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The stability estimation for Korean national biological reference standards: *Bordetella Pertussis* and anti-pertussis

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Biological products include a wide range of products such as vaccines, blood-derived products, toxins, recombinant therapeutic proteins, cell therapy products, and gene therapy products. Reference standard is a biological material one or more of whose property values (potency, amount, etc.) are sufficiently well established to be used in assessing a measurement method or assigning values to other biological materials. According to WHO recommendation, we as national authority, obtain minimum amount of standards from WHO international laboratories and establish our own national biological reference standards (NBRSs). A high degree of stability is one of essential requirements for NBRSs.

In this study, stability tested for *Bordetella Pertussis* Vaccine and anti-pertussis NBRSs were performed. The mouse body weight gain test (MWGT), the leukocytosis-promoting test (LPT), and the histamine sensitization test (HIST) are done for the testing of the specific toxicity of pertussis vaccines. For the anti-pertussis, identification test (Ouchterlony test) was performed. The trend analysis in lymphocytosis promoting units and histamine-sensitizing units were stable but body weight-decreasing units (BWDU) were decreased. Identification test on anti-pertussis showed clear precipitin lines.

Taken together, it has been proposed as follows; *Bordetella Pertussis* vaccines and anti-pertussis which are made by MFDS as a national biological reference standard showed stable potency.

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