真空冷冻干燥技术在疫苗研发与生产中的应用

赵 凡,韩 峰,陈雨曈,赵 耀,张志军,蔡 旭,张世伟

(东北大学机械工程与自动化学院,辽宁 沈阳 110819)

摘 要:目前,世界各国都在积极应对新冠肺炎(COVID-19)疫情所带来的影响。新冠疫苗的研发与生产,已成为各国科研院所和医疗企业关注的焦点。同液体疫苗相比,冻干疫苗的运输和储存较容易,为解决疫苗冷链运输难题提供了一种可行方案。真空冷冻干燥技术作为冻干疫苗生产中的关键一环,对疫苗的安全性和有效性起着至关重要的作用。本文首先介绍了冷冻干燥的基本原理和冻干机的主要结构,随后阐述了疫苗的冻干工艺及冻干疫苗的优缺点,并进一步讨论了影响冻干疫苗质量的主要因素(包括保护剂的选择和冻干参数的设计)。作者希望本文所述内容,能为新冠肺炎疫苗的研发与生产提供些许帮助。

关 键 词:真空冷冻干燥;疫苗;保护剂;工艺参数;新冠肺炎

中图分类号:TQ028.63;R392 **文献标识码**:A **文章编号**:1002-0322(2021)06-0072-07

doi:10.13385/j.cnki.vacuum.2021.06.14

Application of Vacuum Freeze-drying Technology in the Development and Production of Vaccine

ZHAO Fan, HAN Feng, CHEN Yu-tong, ZHAO Yao, ZHANG Zhi-jun, CAI Xu, ZHANG Shi-wei

(*School of Mechanical Engineering and Automation, Northeastern University, Shenyang 110819, China*)

Abstract: Currently, countries around the world are actively responding to the impact of the COVID-19 epidemic. The development and production of COVID-19 vaccines have become the focus of research institutes and medical enterprises. Compared with liquid vaccines, lyophilized vaccines can be transported and stored easily, which provides a feasible solution to solve the problem of cold chain transportation of vaccines. Vacuum freeze-drying technology is a key link in the production of lyophilized vaccines, which plays a vital role in the safety and efficacy of vaccines. In this paper, the basic principle of freeze-drying and the main structure of the freeze dryer are introduced firstly. Then, the freeze-drying process of vaccine and the advantages and disadvantages of freeze-drying vaccine are described. Furthermore, the main factors affecting the quality of freeze-drying vaccine (including the selection of protective agent and the design of freeze-drying parameters) are also discussed. The authors hope that this article may contribute to the development and production of COVID-19 vaccines.

Key words: vacuum freeze-drying; vaccine; protective agent; process parameter; COVID-19

在全世界积极应对新冠肺炎病毒(COVID-19)的今天,疫苗的研发与生产已成为各国科研机构和医疗企业关注的焦点[1]。截至目前,全球处于研发阶段的新冠疫苗已达百余种[2];中国国产新冠疫苗已于 2020 年 9 月亮相中国(北京)国际服务贸易交易会[3],并先后在阿联酋、巴林、埃及、秘鲁等十多个国家和地区合作开展国际临床三期试验[4],接种人数已达数十万人[5],疫苗研发水平居世界前列[6]。

直接采用液体形式封装的新冠疫苗,往往需要全程进行冷链运输(温度一般是在 -20~-80 ℃之间),这为新冠疫苗的储存、分发及接种带来不小的挑战[7]。同液体疫苗相比,冻干疫苗在正常冷藏温度(2~8 ℃)下即可保持稳定,其热稳定性好,有效期长,运输和储存较容易,这为解决疫苗冷链运输难题提供了一种可行方案[8]。冻干疫苗,顾名思义,就是利用真空冻干机,将疫苗制剂干燥后得到的保持免疫原性的干粉。疫苗接种前,一般

收稿日期:2020-12-19

作者简介:赵凡(1992-),男,天津市人,博士。 **通讯作者**:张世伟,教授,博导。