

Poster Abstracts

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ESTABLISHMENT OF VENOM STANDARD FOR POTENCY TEST OF AGKISTRODON (SALMUSA) ANTIVENOM

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Objectives: NIFDS has supplied standardized goods to manufacturer as national venom standard. These are nationally controlled and used in lot release and quality control of manufacturer. It has been ceased to distribute 1st national venom standard because of a shortage of goods in stock. The candidate material for 2nd national venom standard was developed and manufactured in identical process of 1st national standardized goods. The quality of the candidate material which manufactured in manufacturer was validated to meet acceptance of QC test. This study is to establish the potency of the candidate material as 2nd national venom standard.

Methods: Manufactured candidates were evaluated for quality evaluation through quality control tests (lethal dose test, hemorrhagic dose test, lethal toxicity, minimal hemorrhagic dose). The test method is referred to the report of the establishment of 1st venom standard for potency test in Korea. The potency of this candidate preparation was determined using the Reed-Muench method for the lethal test and the standard linear regression analysis for the hemorrhagic test.

Results: In case of lethal toxicity (LD_{50}), the average value for 3 times test results is 27.5 μ g (95% confidence interval : 25.9-29.1), and the average value for 3 times test results is 0.98 μ g (95% confidence interval : 0.72-1.23) in minimal hemorrhagic dose. The average value for 10 times lethal dose test results is 88.9 μ g (95% confidence interval : 85.1-92.9) and hemorrhagic dose test results is 10.2 μ g (95% confidence interval : 9.5-10.9).

Conclusion: The candidates of the 2nd national venom standard are verifying titer maintain and stability though long-term stability test and accelerated testing in manufacturer. After verifying quality, it's availability for the candidate as the 2nd national venom standard shall be verified with further collaborative study with 4 participated institutions to assign the stated potency. Finally, the national standard can be used for quality control of Salmusa antivenom products in Korea after approval by NIFDS.