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Fuzzy Set Qualitative methodology for identifying the Critical Process Parameters and Quality attributes in the manufacturing of *Arogyavardhini Rasa*

Research Article

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Abstract

The traditional drug manufacturing process involves numerous qualitative attributes that directly impact product quality. The Process Analytical Technology approach considers that to enhance process control, identifying critical process parameters and critical quality attributes that affect the manufacturing process is very much necessary. The Ayurvedic drug manufacturing process is more driven by fuzzy qualitative attributes. The present study was executed to identify the Critical Process Parameters and Critical Quality Attributes in the manufacturing process of a herbo-mineral formulation, *viz*. *Arogyavardhini Rasa*. Fuzzy set Qualitative Comparative Analysis (fsQCA) methodology was adopted to observe and identify the critical parameters. The study was executed in three steps, *viz*. Data collection, Data arrangement, and Analysis. The raw data collected was arranged and analyzed in the software R studio using the package QCA in four steps, viz. Calibration, Analysis of Necessity and Sufficiency, Truth Table construction, and Minimization. The results obtained show that Size reduction, *Mardana*, and Drying are the identified Critical Process Parameters that, in combination, lead to the outcome, i.e., good product quality. Thus, this study proves that Fuzzy Set Qualitative Comparative Analysis can be used as an efficient tool for the identification and measurement of the Critical Process Parameters that affect the Critical Quality Attributes and, thereby, the product quality in the manufacturing of *Arogyavardhini Rasa*.

Keywords: Qualitative comparative analysis, Fuzzy set QCA, Process analytical technology, CPPs, *Arogyavardhini*, Qualitative attributes.

Introduction

There has been a rising interest in the use of Ayurvedic drugs and formulations worldwide, which has led to an upsurge in the production of Ayurvedic medicines. This has resulted in the large-scale production of Ayurvedic medicines in the recent past, which has led to its large-scale commercialization (1). In Ayurvedic therapeutics, drugs in both forms are used, crude as well as processed. However, classical medicines are converted into different forms to increase palatability. Hence, the Ayurvedic pharmaceutical industries are entering the market with innovative products in the form of patent and proprietary formulations.

The Process Analytical Technology (PAT) framework was proposed by the United States Food and Drug Administration to enhance process understanding and control the manufacturing process, which is in line with the current drug quality system in that "*Quality cannot be tested into products; it should be built-in or should be by design*" (2). PAT provides a better understanding of the parameters in manufacturing and their impact on product quality. PAT approach assumes that the unit operations and unit processes involved in the drug manufacturing process are multi-factorial. Hence, if the critical attributes are not considered, it may lead to variability in the process, which will affect the Quality of the product. Therefore, to ensure the desired product quality, emphasis should be given to the attributes that qualify during the manufacturing phases.

In Pharmaceutical manufacturing, both Qualitative and Quantitative attributes help achieve good product quality. Likewise, traditional manufacturing is concerned with both Qualitative and Quantitative attributes. However, the Ayurvedic drug manufacturing process is driven more by Qualitative attributes, including Physical attributes. Color, Shape, Texture, Smell, Taste, etc., Intermediate quality attributes *viz*. Consistency, Flow properties, Blend uniformity, Particle size, etc., and Human decision taking. Moreover, during manufacturing, the measurement of the critical endpoint of the unit operations is, at times, done based on Qualitative

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attributes. These Qualitative attributes have a direct impact on product quality. Hence being a part of the manufacturing process, it is very much necessary to identify such Critical Process Parameters (CPPs) which would affect the Critical Quality Attributes (CQAs).

Moreover, these attributes are fuzzy, having no precise distinction. Consequently, there arises uncertainty during decision-making. Therefore, the method implemented for analyzing these fuzzy qualitative attributes must be the same. One promising technique that helps identify the Qualitative attributes responsible for product quality is Fuzzy set Qualitative Comparative Analysis (fsQCA).

fsQCA is a case-oriented research approach based on set theory (3) which is mainly applied in strategic policy decision-making where measuring unit, i.e., the outcome, is highly influenced by many factors, i.e., conditions. Fuzzy set QCA is routinely used for the analysis of Qualitative data in various fields such as Political science (4), Health-care (5), Drug Regulation (6), Food industry (7), Environmental science (8), etc. In complex real-world situations where decision-making is imprecise, fuzzy sets provide the possibility to consider qualitative and quantitative differences by allowing gradations in set membership (9). Henceforth, in the present study, fsQCA was utilized as a tool for PAT to identify the CPPs and CQAs in the manufacturing of *Arogyavardhini Rasa* – a classical herbo-mineral formulation and to analyze their impact on product quality.

Materials and Methods

Authenticated raw materials (in powder form) for the formulation were procured from the Pharmacy, Institute of Teaching and Research in Ayurveda (ITRA). *Nimba patra* was collected from the Botanical garden of ITRA, Jamnagar.

Preparation of *Arogyavardhini Rasa*

After the procurement of raw materials, a batch of *Arogyavardhini Rasa* was prepared as described in the classical text (10). The formulation composition is shown in Table 1.

Table 1: Formulation Composition of *Arogyavardhini Rasa*

Ingredients	Latin Name/English Name	Part used	Proportion	Quantity taken (g)
Kajjali	*Black sulfide of Mercury*	-	2 parts	6.81
Loha bhasma	*Calcinated Iron*	-	1 part	3.40
Abhrak bhasma	*Calcinated Mica*	-	1 part	3.40
Tamra bhasma	*Calcinated Copper*	-	1 part	3.40
Triphala *Haritaki* *Bibhitaki* *Amalaki*	 *Terminalia chebula Retz* *Terminalia bellirica (Gaertn.)Roxb.* *Phyllanthus emblica L.*	Dried fruit	 2 parts 2 parts 2 parts	 6.81 6.81 6.81
Shuddha Shilajit	*Purified Black Bitumen*	-	2 parts	6.81
Shuddha Guggulu	*Purified Commiphora wightii (Arn.) Bhandari*	Resin	4 parts	13.63
Chitrak	*Plumbago zeylanica Linn.*	Dried root	4 parts	13.63
Katuki	*Picrorhiza kurroa Royle ex Benth*	Dried root	22 parts	75
Nimba Patra Swarasa	*Azadirachta indica A. Juss*	Leaf	Q.S.	750 ml

Fresh *Nimba Patra* was collected and washed with water to remove dust. The leaves were then ground to a fine paste and squeezed through a cotton cloth to obtain *Swarasa*. Each ingredient was weighed separately and appropriately mixed. *Kajjali* was taken, and *Loha bhasma, Abhrak bhasma,* and *Tamra bhasma* were added to it and mixed properly. To this, other powdered ingredients were added one by one in the specified proportion and mixed thoroughly. *Shuddha Guggulu* and *Shuddha Shilajit* were dissolved in water for approximately 5 minutes over mild heat. The mixture of dissolved *Guggulu* and *Shilajit* was then added to the blend of powdered ingredients. *Bhavna* was done by adding the required quantity of *Nimba Patra Swarasa* and triturated for three days. The amount of *Swarasa* utilized during the process and the duration of Levigation and soaking were noted (Table 2). After complete trituration, the material was spread as a thin layer over a stainless steel tray and dried in sunlight. After drying, the material was made into a fine powder with the help of a mortar and pestle, weighed, and stored correctly. The yield of *Arogyavardhini Rasa* was calculated, as shown in Table 3, and the same have been discussed in Results and discussion.

Fuzzy Set Qualitative Comparative Analysis (fsQCA):

Fuzzy set Qualitative Comparative Analysis is a method of analyzing the causal contribution of different conditions (factors) to an outcome of interest (11). In fsQCA, a case does not necessarily have to be a full member or a full non-member of a set but can also be a partial member. The membership scores can fall between the two extremes of a full membership value of 1 and a full non-membership value of 0 (12). Thus, fuzzy sets allow partial set membership with cases being more in than out of a set without being full members of the set, and they can be more out than in the set without being full non-members of the set (13). Hence, Fuzzy set QCA helps to identify the qualitative attributes where no clear demarcation can be made or where there is no precise distinction between membership and non-membership functions. Also, it measures the impact of the parameters on the outcome variable, thus providing the benefits of both qualitative

and quantitative techniques. Therefore, fuzzy-set QCA was employed to identify CPPs and CQAs involved in manufacturing *Arogyavardhini Rasa* and find causal conditions in terms of Necessity and sufficiency, which could affect product quality. The study was executed in three steps: Data Collection, Data arrangement, and Analysis.

Data Collection

The study involved the observation and examination of CPPs in the manufacturing of *Arogyavardhini Rasa*. The data was obtained by critical observation of each unit operation involved in the manufacturing of *Arogyavardhini Rasa*, along with the process parameters (quality attributes) examined in the preparation of *Arogyavardhini Rasa*.

Data arrangement

The raw data collected was arranged in order to classify the attributes under study, and the conditions and outcome variables were selected. From the observations made, the quality attributes were identified for the variables or stages involved in the manufacturing process.

Selection of conditions

For fsQCA, the fuzzy attributes were taken into consideration, and the following conditions were chosen:

- Raw material fineness (Particle size of Raw material)
- Heating of *Guggulu* and *Shilajit*
- Consistency
- Drying

Selection of outcome

- On the basis of the impact of CPPs on product quality (CQAs), the following outcomes were chosen:
- Powder fineness
- Color

Data-set Construction

In order to construct a fuzzy set, categories were defined for the attributes (chosen conditions), and membership values were assigned.

Analysis

The data set constructed was analyzed by fsQCA in the following steps (14):

- Software: R studio (version 1.1.383)
- Package: QCA (15)
- Step 1: Calibration
- Step 2: Analysis of Necessity and Sufficiency
- Step 3: Construction of the Truth Table
- Step 4: Minimization

Calibration

Calibration is converting raw data into fuzzy-set membership scores by assigning thresholds to cases based on theoretical and substantive knowledge, transforming continuous variables into categories (16), (17).

In the observational study, categorical variables were considered for constructing the data set. Hence, membership functions were assigned to the categories defined for each condition, and the calibrated data set was constructed.

Analysis of Necessity and Sufficiency

The analysis of Necessity allows us to identify conditions without which outcome does not occur. Sufficiency allows identifying the conditions that are always present when the outcome occurs, but it also identifies other conditions that may lead to the outcome (18). The evaluation of these conditions is done through the measures of consistency and coverage. Consistency indicates how well a relationship between the condition or a combination of conditions and outcome is met, showing the impact of the conditions on the outcome variable. The values of consistency range from 0 to 1 with 0 indicating no consistency and 1 indicating perfect consistency. In contrast, coverage indicates the empirical relevance of a condition to an outcome, thus providing a measure of the variation in the outcome explained by the conditions or a combination of conditions (19). Coverage scores also range between 0 and 1 indicating the measure of sample cases showing a configuration of conditions producing the outcome. In the study, the consistency threshold was set to 0.8.

Truth Table

The truth table represents all possible combinations of conditions resulting in the outcome. While creating a truth table, the consistency threshold must be determined to rule out the configurations that pass the fuzzy set theoretic consistency, i.e., subsets of outcome coded as 1, and those that do not, i.e., not a subset of outcome coded as 0 (20).

For the construction of the truth table, the consistency threshold was set to 0.8, and the frequency threshold was set to 1.

Minimization

The Minimization process simplifies the complex expression into a logical equation for the outcome (21). Thus, to the truth table constructed, Minimization was applied using the Quine-McCluskey algorithm to obtain a more simplified solution of the conditions that account for the outcome.

Results

In the preparation of *Arogyavardhini Rasa*, a total of 750 ml of *Swarasa* was utilized. Table 2 shows the amount of *Swarasa* utilized and the duration of Levigation. The yield of *Arogyavardhini Rasa* is shown in Table 3. After completion of the process, the weight of the final product was found to increase, which might be due to the addition of *Swarasa*. However, it was observed that the parameters *viz.* particle size of raw material, uniformity of mixture, duration of trituration, as well as consistency during *Mardana* and drying mainly affect the product quality.

Table 2: Amount of *Swarasa* utilized And Duration of Levigation Process

S. No.	Parameter	I day	II day	III day	Total
1	Swarasa utilized	350 ml	250 ml	150 ml	750 ml
2	Duration of levigation/ day	12 hr	12 hr	12 hr	36 hr
3	Duration of soaking/ night	12 hr	12 hr	12 hr	36 hr

Table 3: Yield of *Arogyavardhini Rasa*

S. No.	Parameter	Result
1	Initial weight of product (g)	146.51
2	Final weight of product (g)	165
3	Weight gain (g)	18.49
4	% Weight gain	12.62

Based on observations made during the manufacturing of *Arogyavardhini Rasa* the Quality attributes for the probable CPPs were identified, as shown in Table 4.

From the Quality attributes identified in Table 4, only those attributes where there was no clear demarcation of the measurement in 0 or 1, i.e. fuzzy attributes which could take any value between 0 and 1 were selected as conditions for the chosen outcome variables *viz.* Powder fineness and color. The outcome variables were measured in 0 or 1 with 0 indicating absence of outcome and 1 indicating presence of outcome.

Table 4: Variables involved and Quality Attributes

Variables/stages involved	Attributes
Raw material grinding	Fineness
Mixing of raw materials	Uniformity
Heating *Guggulu, Shilajit*	Temperature Proper dissolution
Preparation of *Nimba Patra Swarasa*	Texture of *Kalka* Proper filtration
Mardana	Duration of *Mardana* Smooth consistency
Drying	Free from moisture, completely dried
Powdering	Powder fineness Color

The raw data collected was calibrated by assigning membership values to the defined categories (Table 5), and the calibrated data set was constructed as shown in Table 6.

Categories were defined for the chosen attributes (conditions) *viz.* Raw material fineness (Particle size of raw material), Heating of *Guggulu* and *Shilajit* (Heating temperature), Duration of *Mardana* (Consistency) and Drying based on experimental observations and membership scores were assigned between 0 and 1. The scores closer to 1 indicate good product quality while closer to 0 indicate poor product quality in terms of powder fineness and color.

Table 5: Assigning Membership Scores to Categories

Attribute	Category	Membership score
Raw Material fineness	Coarse	0.05
	Moderately coarse	0.55
	Fine	0.95
	Very fine	0.99
Heating temperature	Mild	0.05
	Moderate	0.55
	High	0.95
Consistency	Dry	0.05
	Semi-solid	0.55
	Dough-like	0.95
Drying	Moist	0.05
	Brittle but moist inside	0.55
	Brittle and dry	0.95

Table 6: Calibrated Data-Set

Case	R.M. fineness	Heating	Consistency	Drying	Outcome
Avr1	0.99	0.55	0.95	0.95	1
Avr2	0.99	0.95	0.95	0.95	1
Avr3	0.95	0.05	0.95	0.55	1
Avr4	0.55	0.55	0.05	0.95	0
Avr5	0.05	0.95	0.55	0.55	0
Avr6	0.99	0.55	0.55	0.95	1
Avr7	0.95	0.95	0.55	0.95	1
Avr8	0.95	0.05	0.55	0.05	0
Avr9	0.05	0.95	0.05	0.95	0
Avr10	0.55	0.55	0.95	0.95	1
Avr11	0.55	0.95	0.95	0.05	0
Avr12	0.99	0.55	0.55	0.55	1
Avr13	0.05	0.95	0.95	0.95	1
Avr14	0.95	0.05	0.05	0.95	0
Avr15	0.95	0.55	0.95	0.55	1
Avr16	0.99	0.95	0.05	0.95	0
Avr17	0.05	0.55	0.55	0.95	1
Avr18	0.55	0.95	0.55	0.05	0
Avr19	0.55	0.55	0.95	0.95	1

Outcome 1 indicates Good Product Quality, 0 indicates Poor Product Quality; cases AVR1-19 indicate samples of prepared batches of *Arogyavardhini Rasa*

After calibration, the analysis of Necessary and Sufficient conditions was carried out, and the results are depicted in Tables 7 and 8, respectively.

Table 7: Results of Necessity

S. No.	Condition	InclN/ Consistency	RoN	CovN
1	Consistency	0.805	0.724	0.760
2	Drying	0.841	0.538	0.673
3	R.M.Fineness +Heating	0.855	0.245	0.565

InclN – Inclusion score for necessity (consistency); RoN – Relevance of necessity; CovN – Coverage; + signifies logical OR; * signifies logical AND

Table 8: Results of Sufficiency

S. No.	Conditions	InclS/ Consistency	CovS
1	Heating*Consistency	0.825	0.386
2	Consistency * Drying	0.899	0.732

InclS – Inclusion score for sufficiency (consistency);
CovS – Coverage; + signifies logical OR;
* signifies logical AND

The results of Necessity and Sufficiency were measured by the software on the basis of two indicators of assessment i.e. consistency (inclusion score) and coverage. The results of Necessity reveal that the conditions Consistency, as well as Drying are necessary conditions with an inclusion score of 0.805 and 0.841, respectively, which implies that good Quality of *Arogyavardhini Rasa* is obtained when these two conditions are met. Also, individually the condition R.M. Fineness or Heating may have an impact on the product quality, but there is no correlation between the two. The results of sufficiency show that the combination of conditions CONSISTENCY*DRYING has an inclusion score of 0.899, which indicates that both Consistency and Drying are sufficient conditions in the manufacturing process of *Arogyavardhini Rasa*.

The truth table, as shown in Table 9, was generated by the software which lists 8 possible causal combinations of conditions that lead to the presence or absence of outcome, i.e., Good Product Quality (1) or Poor Product Quality (0) in terms of color and texture of the final product. The truth table does not consider those configurations or combinations of conditions which are identical but produce different outcomes. Hence, such configurations will be deleted in the truth table producing only 8 possible combinations. The visual representation of the truth table is shown in the Venn diagram (Figure 1), where the area in green indicates the presence of the outcome, whereas yellow indicates the absence of the outcome.

The truth table was further minimized, and the results are depicted in Table 10.

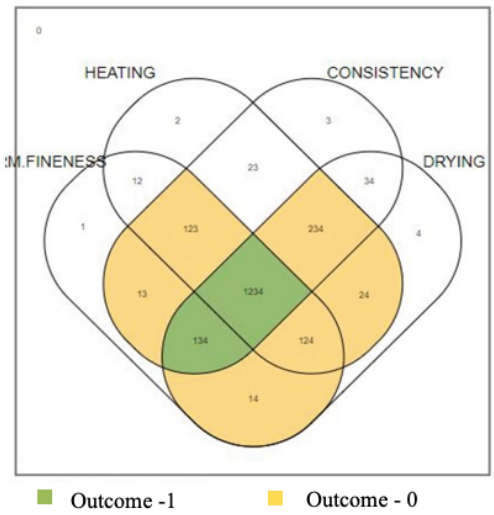
Table 9: Truth Table

S.No.	R.M. Fineness	Heating	Consistency	Drying	Outcome	incl
1	0	1	0	1	0	0.277
2	0	1	1	1	0	0.751
3	1	0	0	1	0	0.443
4	1	0	1	0	0	0.660
5	1	0	1	1	1	0.896
6	1	1	0	1	0	0.493
7	1	1	1	0	0	0.491
8	1	1	1	1	1	0.925

Table 10: Results of Minimization

S. No.	Conditions	InclS/ Consistency	CovS
1	R.M.Fineness*Consistency *Drying	0.936	0.532

Fig. 1: Venn diagram (generated by the software) representing the truth table



Discussion

In the complex Ayurvedic drug manufacturing environment wherein the product quality is influenced by multiple factors, configurational methods that study the combination of different factors and how they work together can serve as a helpful tool rather than the existing quantitative and experimental techniques that assume the isolated effects of single variables. Also, the existing studies have yet to evaluate the effect of the critical factors and their combinations on product quality. Therefore, a qualitative methodology, *viz.* fsQCA, was adopted in the present study, which assumes causal complexity by identifying the necessary and sufficient conditions for an outcome. Data were collected by observing the unit operations and process parameters during the manufacturing of *Arogyavardhini Rasa,* and fsQCA was carried out to explore the CPPs and CQAs impacting product quality.

From the results of the analysis of Necessity and Sufficiency, it can be said that the perception of consistency is the prime factor that affects product quality because if consistency is not perceived properly, then it will directly affect the color and texture of the product. However, although the perception of consistency is necessary, it is not sufficient. In order to achieve good product quality, along with consistency, proper drying must also be ensured as if not, it will lead to microbial contamination of the product due to the presence of moisture. Further, the truth table depicts that the combination of conditions Raw material fineness, Heating, Consistency, and Drying lead to Good Product Quality. The outcome is also achieved with the presence of a combination of conditions Raw material fineness, Consistency, and Drying.

The results of Minimization reveal that the particle size of raw material directly impacts product quality. If proper sieve size is not selected, it leads to variation in size distribution, thereby affecting the dose uniformity and product texture. *Mardana* not only increases drug potential but also influences particle size. Simultaneously the lack of proper drying is reflected in the color and texture of the product. Hence, the

perception of the endpoint of *Mardana*, i.e., consistency as well as proper drying, ensures good product quality.

Thus, based on the results of fsQCA, the CPPs identified were Size reduction, *Mardana*, and Drying. The Critical End Point of completion of these unit operations is routinely made on the basis of Qualitative attributes, *viz*—Fineness, Consistency, and Texture, respectively. Hence, to manufacture good quality *Arogyavardhini Rasa* while manufacturing the above-said CPPs must be very well regulated and measured.

With the help of fsQCA, the Quality control of *Arogyavardhini Rasa* can be efficaciously carried out with the measurement of the above-said Qualitative attributes (CQAs) along with critical monitoring of the identified CPPs. Hence, fsQCA methodology can be utilized in Policy decision-making and Protocol development so that the critical attributes for the process can be identified while designing Quality Control parameters for the product under manufacturing.

Conclusion

In conclusion, fsQCA facilitates in identification and measurement of the CPPs and CQAs involved in the manufacturing process on the basis of Qualitative attributes and thereby assists in process analysis and helps manufacture a good quality product. Implementing fsQCA may prove to be essential before developing guidelines so that unnecessary analysis load can be reduced and the product can be controlled with specifically targeted attributes.

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