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Pharmacopoeia Of The People S Republic Of China (2010pdf

Standard	AGMARK Food Grade II	AGMARK Food Grade I	PhEur 7.0 EU Therapeutic Quality	USP 34 US Therapeutic Quality
Definition	Husk obtained by milling clean psyllium seeds (<i>Plantago ovata</i>) produced in India. It is white to brown in color.	Husk obtained by milling clean psyllium seeds (<i>Plantago ovata</i>) produced in India. It is white to brown in color.	Episperm and collapsed adjacent layers removed from the seeds of Plantago ovata (P. ispaghula).	Cleaned, dried seed coat (epidermis) separated by winnowing and threshing from the seeds of <i>Plantago ovata</i> , known in commerce as Blond psyllium, Indian psyllium, or ispaghula; or from <i>P. arenaria</i> (<i>P. psyllium</i>), known in commerce as Spanish or French psyllium, in whole or in powdered form.
Swell volume	No requirement.	No requirement.	NLT 40 mL/g	NLT 40 mL/g (powder) NLT 35 mL/g (whole)
Identification tests	No ID tests required.	No ID tests required.	Macroscopic Exam A	Microscopic Exam A
	919191919		Microscopic Exam B	Microscopic Exam B
			TLCTest C	Histology Exam
Foreign matter	NMT 12.5% organic impurities (gritty particles, broken or entire embryo, fragments of endosperm and/or capsular wall of fruits). Free from extraneous matter (sand or dirt).	NMT 7.5% organic impurities (gritty particles, broken or entire embryo, fragments of endosperm and/or capsular wall of fruits). Free from extraneous matter (sand or dirt).	NMT 2.0%	NMT 5% Light Extraneous Matter
Loss on drying	NMT 11.5%	NMT 11.5%	NMT 12.0%	NMT 12.0%
Total ash	NMT 3.0%	NMT 2.5%	NMT 4.0%	NMT 4.0%
Acid-insoluble ash	NMT 0.3%	NMT 0.2%	No standard.	NMT 1.0%
Contamination	Free from insect and fungus infestation. Free from extraneous matter, added coloring matter, and musty or other objectionable odor.	Free from insect and fungus infestation. Free from extraneous matter, added coloring matter, and musty or other objectionable odor.	As much as possible, free from impurities such as soil, dust, dirt, and other contaminants such as fungal, insect, and other animal contaminations. Not rotten.	NMT 400 insect fragments, including mites and psocids, per 25 g (powder). NMT 100 insect fragments/25 g (whole).
Heavy metals	No standard.	No standard.	NMT 1.0 ppm cadmium NMT 5.0 ppm lead NMT 0.1 ppm mercury	NMT 2 ppm total heavy metals
Microbiological quality	No standard.	No standard.	Total aerobic microbial count (TAMC): Acceptance criterion: 10 ⁵ cfu/g. Max acceptable count: 500,000 cfu/g. Total combined yeasts/molds count (TYMC): Acceptance criterion: 10 ⁴ cfu/g. Max acceptable count: 50,000 cfu/g. Bile-tolerant gram-negative bacteria: Acceptance criterion: 10 ⁴ cfu/g. Escherichia coli: Absence in 1 g. Salmonella: Absence in 25 g.	Total combined molds and yeasts count: NMT 1,000 cfu/g. Escherichia coli: absent. Salmonella species: absent.
Pesticide residues	No standard.	No standard.	Meets the requirements of General Chapter 2.8.13.	Meets the requirements of General Chapter 561.

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