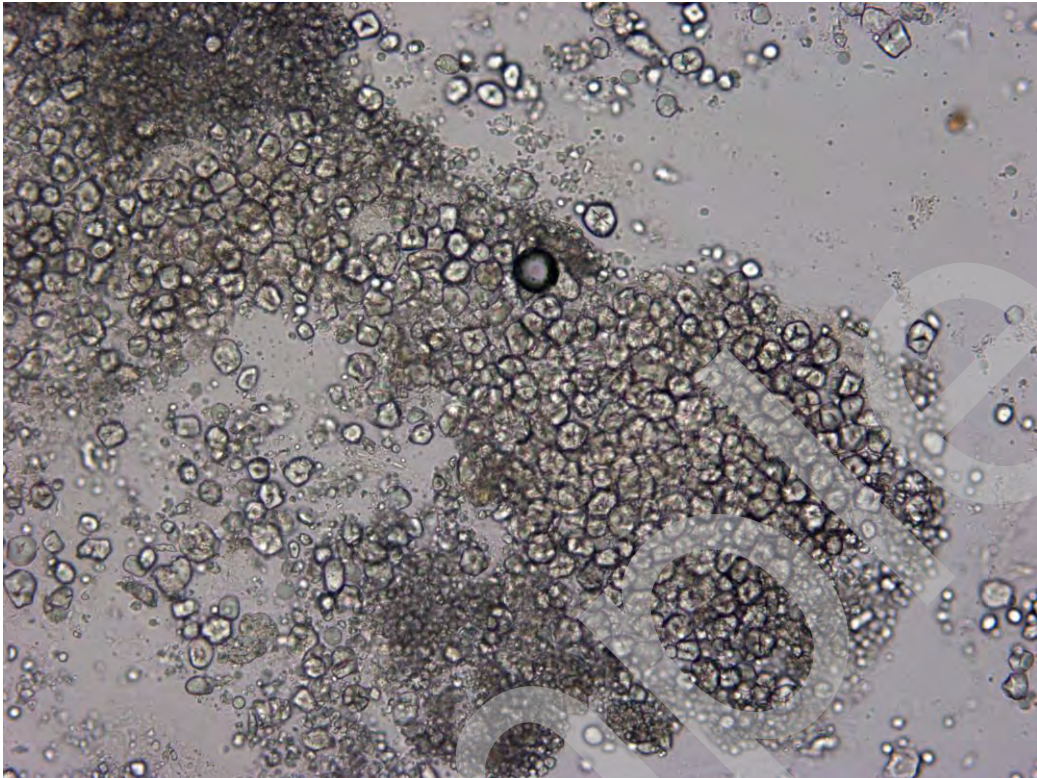
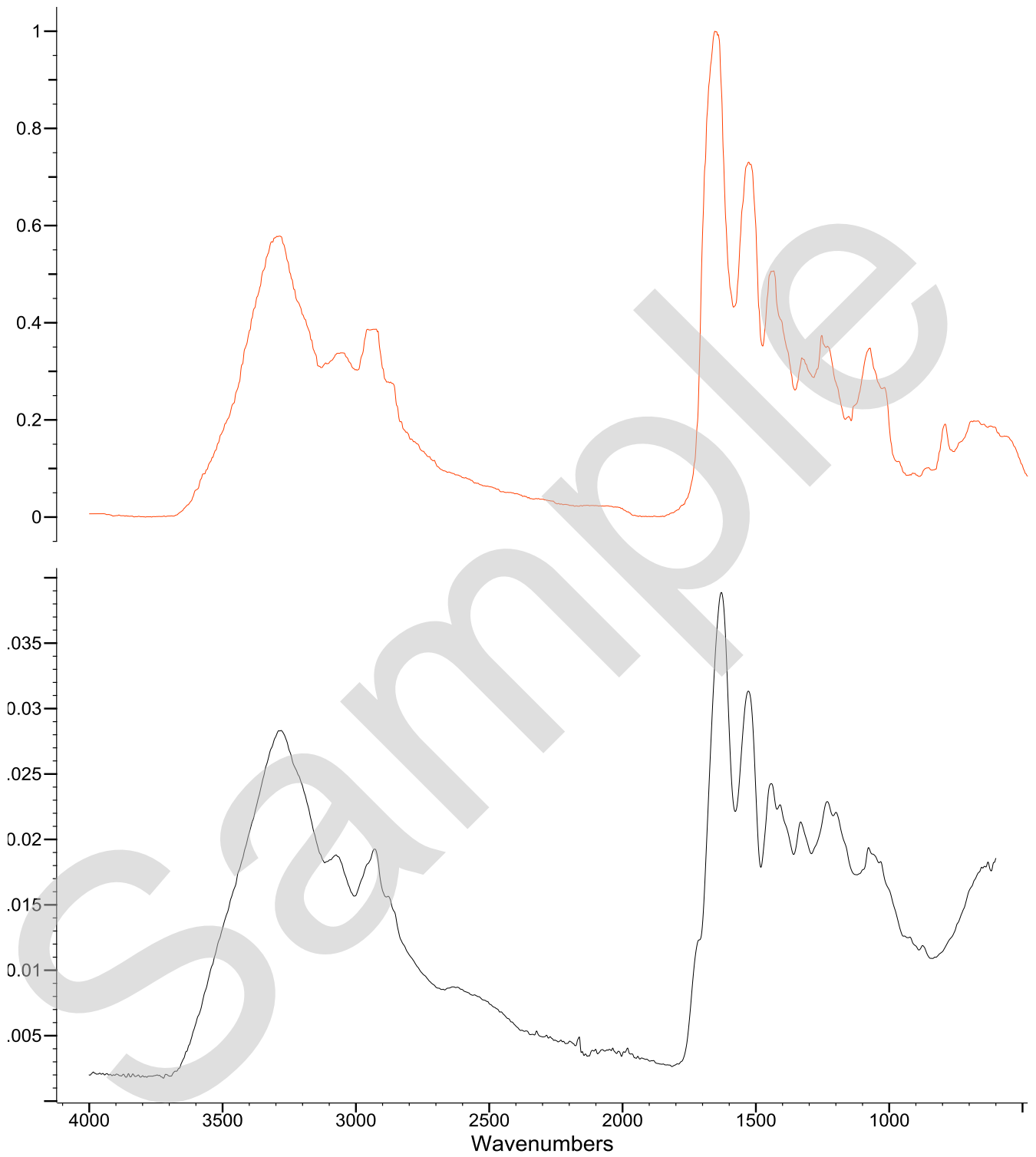


FIGURE 1

Foreign Body Analysis for CampdenBRI



Top spectrum : Gelatine
Bottom spectrum : Complaint Sample