



S.R. LABS

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REAL QUALITY
SOLUTION

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, Moraiya-382223, TA.- Sanand, Dist- Ahmedabad		
Reference no. or letter from the manufacturer	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 drug or Raw material	Yunadent Ayurvedic Dentist Gel		
Sample Quantity	3 X 50g	Mfg. License No.-	GA/1876
Batch No.	Lab-01	Batch Size	NS
Date of Mfg.	01/2020	Date of sample receipt	05/12/2020
Date of Exp.	NS	Date of sample tested	14/06/2021

Description:-

Appearance	Viscous Gel	Color	Brown
Odour	Aromatic	Taste	-

S. No.	Test Parameters	Test method	Unit	Results			Limits
				0 Day	3 months	6 months	
A.	Physiochemical Analysis						
1.	pH Value (10% Solution)	API Part I, Vol.-VI, 2009	-	7.41	7.46	7.53	6.50 to 8.50
2.	Specific Gravity at 25°C	API Part I, Vol.-VI, 2009	-	1.2202	1.2274	1.2347	NLT 0.99
3.	Total Solid	API Part I, Vol.-VI, 2009	%w/w	78.76	79.24	79.85	NMT 85
4.	Refractive Index	API Part I, Vol.-VI, 2009	-	1.465	1.464	1.466	1.40 to 1.50
5.	Total Ash	API Part I, Vol.-VI, 2009	%w/w	14.70	14.25	15.21	NMT 20.0
6.	Acid Insoluble Ash	API Part I, Vol.-VI, 2009	%w/w	11.22	10.89	11.54	NMT 15.0
B.	Microbiological Analysis*						
7.	Total Bacterial Count	API Part I, Vol.-VI, 2009	cfu/g	<10	<10	<10	NMT 100000
8.	Total Fungal Count	API Part I, Vol.-VI, 2009	cfu/g	<10	<10	<10	NMT 1000
C.	Specific Pathogens						
9.	<i>E. coli</i>	API Part-I Vol-VI, 2009	Absent/g	Absent	Absent	Absent	Absent
10.	<i>Salmonella</i>	API Part-I Vol-VI, 2009	Absent/g	Absent	Absent	Absent	Absent
11.	<i>S. aureus</i>	API Part-I Vol-VI, 2009	Absent/g	Absent	Absent	Absent	Absent
12.	<i>Ps. aeruginosa</i>	API Part-I Vol-VI, 2009	Absent/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 IN 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.
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CERTIFICATE OF ANALYSIS (Stability study report)

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

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

Report No.- TR-1312/2020 (R-01)		Sample ID-SRN-20L04-02	
Name of manufacturer from whom sample is received	M/s HCP Wellness LLP, 233 Mahagujarat Industrial, Estate, Opp.- Mangalam Packing, Moraiya-382223, TA.- Sanand, Dist- Ahmedabad		
Reference no. or letter from the manufacturer	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 drug or Raw material	Yunadent Ayurvedic Dentist Gel		
Sample Quantity	3 X 50g	Mfg. License No.-	GA/1876
Batch No.	Lab-02	Batch Size	NS
Date of Mfg.	01/2020	Date of sample receipt	05/12/2020
Date of Exp.	NS	Date of sample tested	14/06/2021

Description:-

Appearance	Viscous Gel	Color	Brown
Odour	Aromatic	Taste	-

S. No.	Test Parameters	Test method	Unit	Results			Limits
A.	Physiochemical Analysis			0 Day	3 months	6 months	
1.	pH Value (10% Solution)	API Part I, Vol.-VI, 2009	-	7.45	7.50	7.56	6.50 to 8.50
2.	Specific Gravity at 25°C	API Part I, Vol.-VI, 2009	-	1.2195	1.2248	1.2304	NLT 0.99
3.	Total Solid	API Part I, Vol.-VI, 2009	%w/w	79.05	78.82	79.68	NMT 85
4.	Refractive Index	API Part I, Vol.-VI, 2009	-	1.470	1.469	1.471	1.40 to 1.50
5.	Total Ash	API Part I, Vol.-VI, 2009	%w/w	14.55	14.90	15.24	NMT 20.0
6.	Acid Insoluble Ash	API Part I, Vol.-VI, 2009	%w/w	11.10	11.55	11.97	NMT 15.0
B.	Microbiological Analysis*						
7.	Total Bacterial Count	API Part I, Vol.-VI, 2009	cfu/g	<10	<10	<10	NMT 100000
8.	Total Fungal Count	API Part I, Vol.-VI, 2009	cfu/g	<10	<10	<10	NMT 1000
C.	Specific Pathogens						
9.	<i>E. coli</i>	API Part-I Vol-VI, 2009	Absent/g	Absent	Absent	Absent	Absent
10.	<i>Salmonella</i>	API Part-I Vol-VI, 2009	Absent/g	Absent	Absent	Absent	Absent
11.	<i>S. aureus</i>	API Part-I Vol-VI, 2009	Absent/g	Absent	Absent	Absent	Absent
12.	<i>Ps. aeruginosa</i>	API Part-I Vol-VI, 2009	Absent/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-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 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.



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

Report No.- TR-1412/2020 (R-01)		Sample ID-SRN-20L04-03	
Name of manufacturer from whom sample is received	M/s HCP Wellness LLP, 233 Mahagujarat Industrial, Estate, Opp.- Mangalam Packing, Moraiya-382223, TA.- Sanand, Dist- Ahmedabad		
Reference no. or letter from the manufacturer	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 drug or Raw material	Yunadent Ayurvedic Dentist Gel		
Sample Quantity	3 X 50g	Mfg. License No.-	GA/1876
Batch No.	Lab-03	Batch Size	NS
Date of Mfg.	01/2020	Date of sample receipt	05/12/2020
Date of Exp.	NS	Date of sample tested	14/06/2021

Description:-							
Appearance		Viscous Gel			Color	Brown	
Odour		Aromatic			Taste	-	
S. No.	Test Parameters	Test method	Unit	Results			Limits
A.	Physiochemical Analysis			0 Day	3 months	6 months	
1.	pH Value (10% Solution)	API Part I, Vol.-VI, 2009	-	7.42	7.48	7.53	6.50 to 8.50
2.	Specific Gravity at 25°C	API Part I, Vol.-VI, 2009	-	1.2198	1.2250	1.2325	NLT 0.99
3.	Total Solid	API Part I, Vol.-VI, 2009	%w/w	77.58	77.95	78.35	NMT 85
4.	Refractive Index	API Part I, Vol.-VI, 2009	-	1.468	1.469	1.470	1.40 to 1.50
5.	Total Ash	API Part I, Vol.-VI, 2009	%w/w	14.88	15.14	15.77	NMT 20.0
6.	Acid Insoluble Ash	API Part I, Vol.-VI, 2009	%w/w	11.25	11.70	12.14	NMT 15.0
B.	Microbiological Analysis*						
7.	Total Bacterial Count	API Part I, Vol.-VI, 2009	cfu/g	<10	<10	<10	NMT 100000
8.	Total Fungal Count	API Part I, Vol.-VI, 2009	cfu/g	<10	<10	<10	NMT 1000
C.	Specific Pathogens						
9.	<i>E. coli</i>	API Part-I Vol-VI, 2009	Absent/g	Absent	Absent	Absent	Absent
10.	<i>Salmonella</i>	API Part-I Vol-VI, 2009	Absent/g	Absent	Absent	Absent	Absent
11.	<i>S. aureus</i>	API Part-I Vol-VI, 2009	Absent/g	Absent	Absent	Absent	Absent
12.	<i>Ps. aeruginosa</i>	API Part-I Vol-VI, 2009	Absent/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-03 "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.

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