



AN STUDY OF CHANGING CLASSICAL CHURNA IN CAPSULE DOSE FORM AND ITS STABILITY AND CLINICAL TRIAL

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ABSTRACT

Dosage Form (DF) is defined as the physical form of a dose of a compound used as a drug or medication intended for administration or consumption. The use of cellulose veggie capsule dose form has develop many year ago and since these early days capsules have evolved significantly to meet the current needs of the patient and pharmaceutical industry Herbal medicine growing demand for across the world has resulted in the large scale manufacture of these products. Large scale production leads to need of easy intake or we can say changing its dose form which could lead to deterioration of products, Stability studies on herbal products

have become necessary to help determine the shelf-life and enhance product quality at all times during storage periods and usage. Appropriate guidelines for stability testing of finished herbal products provide manufacturers, regulatory authorities and research institutions with a harmonized system for stability testing. This paper presents on changing Triphala Churna ,Kutaki Churna,Haritaki Churna dose form into cellulose veggie capsule so it will be suitable for patient to intake that medicine . This information will help in the production of safe, stable and efficacious and easy to intake herbal medicinal.

Keywords: Herbal medicines, Herbal dosage forms, cellulose veggie capsule, Churna, Finished herbal products, Stability testing, Shelf-life.

INTRODUCTION-

Over the last three decades, there has been a huge increase in use of herbal products across the world. About 80% of the world's population, especially those in developing countries, uses herbal medicines as part of their primary health care needs [1, 2]. In Ghana, it has been estimated that 70% of the population use herbal medicinal products either alone or in combination with allopathic medicines for their health needs [3]. Herbal products may be defined as plants, parts of plants or extracts from plants that are used in healthcare or in combating the disease. To avoid confusion with culinary herbs, herbs and plant extracts that

have some association with medical uses (prevention and treatment of diseases) are referred to as 'herbal medicinal products' (HMPs) [4]. Many of the plant species currently being used have been used for centuries in a limited part of the world but the increase in global travel and communications has resulted in many of these now being used worldwide [5]. Churna in general is a fine powder of herbs which is filtered through a clean cloth. A lacuna of Churna dose form is this that some Churna taste is very bitter so patient is unable to take Churna easily for that we find a way that if Churna is filled in cellulose veggie capsule then it would be easy for patient to intake that medicine. In this study I have change dose form of three Churna Triphala Churna, Haritaki Churna and Kutaki Churna and make Triphala cellulose veggie capsule Haritaki cellulose veggie capsule and Kutaki cellulose veggie capsule and going to perform these classical Churna stability study for 6 month after changing its dose form into cellulose veggie capsule to find out self life of classical medicine when changes its dose form from Churna to cellulose veggie capsule, we have also perform a pilot study to find out adverse drug reaction on change in dose if any after changing these Churna in cellulose veggie capsule.

Dosage forms of herbal medicinal products –

Dosage forms are the means by which drug molecules or plant parts are delivered to sites of action within the body. The routes for which herbal dosage forms may be administered include oral, rectal, topical, parenteral, respiratory, nasal, ophthalmic [6]. Categorization of finished herbal products into dosage forms will help to define specific protocols for quality control and stability testing. Herbal medicinal products may be defined as finished, labelled medicinal products that contain as active ingredients aerial or underground parts of plants, or other plant material, or combinations thereof, whether in the crude state or as plant preparations [7, 8]. Herbal medicines may contain excipients in addition to the active ingredients. Medicines containing plant materials combined with chemically defined active substances, including chemically defined, isolated constituents of plants, are not considered to be herbal medicines [9]. Finished herbal products or herbal drug preparations are varied and various solvents may be used for their extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminute or powdered herbal drugs, tinctures, extracts, essential oils, expressed juices and processed exudates [10]

Herbal powders

These are preparations that come as powdered herbal materials meant for direct use or by incorporation into foods, beverages for drinking [11], insufflations [12], and wounds [13]. They may be finely sifted herbal materials from various parts of plants meant for a particular therapeutic effect [14]. Like the herbal teas, the stability of the powder depends on the type and nature of the herbal material as well as the moisture content of the powder in the bags and packaging. The dried herb and extract of the root of *Nauclea latifolia* S. M., an antimalarial plant found growing in Africa, was found to be stable under tropical room temperature conditions for over one year in sealed glass containers [15].

Herbal cellulose veggie capsules

Cellulose veggie capsules are solid dosage forms containing drug and usually, appropriate filler (s) enclosed in a container [16]. Cellulose veggie capsules may be available in capsule for dry powdered herbal ingredients or granules [17], or soft gelatin shells for herbal oils and for herbal ingredients that are dissolved or suspended in oil. The gelatin shell readily ruptures and dissolves following oral administration. Drugs are normally more readily released from cellulose veggie capsules compared to tablets [18]. Cellulose veggie capsules may help mask the unpleasant taste of its contents and uniformity of dosage can be relatively readily achieved .

AIM AND OBJECTIVE-

- 1-to find out any change in shelf life after filling classical Churna in cellulose veggie capsule
- 2-to find out any different finding of standardization parameters after changing classical Churna in cellulose veggie capsule form
- 3-to find out is there any change in therapeutic effect or in dose form after changing classical Churna in cellulose veggie capsule form.

Drug review-

Triphala -

Triphala is a drug widely used in many disorders due to its various pharmacological activities. Triphala is composed of the three myrobalans, Terminalia chebula Retz. (Haritaki), Terminalia bellerica Roxb. (Bibhitaki) and Emblica officinalis Gaertn. (Amalaki) and is one of the most commonly used Ayurvedic preparations. The formulation generally consists of equal proportions of pericarps of this drugs.quality of these drugs are-

Haritaki

Latin name	Terminalia chebula Linn.
Family	Combretaceae
Classical name	Haritaki
Sanskrit synonyms	Haritaki, Pathya, Abhaya, Avyatha, Vayastha, Haimavati, Shiva
Hindi name	Harre, Harad
English name	Chebolic Myrobalan
Rasa	Kashaya
Guna	Laghu, Ruksha
Virya	Ushna
Vipaka	Madhura
Prabhava	Tridoshagna
Dosha karma	Kapha hara
Parts used	Fruit

Vibhitaki

Latin name	Terminalia bellerica Roxb
Family	Combretaceae
Classical name	Vibhitaka
Sanskrit synonyms	Aksh, Karshphala, Kalidrum,
Hindi name	Bahada
English name	Beleric
Rasa	Kashya
Guna	Laghu, Ruksha,
Virya	Ushna
Vipaka	Madhura
Prabhava	Tridoshagna
Dosha karma	Kapha Pitta hara
Parts used	Fruit

Amalaki

Latin name	Emblica officinalis Gartn.
Family	Euphorbiaceae
Classical name	Amalaki, Dhatri
Hindi name	Awala, Amla, Aonla
Sanskrit synonymns	Amalaki, Dhatri, Vyastha
English name	Indian gooseberry
Rasa	Pancharasa (Amla predominance and Lavanarahita)
Guna	Laghu, Ruksha, Sita
Virya	Sita
Vipaka	Madhura
Prabhava	Rasayan
Dosha karma	Tridoshhara, Pittasamaka (mainly)
Parts used	Fruits

Kutki

Kingdom	Plantae
Class	Dicotyledonae
Sub class	Asteride
Order	Scrophulariales
Family	Scrophulariaceae
Genus	Picrorhiza
Species	kurroa and
Sanskrit synonymns	Katuka Tikta

Hindi name	Kutaki
English name	Picrorhiza
Rasa	Tikta
Guna	Laghu, Ruksha,
Virya	Shita
Vipaka	Katu
Prabhava	Tridoshagna
Dosha karma	Kapha Pitta hara
Parts used	Rhizome

Rasa Panchaka

Dravya	Haritaki	Vibhitaki	Amalaki	Triphala
Rasa	Panchrasa(Kasaya)	Katu	Panchrasa(Amla)	Kasaya
Guna	Laghu,Ruksha	Laghu,Ruksha	Laghu,Ruksha, Sita	Ruksha,Sara
Virya	Ushna	Ushna	Sita	Anusna
Vipaka	Madhura	Madhura	Madhura	Madhura
Prabhav	Rasayana	Chedana	Rasayana	Rasayana
Dosha-Karma	Vata	Kapha	Pitta	Tridosha
Karma	Anulomana, Caksusya,Dipana, Hridaya, Medhya, Sarvadosha-	Caksusya, Kesya, Bhedaka. Krminasana, Kasahara	Vrisya, Caksusya	Caksusya, Dipana, Varnaropana , Rucikara, Medohara

Pharmaceutical preparation-

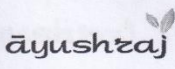
Material–All raw drugs has been collected from the raw drug store of Sbld Ayurved Viswabharati pharmacy,Sardarsahar.

Method-The drugs are cleaned and dried properly. They are finely powdered and sieved. In Triphala each one is separately powdered, sieved, accurately weighed and then all mixed together. The powder is fine to the extent of at least 80 mesh sieves. It should not adhere together or become moist. The finer powder has better therapeutic value.after that powder is going to be fill in cellulose veggie capsule with the help of cellulose veggie capsule filling mechine .



Stability study-

Stability study is done by NABL Certified lab name as ayushraj ,Jaipur.three batch sample of each herbal cellulose veggie capsule six month stability reports are-

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	STABILITY STUDY REPORT				

Product Name	Haritaki Churna Capsule	Ref. No.	2212 K	Test Start Date	11/11/2022
Mfg. by	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403	Packing Quantity	10 Caps.	Test End Date	23/05/2023
Mkt. By	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403	Name of Packing Material	Plastic Bottles	Stability Type	Accelerated
Report No.	SR/220607	Pilot or Commercial Batch	Pilot	Storage Conditions	40±2°C Temp & 75±5% RH
Batch No.	Hc001	Date of Mfg.	15/10/2022	Proposed Date of Exp.	15/10/2024

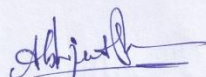
S. No	Particular	Test Method	Specifications	UOM	0 Days	3 Month	6 Month
1.	Description	In House AD/STP/68/00	Clear Transparent Capsules filled with Light Yellow Colored Powder	-	Clear Transparent Capsules filled with Light Yellow Colored Powder	Clear Transparent Capsules filled with Light Yellow Colored Powder	Clear Transparent Capsules filled with Light Yellow Colored Powder
2.	pH (1% Aqueous Solution)	API Part II Vol. IV	3.0-6.0	-	3.55	3.57	3.59
3.	Loss on Drying at 105° C	API Part II Vol. IV	NMT 7.0	% w/w	5.28	5.30	5.37
4.	Total Ash	API Part II Vol. IV	NMT 10.0	% w/w	3.58	3.67	3.62
5.	Acid Insoluble Ash	API Part II Vol. IV	NMT 5.0	% w/w	0.69	0.71	0.70
6.	Water Soluble Extractive	API Part II Vol. IV	NLT 50.0	% w/w	59.90	62.14	60.78
7.	Alcohol Soluble Extractive	API Part II Vol. IV	NLT 50.0	% w/w	71.81	72.54	71.20
Microbiological Analysis							
8.	Total Aerobic Microbial Count	API Part II Vol. IV	<100000	cfu/gm	10000	12000	14000
9.	Total Fungal Count	API Part II Vol. IV	<1000	cfu/gm	250	380	400
10.	<i>Escherichia coli</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
11.	<i>Salmonella</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
12.	<i>Staphylococcus aureus</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
13.	<i>Pseudomonas aeruginosa</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent

API- Ayurvedic Pharmacopoeia of India, NLT-Not Less Than, NMT-Not More Than, UOM-Unit of Measurement, Sr. No. 1-7 Specifications provided by customer, S.No. 8-13 are API Specification

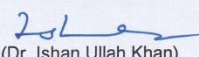
Note:- In the opinion of the undersigned the sample referred to above has been evaluated for stability and is having a claimed shelf life of 2 years as mentioned in D & C act and rules made there under for the reason given below-

"No significant change" occurs during at any time of testing at accelerated storage conditions

---End of Report---


(Abhijeet Sharma)
Microbiologist

Date: 23/05/2023


(Dr. Ishan Ullah Khan)
Person In charge
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Format No. FN/AD/GP/15/001/02



TC-5447



TEST REPORT

[Form 50, Rule 160 D (f)]

[Under the Drugs & Cosmetics Act 1940 and the Drugs & Cosmetics rules 1945 there under]

Name & Address of Customer #	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403		
Name of Sample #	Haritaki Churna Capsule	Sample ID	2324 E-01
Test Report No.	AR/14905/23	Sample Code/ Batch No.#	Hc001
ULR No.	TC544723000001239F	Mfg. License No. #	164 Ayu.
Date of Receipt	18/05/2023	Mfg. Date #	15/10/2022
Date of Sample Testing	18/05/2023 to 23/05/2023	Exp. Date #	15/10/2024
Report Issue Date	23/05/2023	Sample Quantity	1 x 10 Caps.
Environmental Condition	Temperature (°C): As per Standard, Relative Humidity (%): As per Standard		


S.N.	Parameters	Specification	Results	UOM	Test method
1.	Description	Clear Transparent Capsules filled with Light Yellow Colored Powder	Clear Transparent Capsules filled with Light Yellow Colored Powder	-	In House AD/STP/68/00
2.	pH (1% Aqueous Solution)	3.0-6.0	3.59	-	API Part-II Vol.-IV
3.	Loss on Drying at 105° C	NMT 7.0	5.37	% w/w	API Part-II Vol.-IV
4.	Total Ash	NMT 10.0	3.62	% w/w	API Part-II Vol.-IV
5.	Acid Insoluble Ash	NMT 5.0	0.70	% w/w	API Part-II Vol.-IV
6.	Water Soluble Extractive	NLT 50.0	60.78	% w/w	API Part-II Vol.-IV
7.	Alcohol Soluble Extractive	NLT 50.0	71.20	% w/w	API Part-II Vol.-IV
Microbiological Analysis					
8.	Total Aerobic Microbial Count	<100000	14000	cfu/gm	API Part-II Vol.-IV
9.	Total Fungal Count	<1000	400	cfu/gm	API Part-II Vol.-IV
10.	<i>Escherichia coli</i>	Absent	Absent	Per gm	API Part-II Vol.-IV
11.	<i>Salmonella</i>	Absent	Absent	Per gm	API Part-II Vol.-IV
12.	<i>Staphylococcus aureus</i>	Absent	Absent	Per gm	API Part-II Vol.-IV
13.	<i>Pseudomonas aeruginosa</i>	Absent	Absent	Per gm	API Part-II Vol.-IV

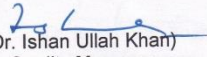
API- Ayurvedic Pharmacopoeia of India, NLT-Not Less Than, NMT-Not More Than, UOM-Unit of Measurement, #-Information Provided by Customer, Sr. No. 1-7 Specifications provided by customer, S. No. 8-13 are API Specifications

Report:- In opinion of the undersigned, The sample referred to above is of **Standard Quality** as defined in the act and the rules made there under for the reason given below:

"The sample conforms to Customer specification & API Specification" with respect to above tested parameters only

----End of Report----

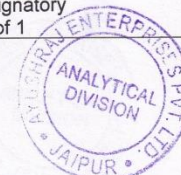

(Abhijeet Sharma)
Technical Manager (Biological)
Authorized Signatory



(Dr. Ishan Ullah Khan)
Quality Manager
Authorized Signatory

Date: 23/05/2023

Note: Party asked for above test only.

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3. The results apply to the sample as received.
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5. Total liability of this laboratory shall be limited the invoice amount.



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STABILITY STUDY REPORT	

Product Name	Haritaki Churna Capsule	Ref. No.	2212 K	Test Start Date	11/11/2022
Mfg. by	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403	Packing Quantity	10 Caps.	Test End Date	23/05/2023
Mkt. By	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403	Name of Packing Material	Plastic Bottles	Stability Type	Accelerated
Report No.	SR/220607	Pilot or Commercial Batch	Pilot	Storage Conditions	40±2°C Temp & 75±5% RH
Batch No.	Hc002	Date of Mfg.	17/10/2022	Proposed Date of Exp.	17/10/2024


S. No	Particular	Test Method	Specifications	UOM	0 Days	3 Month	6 Month
1.	Description	In House AD/STP/68/00	Clear Transparent Capsules filled with Light Yellow Colored Powder		Clear Transparent Capsules filled with Light Yellow Colored Powder	Clear Transparent Capsules filled with Light Yellow Colored Powder	Clear Transparent Capsules filled with Light Yellow Colored Powder
2.	pH (1% Aqueous Solution)	API Part II Vol. IV	3.0-6.0	-	3.56	3.58	3.52
3.	Loss on Drying at 105° C	API Part II Vol. IV	NMT 7.0	% w/w	5.66	5.70	5.75
4.	Total Ash	API Part II Vol. IV	NMT 10.0	% w/w	3.32	3.36	3.38
5.	Acid Insoluble Ash	API Part II Vol. IV	NMT 5.0	% w/w	0.57	0.60	0.62
6.	Water Soluble Extractive	API Part II Vol. IV	NLT 50.0	% w/w	60.13	62.18	61.89
7.	Alcohol Soluble Extractive	API Part II Vol. IV	NLT 50.0	% w/w	72.09	73.19	72.33
Microbiological Analysis							
8.	Total Aerobic Microbial Count	API Part II Vol. IV	<100000	cfu/gm	13000	15000	16000
9.	Total Fungal Count	API Part II Vol. IV	<1000	cfu/gm	223	320	350
10.	<i>Escherichia coli</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
11.	<i>Salmonella</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
12.	<i>Staphylococcus aureus</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
13.	<i>Pseudomonas aeruginosa</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent

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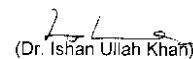
Note: - In the opinion of the undersigned the sample referred to above has been evaluated for stability and is having a claimed shelf life of 3 years as mentioned in D & C act and rules made there under for the reason given below-

"No significant change" occurs during at any time of testing at accelerated storage conditions

----End of Report----


 (Abhijeet Sharma)
 Microbiologist

Date: 23/05/2023


 (Dr. Ishan Ullah Khan)
 Person In charge

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TC-5447



TEST REPORT

[Form 50, Rule 160 D (f)]

[Under the Drugs & Cosmetics Act 1940 and the Drugs & Cosmetics rules 1945 there under]

Name & Address of Customer #	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403		
Name of Sample #	Haritaki Churna Capsule	Sample ID	2324 E-02
Test Report No.	AR/15005/23	Sample Code/ Batch No.#	Hc002
ULR No.	TC544723000001240F	Mfg. License No. #	164 Ayu.
Date of Receipt	18/05/2023	Mfg. Date #	17/10/2022
Date of Sample Testing	18/05/2023 to 23/05/2023	Exp. Date #	17/10/2024
Report Issue Date	23/05/2023	Sample Quantity	1 x 10 Caps.
Environmental Condition	Temperature (°C): As per Standard, Relative Humidity (%): As per Standard		

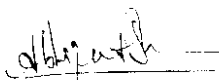
S.N.	Parameters	Specification	Results	UOM	Test method
1.	Description	Clear Transparent Capsules filled with Light Yellow Colored Powder	Clear Transparent Capsules filled with Light Yellow Colored Powder	-	In House AD/STP/68/00
2.	pH (1% Aqueous Solution)	3.0-6.0	3.52	-	API Part-II Vol.-IV
3.	Loss on Drying at 105° C	NMT 7.0	5.75	% w/w	API Part-II Vol.-IV
4.	Total Ash	NMT 10.0	3.38	% w/w	API Part-II Vol.-IV
5.	Acid Insoluble Ash	NMT 5.0	0.62	% w/w	API Part-II Vol.-IV
6.	Water Soluble Extractive	NLT 50.0	61.89	% w/w	API Part-II Vol.-IV
7.	Alcohol Soluble Extractive	NLT 50.0	72.33	% w/w	API Part-II Vol.-IV
Microbiological Analysis					
8.	Total Aerobic Microbial Count	<100000	16000	cfu/gm	API Part-II Vol.-IV
9.	Total Fungal Count	<1000	350	cfu/gm	API Part-II Vol.-IV
10.	<i>Escherichia coli</i>	Absent	Absent	Per gm	API Part-II Vol.-IV
11.	<i>Salmonella</i>	Absent	Absent	Per gm	API Part-II Vol.-IV
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"The sample conforms to Customer specification & API Specification" with respect to above tested parameters only

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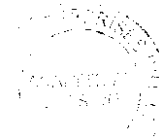

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<p>STABILITY STUDY REPORT</p>	

Product Name	Haritaki Churna Capsule	Ref. No.	2212 K	Test Start Date	11/11/2022
Mfg. by	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403	Packing Quantity	10 Caps.	Test End Date	23/05/2023
Mkt. By	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403	Name of Packing Material	Plastic Bottles	Stability Type	Accelerated
Report No.	SR/220607	Pilot or Commercial Batch	Pilot	Storage Conditions	40±2°C Temp & 75±5% RH
Batch No.	Hc003	Date of Mfg.	26/10/2022	Proposed Date of Exp.	26/10/2024

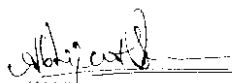
S. No	Particular	Test Method	Specifications	UOM	0 Days	3 Month	6 Month
1.	Description	In House AD/STP/68/00	Clear Transparent Capsules filled with Light Yellow Colored Powder	-	Clear Transparent Capsules filled with Light Yellow Colored Powder	Clear Transparent Capsules filled with Light Yellow Colored Powder	Clear Transparent Capsules filled with Light Yellow Colored Powder
2.	pH (1% Aqueous Solution)	API Part II Vol. IV	3.0-6.0	-	3.53	3.56	3.52
3.	Loss on Dry ng at 105° C	API Part II Vol. IV	NMT 7.0	% w/w	5.55	5.58	5.61
4.	Total Ash	API Part II Vol. IV	NMT 10.0	% w/w	3.49	3.42	3.55
5.	Acid Insoluble Ash	API Part II Vol. IV	NMT 5.0	% w/w	0.53	0.59	0.56
6.	Water Soluble Extractive	API Part II Vol. IV	NLT 50.0	% w/w	59.83	61.08	60.47
7.	Alcohol Soluble Extractive	API Part II Vol. IV	NLT 50.0	% w/w	72.94	73.18	72.29
Microbiological Analysis							
8.	Total Aerobic Microbial Count	API Part II Vol. IV	<100000	cfu/gm	14000	16000	18000
9.	Total Fungal Count	API Part II Vol. IV	<1000	cfu/gm	259	356	400
10.	<i>Escherichia coli</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
11.	<i>Salmonella</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
12.	<i>Staphylococcus aureus</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
13.	<i>Pseudomonas aeruginosa</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent

API- Ayurvedic Pharmacopoeia of India, NLT-Not Less Than, NMT-Not More Than, UOM-Unit of Measurement. Sr. No. 1-7 Specifications provided by customer, S.No. 8-13 are API Specification

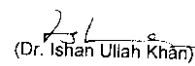
Note:- In the opinion of the undersigned the sample referred to above has been evaluated for stability and is having a claimed shelf life of 2 years as mentioned in D & C act and rules made there under for the reason given below-

"No significant change" occurs during at any time of testing at accelerated storage conditions

----End of Report----


 (Abhijeet Sharma)
 Microbiologist

Date: 23/05/2023


 (Dr. Ishan Ullah Khan)
 Person In charge

Page 1 of 1



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ANALYTICAL DIVISION, JAIPUR

(A Govt. Approved Test House)

Approval No.: Ayush/TL/02

Village Mansinghpura, Dehmi-Begus Road, Ajmer Road, Jaipur (Raj.)-303007, India

Regd. Office: 35 Sushilpura South, Shyam Nagar II, Ajmer Road, Jaipur-302019

E-mail: info@ayushraj.com, Website: www.ayushraj.com

GSTIN No.:08AAICA2524L1ZM, CIN No. U2423RJ2010PTC031000

Format No. FN/AD/GP/15/001/02



TC-5447



TEST REPORT

[Form 50, Rule 160 D (f)]

[Under the Drugs & Cosmetics Act 1940 and the Drugs & Cosmetics rules 1945 there under]

Name & Address of Customer #	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403		
Name of Sample #	Haritaki Churna Capsule	Sample ID	2324 E-03
Test Report No.	AR/15105/23	Sample Code/ Batch No.#	Hc003
ULR No.	TC544723000001241F	Mfg. License No. #	164 Ayu.
Date of Receipt	18/05/2023	Mfg. Date #	26/10/2022
Date of Sample Testing	18/05/2023 to 23/05/2023	Exp. Date #	26/10/2024
Report Issue Date	23/05/2023	Sample Quantity	1 x 10 Caps.
Environmental Condition	Temperature (°C): As per Standard, Relative Humidity (%): As per Standard		


S.N.	Parameters	Specification	Results	UOM	Test method
1.	Description	Clear Transparent Capsules filled with Light Yellow Colored Powder	Clear Transparent Capsules filled with Light Yellow Colored Powder	-	In House AD/STP/68/00
2.	pH (1% Aqueous Solution)	3.0-6.0	3.52	-	API Part-II Vol.-IV
3.	Loss on Drying at 105° C	NMT 7.0	5.61	% w/w	API Part-II Vol.-IV
4.	Total Ash	NMT 10.0	3.55	% w/w	API Part-II Vol.-IV
5.	Acid Insoluble Ash	NMT 5.0	0.56	% w/w	API Part-II Vol.-IV
6.	Water Soluble Extractive	NLT 50.0	60.47	% w/w	API Part-II Vol.-IV
7.	Alcohol Soluble Extractive	NLT 50.0	72.29	% w/w	API Part-II Vol.-IV
Microbiological Analysis					
8.	Total Aerobic Microbial Count	<100000	18000	cfu/gm	API Part-II Vol.-IV
9.	Total Fungal Count	<1000	400	cfu/gm	API Part-II Vol.-IV
10.	<i>Escherichia coli</i>	Absent	Absent	Per gm	API Part-II Vol.-IV
11.	<i>Salmonella</i>	Absent	Absent	Per gm	API Part-II Vol.-IV
12.	<i>Staphylococcus aureus</i>	Absent	Absent	Per gm	API Part-II Vol.-IV
13.	<i>Pseudomonas aeruginosa</i>	Absent	Absent	Per gm	API Part-II Vol.-IV

API- Ayurvedic Pharmacopoeia of India. NLT-Not Less Than, NMT-Not More Than, UOM-Unit of Measurement, #-Information Provided by Customer, Sr. No. 1-7 Specifications provided by customer, S. No. 8-13 are API Specifications


Report:- In opinion of the undersigned, The sample referred to above is of **Standard Quality** as defined in the act and the rules made there under for the reason given below:

"The sample conforms to Customer specification & API Specification" with respect to above tested parameters only

---End of Report---


(Abhijeet Sharma)
Technical Manager (Biological)
Authorized Signatory


Date: 23/05/2023


(Dr. Ishan Ullah Khan)
Quality Manager
Authorized Signatory
Page 1 of 1

Note: Party asked for above test only.

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4. The jurisdiction for any legal case shall be limited to courts at Jaipur only.
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	Vill. Mansinghpura, Dehmi Begus Road, Ajmer Road, Jaipur- 303007 E mail: info@ayushraj.com Website: www.ayushraj.com DTL Lic. No. Ayush/TL/02
STABILITY STUDY REPORT	

Product Name	Kutki Churna Capsule	Ref. No.	2212 K	Test Start Date	11/11/2022
Mfg. by	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403	Packing Quantity	10 Caps.	Test End Date	23/05/2023
Mkt. By	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403	Name of Packing Material	Plastic Bottles	Stability Type	Accelerated
Report No.	SR/220608	Pilot or Commercial Batch	Pilot	Storage Conditions	40±2°C Temp & 75±5% RH
Batch No.	Kc001	Date of Mfg.	15/10/2022	Proposed Date of Exp.	15/10/2024


S. No	Particular	Test Method	Specifications	UOM	0 Days	3 Month	6 Month
1.	Description	In House AD/STP/68/00	Clear Transparent Capsules filled with Brown Colored Powder	-	Clear Transparent Capsules filled with Brown Colored Powder	Clear Transparent Capsules filled with Brown Colored Powder	Clear Transparent Capsules filled with Brown Colored Powder
2.	pH (1% Aqueous Solution)	API Part II Vol. IV	3.0-6.0	-	4.96	5.01	5.05
3.	Loss on Drying at 105° C	API Part II Vol. IV	NMT 7.0	% w/w	4.05	4.08	4.12
4.	Total Ash	API Part II Vol. IV	NMT 10.0	% w/w	3.24	3.25	3.22
5.	Acid Insoluble Ash	API Part II Vol. IV	NMT 5.0	% w/w	0.27	0.31	0.28
6.	Water Soluble Extractive	API Part II Vol. IV	NLT 30.0	% w/w	43.96	45.16	44.66
7.	Alcohol Soluble Extractive	API Part II Vol. IV	NLT 30.0	% w/w	41.87	42.58	42.12
Microbiological Analysis							
8.	Total Aerobic Microbial Count	API Part II Vol. IV	<100000	cfu/gm	15000	16000	18000
9.	Total Fungal Count	API Part II Vol. IV	<1000	cfu/gm	227	520	550
10.	<i>Escherichia coli</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
11.	<i>Salmonella</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
12.	<i>Staphylococcus aureus</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
13.	<i>Pseudomonas aeruginosa</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent

API- Ayurvedic Pharmacopoeia of India, NLT-Not Less Than, NMT-Not More Than, UOM-Unit of Measurement, Sr. No. 1-7 Specifications provided by customer, S.No. 8-13 are API Specification

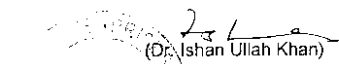
Note:- In the opinion of the undersigned the sample referred to above has been evaluated for stability and is having a claimed shelf life of 2 years as mentioned in D & C act and rules made there under for the reason given below-

"No significant change" occurs during at any time of testing at accelerated storage conditions

---End of Report---


 (Abhijeet Sharma)
 Microbiologist

Date: 23/05/2023


 (Dr. Ishan Ullah Khan)
 Person In charge
 Page 1 of 1

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ANALYTICAL DIVISION, JAIPUR

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GSTIN No.:08AAICA2524L1ZM, CIN No. U2423RJ2010PTC031000

Format No. FN/AD/GP/15/001/02



TC-5447



TEST REPORT

[Form 50, Rule 160 D (f)]

[Under the Drugs & Cosmetics Act 1940 and the Drugs & Cosmetics rules 1945 there under]

Name & Address of Customer #	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403		
Name of Sample #	Kutki Churna Capsule	Sample ID	2324 E-04
Test Report No.	AR/15205/23	Sample Code/ Batch No.#	Kc001
ULR No.	TC544723000001242F	Mfg. License No. #	164 Ayu.
Date of Receipt	18/05/2023	Mfg. Date #	15/10/2022
Date of Sample Testing	18/05/2023 to 23/05/2023	Exp. Date #	15/10/2024
Report Issue Date	23/05/2023	Sample Quantity	1 x 10 Caps.
Environmental Condition	Temperature (°C): As per Standard, Relative Humidity (%): As per Standard		

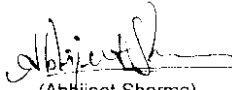
S.N.	Parameters	Specification	Results	UOM	Test method
1.	Description	Clear Transparent Capsules filled with Brown Colored Powder	Clear Transparent Capsules filled with Brown Colored Powder	-	In House AD/STP/68/00
2.	pH (1% Aqueous Solution)	3.0-6.0	5.05	-	API Part-II Vol.-IV
3.	Loss on Drying at 105° C	NMT 7.0	4.12	% w/w	API Part-II Vol.-IV
4.	Total Ash	NMT 10.0	3.22	% w/w	API Part-II Vol.-IV
5.	Acid Insoluble Ash	NMT 5.0	0.28	% w/w	API Part-II Vol.-IV
6.	Water Soluble Extractive	NLT 30.0	44.66	% w/w	API Part-II Vol.-IV
7.	Alcohol Soluble Extractive	NLT 30.0	42.12	% w/w	API Part-II Vol.-IV
Microbiological Analysis					
8.	Total Aerobic Microbial Count	<100000	18000	cfu/gm	API Part-II Vol.-IV
9.	Total Fungal Count	<1000	550	cfu/gm	API Part-II Vol.-IV
10.	<i>Escherichia coli</i>	Absent	Absent	Per gm	API Part-II Vol.-IV
11.	<i>Salmonella</i>	Absent	Absent	Per gm	API Part-II Vol.-IV
12.	<i>Staphylococcus aureus</i>	Absent	Absent	Per gm	API Part-II Vol.-IV
13.	<i>Pseudomonas aeruginosa</i>	Absent	Absent	Per gm	API Part-II Vol.-IV

API- Ayurvedic Pharmacopoeia of India, NLT-Not Less Than, NMT-Not More Than, UOM-Unit of Measurement, #-Information Provided by Customer, Sr. No. 1-7 Specifications provided by customer, S. No. 8-13 are API Specifications

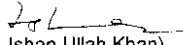
Report:- In opinion of the undersigned, The sample referred to above is of **Standard Quality** as defined in the act and the rules made there under for the reason given below:

"The sample conforms to Customer specification & API Specification" with respect to above tested parameters only

---End of Report---


(Abhijeet Sharma)
Technical Manager (Biological)
Authorized Signatory


Date: 23/05/2023


(Dr. Ishan Ullah Khan)
Quality Manager
Authorized Signatory

Page 1 of 1

Note: Party asked for above test only.

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	STABILITY STUDY REPORT

Product Name	Kutki Churna Capsule	Ref. No.	2212 K	Test Start Date	11/11/2022
Mfg. by	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403	Packing Quantity	10 Caps.	Test End Date	23/05/2023
Mkt. By	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403	Name of Packing Material	Plastic Bottles	Stability Type	Accelerated
Report No.	SR/220608	Pilot or Commercial Batch	Pilot	Storage Conditions	40±2°C Temp & 75±5% RH
Batch No.	Kc002	Date of Mfg.	17/10/2022	Proposed Date of Exp.	17/10/2024

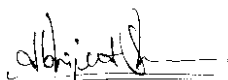
S. No	Particular	Test Method	Specifications	UOM	0 Days	3 Month	6 Month
1.	Description	In House AD/STP/68/00	Clear Transparent Capsules filled with Brown Colored Powder	-	Clear Transparent Capsules filled with Brown Colored Powder	Clear Transparent Capsules filled with Brown Colored Powder	Clear Transparent Capsules filled with Brown Colored Powder
2.	pH (1% Aqueous Solution)	API Part II Vol. IV	3.0-6.0	-	5.06	5.10	5.14
3.	Loss on Drying at 105° C	API Part II Vol. IV	NMT 7.0	% w/w	3.82	3.90	3.96
4.	Total Ash	API Part II Vol. IV	NMT 10.0	% w/w	3.27	3.30	3.33
5.	Acid Insoluble Ash	API Part II Vol. IV	NMT 5.0	% w/w	0.29	0.31	0.30
6.	Water Soluble Extractive	API Part II Vol. IV	NLT 30.0	% w/w	44.41	46.25	45.78
7.	Alcohol Soluble Extractive	API Part II Vol. IV	NLT 30.0	% w/w	39.92	42.01	41.27
Microbiological Analysis							
8.	Total Aerobic Microbial Count	API Part II Vol. IV	<100000	cfu/gm	16000	18000	20000
9.	Total Fungal Count	API Part II Vol. IV	<1000	cfu/gm	241	350	380
10.	<i>Escherichia coli</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
11.	<i>Salmonella</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
12.	<i>Staphylococcus aureus</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
13.	<i>Pseudomonas aeruginosa</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent

API- Ayurvedic Pharmacopoeia of India, NLT-Not Less Than, NMT-Not More Than, UOM-Unit of Measurement, Sr. No. 1-7 Specifications provided by customer, S.No. 8-13 are API Specification

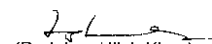
Note:- In the opinion of the undersigned the sample referred to above has been evaluated for stability and is having a claimed shelf life of 2 years as mentioned in D & C act and rules made there under for the reason given below-

"No significant change" occurs during at any time of testing at accelerated storage conditions

---End of Report---


 (Abhijeet Sharma)
 Microbiologist

Date: 23/05/2023


 (Dr. Ishan Ullah Khan)
 Person In charge

Page 1 of 1



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GSTIN No.:08AAICA2524L1ZM, CIN No. U2423RJ2010PTC031000

Format No. FN/AD/GP/15/001/02



TC-5447



TEST REPORT

[Form 50, Rule 160 D (f)]

[Under the Drugs & Cosmetics Act 1940 and the Drugs & Cosmetics rules 1945 there under]

Name & Address of Customer #	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403		
Name of Sample #	Kutki Churna Capsule	Sample ID	2324 E-05
Test Report No.	AR/15305/23	Sample Code/ Batch No.#	Kc002
ULR No.	TC544723000001243F	Mfg. License No. #	164 Ayu.
Date of Receipt	18/05/2023	Mfg. Date #	17/10/2022
Date of Sample Testing	18/05/2023 to 23/05/2023	Exp. Date #	17/10/2024
Report Issue Date	23/05/2023	Sample Quantity	1 x 10 Caps.
Environmental Condition	Temperature (°C): As per Standard, Relative Humidity (%): As per Standard		

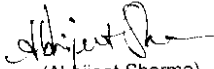
S.N.	Parameters	Specification	Results	UOM	Test method
1.	Description	Clear Transparent Capsules filled with Brown Colored Powder	Clear Transparent Capsules filled with Brown Colored Powder	-	In House AD/STP/68/00
2.	pH (1% Aqueous Solution)	3.0-6.0	5.14	-	API Part-II Vol.-IV
3.	Loss on Drying at 105° C	NMT 7.0	3.96	% w/w	API Part-II Vol.-IV
4.	Total Ash	NMT 10.0	3.33	% w/w	API Part-II Vol.-IV
5.	Acid Insoluble Ash	NMT 5.0	0.30	% w/w	API Part-II Vol.-IV
6.	Water Soluble Extractive	NLT 30.0	45.78	% w/w	API Part-II Vol.-IV
7.	Alcohol Soluble Extractive	NLT 30.0	41.27	% w/w	API Part-II Vol.-IV
Microbiological Analysis					
8.	Total Aerobic Microbial Count	<100000	20000	cfu/gm	API Part-II Vol.-IV
9.	Total Fungal Count	<1000	380	cfu/gm	API Part-II Vol.-IV
10.	Escherichia coli	Absent	Absent	Per gm	API Part-II Vol.-IV
11.	Salmonella	Absent	Absent	Per gm	API Part-II Vol.-IV
12.	Staphylococcus aureus	Absent	Absent	Per gm	API Part-II Vol.-IV
13.	Pseudomonas aeruginosa	Absent	Absent	Per gm	API Part-II Vol.-IV

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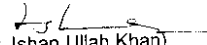
Report:- In opinion of the undersigned, The sample referred to above is of **Standard Quality** as defined in the act and the rules made there under for the reason given below:

"The sample conforms to Customer specification & API Specification" with respect to above tested parameters only

---End of Report---

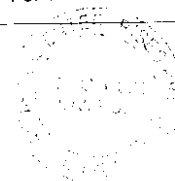

(Abhijeet Sharma)
Technical Manager (Biological)
Authorized Signatory

Date: 23/05/2023



(Dr. Ishan Ullah Khan)
Quality Manager
Authorized Signatory
Page 1 of 1

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(ANALYTICAL DIVISION)

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<p>STABILITY STUDY REPORT</p>	

Product Name	Kutki Churna Capsule	Ref. No.	2212 K	Test Start Date	11/11/2022
Mfg. by	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403	Packing Quantity	10 Caps.	Test End Date	23/05/2023
Mkt. By	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403	Name of Packing Material	Plastic Bottles	Stability Type	Accelerated
Report No.	SR/220608	Pilot or Commercial Batch	Pilot	Storage Conditions	40±2°C Temp & 75±5% RH
Batch No.	Kc003	Date of Mfg.	26/10/2022	Proposed Date of Exp.	26/10/2024

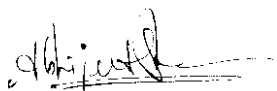
S. No	Particular	Test Method	Specifications	UOM	0 Days	3 Month	6 Month
1.	Description	In House AD/STP/68/00	Clear Transparent Capsules filled with Brown Colored Powder	-	Clear Transparent Capsules filled with Brown Colored Powder	Clear Transparent Capsules filled with Brown Colored Powder	Clear Transparent Capsules filled with Brown Colored Powder
2.	pH (1% Aqueous Solution)	API Part II Vol. IV	3.0-6.0	-	4.94	4.96	4.99
3.	Loss on Drying at 105° C	API Part II Vol. IV	NMT 7.0	% w/w	4.19	4.23	4.20
4.	Total Ash	API Part II Vol. IV	NMT 10.0	% w/w	3.14	3.21	3.18
5.	Acid Insoluble Ash	API Part II Vol. IV	NMT 5.0	% w/w	0.31	0.35	0.32
6.	Water Soluble Extractive	API Part II Vol. IV	NLT 30.0	% w/w	43.55	45.12	44.96
7.	Alcohol Soluble Extractive	API Part II Vol. IV	NLT 30.0	% w/w	41.88	42.81	41.68
Microbiological Analysis							
8.	Total Aerobic Microbial Count	API Part II Vol. IV	<100000	cfu/gm	15000	18000	20000
9.	Total Fungal Count	API Part II Vol. IV	<1000	cfu/gm	232	360	400
10.	<i>Escherichia coli</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
11.	<i>Salmonella</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
12.	<i>Staphylococcus aureus</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
13.	<i>Pseudomonas aeruginosa</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent

API- Ayurvedic Pharmacopoeia of India, NLT-Not Less Than, NMT-Not More Than, UOM-Unit of Measurement, Sr. No. 1-7 Specifications provided by customer, S.No. 8-13 are API Specification

Note:- In the opinion of the undersigned the sample referred to above has been evaluated for stability and is having a claimed shelf life of 2 years as mentioned in D & C act and rules made there under for the reason given below-

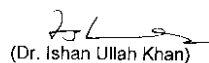
"No significant change" occurs during at any time of testing at accelerated storage conditions

----End of Report----



(Abhijeet Sharma)
Microbiologist

Date: 23/05/2023



(Dr. Ishan Ullah Khan)
Person In charge

Page 1 of 1



Format No. FN/AD/GP/15/001/02

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AYUSHRAJ ENTERPRISES PVT.LTD.
ANALYTICAL DIVISION, JAIPUR

(A Govt. Approved Test House)
Approval No.: Ayush/TL/02

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Regd. Office: 35 Sushilpura South, Shyam Nagar II, Ajmer Road, Jaipur-302019
E-mail: info@ayushraj.com, Website: www.ayushraj.com
GSTIN No.:08AAICA2524L1ZM, CIN No. U2423RJ2010PTC031000



TC-5447



TEST REPORT

[Form 50, Rule 160 D (f)]

(Under the Drugs & Cosmetics Act 1940 and the Drugs & Cosmetics rules 1945 there under)

Name & Address of Customer #	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403		
Name of Sample #	Kutki Churna Capsule	Sample ID	2324 E-06
Test Report No.	AR/15405/23	Sample Code/ Batch No.#	Kc003
ULR No.	TC544723000001244F	Mfg. License No. #	164 Ayu.
Date of Receipt	18/05/2023	Mfg. Date #	26/10/2022
Date of Sample Testing	18/05/2023 to 23/05/2023	Exp. Date #	26/10/2024
Report Issue Date	23/05/2023	Sample Quantity	1 x 10 Caps.
Environmental Condition	Temperature (°C): As per Standard, Relative Humidity (%): As per Standard		

S.N.	Parameters	Specification	Results	UOM	Test method
1.	Description	Clear Transparent Capsules filled with Brown Colored Powder	Clear Transparent Capsules filled with Brown Colored Powder	-	In House AD/STP/68/00
2.	pH (1% Aqueous Solution)	3.0-6.0	4.99	-	API Part-II Vol.-IV
3.	Loss on Drying at 105° C	NMT 7.0	4.20	% w/w	API Part-II Vol.-IV
4.	Total Ash	NMT 10.0	3.18	% w/w	API Part-II Vol.-IV
5.	Acid Insoluble Ash	NMT 5.0	0.32	% w/w	API Part-II Vol.-IV
6.	Water Soluble Extractive	NLT 30.0	44.96	% w/w	API Part-II Vol.-IV
7.	Alcohol Soluble Extractive	NLT 30.0	41.68	% w/w	API Part-II Vol.-IV
Microbiological Analysis					
8.	Total Aerobic Microbial Count	<100000	20000	cfu/gm	API Part-II Vol.-IV
9.	Total Fungal Count	<1000	400	cfu/gm	API Part-II Vol.-IV
10.	Escherichia coli	Absent	Absent	Per gm	API Part-II Vol.-IV
11.	Salmonella	Absent	Absent	Per gm	API Part-II Vol.-IV
12.	Staphylococcus aureus	Absent	Absent	Per gm	API Part-II Vol.-IV
13.	Pseudomonas aeruginosa	Absent	Absent	Per gm	API Part-II Vol.-IV

API- Ayurvedic Pharmacopoeia of India, NLT-Not Less Than, NMT-Not More Than, UOM-Unit of Measurement, #-Information Provided by Customer, Sr. No. 1-7 Specifications provided by customer, S. No. 8-13 are API Specifications

Report:- In opinion of the undersigned, The sample referred to above is of **Standard Quality** as defined in the act and the rules made there under for the reason given below:

"The sample conforms to Customer specification & API Specification" with respect to above tested parameters only

---End of Report---

(Abhijeet Sharma)
Technical Manager (Biological)
Authorized Signatory


(Dr. Ishan Ullah Khan)
Quality Manager
Authorized Signatory
Page 1 of 1

Date: 23/05/2023

Note: Party asked for above test only.

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4. The jurisdiction for any legal case shall be limited to courts at Jaipur only.
5. Total liability of this laboratory shall be limited the invoice amount.



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	Vill. Mansinghpura, Dehmi Begus Road, Ajmer Road, Jaipur- 303007 E mail: info@ayushraj.com Website: www.ayushraj.com DTL Lic. No. Ayush/TL/02
STABILITY STUDY REPORT	

Product Name	Triphala Churna Capsule	Ref. No.	2212 K	Test Start Date	11/11/2022
Mfg. by	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403	Packing Quantity	10 Caps.	Test End Date	23/05/2023
Mkt. By	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403	Name of Packing Material	Plastic Bottles	Stability Type	Accelerated
Report No.	SR/220609	Pilot or Commercial Batch	Pilot	Storage Conditions	40±2°C Temp & 75±5% RH
Batch No.	Tc001	Date of Mfg.	15/10/2022	Proposed Date of Exp.	15/10/2024

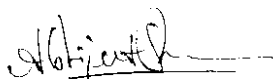
S. No	Particular	Test Method	Specifications	UOM	0 Days	3 Month	6 Month
1.	Description	In House AD/STP/68/00	Clear Transparent Capsules filled with Light Yellow Colored Powder	-	Clear Transparent Capsules filled with Light Yellow Colored Powder	Clear Transparent Capsules filled with Light Yellow Colored Powder	Clear Transparent Capsules filled with Light Yellow Colored Powder
2.	pH (1% Aqueous Solution)	API Part II Vol. IV	3.0-6.0	-	3.20	3.22	3.29
3.	Loss on Drying at 105° C	API Part II Vol. IV	NMT 7.0	% w/w	5.27	5.30	5.35
4.	Total Ash	API Part II Vol. IV	NMT 10.0	% w/w	4.07	4.15	4.12
5.	Acid Insoluble Ash	API Part II Vol. IV	NMT 5.0	% w/w	1.08	1.05	1.07
6.	Water Soluble Extractive	API Part II Vol. IV	NLT 50.0	% w/w	57.59	60.18	59.44
7.	Alcohol Soluble Extractive	API Part II Vol. IV	NLT 50.0	% w/w	58.98	57.42	57.92
Microbiological Analysis							
8.	Total Aerobic Microbial Count	API Part II Vol. IV	<100000	cfu/gm	10000	15000	18000
9.	Total Fungal Count	API Part II Vol. IV	<1000	cfu/gm	250	450	500
10.	<i>Escherichia coli</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
11.	<i>Salmonella</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
12.	<i>Staphylococcus aureus</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
13.	<i>Pseudomonas aeruginosa</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent

API- Ayurvedic Pharmacopoeia of India, NLT-Not Less Than, NMT-Not More Than, UOM-Unit of Measurement, Sr. No. 1-7 Specifications provided by customer, S.No. 8-13 are API Specification

Note:- In the opinion of the undersigned the sample referred to above has been evaluated for stability and is having a claimed shelf life of 2 years as mentioned in D & C act and rules made there under for the reason given below-

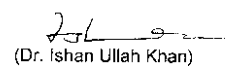
"No significant change" occurs during at any time of testing at accelerated storage conditions

---End of Report---



(Abhijeet Sharma)
Microbiologist

Date: 23/05/2023



(Dr. Ishan Ullah Khan)
Person In charge

Page 1 of 1



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ANALYTICAL DIVISION, JAIPUR

(A Govt. Approved Test House)

Approval No.: Ayush/TL/02

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Regd. Office: 35 Sushilpura South, Shyam Nagar II, Ajmer Road, Jaipur-302019

E-mail: info@ayushraj.com, Website: www.ayushraj.com

GSTIN No.:08AAICA2524L12M, CIN No. U2423RJ2010PTC031000

Format No. FN/AD/GP/15/001/02



TC-5447



TEST REPORT

[Form 50, Rule 160 D (f)]

[Under the Drugs & Cosmetics Act 1940 and the Drugs & Cosmetics rules 1945 there under]

Name & Address of Customer #	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar. Churu 331403		
Name of Sample #	Triphala Churna Capsule	Sample ID	2324 E-07
Test Report No.	AR/15505/23	Sample Code/ Batch No.#	Tc001
ULR No.	TC544723000001245F	Mfg. License No. #	164 Ayu.
Date of Receipt	18/05/2023	Mfg. Date #	15/10/2022
Date of Sample Testing	18/05/2023 to 23/05/2023	Exp. Date #	15/10/2024
Report Issue Date	23/05/2023	Sample Quantity	1 x 10 Caps.
Environmental Condition	Temperature (°C): As per Standard, Relative Humidity (%): As per Standard		

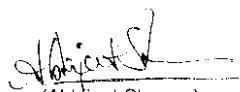
S.N.	Parameters	Specification	Results	UOM	Test method
1.	Description	Clear Transparent Capsules filled with Light Yellow Colored Powder	Clear Transparent Capsules filled with Light Yellow Colored Powder	-	In House AD/STP/68/00
2.	pH (1% Aqueous Solution)	3.0-6.0	3.29	-	API Part-II Vol.-IV
3.	Loss on Drying at 105° C	NMT 7.0	5.35	% w/w	API Part-II Vol.-IV
4.	Total Ash	NMT 10.0	4.12	% w/w	API Part-II Vol.-IV
5.	Acid Insoluble Ash	NMT 5.0	1.07	% w/w	API Part-II Vol.-IV
6.	Water Soluble Extractive	NLT 50.0	59.44	% w/w	API Part-II Vol.-IV
7.	Alcohol Soluble Extractive	NLT 50.0	57.92	% w/w	API Part-II Vol.-IV
Microbiological Analysis					
8.	Total Aerobic Microbial Count	<100000	18000	cfu/gm	API Part-II Vol.-IV
9.	Total Fungal Count	<1000	500	cfu/gm	API Part-II Vol.-IV
10.	<i>Escherichia coli</i>	Absent	Absent	Per gm	API Part-II Vol.-IV
11.	<i>Salmonella</i>	Absent	Absent	Per gm	API Part-II Vol.-IV
12.	<i>Staphylococcus aureus</i>	Absent	Absent	Per gm	API Part-II Vol.-IV
13.	<i>Pseudomonas aeruginosa</i>	Absent	Absent	Per gm	API Part-II Vol.-IV

API- Ayurvedic Pharmacopoeia of India, NLT-Not Less Than, NMT-Not More Than, UOM-Unit of Measurement, #-Information Provided by Customer, Sr. No. 1-7 Specifications provided by customer, S. No. 8-13 are API Specifications

Report:- In opinion of the undersigned, The sample referred to above is of **Standard Quality** as defined in the act and the rules made there under for the reason given below:

"The sample conforms to Customer specification & API Specification" with respect to above tested parameters only

----End of Report----


(Abhijeet Sharma)

Technical Manager (Biological)
Authorized Signatory


Date: 23/05/2023


(Dr. Ishan Ullah Khan)
Quality Manager
Authorized Signatory

Page 1 of 1

Note: Party asked for above test only.

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STABILITY STUDY REPORT	

Product Name	Triphala Churna Capsule	Ref. No.	2212 K	Test Start Date	11/11/2022
Mfg. by	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403	Packing Quantity	10 Caps.	Test End Date	23/05/2023
Mkt. By	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403	Name of Packing Material	Plastic Bottles	Stability Type	Accelerated
Report No.	SR/220609	Pilot or Commercial Batch	Pilot	Storage Conditions	40±2°C Temp & 75±5% RH
Batch No.	Tc002	Date of Mfg.	17/10/2022	Proposed Date of Exp.	17/10/2024


S. No	Particular	Test Method	Specifications	UOM	0 Days	3 Month	6 Month
1.	Description	In House AD/STP/68/00	Clear Transparent Capsules filled with Light Yellow Colored Powder	-	Clear Transparent Capsules filled with Light Yellow Colored Powder	Clear Transparent Capsules filled with Light Yellow Colored Powder	Clear Transparent Capsules filled with Light Yellow Colored Powder
2.	pH (1% Aqueous Solution)	API Part II Vol. IV	3.0-6.0	-	3.24	3.28	3.31
3.	Loss on Drying at 105° C	API Part II Vol. IV	NMT 7.0	% w/w	5.47	5.50	5.56
4.	Total Ash	API Part II Vol. IV	NMT 10.0	% w/w	3.92	4.08	4.04
5.	Acid Insoluble Ash	API Part II Vol. IV	NMT 5.0	% w/w	1.02	1.05	1.03
6.	Water Soluble Extractive	API Part II Vol. IV	NLT 50.0	% w/w	56.01	58.84	57.69
7.	Alcohol Soluble Extractive	API Part II Vol. IV	NLT 50.0	% w/w	59.77	61.43	60.12
Microbiological Analysis							
8.	Total Aerobic Microbial Count	API Part II Vol. IV	<100000	cfu/gm	12000	15000	18000
9.	Total Fungal Count	API Part II Vol. IV	<1000	cfu/gm	200	400	450
10.	<i>Escherichia coli</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
11.	<i>Salmonella</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
12.	<i>Staphylococcus aureus</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
13.	<i>Pseudomonas aeruginosa</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent

API- Ayurvedic Pharmacopoeia of India, NLT-Not Less Than, NMT-Not More Than, UOM-Unit of Measurement, Sr. No. 1-7 Specifications provided by customer, S.No. 8-13 are API Specification

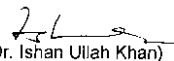
Note:- In the opinion of the undersigned the sample referred to above has been evaluated for stability and is having a claimed shelf life of 2 years as mentioned in D & C act and rules made there under for the reason given below-

"No significant change" occurs during at any time of testing at accelerated storage conditions

----End of Report----


 (Abhijeet Sharma)
 Microbiologist

Date: 23/05/2023


 (Dr. Ishan Ullah Khan)
 Person In charge

Page 1 of 1



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E-mail: info@ayushraj.com, Website: www.ayushraj.com

GSTIN No.:08AAICA2524L1ZM, CIN No. U2423RJ2010PTC031000



TC-5447



TEST REPORT

[Form 50, Rule 160 D (f)]

[Under the Drugs & Cosmetics Act 1940 and the Drugs & Cosmetics rules 1945 there under]

Name & Address of Customer #	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403		
Name of Sample #	Triphala Churna Capsule	Sample ID	2324 E-08
Test Report No.	AR/15805/23	Sample Code/ Batch No.#	Tc002
ULR No.	TC544723000001246F	Mfg. License No. #	164 Ayu.
Date of Receipt	18/05/2023	Mfg. Date #	17/10/2022
Date of Sample Testing	18/05/2023 to 23/05/2023	Exp. Date #	17/10/2024
Report Issue Date	23/05/2023	Sample Quantity	1 x 10 Caps.
Environmental Condition	Temperature (°C): As per Standard, Relative Humidity (%): As per Standard		

S.N.	Parameters	Specification	Results	UOM	Test method
1.	Description	Clear Transparent Capsules filled with Light Yellow Colored Powder	Clear Transparent Capsules filled with Light Yellow Colored Powder	-	In House AD/STP/68/00
2.	pH (1% Aqueous Solution)	3.0-6.0	3.31	-	API Part-II Vol.-IV
3.	Loss on Drying at 105° C	NMT 7.0	5.56	% w/w	API Part-II Vol.-IV
4.	Total Ash	NMT 10.0	4.04	% w/w	API Part-II Vol.-IV
5.	Acid Insoluble Ash	NMT 5.0	1.03	% w/w	API Part-II Vol.-IV
6.	Water Soluble Extractive	NLT 50.0	57.69	% w/w	API Part-II Vol.-IV
7.	Alcohol Soluble Extractive	NLT 50.0	60.12	% w/w	API Part-II Vol.-IV

Microbiological Analysis

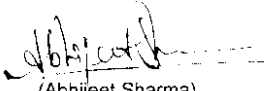
8.	Total Aerobic Microbial Count	<100000	18000	cfu/gm	API Part-II Vol.-IV
9.	Total Fungal Count	<1000	450	cfu/gm	API Part-II Vol.-IV
10.	<i>Escherichia coli</i>	Absent	Absent	Per gm	API Part-II Vol.-IV
11.	<i>Salmonella</i>	Absent	Absent	Per gm	API Part-II Vol.-IV
12.	<i>Staphylococcus aureus</i>	Absent	Absent	Per gm	API Part-II Vol.-IV
13.	<i>Pseudomonas aeruginosa</i>	Absent	Absent	Per gm	API Part-II Vol.-IV

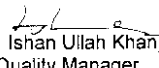
API- Ayurvedic Pharmacopoeia of India, NLT-Not Less Than, NMT-Not More Than, UOM-Unit of Measurement, #-Information Provided by Customer, Sr. No. 1-7 Specifications provided by customer, S. No. 8-13 are API Specifications

Report:- In opinion of the undersigned, The sample referred to above is of **Standard Quality** as defined in the act and the rules made there under for the reason given below:

"The sample conforms to Customer specification & API Specification" with respect to above tested parameters only

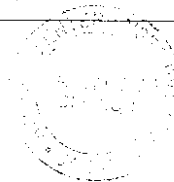
---End of Report---



(Abhijeet Sharma)
Technical Manager (Biological)
Authorized Signatory
Date: 23/05/2023


(Dr. Ishan Ullah Khan)
Quality Manager
Authorized Signatory
Page 1 of 1

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STABILITY STUDY REPORT	

Product Name	Triphala Churna Capsule	Ref. No.	2212 K	Test Start Date	11/11/2022
Mfg. by	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403	Packing Quantity	10 Caps.	Test End Date	23/05/2023
Mkt. By	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403	Name of Packing Material	Plastic Bottles	Stability Type	Accelerated
Report No.	SR/220609	Pilot or Commercial Batch	Pilot	Storage Conditions	40±2°C Temp & 75±5% RH
Batch No.	Tc003	Date of Mfg.	26/10/2022	Proposed Date of Exp.	26/10/2024

S. No	Particular	Test Method	Specifications	UOM	0 Days	3 Month	6 Month
1.	Description	In House AD/STP/66/00	Clear Transparent Capsules filled with Light Yellow Colored Powder	-	Clear Transparent Capsules filled with Light Yellow Colored Powder	Clear Transparent Capsules filled with Light Yellow Colored Powder	Clear Transparent Capsules filled with Light Yellow Colored Powder
2.	pH (1% Aqueous Solution)	API Part II Vol. IV	3.0-6.0	-	3.28	3.30	3.32
3.	Loss on Drying at 105° C	API Part II Vol. IV	NMT 7.0	% w/w	4.98	4.95	4.96
4.	Total Ash	API Part II Vol. IV	NMT 10.0	% w/w	4.15	4.18	4.16
5.	Acid Insoluble Ash	API Part II Vol. IV	NMT 5.0	% w/w	1.13	1.14	1.12
6.	Water Soluble Extractive	API Part II Vol. IV	NLT 50.0	% w/w	57.91	59.33	58.72
7.	Alcohol Soluble Extractive	API Part II Vol. IV	NLT 50.0	% w/w	59.92	61.17	60.25
Microbiological Analysis							
8.	Total Aerobic Microbial Count	API Part II Vol. IV	<100000	cfu/gm	11000	14000	16000
9.	Total Fungal Count	API Part II Vol. IV	<1000	cfu/gm	300	500	550
10.	<i>Escherichia coli</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
11.	<i>Salmonella</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
12.	<i>Staphylococcus aureus</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent
13.	<i>Pseudomonas aeruginosa</i>	API Part II Vol. IV	Absent	Per gm	Absent	Absent	Absent

API- Ayurvedic Pharmacopoeia of India, NLT-Not Less Than, NMT-Not More Than, UOM-Unit of Measurement, Sr. No. 1-7 Specifications provided by customer, S.No. 8-13 are API Specification

Note:- In the opinion of the undersigned the sample referred to above has been evaluated for stability and is having a claimed shelf life of 2 years as mentioned in D & C act and rules made there under for the reason given below-

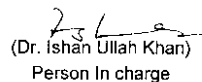
"No significant change" occurs during at any time of testing at accelerated storage conditions

---End of Report---

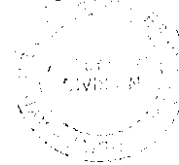


(Abhijeet Sharma)
Microbiologist

Date: 23/05/2023


(Dr. Ishan Ullah Khan)
Person In charge

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ayushraj

An ISO 22000:2018
Certified Company

AYUSHRAJ ENTERPRISES PVT.LTD.
ANALYTICAL DIVISION, JAIPUR

(A Govt. Approved Test House)

Approval No.: Ayush/TL/02

Village Mansinghpura, Dehmi-Begus Road, Ajmer Road, Jaipur (Raj.)-303007, India

Regd. Office: 35 Sushilpura South, Shyam Nagar II, Ajmer Road, Jaipur-302019

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GSTIN No.:08AAICA2524L1ZM, CIN No. U2423RJ2010PTC031000

Format No. FN/AD/GP/15/001/02



TC-5447



TEST REPORT

[Form 50, Rule 160 D (f)]

[Under the Drugs & Cosmetics Act 1940 and the Drugs & Cosmetics rules 1945 there under]

Name & Address of Customer #	Shri Bhanwarlal Dugar Ayurved Vishwa Bharti Rasayanshala Gandhi Vidhya Mandir Sardarshahar, Churu 331403		
Name of Sample #	Triphala Churna Capsule	Sample ID	2324 E-09
Test Report No.	AR/15705/23	Sample Code/ Batch No.#	Tc003
ULR No.	TC544723000001247F	Mfg. License No. #	164 Ayu.
Date of Receipt	18/05/2023	Mfg. Date #	26/10/2022
Date of Sample Testing	18/05/2023 to 23/05/2023	Exp. Date #	26/10/2024
Report Issue Date	23/05/2023	Sample Quantity	1 x 10 Caps.
Environmental Condition	Temperature (°C): As per Standard, Relative Humidity (%): As per Standard		

S.N.	Parameters	Specification	Results	UOM	Test method
1.	Description	Clear Transparent Capsules filled with Light Yellow Colored Powder	Clear Transparent Capsules filled with Light Yellow Colored Powder	-	In House AD/STP/68/00
2.	pH (1% Aqueous Solution)	3.0-6.0	3.32	-	API Part-II Vol.-IV
3.	Loss on Drying at 105° C	NMT 7.0	4.96	% w/w	API Part-II Vol.-IV
4.	Total Ash	NMT 10.0	4.16	% w/w	API Part-II Vol.-IV
5.	Acid Insoluble Ash	NMT 5.0	1.12	% w/w	API Part-II Vol.-IV
6.	Water Soluble Extractive	NLT 50.0	58.72	% w/w	API Part-II Vol.-IV
7.	Alcohol Soluble Extractive	NLT 50.0	60.25	% w/w	API Part-II Vol.-IV
Microbiological Analysis					
8.	Total Aerobic Microbial Count	<100000	16000	cfu/gm	API Part-II Vol.-IV
9.	Total Fungal Count	<1000	550	cfu/gm	API Part-II Vol.-IV
10.	<i>Escherichia coli</i>	Absent	Absent	Per gm	API Part-II Vol.-IV
11.	<i>Salmonella</i>	Absent	Absent	Per gm	API Part-II Vol.-IV
12.	<i>Staphylococcus aureus</i>	Absent	Absent	Per gm	API Part-II Vol.-IV
13.	<i>Pseudomonas aeruginosa</i>	Absent	Absent	Per gm	API Part-II Vol.-IV

API- Ayurvedic Pharmacopoeia of India, NLT-Not Less Than, NMT-Not More Than, UOM-Unit of Measurement, #-Information Provided by Customer, Sr. No. 1-7 Specifications provided by customer, S. No. 8-13 are API Specifications

Report:- In opinion of the undersigned, The sample referred to above is of **Standard Quality** as defined in the act and the rules made there under for the reason given below:

"The sample conforms to Customer specification & API Specification" with respect to above tested parameters only

---End of Report---

(Abhijeet Sharma)
Technical Manager (Biological)
Authorized Signatory

Date: 23/05/2023

(Dr. Ishan Ullah Khan)
Quality Manager
Authorized Signatory

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Note: Party asked for above test only.

1. The results relate only to the item tested.
2. The report shall not be reproduced except in full without approval of the laboratory.
3. The results apply to the sample as received.
4. The jurisdiction for any legal case shall be limited to courts at Jaipur only.
5. Total liability of this laboratory shall be limited to the invoice amount.

Clinical study (pilot study)-

Triphala capsule

Sample size-20 patient

Inclusion crieteria-patient suffering from constipation ,dhatu kshaya.

Exclusion crieteria-patient suffering from diarrhea,dysentery.

Dose- 6 gram of Churna that is 4 cellulose veggie capsule mean 2gram dose thrice a day.

Haritaki capsule

Sample size-20 patient

Inclusion crieteria-patient suffering from constipation ,dhatu kshaya.

Exclusion crieteria-patient suffering from diarrhea,dysentery.

Dose- 6 gram of Churna that is 4 cellulose veggie capsule mean 2gram dose thrice a day.

Kutaki capsule

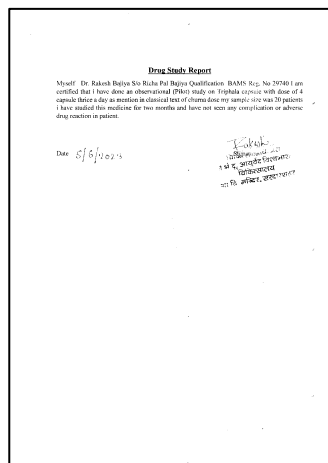
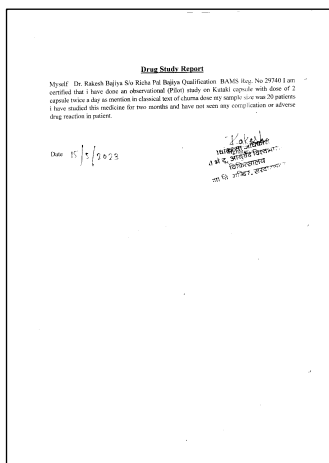
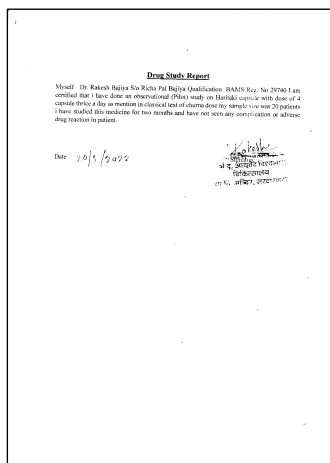
Sample size-20 patient

Inclusion crieteria-patient suffering from pitta vridhi,constipation.fatty liver'hepatomegaly.

Exclusion crieteria-patient suffering from diarrhea,dysentery.

Dose- 2 gram of Churna that is 2 cellulose veggie capsule mean 1 gram dose twice a day

We have done trial in patients for a long time have not seen any adverse effect of these cellulose veggie capsules



Discussion-

In the present study, the development of polyherbal capsules incorporating the herbs in standardized form provides an opportunity to validate its traditional claim regarding its therapeutic efficacy. The standardization of the polyherbal formulation development approach is likely to be helpful for quality control, observational study as it can be produced and managed as a consistent product. In this study we have change the dose form and find that there is no significant change in therapeutic application and we do not find any adverse effect of classical Churna after changing its dose form from Churna to cellulose veggie capsule.

Conclusion-

Conclusively, the present study exhibited the successful development of quality control, stability and observational study of polyherbal classical cellulose veggie capsules which are Triphala capsule, Haritaki capsule and Kutaki capsule. Thus, formulate patient friendly dosage form of various classical based medicinal preparations.

Acknowledgment-

The authors would like to thankful to Mr. Himanshu Dugar, President, GVM, Sardarsahar and Dr Ravindra kumar, Principal, Sblid Ayurved Viswabharati, Sardarsahar for providing the necessary facilities and infrastructure for carrying out this work and for their support in the collection of information presented herein.

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