

**ANALYTICAL SPECIFICATIONS****Product Name:** KSM-66<sup>®</sup> Ashwagandha (*Withania somnifera*)**Plant Part:** Roots**Country of Origin:** India**Extract Solvent:** Water

No.	Tests	Limits	Protocol
1	<b>Description</b>	Light yellow brown hygroscopic powder	
2	<b>Identification</b>	To pass the test	TLC (Thin Layer Chromatography)
3	<b>Physicochemical analysis</b>		
	Moisture Content (% w/w)	< 5.0	As per USP 24<561> Vegetable Drugs pg. 1885. Pg.2005
	Ash content (%W/W)	< 8.0	
	Acid insoluble ash (%w/w)	< 5.0	
	pH of 5%w/v solution	4.0 – 6.5	As per USP<791> pg.1977
4	<b>Particle Size</b>		
	Passing through 40 mesh sieve	>95% (w/w)	
	Passing through 80 mesh sieve	>85% (w/w)	
5	<b>Density</b>		
	Bulk density (g/cc)	0.2 – 0.6	As per USP 24<616>19131914 Method I
	Tapped bulk density (g/cc)	0.2 – 0.8	
6	<b>Heavy metals</b>		
	Lead	<1 ppm	AOAC/AAS
	Cadmium	<1 ppm	AOAC/AAS
	Arsenic	<2 ppm	AOAC/AAS
	Mercury	<0.1 ppm	AOAC/AAS
7	<b>Microbiological analysis as per FIP guidelines</b>		
	Total viable aerobic count	<10 <sup>4</sup> cfu g <sup>-1</sup>	As per WHO/PHARMA/92.559/Rev.1/pg.4952
	Total enterobacteriaceae	<10 <sup>2</sup> cfu g <sup>-1</sup>	
	Total fungal count	<10 <sup>2</sup> cfu g <sup>-1</sup>	
8	<b>Test for specific pathogens as per FIP guidelines</b>		
	E.Coli	Absent	IS:5887 (Part I): 1976
	Salmonella sp. (cfu/10g)	Absent	IS: 15187:2002
	S.aureus	Absent	IS:5887 (Part II): 1976
9	<b>Aflatoxins (B1, B2, G1, G2)</b>	< 5 ppb	AOAC Chap 49/HPLC
10	<b>Pesticides residue analysis as per USP and BP limits</b>		
	Organochlorine pesticides	To comply with USP	AOAC Chap.10/GC/ECD/USP 24
	Organophosphorous pesticides		
	Organosulpher		IS: 138321993
11	<b>Phytochemical analysis</b>		
	Total Withanolides (%w/w)	> 5 %	By HPLC
	( Withaferin A )	< 0.1 %	

**Storage:** Store in original, sealed containers at controlled room temperature of 15°-30°C. Avoid light and keep away from excessive humidity.

**Stability:** 3 years from the date of manufacture.