

Specification

Withania somnifera extract 7% (Ashwagandha)

Grade	: 7%	Product code:	: SK0068
Excipients	: 25 - 30% Maltodextrin	Shelf life	: 3 years
Plant	: Withania somnifera	Parts used	: Root
Origin	: India	Extraction Solvent	: Ethanol, Water

Sl. #	Test	Limit	Test Protocol
1	Description	Pale brown to brown hygroscopic powder	Visual
2	Identification	To pass for withanolides	By TLC
3	Physico-chemical analysis		
	Loss of Drying (%w/w)	≤ 5.00	USP <731>
	Water Solubles (%w/w)	≥ 70	USP
	Alcohol Solubles (%w/w)	≥ 60	
4	Particle Size		
	Bulk Density (g/ml)	≥ 0.45	USP <616>
	Tapped bulk density (g/ml)	≥ 0.30	
	Material passing through (%w/w)		USP <786>
	20#	≥ 100.00	
	40#	≥ 85.00	
	80#	≥ 70.00	
5	Residual Solvents	To comply with EU Directive	EU Directive 2009/32/EC
6	Residual Pesticides	To comply with EU Directive	EU Directive 396/2005/EC
7	Heavy metal analysis		
	Lead	≤ 3 ppm	ICP-MS
	Arsenic	≤ 1 ppm	
	Cadmium	≤ 1 ppm	
	Mercury	≤ 0.1 ppm	
8	Microbiological analysis		
	Total aerobic microbial count	≤ 5000 cfu/g	USP <2021>
	Yeast & Mould	≤ 100 cfu/g	USP <2021>
	<i>E. coli</i> (1g)	Absent	USP <2022>
	<i>Salmonella Sp.</i> (10g)	Absent	USP <2022>
	<i>Staphylococcus aureus</i> (1g)	Absent	USP <2022>
	<i>Pseudomonas aeruginosa</i> (1g)	Absent	USP <62>
	Enterobacteriaceae (1g)	≤ 100 cfu/g	USP <2021>
9	Assay (in %w/w on dried basis)		
	Total Alkaloids	≥ 1.00	By Gravimetry
	Total Withanolides (free Withanolides and Glycowithanolides)	≥ 7.00	By Gravimetry
	Withaferin-A	≥ 0.25	By HPLC