

SUANFARMA

PRODUCT SPECIFICATION SHEET

REVISION 1.2020

IDENTIFICATION

NAME	ASHWAGANDHA EXTRACT 5%
PLANT PART USED	Root
FRESH/DRY	Dry
PRODUCT CODE	ASE05
EXCIPIENTS	None
SOLVENT	Methanol
FINAL EXTRACT RATIO	15: 1
SHELF LIFE	36 Months
COUNTRY OF ORIGIN	India

PHYSICAL & CHEMICAL ANALYSIS

PARAMETER	SPECIFICATION	METHOD
1. APPEARANCE	Hygroscopic Powder	Visual
COLOR	Light yellowish brown to brown	Visual
2. IDENTIFICATION	To comply with HPTLC	HPTLC
3. MOISTURE	NMT 6.0% w/w	USP<921>
4. ACID INSOLUBLE ASH	NMT 7.0% w/w	USP<561>
5. Ph (2% w/v SOLUTION)	4.0 – 7.0	USP<791>
6. ALCOHOL EXTRACTIVE VALUE	NLT 60.0% w/w	USP<561>
7. BULK DENSITY	0.5 g/ml – 0.8 g/ml	USPUSP<616>
8. TAPPED BULK DENSITY	0.7 g/ml – 1.0 g/ml	USP<616>
9. PARTICLE SIZE	NLT 95% through 40 mesh	USP<786>
10. TOTAL WITHANOLIDES CONTENT	NLT 5.00% w/w	HPLC
11. AFLATOXINS	NMT 5.0 ppb	USP
12. METHANOL	To comply with USP	USP<467>
13. PESTICIDE RESIDUE ANALYSIS	To comply with USP	USP<565>
14. HEAVY METALS		
ARSENIC	NMT 2.0 ppm	ICP-MS
LEAD	NMT 3.0 ppm	ICP-MS
CADMIUM	NMT 2.0 ppm	ICP-MS
MERCURY	NMT 0.1 ppm	ICP-MS

MICROBIOLOGY CONTROL

TOTAL PLATE COUNT	NMT 10,000 cfu/g	USP<2021>
YEAST AND MOLD	NMT 100 cfu/g	USP<2021>
E. COLI	Absent	USP<2022>
SALMONELLA (25g)	Absent	USP<2022>
S. AUREUS	Absent	USP<2022>
P. AEURIGINOSA	Absent	USP<62>

STORAGE CONDITIONS: PRESERVE IN TIGHTLY-SEALED CONTAINERS UNDER COOL, DRY CONDITIONS. AVOID EXCESSIVE EXPOSURE TO SUNLIGHT.
MANUFACTURING SITE: THIS MATERIAL IS CUSTOM MADE AND PROCESSED PLOT NO-50-3RD, ROAD, KIADB INDUSTRIAL AREA, JIGANI BANGALORE-560105 KARNATAKA, INDIA TO MEET SUAN FARMA, INC. SPECIFICATIONS.

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