

分析报告 Certificate of Analysis

产品名称 Product Name	Ginseng Root Extract	批号 Batch Number	20170739
拉丁名 Latin Name	Panax ginseng C.A. Meyer	数量 Quantity	55kg
使用部位 Part Used	Dried Korean ginseng root	生产日期 Manufacture Date	07/25/2017
提取溶剂 Extract Solvent	Ethanol & Water	报告日期 Report Date	08/02/2019

项目 Item	标准 Specification	结果 Result	检测方法 Test Method
有效成分 Active Ingredients			
含量 Assay	Total of Ginsenosides≥20.1%	20.1%(Rg1, 0.92%.Re,2.21%.Rf,0 .43%.Rb1,5.08%.Rc, 5.47%.Rb2,3.20%Rd, 2.8%.)	HPLC
物理控制 Physical Control			
性状 Appearance	Fine Powder	Complies	Visual
颜色 Color	Reddish Brown	Complies	Visual
气味 Odor & Taste	Characteristic Odor & Taste	Complies	Organoleptic
干燥失重 Loss on Drying	NMT 5.0%	3.5%	ChP2015
灰分 Ash	NMT 5.0%	2.2%	ChP2015
粒度 Particle Size	NLT 95% through 80 mesh	99.5%	ChP2015
化学控制 Chemical Control			
总重金属 Total Heavy Metals	NMT 10mg/kg	Complies	Atomic Absorption
铅 Lead (Pb)	NMT 2mg/kg	Complies	Atomic Absorption
砷 Arsenic (As)	NMT 1mg/kg	Complies	Atomic Absorption
汞 Mercury (Hg)	NMT 0.2mg/kg	Complies	Atomic Absorption
镉 Cadmium (Cd)	NMT 0.1mg/kg	Complies	Atomic Absorption
PAH(4)	NMT 50ppb	Complies	GC-MS
农药残留 Pesticide Residues	Not Detected(462 pesticides)	Complies	LC/GC-MS
微生物控制 Microbiological Control			
细菌总数 Total Plate Count	NMT 1000cfu/g	Complies	AOAC
霉菌和酵母菌 Yeast & Mold	NMT 100cfu/g	Complies	AOAC
大肠杆菌 E. Coli.	Negative	Negative	AOAC
沙门氏菌 Salmonella	Negative	Negative	AOAC
包装、储存及有效期 Package, Storage and Shelf Life			
包装 Package	Inner packing with two layers of plastic bag, outer packing with 25kg cardboard drum.		
储存 Storage	Store in a well-closed container away from moisture and direct sunlight.		
有效期 Shelf Life	2 years if sealed and stored properly.		
承诺说明 Commitment Note:	Non-GMO, Non-irradiation.		

Test Method

1.1 The total content of ginsenoside Rg1, Re, Rf, Rb1, Rc, Rb2 and Rd are detected with high performance liquid chromatography(HPLC) in accordance with the current edition of China Pharmacopoeia appendix D.

1.1.1 The chromatographic conditions and system suitability experiment

Ostade-cylsilane(ODS) as filler(column length 250mm, inner diameter 4.6mm, partial size 5μm), acetonitrile as mobile phase A, 0.1% phosphoric acid solution as mobile phase B, we follow below form to do gradient elution, the detection wavelength is 203nm. Calculated with the peak value of Re, the theoretical plate number should be higher than 3000.

Time(Min)	Mobile Phase A (%)	Mobile Phase B (%)
0~30	19	81
30~35	19→24	81→76
35~60	24→40	76→60

1.1.2 The preparation of the reference substance solution

Fetch proper amount of ginsenoside reference substance Rg1, Re, Rf, Rb1, Rc, Rb2 and Rd, accurately weigh them, then add methanol, in order to make 1ml mixed solution which contains ginsenoside reference substance Rg1 250μg, Re 250μg, Rf 50μg, Rb1 50μg, Rc 60μg, Rb2 70μg and Rd 150μg separately.

1.1.3 The preparation of sample solution

Fetch a 20mg sample, accurately weigh it, put it into a 10ml measuring bottle, add methanol, and put the bottle in supersonic cleaner for 30 minutes to dissolve it, at last, dilute it until its volume is 10ml.

1.1.4 Mensuration

Accurately suck up the sample solution 10~20μl and reference substance solution 20μl, inject them into the liquid chromatograph separately, measure them, then calculate the content of ginsenoside Rg1, Re, Rf, Rb1, Rc, Rb2 and Rd.

$$C_{(\text{sample concentration})} = \frac{A_{(\text{Peak area of sample})} * C * V}{A_{(\text{Peak area of reference substance})} * M_{(\text{sample})}} \quad (\text{mg/g})$$

Definition

C: Reference substance concentration

V: Solvent volume of diluent

C(sample concentration): Sample concentration

A(Peak area of sample): Peak area of sample

M(sample): Weight of sample

A(Peak area of reference substance) : Peak area of reference substance

Item	Content %	Rg1	Re	Rf	Rb1	Rc	Rb2	Rd	Rb2/Rb1 ≥ 0.4	Re/Rb1 ≤ 2.0
Ginseng Root Extract	20.1%	0.92	2.21	0.43	5.08	5.47	3.20	2.80	0.62	0.43

100% Ginseng Root Extract must meet two conditions:

Rb2/Rb1 ≥ 0.4

Re/Rb1 ≤ 2.0

If not, we can judge it is not 100% ginseng root extract, maybe ginseng leaf extract or ginseng leaf extract mixed with ginseng root extract.