

3.2.S.5 Reference Standards of Materials

3.2.S.5.1 Reference Standards of Materials

1) National standard products

National standard products are mainly used for testing and calibration of raw materials or finished products.

2) Working standard products

Working standard products are calibrated by national standard products or pharmacopoeia standard products and used for finished product testing or raw material testing. The preparation and calibration of working standard product can be referred to the preparation and calibration of SOP for each working standard product.

Normally, the validity period of the working standard product is one year. At the end of half a year, the calibration will be carried out again. The comparative test is carried out by the technical person in charge of each post, with the relative standard deviation less than 2%. Working standard products can only be used for testing if they are approved by the QC Department head. The comparative test results shall be recorded and the test report shall be issued.

3) Preservation of Standard product

The chemical standard product should be stored in refrigerator at 2-8 °C. If the condition of preservation is indicated on the label, it should be preserved according to that condition.

3.5.S.5.2 List of standard substance

Standard substance	Source	Specifications	Content	Application
L-Ornithine L-Aspartate	National Institutes for Food and Drug Control	50 mg/bottle	96.6%	For identification and content determination

