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Pharmaceutical Preparation of Modified Form of *Gairikadi Anjana* w.s.r to Ophthalmic Ointment

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ABSTRACT:

Background – *Anjana (Collyrium)* is a classical therapeutic procedure explained in context of maintaining health of healthy individuals. It is indicated in almost all diseases explained in classics starting from *Jwara* (Fever), *Visha* (Poisoning), till Shalakya tantra (treatment of disorders above clavicle) related disorders. Lack of proper commercial pharmaceutical dispensing form and unexplored clinical utility of *Anjana* (Collyrium) made its concept doubtful / un-explored. **Methodology –** Here, is an attempt made to bring *Anjana* (Collyrium) in practice with utility of modern pharmaceutical preparation without disturbing classical principles. Single Batch of Ointment was prepared.
Result – The ointment was prepared (Single batch) under all aseptic conditions and microbial analysis was done and was clinically tried and found effective. **Conclusion –** *Gairikaadi Anjana* can be successfully turned into an Ophthalmic Ointment and was proven clinically effective.
Keywords – *Anjana, Jwara, Visha, Gairikaadi Anjana, Abhishyanda, Adhimantha*, eye ointment

INTRODUCTION

Anjana (Collyrium) is one among the *Netrakriyakalpa (Ocular therapeutic Procedures)* explained in classics during *Dinacharya (Daily Regimen*[1] */ Rutucharya(Seasonal regimen)*[2] as well as *Chikitsa Upakrama* (Therapeutic Methods) of various diseases like *Jwara* (Disease),[3]*Kamala(Jaundice),*[4]*Visha* (Poisoning),[5] *Graha Roga (Psycatric Disease),*[6] *Netraroga* (disease of Eye), etc. Mere translation of word *Anjana* into collyrium does not convey the real therapeutic values. Collyrium is a cosmetic procedure which mimic like *Anjana*. The main limitation of the practice of *Anjana* is the availability of compatible form, sterilization issues, preparation and application / therapeutic utility of *Anjana*, etc. Previously a study was conducted and eye ointment was prepared of *Punarnava (Boerhavia diffusa)* with HPMC as the gel base[7]. Recent studies published reveals that Carbopol 940 based ophthalmic preparations are more viable and has prolonged drug retention activity[8]. Hence, in this study, *Gairikadi Anjana* explained by *Sushruta* in *Vataja Adhimantha*[9] is converted into an ophthalmic ointment with carbopol 940 as a gel base is prepared.

Practical Pitfalls in *Anjana* Practices / Need of Study

The medications to be prepared as per the proportionate formulation and stored in the form of *Vati (Tablet) / Gutika*

(Tablet) / Varti (Wick) & *Choorna (powder)* forms.[11] As per classical advice, these pharmaceutical preparations should be stored in particular metal containers prepared out of gold, silver, copper, metal, stone,[12] etc according to desired actions / therapeutic effects. During its therapeutic usage, these drugs should be utilized with specific *Anupana (Adjuvent)* like *Mastu , Kshoudra (Honey), Jala (Water), Ksheera (Milk),*[13] etc. When it comes to the context of practical ophthalmology, the issues of sterilization & stability arises. Thus, it becomes a great talk among the scientific society regarding standard parameters for global acceptance in *Ayurvedic* clinical practices for *Anjana* practices.

MATERIALS AND METHODS

Gairikaadi Anjana (Formulation made of Drugs like Red Orche). It is a formulation explained by *Susruta* in context of *Abhishyanda Chikitsa* (Disease of Eye Ball Proper). The formulation contains *Gairika* (Red Orche), *Saindhava Lavana* (Rock Salt), *Pippali* (Piper longum L) *and Shunti (*Zingiber *officinale* Roscoe) in proportion of 1:2:4:8. All the ingredients were readily available and commonly used drugs in routine eye diseases. Hence forth, this preparation was selected for preparation of gel based ophthalmic ointment for of *Anjana* (Collyrium).

Ingredients of *Gairikaadi Anjana* in Ointment Form (Fig. 1)

Ingredients

- *Shodhita Gairika – Swarna Gairika* (*Red Orche* Fine powder) – 1 Part
- *Saindhava Lavana* (*Rock Salt* Fine Powder) – 2 Parts
- *Pippali* (*(Piper longum* L Fine Powder 300 Mesh) – 4 Parts
- *Shunti* (Zingiber *officinale* Roscoe Powder 300 Mesh – 8 Parts

Base and Preservatives

- Carbopol 940 for base – 2g in 20ml of Sterile water concentration[10]
- Benzalkonium chloride– 0.02% as preservative[11]

Method Of Preparation (Standard Operative Procedure SOP)

All the ingredients received (procured, processed, and Purified as per SOP) from GMP Certified KLE Ayurveda Pharmacy after ascertaining AYUSH certified Drug Testing Laboratory with identification, authentication, analytical study and certification as per API standard under supervision of experts (Fig 7 and 8). All the received ingredients subjected for microbial load test (MLT) and total microbial limit (TML) under microbiology unit of AYUSH certified drug testing laboratory.

All the ingredients and dispensing \ Storage material were packed in airtight containers under triple layer packing and subjected to gamma radiation sterilization (6kgY)[12] to ascertain sterilization and asepsis. Received ingredients were again subjected for microbial load test (MLT) and total microbial limit (TML) to ensure sterilization of sample(Fig 9).

Ointment preparation will be done in sterile Ophthalmic Operation Theatre with double sterilization and as per NABH Standards to ensure sterilization and aseptic measures and microbial load is analysed (Fig 10).

One should wear Ophthalmic OT dress, mask, cap and follow all the general manners / conducts. Do scrubbing & other aseptic measures as per SOP. Wear sterile OT gown, powder less sterile gloves and prepare OT trolley for preparation. With the help of assistant open the outer packages. Remove inner packing and ingredients under all aseptic measures. Take 100 g Carbopol 940 (as a base for preparation of gel) in a sterile glass vessel and add with 1L sterile water for injection. Keep it covered with aluminium foil and kept for overnight. Next day follow the same sterile measure in OT and remove the covering of foil and add 0.02% preservative (Benzalkonium chloride) to the thoroughly formed gel base. Then add all ingredients (in the proportion fixed as per classical reference) to the base prepared with preservative. Stir the mixture cautiously till it becomes homogenous uniform mixture gel is obtained (Fig 3) . With all septic measures, prepared gel is filled in 50g sterile syringe and then filled in aluminum eye ointment tubes of 5gms capacity and packed with seal (Fig 5and Fig 6).After filling tubes proper labeling is done as per the standards. Triple layer packing is done for the prepared tube and will be sent for gamma radiation sterilization (10kgY). To ascertain sterile and asepsis 1 tube will be sent for microbial load test (MLT) and total microbial limit (TML). Once sample is received after sterilization, every 15th day one sample will be sent to AYUSH Certified Drug Testing Laboratory for microbial analysis.

Preparation Of Gel Base

Considering the sterilization issues in contemporary sciences, the initiative of converting the *Anjana* preparation in to Ophthalmic Eye Ointment was brought into practice. For this reason, a non-reactive base was required. Hence, carbopol 940 was selected which is commonly used in majority of eye ointments.

Benzalkonium chloride used as preservative was selected since it is commonly used in all modern ophthalmic preparations.

Ideal consistency of Gel proposed for preparing *Anjana* in Ophthalmic Eye ointment was fixed as follows –

1. Base and liquid portion of distilled water should not be separated
2. All the ingredients (hygroscopic, hydrophobic, water soluble, water non-soluble, etc of any kind) should form uniform mixture
3. All added ingredients should not be separated when the final product is taken on glass slides for examination of consistency
4. After preparation of finished product, it should be in a position to deliver in the form of homogenous mixture like a streak / thread

For fixing the proportion of the ingredients permutation and combination at various concentrations were tried. Initially, 1g of Carbopol in 10 ml, 20ml and 30ml of distilled water (1:10, 1:20 & 1:30 proportion) mixed together and kept undisturbed for 12 hours. After performing this pilot study, following proportions were tried in order to achieve desired density, consistency and herbal drugs carrying capacity of gel.

- 1g of Carbopol – 20 ml & 30 ml of distilled water
- 1.5g of Carbopol – 20ml & 30 ml of distilled water
- 2g of Carbopol – 20ml & 30 ml of distilled water
- 2.5g of Carbopol – 20ml & 30 ml of distilled water
- 3g of Carbopol – 20 ml & 30 ml of distilled water

After performing 10 permutations 2g of Carbopol in 20 ml of distilled water was giving ideal consistency as shown in Fig 2. Benzalkonium chloride was added as preservative at a concentration of 0.02% of total formulation. Fine powders of all ingredients (300 mesh size) were added and mixed till uniform gel mixture was obtained.

DISCUSSION

The ideal gel base should be inert in action and should be able to mix uniformly with all ingredients. Carbopol 940 is used as gel base in majority of ophthalmic ointments.[13] Hence, the same was used in this preparation. Different permutations and combinations for preparation of gel base and ingredients were tried. The ideal gel base was obtained in 2g of carbopol in 20ml of distilled water along with classical proportionate drug mixture.

From of Drugs and particle size

Usually trade preparations of fine powders are available with 120 mesh size. Fine powders with mesh size of 300 are also available with few pharmacies. Both sized powders were used to prepare eye ointment.

The ointment prepared with 120 mesh size powders were reported with foreign body sensation during pilot trials.

Ointment prepared with 300 mesh size was found ideal and were reported with no foreign body sensation except burning sensation, watering and uniform spreading noted.

This ophthalmic eye ointment also prepared with extracts of same herbs was tried. The extracts didn't form uniform mixture instead extracts sediment at the bottom and the water from gel base was separated.

The reason behind the failure of use of extracts would be loss of fiber contents from herbs during the process of extraction. Whereas raw drugs with any mesh size will have enough fiber contents to withhold the water and gel together simultaneously.

Preservatives

The usage of preservative in the ointment is also a debatable issue. Certain studies state that there is no necessity of preservatives in eye ointments but since herbal ingredients are used in this preparation as chances of bacterial and fungal growth was considered.[14] Hence, benzalkonium chloride was used at a minimal proportion of 0.02%.During preparation with various permutations and combination, it was observed that, visible fungal growth was noted after 20 days of preparation without preservatives. Preparation with preservative was stored unaltered even after 1 year of its preparation .

Outcome and Limitations of Study

In this study the ointment was prepared under all aseptic conditions and they were analysed for any microbial growth and was found that the sample was sterile(Fig 11). Once the sterility was certified it was applied in patients to check for palatability and any other associated discomforts. The ointment was compatible to all the patients and didn't show any sort of discomfort, foreign body sensation and no adverse drug reactions were reported.

The major limitation of the study was the availability of lab required for the preparation of the ophthalmic products. After discussion with experts from field of Pharmacy a sterile are was created in the Ophthalmic Operation Theatre following all standards.

CONCLUSION

In the study preparation of single batch of eye ointment was done under the standard conditions and the sample was reported to be free from any microbial growth. A pilot study was done to assess the compatibility of the drug and

was free from adverse events. Thus a universally acceptable dosage form of *Anjana(Collyrium)* in the form of eye ointment was prepared and tested.

Scope For Future Research

Like *Gairikadi Anjana* other various *Anjana* formulations explained in classics under various contexts can be prepared by the above method of preparation. Selection of appropriate base and the consistency of the ingredients are to be considered accordingly.

In this study, *Gairikaadi Anjana* was prepared, similarly many other *Anjana*, *Bidalaka*, *Lepa* can be turned into gel form. This will facilitate easy dispensing and clinical utility without altering the classical principles under the purview of modern pharmaceuticals. Various additional works on the similar principle are undergoing research projects.

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Conflicts Of Interest- Nil

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Fig 1. Drugs used in preparation

Fig 2. Preparation of Gel Base

Fig 3. Mixing of Ingredients

Fig 4. Final Mixture

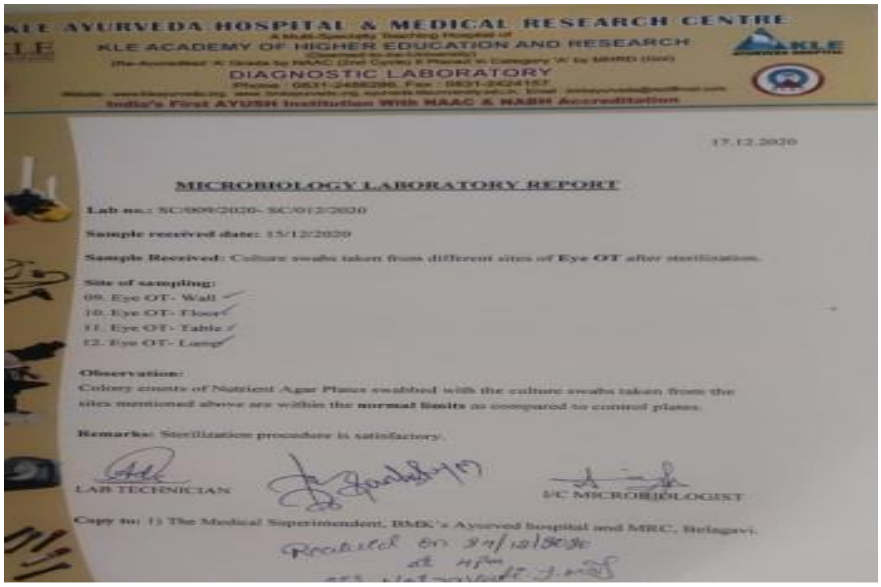
Fig 5. Filling in ointment tubes

Fig 6. Final Product

Fig 7 Analytical Reports

Fig 8 Authentication Reports

Fig 9. Gamma Radiation Reports



KLE AYURVEDA HOSPITAL & MEDICAL RESEARCH CENTRE
KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
DIAGNOSTIC LABORATORY

17.12.2020

MICROBIOLOGY LABORATORY REPORT

Lab no.: SC/009/2020- SC/012/2020

Sample received date: 15/12/2020

Sample Received: Culture swabs taken from different sites of Eye OT after sterilization.

Site of sampling:
09. Eye OT- Wall
10. Eye OT- Floor
11. Eye OT- Table
12. Eye OT- Lamp

Observation:
Colony counts of Nutrient Agar Plates swabbed with the culture swabs taken from the sites mentioned above are within the normal limits as compared to control plates.

Remarks: Sterilization procedure is satisfactory.

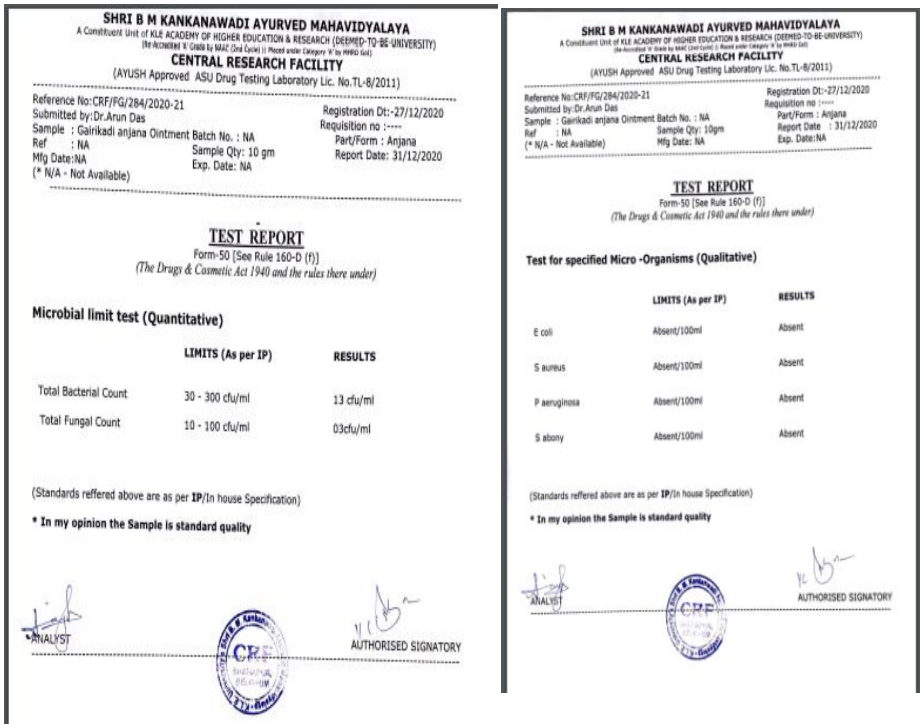
LAB TECHNICIAN

I/C MICROBIOLOGIST

Copy to: 1) The Medical Superintendent, BMK's Ayurved hospital and MRC, Belagavi.

Received on 21/12/2020 at 4pm

Fig 10.Microbial Sab culture report of preparation room (Eye 0T)



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A Constituent Unit of KLE ACADEMY OF HIGHER EDUCATION & RESEARCH (DEEMED-TO-BE-UNIVERSITY)
CENTRAL RESEARCH FACILITY
(AYUSH Approved ASU Drug Testing Laboratory Lic. No.TL-8/2011)

Reference No:CRF/FG/284/2020-21
Submitted by:Dr.Arun Das
Sample : Gairikadi anjana Ointment Batch No. : NA
Ref : NA
Mfg Date:NA
(* N/A - Not Available)
Sample Qty: 10 gm
Exp. Date: NA
Registration Dt:-27/12/2020
Requisition no :----
Part/Form : Anjana
Report Date: 31/12/2020

TEST REPORT
Form-50 [See Rule 160-D (f)]
(The Drugs & Cosmetic Act 1940 and the rules there under)

Microbial limit test (Quantitative)

	LIMITS (As per IP)	RESULTS
Total Bacterial Count	30 - 300 cfu/ml	13 cfu/ml
Total Fungal Count	10 - 100 cfu/ml	03cfu/ml

(Standards reffered above are as per **IP**/In house Specification)

*** In my opinion the Sample is standard quality**

ANALYST

AUTHORISED SIGNATORY

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Reference No:CRF/FG/284/2020-21
Submitted by:Dr.Arun Das
Sample : Gairikadi anjana Ointment Batch No. : NA
Ref : NA
(* N/A - Not Available)
Sample Qty: 10gm
Mfg Date: NA
Registration Dt:-27/12/2020
Requisition no :----
Part/Form : Anjana
Report Date : 31/12/2020
Exp. Date:NA

TEST REPORT
Form-50 [See Rule 160-D (f)]
(The Drugs & Cosmetic Act 1940 and the rules there under)

Test for specified Micro -Organisms (Qualitative)

	LIMITS (As per IP)	RESULTS
E coli	Absent/100ml	Absent
S aureus	Absent/100ml	Absent
P aeruginosa	Absent/100ml	Absent
S abony	Absent/100ml	Absent

(Standards reffered above are as per **IP**/In house Specification)

*** In my opinion the Sample is standard quality**

ANALYST

AUTHORISED SIGNATORY

Fig 11.Microbial report of prepared eye ointment