



陕西绿清生物工程有限公司

Shaanxi Green Bio-Engineering Co.,Ltd

Cytisine test method

Properties: This product needs to be a white powder; it can pass through an 80-mesh sieve 100%; it is odorless and has a special smell

Loss on drying: Measured in accordance with the 0831 method of the 2015 edition of the Chinese Pharmacopoeia, requiring a loss on drying $\leq 1\%$

Heavy metals: Measured in accordance with the 0821 method of the General Principles of the Chinese Pharmacopoeia 2015 Edition. The total amount of heavy metals is required to be $\leq 10\text{PPM}$, arsenic $\leq 2\text{PPM}$, and lead $\leq 2\text{PPM}$. **Heavy metals:** The total amount of heavy metals is required to be $\leq 10\text{PPM}$

Ash content: Refer to the general rule 2302 method of the 2015 edition of the Chinese Pharmacopoeia for determination, and the ash content is required to be $\leq 0.1\%$

Microbiological indicators: follow the guidelines of the Pharmacopoeia

Pesticide residues: take batches and send them to a third-party testing agency for testing, according to relevant standards

Content determination (HPLC): $\geq 98\%$ based on the company's reference substance

Detection wavelength: 230nm

Chromatographic column: Hypersil ODS2 C18 5μ 250*4.6mm

Mobile phase: acetonitrile: 0.02% ammonium acetate: triethylamine = 15: 85: 0.02ml

Flow rate: 0.8 ml/min

Configuration of reference solution

Accurately weigh 10 mg of genistein reference substance in a 25 ml volumetric flask, dissolve it with 15 ml methanol ultrasonically, after cooling, dilute it and place it in a 25 ml volumetric flask, and shake it well.

Preparation of test solution:

Precisely weigh: the genistein test product equivalent to the reference substance is placed in a 25 ml volumetric flask, dissolved in 15 ml methanol ultrasonically, after cooling, diluted and placed in a 25 ml volumetric flask, and shake well to obtain.

Determination: Precisely draw 15µl each of the reference substance solution and the test substance solution, and inject it into the liquid chromatograph for measurement, and record the peak area of the reference substance and the test substance.

calculate:

Test product content $W_x = A_1 * C_2 * W_s / A_2 * C_1$

C1-----Concentration of test product

C2-----Concentration of reference substance

A1-----The peak area of the test product

A2-----The peak area of the reference substance

W_s----- (Our company) The content of reference substance is calculated as 98%

W_x-----test product content