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NATIONAL STANDARD OF THE
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YBB 00022003-2015

Test for Pyrogen

[Test procedure] TAKE 3 suitable household-rabbits to measure their normal body-temperature. Within 15 minutes after the normal body-temperature conforms to requirements, from the auricular vein, Slowly INJECT the test solution of which the temperature is lukewarm to about 38 °C. The injection dose is 10 ml/kg. Then, the body-temperature is measured once every 30 minutes according to the previous method, totaling 6 times. The normal body-temperature is subtracted from the highest one of the 6 body-temperatures, to obtain the household-rabbit body-temperature rise (°C). If the temperature of 1 of the 3 household-rabbits is raised by 0.6 °C or higher than 0.6 °C, or the sum of the 3 household-rabbits' temperature rises is 1.3 °C or higher than 1.3 °C, another 5 household-rabbits shall be taken for retest; the test procedure is the same as above.

[Result judgment] If, among the 3 household-rabbits for the first test, the temperature rise is lower than 0.6 °C, and the sum of the body-temperature rise of the 3 household-rabbits is lower than 1.3 °C; or, among the 5 household-rabbits for the retest, the number of household-rabbits whose body-temperature is raised by 0.6 °C or higher than 0.6 °C does not exceed 1 household-rabbit, and the sum of the body-temperature rise of the 8 household-rabbits in the first test and retest is 3.5 °C or lower than 3.5 °C; then, it is determined that the pyrogen test of the test sample meets the requirements.

If, among the 3 household-rabbits for the first test, the number of household-rabbits whose body-temperature is raised by 0.6 °C or higher than 0.6 °C exceeds 1 household-rabbit; or, among the 5 household-rabbits for the retest, the number of household-rabbits whose body-temperature is raised by 0.6 °C or higher than 0.6 °C exceeds 1 household-rabbit; or, the sum of the body-temperature rise of the 8 household-rabbits in the first test and retest exceeds 3.5 °C; then, it is determined that the pyrogen test of the test sample does not meet the requirements.

When the temperature rise in these household-rabbits is negative, it is calculated by 0 °C.

_____ **END** _____

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