



Figure 4. Chromatogram and spectrum of formaldehyde peak in sample.

Conclusion

This application note presents a simple and effective method for the determination of formaldehyde in pharmaceutical excipients using SHS-GC/MS. The method is fast, reliable and can be used for the quantification of low-molecular-weight aldehydes in most excipients commonly used in pharmaceutical products. Excellent quantification and linear instrument response was reported across a 1 to 50 ppb concentration range of formaldehyde. The method was validated using several samples obtained from a local pharmaceutical company and observed recovery values were all between 80-120%. By combining GC with MS, formaldehyde oxime was identifiable not only through retention time matching but by the resulting mass spectrum, which was confirmed by library search.

References

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