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Accession Number : ADA457188

Title : Enhancement of an Analytical Method for the Determination of Squalene in Anthrax Vaccine Absorbed Formulations

Descriptive Note : JOurnal article

Corporate Author : SRI INTERNATIONAL MENLO PARK CA

Personal Author(s) : Spanggord, Ronald J ; Sun, Meg ; Lim, Peter ; Ellis, William Y

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Abstract : Specific lots of anthrax vaccine adsorbed administered to members of the U.S. Armed Forces have been alleged to contain squalene, a chemical purported to be associated with illnesses of Gulf War veterans. A method of enhanced sensitivity for determining squalene in anthrax vaccine adsorbed using high-performance liquid chromatography with photodiode array detection has been developed, validated, and applied to 44 bottles of 38 lots of anthrax vaccine. In 43 bottles of 37 lots, no squalene was detected within a detection limit of 1 ng/0.5 ml dose (2 parts-per-billion). One lot, FAV008, was found to contain trace amounts of squalene at 7, 9, and 1 microgram 1(exp-1) 1, levels considerably below normal human plasma levels (290 microngram 1(exp-1)). The overall results of this investigation provide direct evidence for the absence of squalene in nearly all of anthrax vaccine preparations tested.

Descriptors : *LIQUID CHROMATOGRAPHY , *ANTHRAX , *FORMULATIONS(CHEMISTRY) , *VACCINES , REPRINTS , WARFARE , GULFS , ADSORBATES , PHOTODIODES , DETECTION , PREPARATION , PERFORMANCE(ENGINEERING) , ARRAYS

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