

## Accepted Manuscript

Title: Determination of free polysaccharide in Vi glycoconjugate vaccine against typhoid fever

Authors: C. Giannelli, E. Cappelletti, R. Di Benedetto, F. Pippi, M. Arcuri, V. Di Cioccio, L.B. Martin, A. Saul, F. Micoli



PII: S0731-7085(16)31251-1  
DOI: <http://dx.doi.org/doi:10.1016/j.jpba.2017.02.042>  
Reference: PBA 11109

To appear in: *Journal of Pharmaceutical and Biomedical Analysis*

Received date: 28-11-2016  
Revised date: 13-2-2017  
Accepted date: 20-2-2017

Please cite this article as: C.Giannelli, E.Cappelletti, R.Di Benedetto, F.Pippi, M.Arcuri, V.Di Cioccio, L.B.Martin, A.Saul, F.Micoli, Determination of free polysaccharide in Vi glycoconjugate vaccine against typhoid fever, Journal of Pharmaceutical and Biomedical Analysis <http://dx.doi.org/10.1016/j.jpba.2017.02.042>

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

# Determination of free polysaccharide in Vi glycoconjugate vaccine against typhoid fever

C. Giannelli, E. Cappelletti, R. Di Benedetto, F. Pippi, M. Arcuri, V. Di Cioccio, L. B. Martin, A. Saul, F. Micoli

GSK Vaccines Institute for Global Health S.r.l. (former Novartis Vaccines Institute for Global Health NVGH), Via Fiorentina 1, 53100 Siena, Italy.

Corresponding author: Carlo Giannelli, [carlo.x.giannelli@gsk.com](mailto:carlo.x.giannelli@gsk.com), Via Fiorentina 1, 53100 Siena, Italy.

## Highlights:

- A novel quantitative method for free Vi determination in glycoconjugates.
- The method works for Vi conjugates with different carrier proteins.
- The method is reproducible and allows Vi quantification in diluted samples.
- An improved quality control method for reliable Vi conjugates characterization.

## Abstract

Glycoconjugate vaccines based on the Vi capsular polysaccharide directed against *Salmonella enterica* serovar Typhi are licensed or in development against typhoid fever, an important cause of morbidity and mortality in developing countries. Quantification of free polysaccharide in conjugate vaccines is an important quality control for release, to monitor vaccine stability and to ensure appropriate immune response. However, we found that existing separation methods based on size are not appropriate as free Vi non-specifically binds to unconjugated and conjugated protein. We developed a method based on free Vi separation by Capto Adhere resin and quantification by HPAEC-PAD. The method has been tested for conjugates of Vi derived from *Citrobacter freundii* with different carrier proteins such as CRM<sub>197</sub>, Tetanus Toxoid and Diphtheria Toxoid.

Download English Version:

<https://daneshyari.com/en/article/5138121>

Download Persian Version:

<https://daneshyari.com/article/5138121>

[Daneshyari.com](https://daneshyari.com)