ELISA法检测疫苗中残余牛血清蛋白含量的方法学验证

田博　北京 北京天坛生物制品股份有限公司 100024

杨冰　北京 北京天坛生物制品股份有限公司 100024

董小曼 等 北京 北京天坛生物制品股份有限公司 100024

摘　要：为验证ELISA法检测病毒性疫苗中残余牛血清蛋白方法的可靠性，由2个部门对12个样品进行4人连续3天的验证。结果表明：4人连续3天的12次检测结果均满足牛血清白蛋白ELISA法（BSP-ELISA法）标准曲线成立的条件，建立合格标准曲线的成功率为100%；对5ng/mL、10ng/mL、20ng/mL浓度的牛血清白蛋白（BSP）标准品，不同实验人员间测定结果的变异系数在2.87%~6.33%之间，精密度较好；回收率在92.9%~103.1%之间，说明不同人的测定结果准确度高。分别采用该方法与已上市的牛血清白蛋白试剂盒对7种疫苗中100个样品的残余BSP含量进行检测，二者的检测结果合格符合率为100%，用该方法对已上市的检测BSA试剂盒中的4个标准品进行检测，回收率在90.0%~117.1%，检测灵敏度为2.5ng/mL，表明BSP-ELISA法可以敏感、准确地定量检测BSA，可用于目前我公司疫苗制品中残余牛血清白蛋白的质量控制。

关键词：

Methodology validation totest the residue protein if bovine serum in the

100024

100024

100024

Abstract：To validate the reliability of BSP-ELISA method on detecting residual bovine serum contents in virus vaccines. Collaboration verification of BSP-ELISA method was carried on by four personnels from two departments, the outcome demonstrated that all twelve tests done by four personnels had met tenable condition of standard curve of BSP-ELISA method and the mission success rate of building tenable standard curve was 100%;the precision was preferable because the coefficients of variation of the results among personnel detecting the BSP standards of 5,10,20ng/mL concentrations were from 2.87% to 6.33%, and the recovery from 92.9% to 103.1% indicated measuring results by various personnel had return accuracy. Furthermore, the detection accord rate of residual bovine serum proteins between BSP-ELISA method and BSA-ELISA method in seven kinds of vaccines was 100%. Moreover, the recovery rate was between 90.0% and 117.1% and detection sensitivity was as low as 2.5ng/mL when measuring four BSA standards of BSA detection kit with BSP-ELISA method, which showed the BSP-ELISA method could detect BSA contents in vaccines with good sensitivity and accuracy. The method would be useful for data quality monitoring of residual bovine serum albumin in vaccines of our company.

Key words：