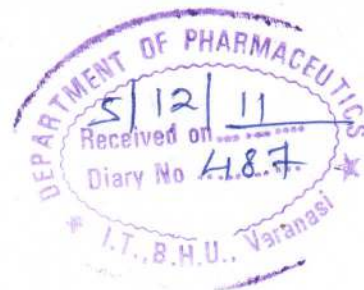


Chapter-8



Appendices

BANARAS HINDU UNIVERSITY
FACULTY OF MEDICINE
INSTITUTE OF MEDICAL SCIENCES



No. Dean/11-12/ CAEC/325

Dated: 30.11.2011

Head,
Department of Pharmaceutics
Institute of Technology
Banaras Hindu University

Dear Sir,

A meeting of the Central Animal Ethical Committee of the University was held on 29.11.2011 at 3.00 P.M in the Committee, IMS for animal ethical clearance of the proposal submitted by the following. :

Name of the student : Mr. Ajit Kumar Thakur
Title — Neuropsychopharmacological studies on <i>Andrographis paniculata</i> : A preclinical study
Ethical Observation-
Remarks: The above proposal is approved by the Central Animal Ethical Committee of the University

This is for your information and necessary action at your end.

Yours sincerely,


(B D BHATIA)
DEAN
&
CHAIRMAN

CENTRAL ANIMAL ETHICAL COMMITTEE OF THE UNIVERSITY

NATURAL REMEDIES
PRIVATE LIMITED

5B, Veerasandra Indl. Area, Hosur Road. Bangalore-560 100

Tel: 91-80-40209997 to 99 Fax: 91-80-40209817

E-mail: qc@naturalremedy.com

Quality Control Department

CERTIFICATE OF ANALYSIS

Product name	: KalmCold™ (A specialized extract of Kalmegh)	Batch No.	: RD/2507
Plant part	: Leaves of <i>Andrographis paniculata</i>	Lab Reference/Report No	: FP1101050
Final extract ratio	: 14 : 1 (13 – 15 : 1)	Date of Report	: 31.01.2011
Extract solvent/s	: Confidential	Mfg. Date	: January 2011
Excipients	: Nil	Retest Date	: January 2013
		Country of origin	: India

TEST RESULTS

SL. NO.	TESTS	SPECIFICATION	RESULT	TEST PROTOCOL
1.	Description	Green to Brownish green powder with bitter taste	Green powder	-
2.	Identification	To pass the test	Passes the test	TLC [NR/QCD/APM05 WI(77)]
3.	Moisture (% w/w)	< 5.0	3.2	As per USP <921> Method II
4.	Acid insoluble Ash (% w/w)	< 3.0	0.5	As per USP <561>
5.	Bulk density (g/cc)	0.20 – 0.60	0.46	
6.	Tapped bulk density (g/cc)	0.20 – 0.80	0.76	As per USP <616> Method I
7.	Material passing through 30# BS/35 ASTM (% w/w)	> 99.0	100	As per USP <786> Particle size distribution
8.	Heavy Metals			ICP –MS
	Lead	< 10.0 ppm	0.2	
	Arsenic	< 2.0 ppm	< 0.1	
	Cadmium	< 1.0 ppm	< 0.1	
	Mercury	< 0.1 ppm	< 0.1	
9.	Microbiology Test			As per USP <61> & <62>
	Total viable aerobic count	< 10 ⁴ cfu g ⁻¹	200	
	Total fungal count	< 10 ² fs g ⁻¹	No growth	
	Total enterobacteriaceae	< 10 ² org g ⁻¹	< 1	
	E. coli	Absent/ g	Absent	
	Salmonella species	Absent/ 10 g	Absent	
	S. aureus	Absent/ g	Absent	
10.	Aflatoxins (ppb)	< 5.0	Complies	As per USP
11.	Pesticide residue analysis	To comply with USP	Complies	As per AOAC/USP
12.	Residual solvent analysis	To comply with BP	Complies	As per BP/USP
13.	Bio-Assay			[NR/BSY/SOP/019/02]
	Lipoxygenase inhibition assay IC ₅₀ (mcg/ml)	< 550.0	Complies	
14.	Phytochemical Analysis			By HPLC [NR/QCD/APM04 WI(77)]
	Andrographolide (% w/w)	> 30.0	32.5	
	Isoandrographolide (% w/w)	> 0.3	0.5	
	Neoandrographolide (% w/w)	> 1.0	2.7	
	Andrograpanin (% w/w)	> 0.3	0.9	
	14-Deoxy-11, 12-didehydroandrographolide (% w/w)	> 5.0	4.7	
	Skullcapflavone-1 (% w/w)	> 0.05	0.06	
	7-O—Methylwogonin (% w/w)	> 0.05	0.09	
	Total Andrographolides (% w/w)	≥ 33.0	41.5	

Remarks : The above referred batch conforms to the specification of KalmCold™ with respect to above mentioned tests.


ANALYST

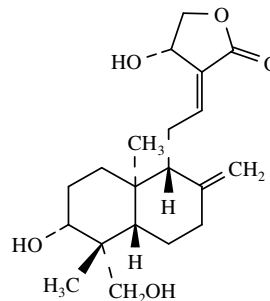

AUTHORISED SIGNATORY

CERTIFICATE OF ANALYSIS

Date: 09.02.2013

ANDROGRAPHOLIDE

Product code : **A009**
Lot. no. : T12A001
Storage : At 18-25°C



Valid up to : Jan 2014

Molecular formula : C₂₀H₃₀O₅
Formula weight : 350.454
CAS No : 5508-58-7

TESTS	RESULTS
Description	: Off white powder
Solubility	: Soluble in alcohol. Insoluble in benzene, acetone and water
Identity & Purity (by Spectroscopy & Chromatography)	
TLC & HPTLC	: Gives a single principle spot
UV absorption	: Exhibits maxima at 225 nm
FTIR	: Characteristic of 'Andrographolide'
¹ H NMR	: Characteristic of 'Andrographolide'
¹³ C NMR	: Characteristic of 'Andrographolide'
MASS	: Characteristic of 'Andrographolide'
HPLC purity (% w/w)	: 99.0 %


ANALYST


AUTHORISED SIGNATORY

CERTIFICATE OF ANALYSIS

Product name	: Powdered Ashwagandha Root extract	Batch No.	: RD/2946
Botanical name	: <i>Withania somnifera</i>	Lab Reference / Report No.	: FP1302044
Code	: NRPARE2.5-USP	Date of Report	: 12.02.2013
Plant part	: Root	Mfg. date	: February 2013
Fresh/Dry	: Dry	Retest date	: February 2015
Solvent	: Methanol, Water	Country of origin	: India
Excipient/s	: Nil		
Herb to extract ratio	: 10 : 1		

TEST RESULTS

SL. NO.	TESTS	SPECIFICATION	RESULT	TEST PROTOCOL
1.	Description	Light yellowish-brown to Brown powder	Brown powder	-
2.	Identification			
	a) TLC	To pass the test	Passes the test	As per USP
	b) HPLC			
3.	Phytochemical Analysis			
	Sum of withanolide aglycones and withanolide glycosides by HPLC (% w/w)	2.5 - 2.8	2.6	As per USP
	Withaferin A (%w/w)*	>0.6	0.7	By HPLC
4.	Impurities			
	Inorganic Impurities			
	Heavy metal analysis (ppm)	< 20	Complies	As per USP Method II <231>
5.	Organic Impurities			
	Pesticide residue analysis	To pass the test	Passes the test (Refer Annexure - I)	As per USP <561>
6.	Specific Tests			
	Loss on drying (%w/w)	< 6.0	3.6	As per USP <731>
7.	Microbial Enumeration Tests			
	Total aerobic bacterial count	< 10 ⁴ cfu g ⁻¹	100	As per USP <2021>
	Total combined yeast and mold count	< 10 ³ fs g ⁻¹	No growth	
8.	Microbiologica procedures for absence of specified micro organisms			
	Salmonella Species (10g)	Absent	Absent	As per USP <2022>
	Escherichia coli (1g)	Absent	Absent	
9.	Aflatoxins	To pass the test	Passes the test	As per USP <561>
10.	Residual solvent			
	Methanol	< 3000 ppm	359	As per USP <565>

Remarks: The above referred batch conforms to the specification of Powdered Ashwagandha root extract with respect to above mentioned tests.

* Additional Phytochemical specifications (Not given in USP monograph)

Packaging and Storage: Preserve in well-stored containers, protected from light and moisture, and store at controlled room temperature



ANALYST



AUTHORISED SIGNATORY