

Linking 3DP manufacturing with SIFT-MS Volatiles Organic Compound Analysis

Elke Prasad^a, Ecaterina Bordos^a, Vaughan Langford^b, Mark Perkins^c, John Robertson^a, Gavin W. Halbert^a

^a CMAC, University of Strathclyde, Glasgow, UK

^b Syft-Technologies, ^c Element Materials Technology

CONTACT INFORMATION: elke.prasad@strath.ac.uk



PURPOSE

3D printing (3DP) oral solid dose forms by Fused Filament Fabrication has gained increased interest in recent years. To facilitate efficient formulation and process development, some studies developed and implemented rheological and mechanical screening tests [1-3]. However, changes in the formulated polymeric system due to processing at elevated temperatures and shear have not been addressed. In this study, SIFT-MS Volatiles Organic Compound Analysis was employed to monitor a 3DP manufacturing process.

OBJECTIVE(S)

To monitor volatile organic compounds during a material extrusion 3D printing process.

METHOD(S)

A 50% w/w Paracetamol formulation in Co-povidone (Plasdone™ S-630, Ashland) was processed at 130°C with a linear printing speed of 40 mm/s on a filament free 3D printer (Intellectual Property Office UK, patent application number 2101534.2). The tablet weight over time was monitored during the manufacturing process. SIFT-MS analysis mass scan from 15 - 400 m/z employing H30+, NO+ and O2+ reagents was performed during the manufacturing process on volatiles extracted from the vent port of the Hot-Melt-Extruder of the 3D printer.

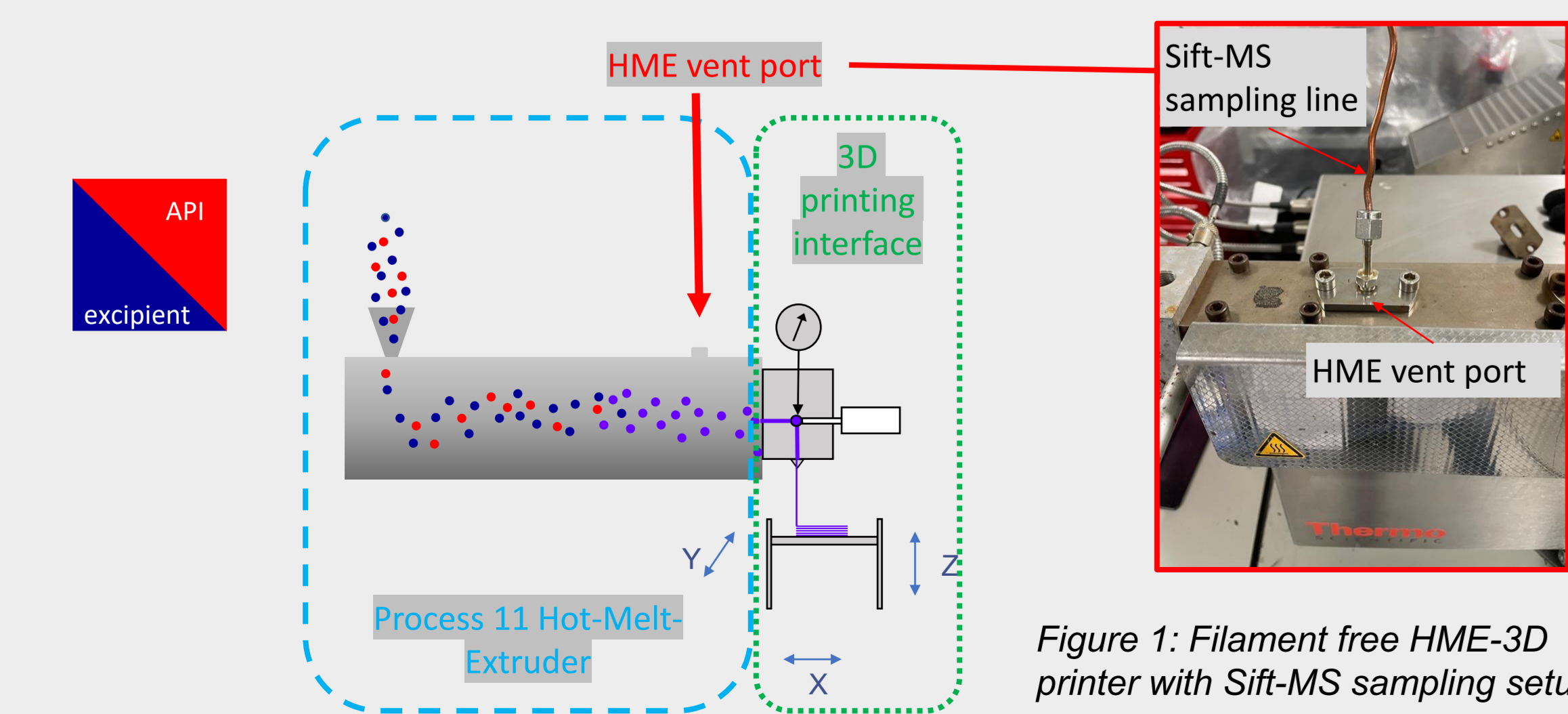


Figure 1: Filament free HME-3D printer with Sift-MS sampling setup.

RESULT(S)

- Weight increase of 50% w/w Paracetamol - Plasdone S-630™ 3D printed tablets after 16 prints (Figure 1)
- SIFT-MS VOC analysis monitored changes in volatile organic compounds over time exiting the HME vent port (Figure 4A – 6B)
- PCA analysis on sampling interval datapoints showed a clear difference of sampling interval G1 to all other sampling intervals (G2 – G 5) (Figure 4B-6B).
- Further studies are required to identify these products, the associated changes in the polymer system and the impact of manufacturing process conditions on these.

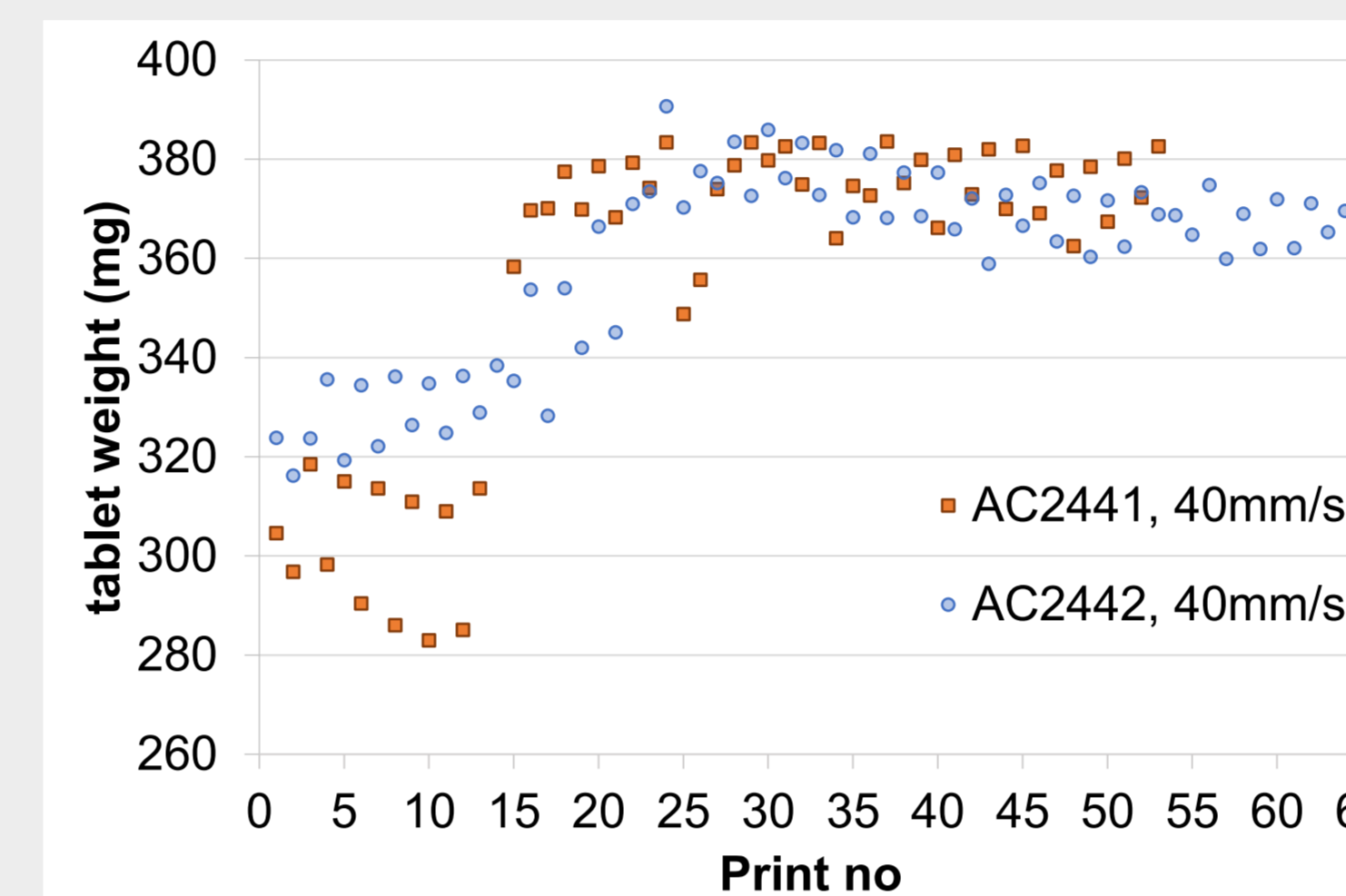
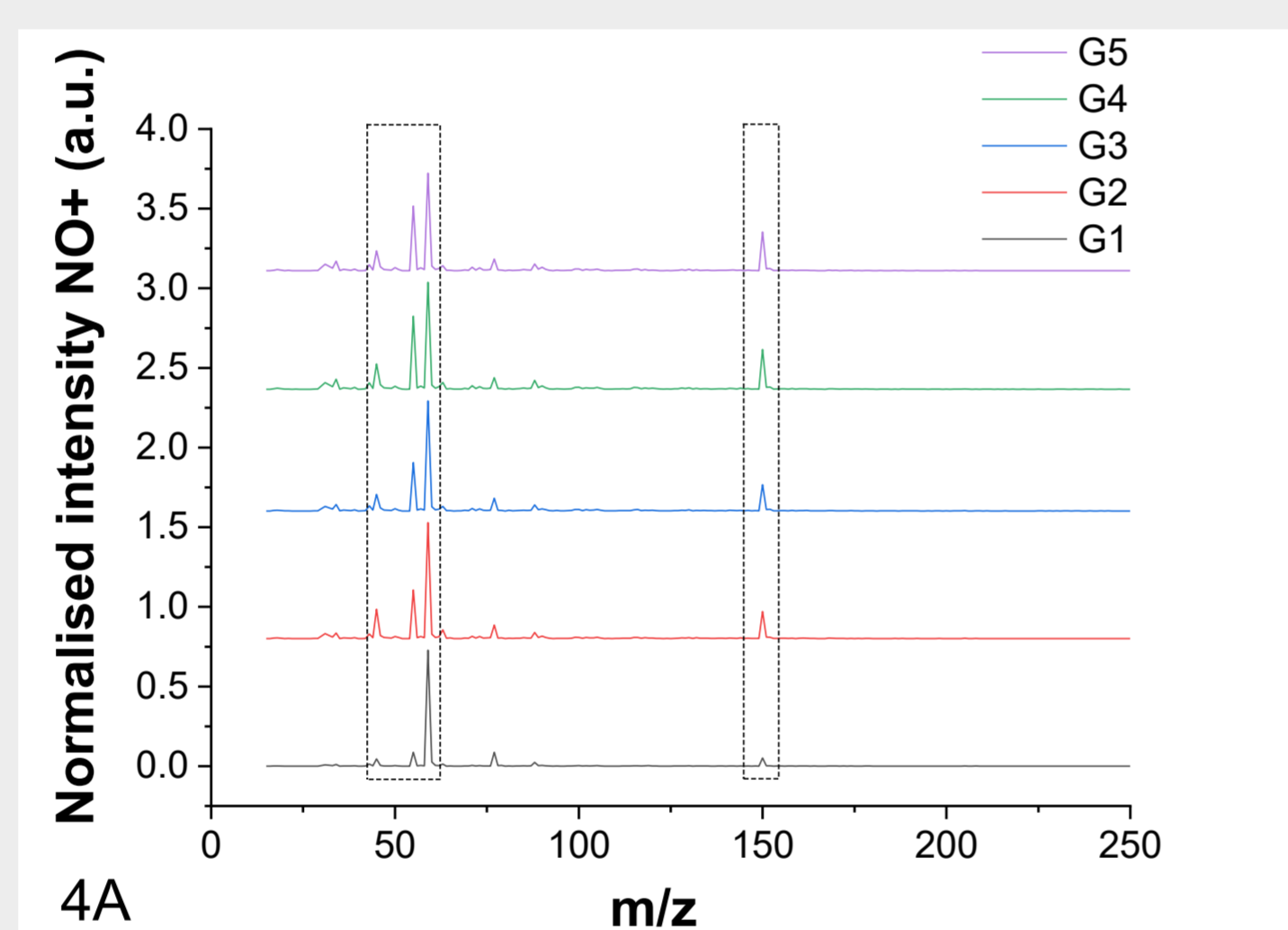


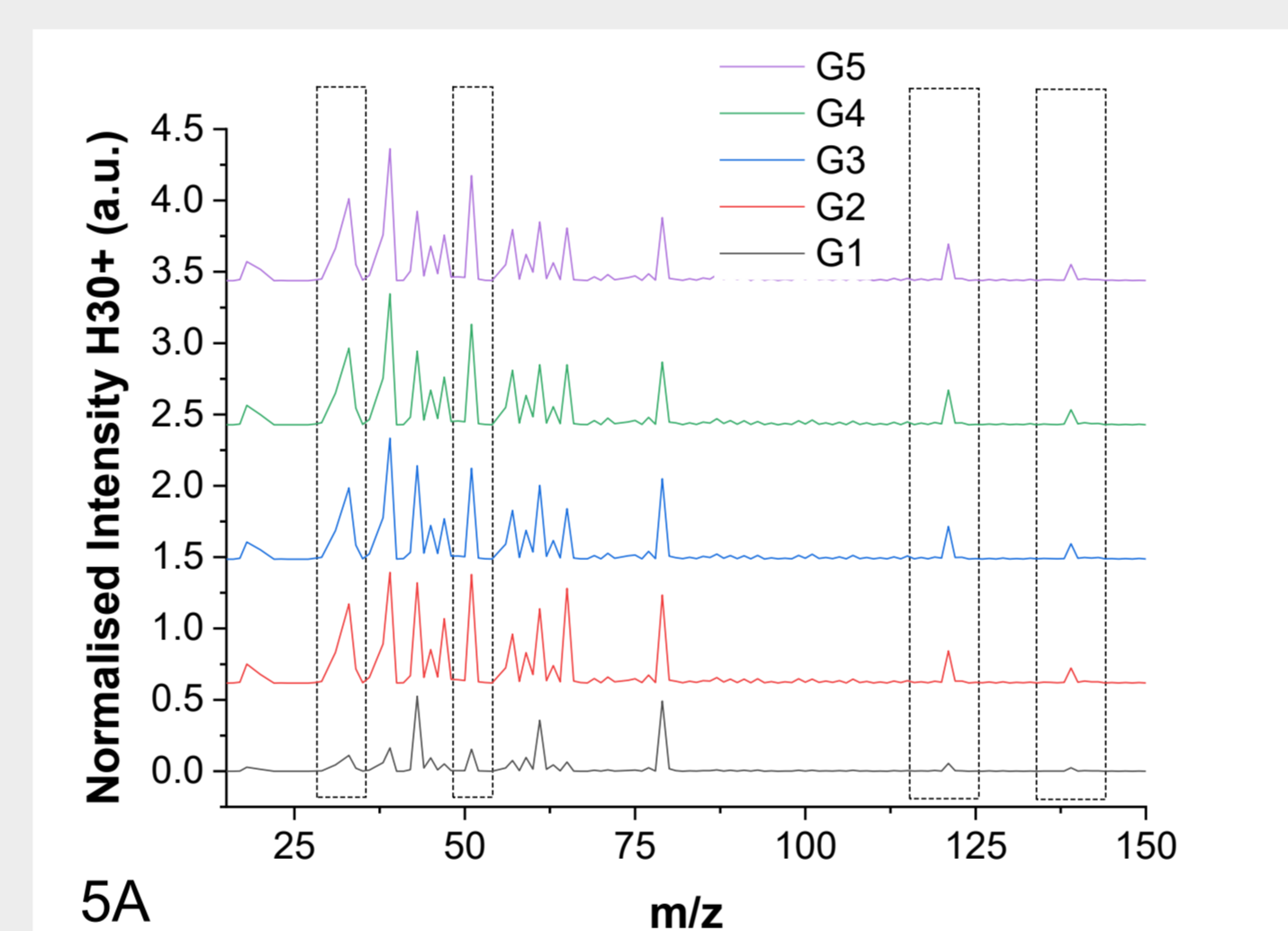
Figure 2: 3DP Tablet weight versus number of prints of a 50 % w/w PCM-Plasdone™ S-630 formulation processed at 130 °C and linear print speed of 40 mm/s: orange squares – manufacture run 1, blue circles – manufacture run 2.



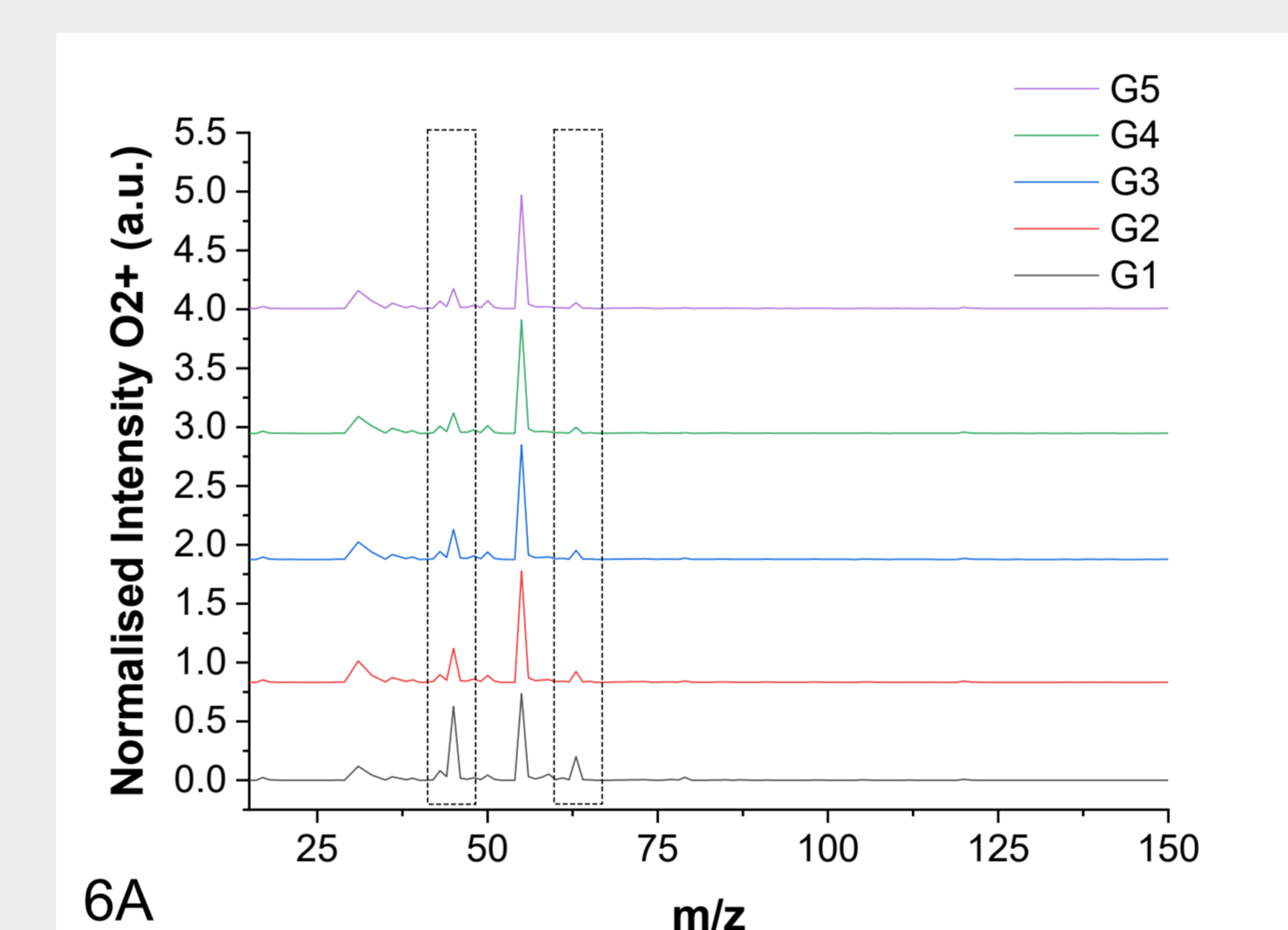
Figure 3: Voice200Ultra, Syft Technologies.



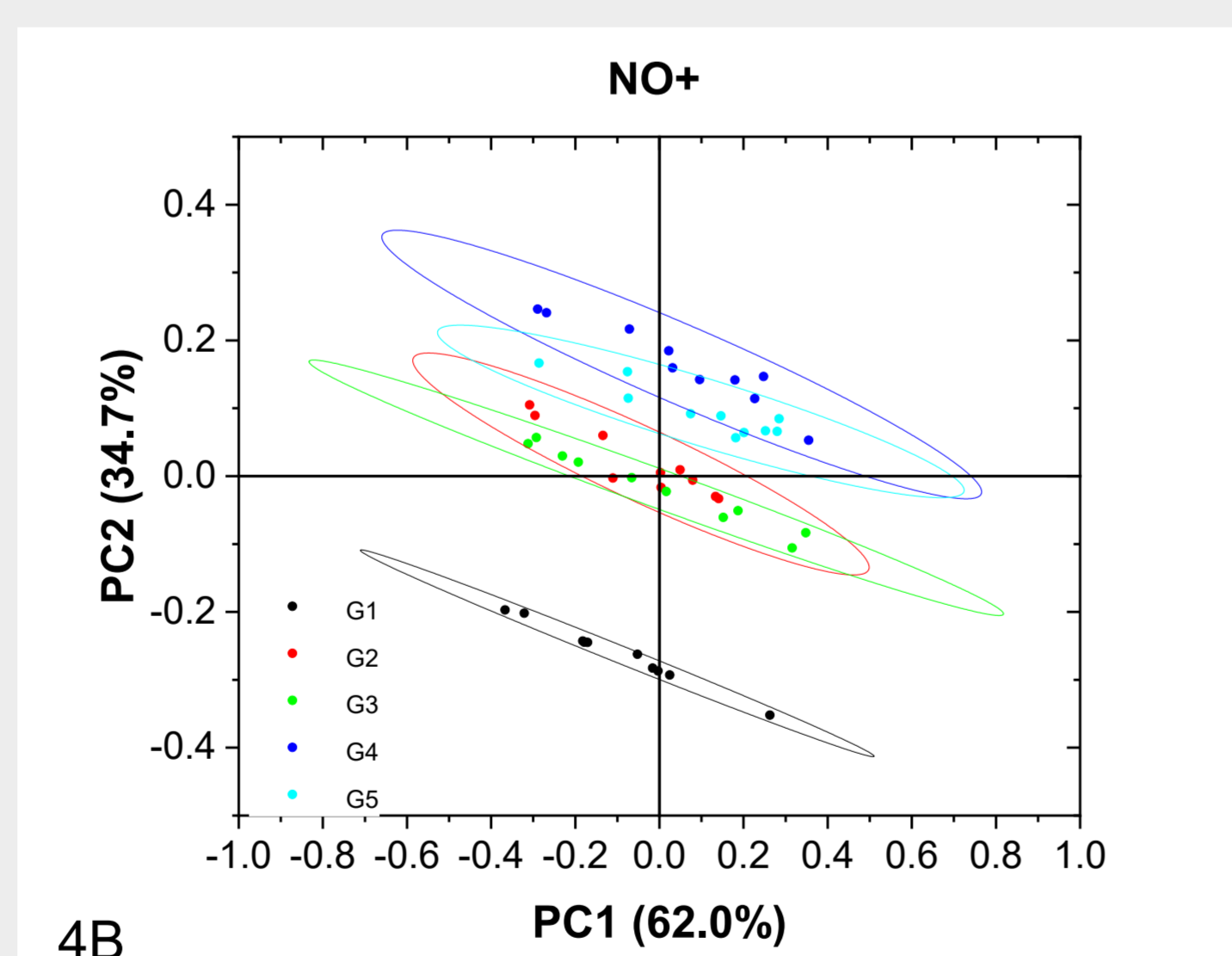
4A



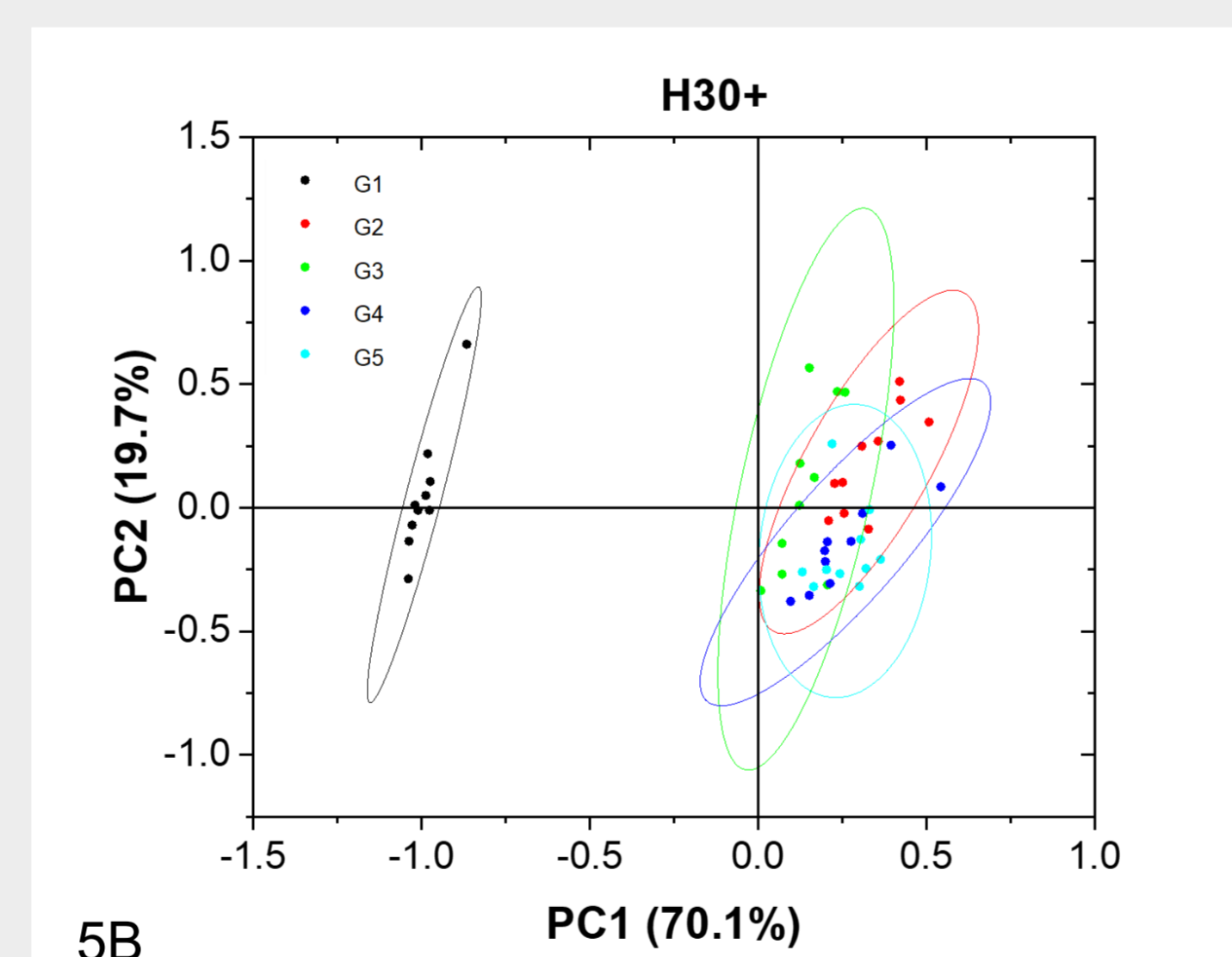
5A



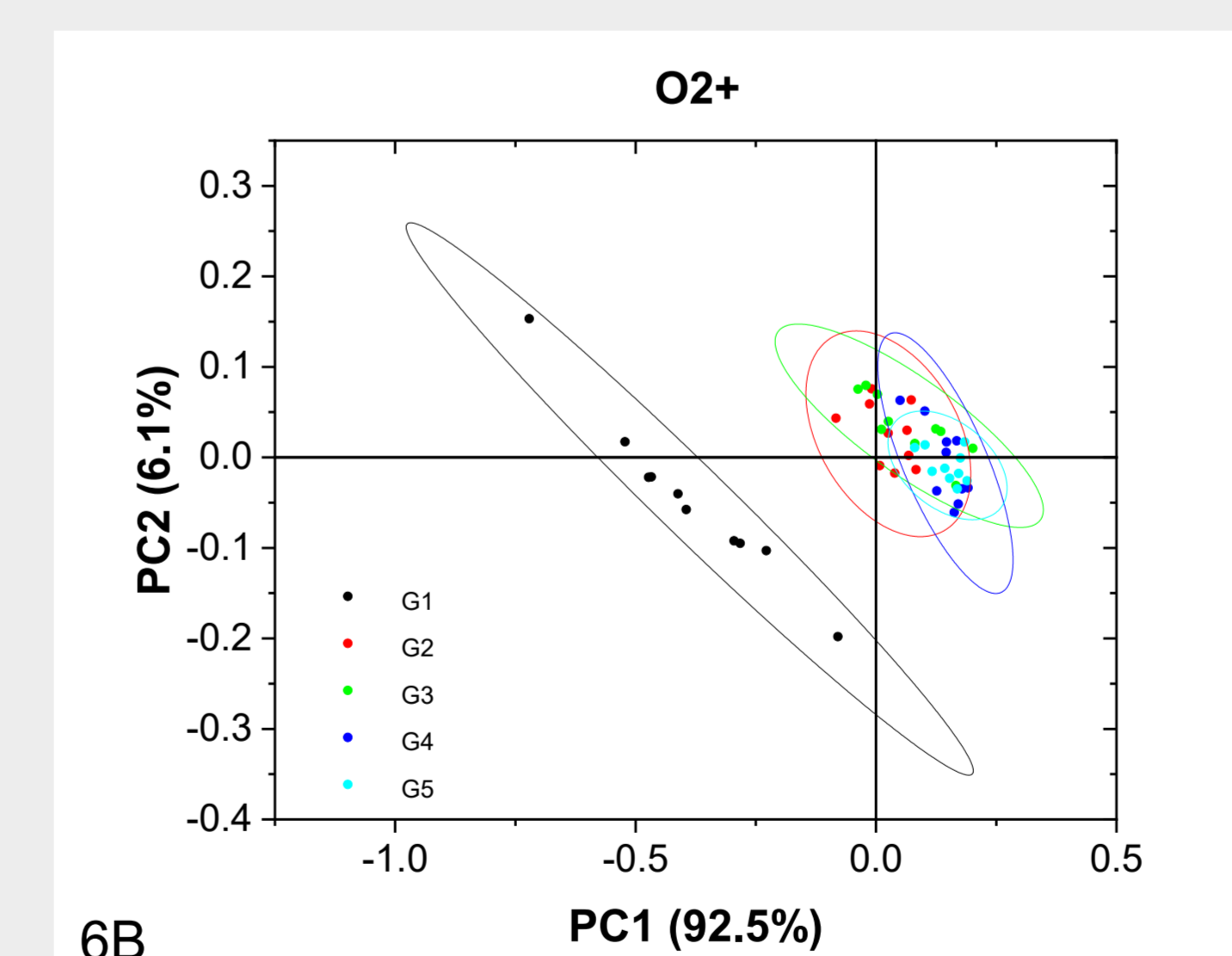
6A



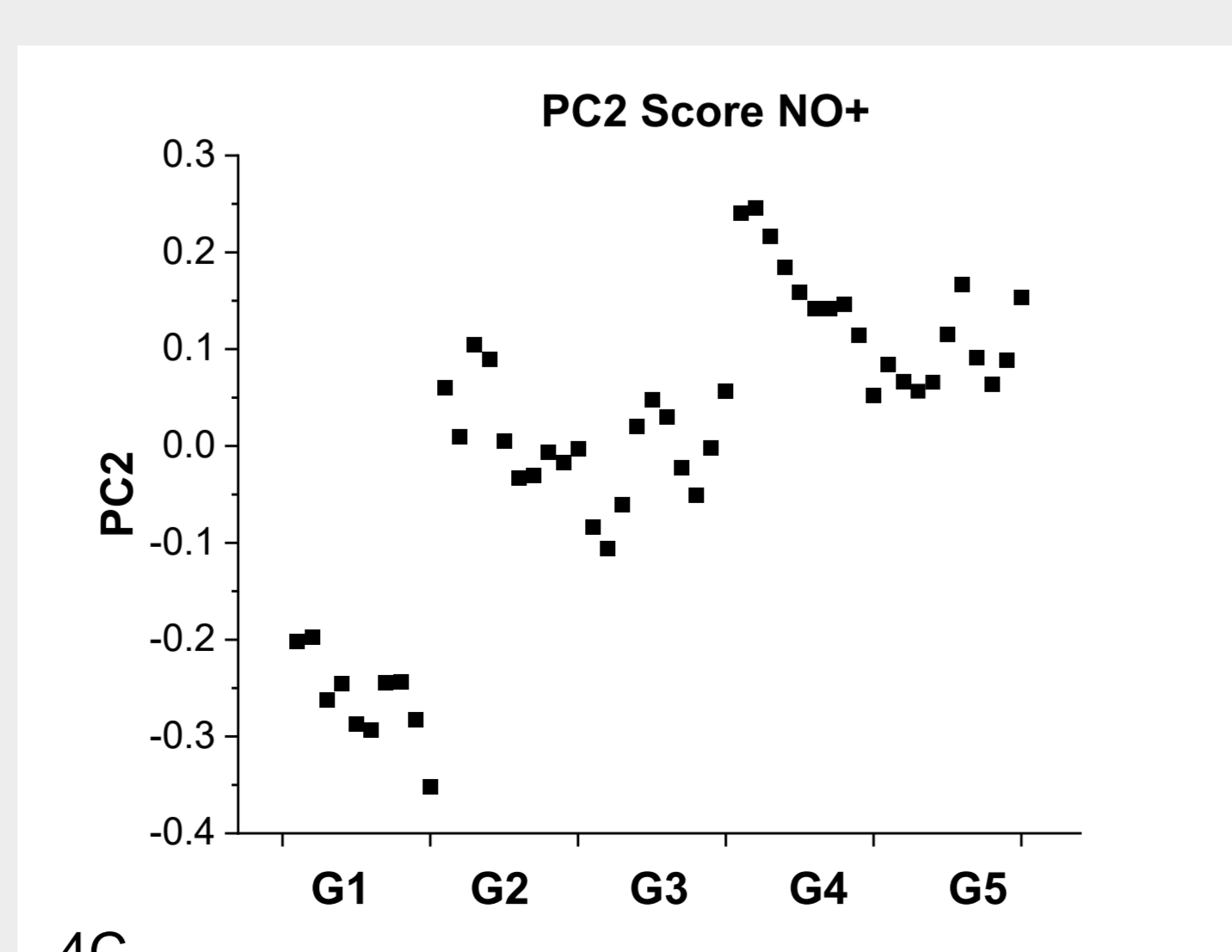
4B



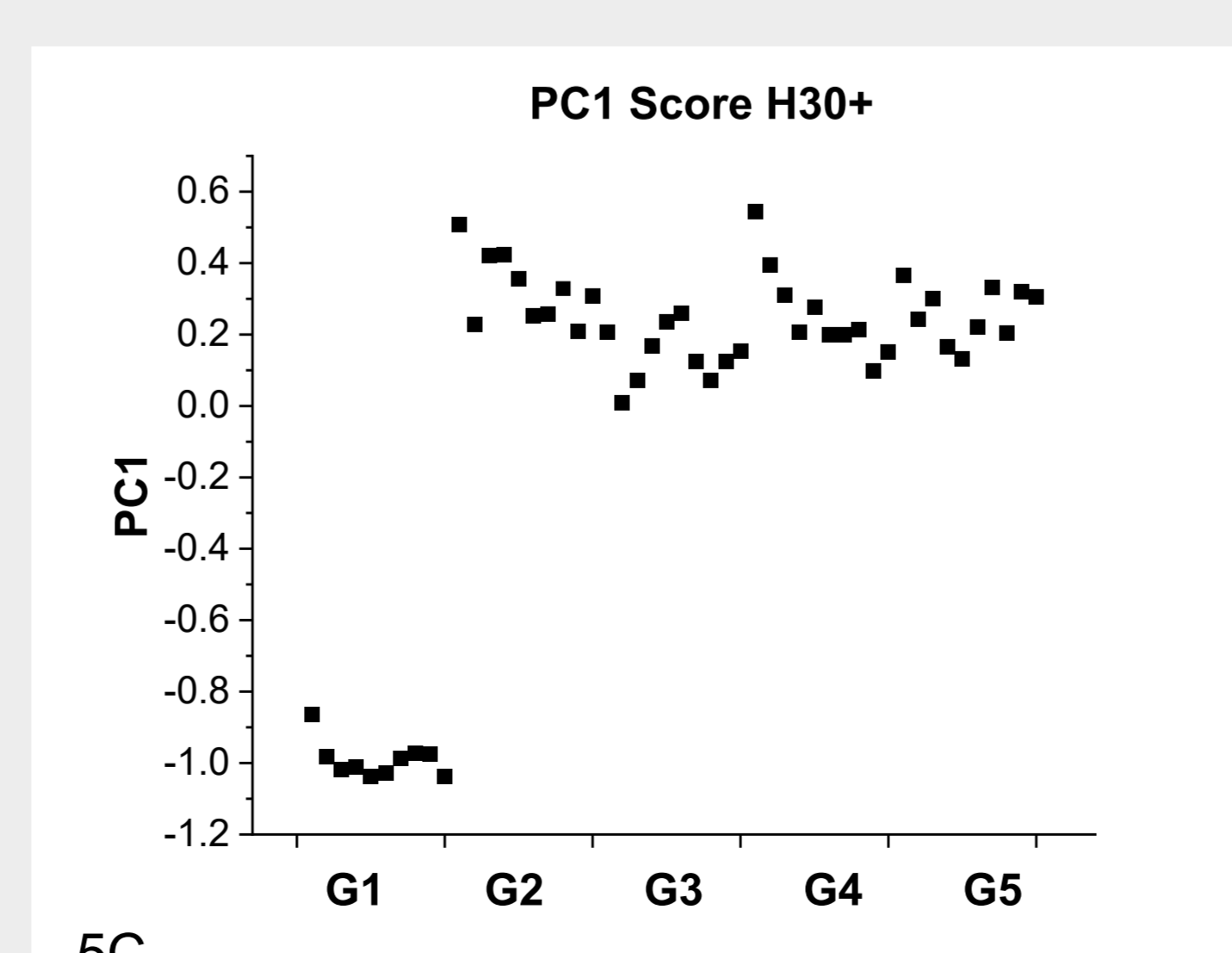
5B



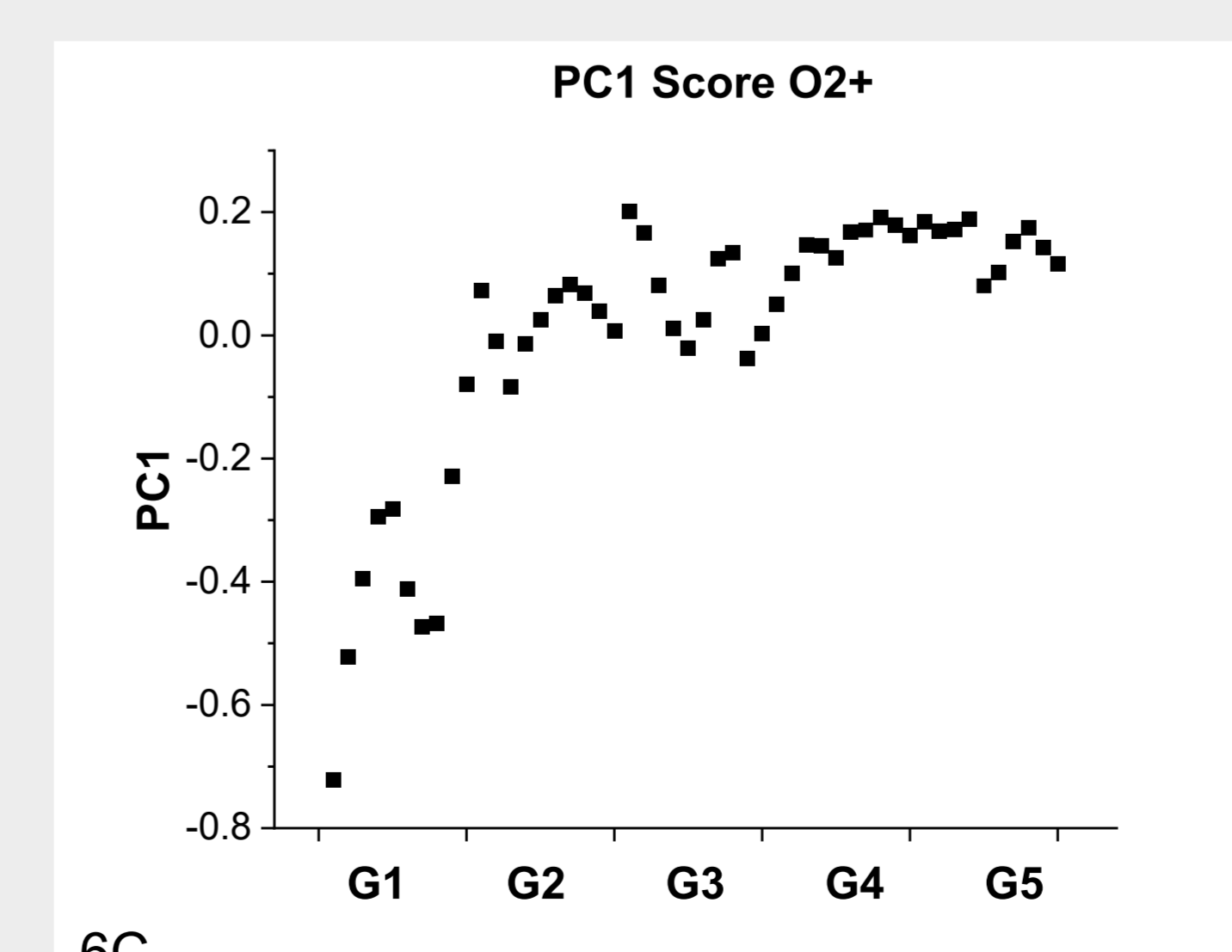
6B



4C



5C



6C

Figure 4: SIFT-MS mass scan NO+ reagent (n=10): A) Intensity versus m/z ratio. Sampling intervals: G1, G2, G3, G4, G5; B) PCA score plot PC1 versus PC2; C) PC2 score versus sampling interval G1-G5.

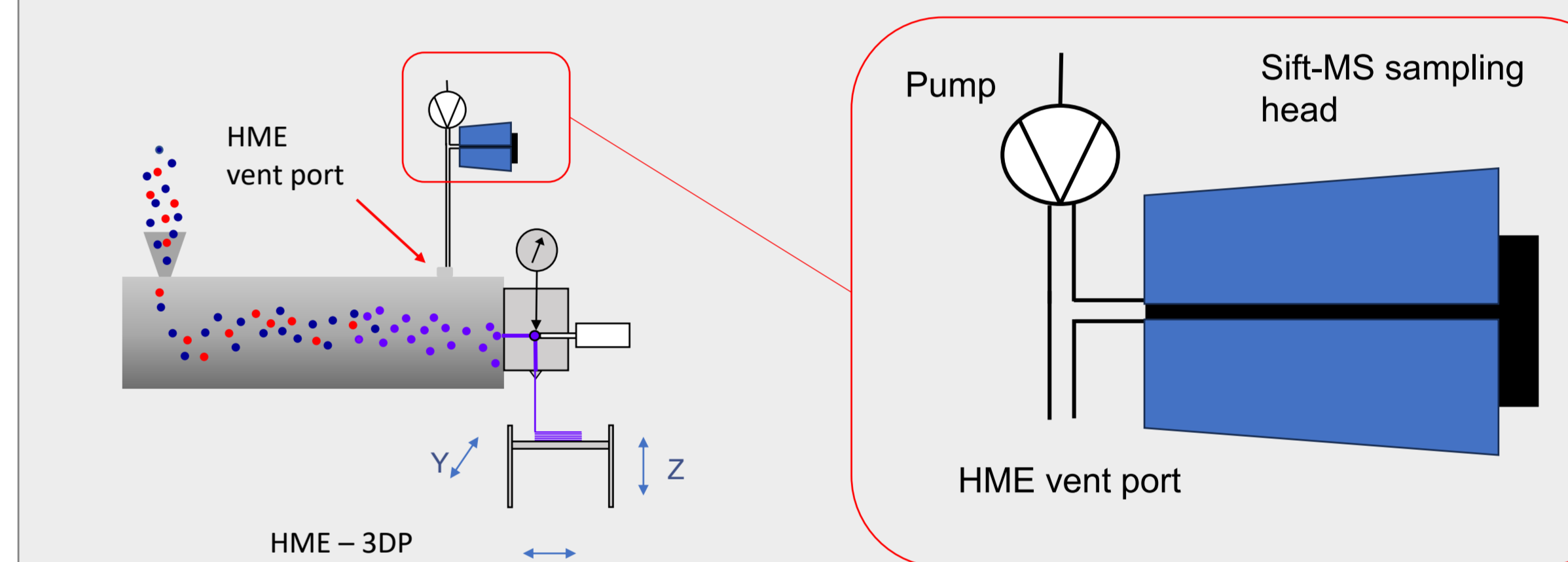
Figure 5: SIFT-MS mass scan H30+ reagent (n=10): A) Intensity versus m/z ratio. Sampling intervals: G1, G2, G3, G4, G5; B) PCA score plot PC1 versus PC2; C) PC2 score versus sampling interval G1-G5.

Figure 6: SIFT-MS mass scan O2+ reagent (n=10): A) Intensity versus m/z ratio. Sampling intervals: G1, G2, G3, G4, G5; B) PCA score plot PC1 versus PC2; C) PC1 score versus sampling interval G1-G5.

CONCLUSION(S)

SIFT-MS analysis of a 3DP manufacturing process related a change in volatile organic compounds profile to changes in weight of the final pharmaceutical product.

FUTURE WORK



FUNDING/GRANT/ENCORE/REFERENCE OR OTHER USE

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