

## S.R. LABS

Office & Works: 230/20, Sector 23, Haldighati Marg, Pratap Nagar, Sanganer, Jaipur-302033

Rajasthan, INDIA | Mob.: 7340031402-03-04, E. Mail: srlabjpr@gmail.com

Website: www.srlabindia.com

An AYUSH Approved (Ayush DTL/03) and ISO 9001:2015 Certified Laboratory

#### CERTIFICATE OF ANALYSIS

(Stability study report) [FORM 50, rule 160-D (f)]

[Under the Drugs & cosmetics Act 1940& rules 1945]

Report No TR-1212/2020 (R-01)					Sample ID-SRN-20L04-01							
Name of manufacturer from whom sample is received				M/s HCP Wellness LLP, 233 Mahagujarat Industrial, Estate, Opp Mangalam Packing,								
D. C. Letter from the				Moraiya-382223, TA Sanand, Dist- Ahmedabad TRF-20L04 Dated-05/12/2020, "6 months - Accelerated Stability Study for								
Reference no. or letter from the manufacturer				6 months and storage condition Temperature-40±2°C, Humidity-75±5%"								
GINNESUM SCH	MI Waliotta (2000)	D	.1.1	Vunadant Assum	adic D	ontis	t Cel	crature 10-	. 0,11			
Name of ASU drug or Raw material				Yunadent Ayurvedic Dentist Gel 3 X 50g Mfg. License No GA/1						76		
	e Quantity	,		Lab-01 Batch Size				NS				
Batch Date o				01/2020 Date of sample receipt					05/12/2020			
Date o				NS Date of sample tested					14/06/2021			
				110								
Descrip		Viscous Gel						Color	Brown	-		
Appearance Viscous Gel Odour Aromatic						Taste						
S. No.				Test method	Unit			Results		Limits		
A.							0 Day	3 months	6 months			
1.	pH Value (	10% Solution)	API P	Part I, VolVI, 2009	-		7.41	7.46	7.53	6.50 to 8.50		
2.			APIF	Part I, VolVI, 2009	-		1.2202	1.2274	1.2347	NLT 0.99		
3.			API F	Part I, VolVI, 2009	%w	/w	78.76	79.24	79.85	NMT 85		
4.	Refractive Index API		API F	Part I, VolVI, 2009	-		1.465	1.464	1.466	1.40 to 1.50		
5.	Total Ash API F		art I, VolVI, 2009	%w/w		14.70	14.25	15.21	NMT 20.0			
6.	Acid Insoluble Ash API P		art I, VolVI, 2009	, VolVI, 2009 %w/		11.22	10.89	11.54	NMT 15.0			
В.		ogical Analysis*										
7.	Total Bacterial Count API F		Part I, VolVI, 2009	cfu/	g	<10	<10	<10	NMT 100000			
8.			art I, VolVI, 2009	cfu/	g	<10	<10	<10	NMT 1000			
C.	Specific Pa	athogens										
9.			Part-I Vol-VI, 2009	Abser	nt/g	Absent	Absent	Absent	Absent			
10.	100		Part-I Vol-VI, 2009	Abser	nt/g	Absent	Absent	Absent	Absent			
11.	P.		art-I Vol-VI, 2009	Abser	_	Absent	Absent	Absent	Absent			
12.	Ps. aeruginosa API I			art-I Vol-VI, 2009	Abser	ıt/g	Absent	Absent	Absent	Absent		

API- Ayurvedic Pharmacopoeia of India, cfu-colony-forming unit, NMT-Not More than, NLT-Not less than, NS- Not Specified Note: -Above results of Batch-Lab-01 "0 day, 3 months, and 6 months" data of sample testing of Accelerated Stability study of 6 months.

Opinion-On the basis of above "Accelerated Stability Study" results, it is hereby confirmed that the product tested is of STANDARD QUALITY with respect to below statement: The samples tested conform with "Ayurvedic Pharmacopoeia of India" and limits provided by customer. The testing observations do not reflect any major significant difference in "0, 3 and 6 months" result data.

Remark: - Shelf life of above tested sample declared to be 6 months on basis of stability study results

Date: 14/06/2021 Place: Jaipur, Raj.

PERSON N-CHARGE TESTING

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- Note: Party asked for above test only. The result listed refer only to the sample (as provided by the party) and tested for applicable parameter, on the date of analysis, endorsement of products is neither inferred nor implied.
- The certificate of analysis is not to be reproduced -wholly or in part and cannot be used as an evidence in the court of law and should not be used in any advertising media without our special permission in writing.
- The jurisdiction for any legal case shall be limited to competent courts at Jaipur only.

<sup>\*</sup> We provide complete testing and research solution in Ayurved (AYUSH) Pharmaceutical, Food and Nutraceutical products.



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[FORM 50, rule 160-D (f)]

	[U]	nder the Drugs & cosme	tics Act 1940& rules 1945]				
Ren	ort No TR-1312/2020	(R-01)	Sample ID-SRN-20L04-02				
Name of manufacturer from whom sample is received  Reference no. or letter from the manufacturer		M/s HCP Wellness LLP, 233 Mahagujarat Industrial, Estate, Opp Mangalam Packing, Moraiya-382223, TA Sanand, Dist- Ahmedabad					
		6 months and sto	TRF-20L04 Dated-05/12/2020, "6 months - Accelerated Stability Study for 6 months and storage condition Temperature-40±2°C, Humidity-75±5%"				
Name of ASU	lrug or Raw material	Yunadent Ayury	redic Dentist Gel		GA/1876		
Sample Quanti		3 X 50g	Mfg. License No	Mfg. License No			
Batch No.	· ·	Lab-02	Batch Size	Batch Size			
Date of Mfg.		01/2020	Date of sample i	Date of sample receipt			
Date of Exp.		NS	Date of sample t	Date of sample tested			
Description:-							
Appearance Viscous Gel				Color	Brown		
Odour	Aromatic			Taste	-		

Appear	rance	nce Viscous Gel					Color Brown		
Odour			T		Taste	-			
S. No.		t Parameters	Test method	Unit		Re	sults		Limits
A.	Physiochemical Analysis				0 Day	3 mon	ths	6 months	
1.	pH Value (10% Solution)		API Part I, VolVI, 2009	-	7.45	7.5	50	7.56	6.50 to 8.50
2.	Specific (	Gravity at 25°C	API Part I, VolVI, 2009	-	1.2195	1.22	248	1.2304	NLT 0.99
3.	Total Sol	id	API Part I, VolVI, 2009	%w/w	79.05	78.	82	79.68	NMT 85
4.	Refractive Index		API Part I, VolVI, 2009	-	1.470	1.4	69	1.471	1.40 to 1.50
5.	Total Ash		API Part I, VolVI, 2009	%w/w	14.55	14.	90	15.24	NMT 20.0
6.	Acid Insoluble Ash		API Part I, VolVI, 2009	%w/w	11.10	11.	55	11.97	NMT 15.0
В.	Microbio	ological Analysis*							
7.	Total Bacterial Count		API Part I, VolVI, 2009	cfu/g	<10	<1	0	<10	NMT 100000
8.	Total Fungal Count		API Part I, VolVI, 2009	cfu/g	<10	<1	0	<10	NMT 1000
C.	Specific 1	Pathogens							
9.	E. coli		API Part-I Vol-VI, 2009	Absent/g	Absent	Abse	ent	Absent	Absent
10.	Salmonella		API Part-I Vol-VI, 2009	Absent/g	Absent	Abso		Absent	Absent
11.	S. aureus		API Part-I Vol-VI, 2009	Absent/g	Absent	Abse	ent	Absent	Absent
12.	Ps. aeruginosa		API Part-I Vol-VI, 2009	Absent/g	Absent	Abse	ent	Absent	Absent

API- Ayurvedic Pharmacopoeia of India, cfu-colony-forming unit, NMT-Not More than, NLT-Not less than, NS- Not Specified Note: -Above results of Batch-Lab-02 "0 day, 3 months, and 6 months" data of sample testing of Accelerated Stability study of 6 months.

Opinion-On the basis of above "Accelerated Stability Study" results, it is hereby confirmed that the product tested is of STANDARD QUALITY with respect to below statement: The samples tested conform with "Ayurvedic Pharmacopoeia of India" and limits provided observations do not reflect any major significant difference in "0, 3 and 6 months" result data.

Remark: - Shelf life of above tested sample declared to be 6 months on basis of stability study results

Date: 14/06/2021 Place: Jaipur, Raj

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(Page T of I)

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Sample ID-SRN-20L04-03 Report No.- TR-1412/2020 (R-01) M/s HCP Wellness LLP, Name of manufacturer from whom 233 Mahagujarat Industrial, Estate, Opp.- Mangalam Packing, sample is received Moraiya-382223, TA.- Sanand, Dist- Ahmedabad TRF-20L04 Dated-05/12/2020, "6 months - Accelerated Stability Study for Reference no. or letter from the 6 months and storage condition Temperature-40±2°C, Humidity-75±5%" manufacturer Yunadent Ayurvedic Dentist Gel Name of ASU drug or Raw material Mfg. License No.-GA/1876 3 X 50g Sample Quantity **Batch Size** NS Lab-03 Batch No. 05/12/2020 01/2020 Date of sample receipt Date of Mfg. Date of sample tested 14/06/2021 NS Date of Exp.

	ption:-	17. 01				Cal	or Brown	
Appearance		Viscous Gel		Col		1		
Odour	2	Aromatic				Tas	ste -	
S. No.	Test Parameters		Test method Uni			Results		Limits
A.	Physiochemical Analysis				0 Day	3 months	6 months	
1.	pH Value (10% Solution)		API Part I, VolVI, 2009	-	7.42	7.48	7.53	6.50 to 8.50
2.	Specific Gravity at 25°C		API Part I, VolVI, 2009	-	1.2198	1.2250	1.2325	NLT 0.99
3.	Total Solid		API Part I, VolVI, 2009	%w/w	77.58	.77.95	78.35	NMT 85
4.	Refractive Index		API Part I, VolVI, 2009	-	1.468	1.469	1.470	1.40 to 1.50
5.	Total Ash		API Part I, VolVI, 2009	%w/w	14.88	15.14	15.77	NMT 20.0
6.	Acid Insoluble Ash		API Part I, VolVI, 2009	%w/w	11.25	11.70	12.14	NMT 15.0
В.	Microbio	logical Analysis*						1
7.	Total Bacterial Count		API Part I, VolVI, 2009	cfu/g	<10	<10	<10	NMT 100000
8.	Total Fungal Count		API Part I, VolVI, 2009	cfu/g	<10	<10	<10	NMT 1000
C.	Specific P	athogens						
9.	E. coli		API Part-I Vol-VI, 2009	Absent/g	Absent	Absent	Absent	Absent
10.	Salmonella		API Part-I Vol-VI, 2009	Absent/g	Absent	Absent	Absent	Absent
11.	S. aureus		API Part-I Vol-VI, 2009	Absent/g	Absent Abse		Absent	Absent
12.	Ps. aeruginosa		API Part-I Vol-VI, 2009	Absent/g	Absent	Absent	Absent	Absent

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Opinion-On the basis of above "Accelerated Stability Study" results, it is hereby confirmed that the product tested is of STANDARD QUALITY with respect to below statement: The samples tested conform with "Ayurvedic Pharmacopoeia of India" and limits provided by customer. The testing observations do not reflect any major significant difference in "0, 3 and 6 months" result data.

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