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# Study on the Stability of Kangxuan Granules

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**Abstract.** To observe the stability of Kangxuan granules within 6 months. Three batches of Kangxuan granules were selected for identification (ligustrazine), determination of content (determination of puerarin in *Pueraria lobata*), granularity, moisture, melting, microbial limit examination. Results: after 6 months observation and detection, all the indexes of Kangxuan granules were in accordance with the pharmacopoeia. The quality of Kangxuan granules is stable at room temperature, so it is valid for 18 months.

## INTRODUCTION

Kangxuan granule is a pure traditional Chinese medicine preparation developed by the 371st Hospital of PLA. It is prepared by steeping and extracting eight kinds of traditional Chinese medicine, such as hook vine, *Pueraria lobata*, magnetite, *salvia miltiorrhiza*, *Prunella vulgaris*, *Radix Achyranthes bidentata*, *Rhizoma Pinelliae* and *Ligusticum chuanxiong*. It has the effect of calming the liver and burying yang, activating blood circulation and regulating orifices, exhaling wind and fixing dizziness [1]. It is used clinically for hypertension, cerebral arteriosclerosis, vertebrobasilar artery insufficiency, Meniere's disease, vertigo caused by autonomic nerve dysfunction, head, foot, walking instability and so on [2-5]. In order to ensure the quality of the preparation, according to the provisions of the Pharmacopoeia and the requirements of the guiding principle of the stability test of traditional Chinese medicine, a long-term stability test of Kangxuan granules was carried out. The inspection is introduced below.

## MATERIALS AND METHODS

### Sample

Samples of the traditional Chinese medicine Kangxuan Granules are from: medicine and Ordnance Department, 371 Hospital. Lot number: 20120806 20121006 20121030, Size: 10g / bag.

### Inspection Conditions

The experiment was performed under room temperature.

Three batches of samples (20060806 20061006 20061030) were packed and stored at room temperature for 18 months.

Test items: traits, identification, content determination, particle size, moisture, solubility, microbial limit test.

## RESULTS

Experimental results: see the Table 1, 2, 3.

**TABLE 1.** Results of the stability test of preparations (Sample: Kangxuan granules, lot number: 20120806, Date of production: Aug. 6, 2012)

Item*	Result	Time (Months)						
		0	1	2	3	6	12	18
Characteristics	This product is brown granules							
Fluorescent spot identification	Fluorescent spots of Rhizoma Chuanxiong and Salvia miltiorrhiza detected							
Content determination	16.5mg	16.5mg	16.5mg	16.5mg	16.4mg	16.4mg	16.2mg	
Particle size	3.2%	3.3%	3.2%	3.5%	3.2%	3.2%	3.1%	
Moisture content	3.10%	3.10%	3.10%	3.10%	3.00%	3.20%	3.40%	
dissolubility	all dissolved							
microbiological detection	bacterials	Comply with regulations						
	Molds, yeasts	Comply with regulations						
	Escherichia coli	Not detected						

\*Note: Content determination should be no less than 10.0 mg of puerarin per bag of Pueraria lobate; Particle size should be under 15%; Moisture content should be under 6%.

**TABLE 2.** Report on stability test of preparation (Sample: Kangxuan granules, lot number: 20121006, Date of manufacture: Oct. 6, 2012)

Item	Result	Time (Months)						
		0	1	2	3	6	12	18
Characteristics	This product is brown granules							
Fluorescent spot identification	Fluorescent spots of Rhizoma Chuanxiong and Salvia miltiorrhiza detected.							
Content determination	17.2mg	17.2mg	17.2mg	17.2mg	17.1mg	17.0mg	16.8mg	
Particle size	2.6%	2.5%	2.7%	2.3%	2.8%	2.6%	2.4%	
Moisture content	3.50%	3.50%	3.50%	3.60%	3.60%	3.70%	3.90%	
dissolubility	all dissolved							
Microbiologic al detection	bacterials	Comply with regulations						
	Molds, yeasts	Comply with regulations						
	Escherichia coli	Not detected						

**TABLE 3.** Report on stability test of preparation (Sample: Kangxuan granules, Lot number: 20121030, Date of manufacture: Oct. 30, 2012)

Item*	Result	Time (Months)						
		0	1	2	3	6	12	18
Characteristics	This product is brown granules							
Fluorescent spot identification	Fluorescent spots of Rhizoma Chuanxiong and Salvia miltiorrhiza							
Content determination	16.8mg	16.8mg	16.8mg	16.8mg	16.7mg	16.5mg	16.3mg	
Particle size	2.4%	2.5%	2.5%	3.1%	2.5%	2.1%	2.3%	
Moisture content	3.80%	3.80%	3.80%	3.80%	4.00%	4.10%	4.30%	
dissolubility	off-bottom							
Microbiological detection	bacterials	Comply with regulations						
	Molds, yeasts	Comply with regulations						
	Escherichia coli	Not detected						

\*Note: Content determination should be no less than 10.0 mg of puerarin per bag of Pueraria lobate; Particle size should be under 15%; Moisture content should be under 6%.

## CONCLUSION

The results of the above items in each of the three batches of Kangxuan granules were in accordance with the regulations, but there was no obvious change. The results indicated that the quality of Kangxuan granules was stable in the 18 months of long-term stability test. According to the stability of the product and the relevant provisions, anti-xuan granules are tentatively valid for 18 months.

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