



Vendor Validation of Pharmaceutical Binding Agent (GUM ACACIA)

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Abstract-

Gum Acacia is the dried gummy exudation obtained from the stem and branches of acacia arabica belongs to *leguminosae* family found throughout India. The gum of this tree has been used in some parts of the country for its salutary therapeutic benefits. Vendor validation is an initial important step of evaluation of raw materials; Selecting best vendor for institute or industry is beneficiary for outcome of good finished product. The parameters applied for the present study include ash value, loss on drying, melting point, identification and confirmatory test, functional group detection test, test of purity etc. The result of present study showed that which sample is better for further application in industry using qualitative and quantitative analysis.

Keywords - Gum Acacia, Ash value, Moisture content

Introduction -

Validation – “Creating recorded evidence that a given process will consistently generate a product that meets its preset parameters and a procedure that produces consistent results.”

Types –

- I. Process validation
- II. Equipment Validation
- III. Analytical Validation
- IV. Cleaning Validation
- V. Vendor Validation

Vendor Validation - "It is documented evidence and process of evaluating and approving potential supplier by qualitative assessment."

Vendor - "It is the authorised seller or the supplier who provides the raw material (API), packaging material and equipment to the pharmaceutical organization for the production good quality of product."⁽¹⁻³⁾

Why Vendor validation ?

- Used to determine if the vendor is appropriate for the scope of work.
- Supplier or customer commitment to a long term relationship.
- Information sharing.
- Joint agreement or specifications and performance standards.
- Performance measurement and feedback.
- Customer confidence.

Steps in Vendor Validation :

1. Requirement for validation
2. Regulatory Agencies
3. Flow Process for sample analysis
4. Classification of Vendor
5. Selection of Vendor
6. Quality Assessment of Vendor
7. Change control and Production Assessment
8. Monitoring and Evaluation⁽⁴⁻⁶⁾

Gum acacia is a powerful medication with a wide range of pharmacological effects and therapeutic potential. It is used to treat diarrhoea and dysentery, as well as stomach and intestinal irritations and ulcers.⁽⁷⁾

Taxonomical Classification -⁽⁸⁾

Kingdom	Plantae
Family	Leguminosae
Subfamily	Mimosoideae
Class	Magnoliopsida
Subclass	Rosidae
Order	Fabales
Genus	Acacia
Species	Senegal

Materials and Methods -

1. Preparation of Sample-

By wiping the nodule's surface with water, the selected lumps of gum were cleaned to remove any debris. After that, it was air dried before being crushed in a mechanical grinder. After that, the powdered material was put in a clean, sterilised glass container. It was then kept at room temperature in a dry, dark place.⁽⁹⁾

2. Identification Test -

Sr. No.	Test	Observation
A1	Nature	Solid
A2	Color	Yellowish white to Pale Yellow or Amber Color
A3	Odor	Odorless
A4	1gm sample + 2ml water + 2 ml Alcohol + Stir + (Mucilage gelatinous forms) + 10ml Water	Becomes Fluid
A5	1ml 10% solution + 4ml water + 0.1 gm of resorcinol + 2ml HCl + Heat on water bath	No Yellow or pink Color Develops
A6	10ml of 10% solution + 1ml FeCl ₃	No Blue Color
A7	10ml of 10% Solution + 0.2 ml lead acetate	No PPT
A8	Boil the Solution + Iodine Solution	No Bluish appears

3. Confirmatory Test -

Sr. No.	Test	Observation
B1	Aq. Solution + Lead acetate solution	White PPT
B2	Aq. Solution + Dil. HCl + Fehling Solution + Boil	Brick Red PPT
B3	Aq. Solution + Benzidine in alcohol + H ₂ O ₂	Distinct Blue Color
B4	Aq. Solution + Borax	Translucent Mass
B5	10% aq. Solution + FeCl ₃ Solution	No Bluish Black Color

4. Ash Value Determination -⁽¹⁰⁾

Allow a silica or platinum crucible to cool in a desiccator for 10 minutes before weighing. Transfer 1 g of the item under investigation to the crucible and properly weigh the crucible and contents, unless otherwise instructed in the specific monograph. Ignite, gently at first, until the substance is thoroughly charred. After cooling, wet the residue with 1 mL of sulphuric acid, slowly heat until no white vapours are produced, then ignite at 800° until all black particles have vanished. Conduct the ignition in an area free of air currents. Allow the crucible to cool before adding a few drops of sulfuric acid and heating it. Ignite as before, cool, and weigh.

$$\% \text{ of Ash} = \frac{\text{Weight of Ash (W3 - W1)}}{\text{Weight of the Sample (W2 - W1)}} \times 100$$

5. Loss on Drying / Moisture Content ⁽⁹⁾

Prior to use, the porcelain crucibles were properly cleaned and cleansed. It was then dried for 10 minutes in a hot air oven at 110°C. The crucibles were then carefully placed in a desiccator for 30 minutes before being weighed again. This method was repeated until a consistent weight was reached. The obtained weight was given the code W1. 2 grams of powdered material were carefully weighed, deposited in previously weighed crucibles, and reweighed; the resulting weight was labelled W2. The crucibles containing the samples were placed in a 103°C oven for 14 hours. They were taken out, cooled in desiccators, and weighed again. The technique was repeated several times to achieve the final weight until the constant weight was obtained (W3). The moisture content was calculated as a percentage.

$$\text{LOD} = \frac{(W2 - W3)}{\text{Weight of Sample}} \times 100$$

6. Test for Purity -

To 1gm sample add 100 ml of water and shake. Then add 0.1 ml of Methyl Red Solution as a indicator which shows end point change of color of solution when titrate against 0.01M NaOH solution. NMT 5 ml of 0.01M should be required to change color.⁽¹¹⁾

Sample No.	MI of NaOH Req.
A	0.4
B	1.2
C	3.2
D	3.5
E	4.1
F	1.1
G	1.5

7. Melting Point -

Melting point is determined using digital melting point apparatus.

Result and Discussion -

1. Ash Value Determination-

Sample No.	% w/w	Ranking
A	4	6
B	3	5
C	4	6
D	2.4	3
E	2	2
F	1.1	1
G	2.8	4

The IP limit for sulphated ash is NMT 5%; lower the sulphated ash higher is the quality, according to that ranking is given.

2. Loss on drying-

Sample No.	% w/w	Ranking
A	9	4
B	6	2
C	9	4
D	7	3
E	6	2
F	7	3
G	4	1

The IP limit for loss on drying of gum acacia is NMT 14%w/w. Lower % loss on drying means lower moisture content which indicates higher quality of raw material; as per this ranking is given.

3. Melting Point Determination-

Sample No.	Melting Point °C	Ranking
A	100-102	1
B	102-104	3
C	98-100	2
D	102-104	3
E	100-102	1
F	102-104	3
G	104-106	4

Std melting point of gum acacia is 100°C and the sample whose melting point approximately to std is found to be more good quality raw product.

4. Test of Purity-

Sample No.	MI of NaOH Req.	Ranking
A	0.4	1
B	1.2	3
C	3.2	5
D	3.5	6
E	4.1	7
F	1.1	2
G	1.5	4

To check the adulteration of acacia the ml of NaOH required should not be more than 5ml. The less amount of NaOH required to change colour of flask shows more quality of raw product; according to this ranking has been given.

5. Overall Results-

Sample No.	Identification Test	Confirmatory Test	Ash Value	Loss on Drying	Melting Point	Test of Purity	Final Ranking
A	1	1	6	4	1	1	2.33=1
B	7	6	5	2	3	3	4.33=6
C	2	4	6	4	2	5	3.83=4
D	8	5	3	3	3	6	4.66=7
E	6	7	2	2	1	7	4.16=5
F	5	2	1	3	3	2	2.66=2
G	4	3	4	1	4	4	3.33=3

Conclusion

The vendor validation provides one of the important approaches where one can firmly say that all raw material used for manufacturing are of high quality, purity and safe. In present investigation the supply of raw material procedure is validated by determining various different suppliers of gum acacia. The sample was evaluated as per IP standards of gum acacia; from the comparative score best vendor is found to be **Sample no. A**

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