Journal of Chromatography, 477 (1989) 474–476
Elsevier Science Publishers B.V., Amsterdam — Printed in The Netherlands

CHROM. 21 566

Note

Quantitation of polydimethylsiloxane in pharmaceutical formulations by gel permeation chromatography

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(First received January 16th, 1989; revised manuscript received April 12th, 1989)

The analysis and quantitation of polydimethylsiloxane are routinely performed by infrared (IR) spectroscopy[1]. If the matrix is simple, reliable and straightforward results are generated. However, quantitation of polydimethylsiloxane in emulsions and oral suspensions requires careful sample handling and extensive background subtraction of the sample matrix[2,3].

For example, Fourier transform infrared (FTIR) spectroscopy has been used for the quantitation of dimethicone (a mixture containing polydimethylsiloxane and silicon dioxide) in lotions[3]. Despite the use of liquid–liquid extraction followed by column liquid–solid extraction prior to the FTIR analysis and matrix subtraction, a slightly positive bias due to matrix interference was obtained.

The molecular weight distribution of polysiloxane is commonly assessed by gel permeation chromatography (GPC) utilizing refractive index (RI) detection[4–6]. This technique, despite its selectivity for large molecules, has not been extensively used for quantitation of macromolecules. In this paper the usefulness of GPC-RI together with a simple work-up procedure for the quantitation of polidimethylsiloxane (PDMS) in complex matrices as emulsions is described.

EXPERIMENTAL

Chemicals

Chloroform, dichloromethane, *n*-hexane, toluene and methyl isobutyl ketone were of LiChrosolv or analytical grade (Merck, Darmstadt, F.R.G.).

As a standard, Antifoam M (Dow Corning, Glamorgan, U.K.) was used. The amount of PDMS in this standard was determined by IR spectroscopy[1].

Apparatus

The liquid chromatograph consisted of a Shimadzu LC-pump (Model LC-3A, Shimadzu, Kyoto, Japan) with a Shimadzu autoinjector (Model SIL-6A) and an ERMA refractive index detector (Model ERC-7512; Erma, Tokyo, Japan). A Shimadzu, Model C-R3A integrator was used.

Sample preparation

An 100 ± 10 mg emulsion was accurately weighed and dissolved in 10.0 ml

0021-9673/89/$03.50