



**ANALYTICAL SPECIFICATION
QUALITY CONTROL DEPARTMENT**

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TITLE : Kalmcold Ethanol

Product name	: Kalmcold Ethanol (NRAPE30E)
Plant part	: Leaves rich part of <i>Andrographis paniculata</i>
Fresh/Dry	: Dry
Final Extract Ratio	: 14 : 1 (13 – 15:1)
Extract solvent/s	: Ethanol, Water
Processing solvent (If required)	: Ethyl acetate
Excipient/s	: Nil
Country of origin	: India

Sl. No.	Tests	Limits	Protocol
1.	Description	Green to Brownish green powder with bitter taste.	
2.	Identification	To pass the test	By TLC
3.	Physico-chemical analysis		
	Loss on drying (%w/w)	< 5.0	As per USP <921> Method III
	Acid insoluble ash (%w/w)	< 3.0	As per USP <561>
4.	Particle Size		
	Bulk Density (g/cc)	0.25 – 0.60	As per USP <616> Method – I
	Tapped bulk density (g/cc)	0.30 – 1.00	
	Material passing through 30# BS/35 ASTM (%w/w)	> 99.0	As per USP <786> Particle Size distribution.
5.	Heavy metal analysis	To comply with Regulation (EC) 1881/2006 & 629/2008	
	Lead	< 3.0 ppm	AAS / ICP –ES / ICP - MS
	Arsenic	< 2.0 ppm	
	Cadmium	< 1.0 ppm	
	Mercury	< 0.1 ppm	
6.	Microbiological analysis		
	Total aerobic microbial count	< 10 ⁴ cfu g ⁻¹	As per USP <61> & <62> / WHO/PHARMA/92.559/Rev.1 Pg.49-52
	Total yeast and mould count	< 10 ² cfu g ⁻¹	
	Bile tolerant gram negative bacteria	< 10 ² org g ⁻¹	
7.	Test for Specific Pathogen		
	<i>E.coli</i> (1g)	Absent	
	<i>Salmonella Sp.</i> (10g)	Absent	
	<i>S.aureus</i> (1g)	Absent	
8.	Mycotoxin analysis	Complies with Regulation (EC) 1881/2006	As per USP Test for Aflatoxins
	Aflatoxins (B ₁ + B ₂ + G ₁ + G ₂)		As per BP/USP
9.	Residual solvent analysis	Complies with Directive 2009/32/EC	
	Ethanol (ppm)	< 5000	
10.	Polycyclic aromatic hydrocarbons	To comply with Commission Regulation (EU) 2015/1933 amending Regulation (EC) No. 1881/ 2006	As per AOAC / HPLC
	Benzo(a)pyrene	< 10.0 ppb	
	Total Polycyclic aromatic hydrocarbons (Sum of Benzo-a-anthracene, Chrysene, Benzo-b-fluoranthene and benzo(a) pyrene)	< 50.0 ppb	
11.	Pesticide residue analysis		
	Organochlorine Pesticides	To comply with Regulation (EC) No. 396/2005	As per AOAC / USP
	Organophosphorus Pesticides		
	Synthetic pyrethroids		
12.	Phytochemical Analysis		
	i) Andrographolide (% w/w)	35.0 (31.5-42.0)	By HPLC [NR/QCD/APM04/W1(77)]
	ii) Diterpene lactones (% w/w) (Sum of Andrographolide, Neo Andrographolide, 14-deoxy-11,12-didehydroandrographolide and Andrograpanin) (%w/w)	33.0-43.0	
	iii) 14-Deoxy-11, 12-didehydroandrographolide (%w/w)	(< 15% of the content of diterpene lactones)	
	iv) Skullcapflavone-I (%w/w)	For Records	
	v) 7-O-Methylwogonin (%w/w)	For Records	

Natural Remedies Private Limited

Regd. Office & R&D

CIN No: U24232KA1998PTC023573

Plot No. 5B, Veersandra Industrial Area, 19th KM Stone, Hosur Road, Electronic City Post, Bangalore 560100. INDIA

Tel: 91 8040209999/8/7,27382265, Fax: 91 80 40209817, Web: www.naturalremedy.com

E-Mail: qc@naturalremedy.com, info@naturalremedy.com