Establishment of quality function deployment with special reference to good manufacturing practice of *Chandraprabha Vati*

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Abstract

Context: Quality function deployment (QFD) is a powerful tool for the translation of vague, imprecise customer requirements into clear, measurable technical requirements. **Aims:** The objective of this article is twofold: (a) to propose a platform conceptual model for *Chandraprabha Vati* and (b) to present 10-step procedure to build QFD matrix. **Materials and Methods:** The method deals with, first, preparing two conceptual models for *Chandraprabha Vati* for the sake of manufacturing unit. The survey study was carried out for two products for the selection of customer requirement. Then, with the help of survey study QFD's house of quality matrix was prepared which contained two products, i.e., classical product prepared by pharmacy of university and marketed product. High performance thin layer chromatography study was also carried out. **Statistical Analysis Used:** Principal component analysis (PCA) was applied to the data using unscrambler software. **Results:** The results of QFD chart and PCA analysis were obtained from the two surveys. The first survey reveals that if proper care is taken during preparation on hardness and capping of *Vati,* then product goes toward zero defects. The second survey reveals that if proper care is taken during preparation on hardness, capping and sticking, then physically *Vati* goes toward zero defects. **Conclusions:** The 10-step procedure facilitates the process of reasoning and reduces the time spent for manufacturing with zero defect in product.

Keywords: *Ayurvedic* pharmaceuticals, *Chandraprabha Vati,* conceptual model, matrix, quality function deployment

Introduction

Quality function deployment (QFD) presents a prima facie case as it is based on the first impression or accepted as correct until proved otherwise. QFD is prepared by a set of matrices. Moreover, it provides a logical and systematic methodology to the industry for the problem solving. Despite the simplicity of QFD, many organizations find it difficult to apply in favor of less rigorous approaches.[1]

Various operational units of quality deployment are tables and matrices conceptual models. The importance of conceptual model should be highlighted because it is the representation of the cause–effect architecture needed for achieving the quality assurance of a product. It is through the construction of conceptual model that one comes to identify the tables and the matrices that are needed. The information brought out by the conceptual model is that standards which are elaborated before the production begins.[2-4]

For *Chandraprabha Vati*, the concept of platform was introduced into the conceptual model building process because the similarity of its manufacturing process fulfills the definition of platform. Later, QFD was introduced in the study on manufacture of *Chandraprabha Vati* which had four phases of QFD. The phases are product planning, product design, process planning and process control. From these four steps, various matrices were formed.[5]

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Materials and Methods

The method of preparation of *Chandraprabha Vati*

Thirty-seven ingredients are used for the preparation of *Chandraprabha Vati*. The method of preparation of *Chandraprabha Vati* is shown in Figure 1. The figure portrays the stepwise procedure for the preparation of *Chandraprabha Vati*. Moreover, the study is concerned with

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the QFD, so ingredients of *Chandraprabha Vati* are not mentioned in detail.[6]

High performance thin layer chromatography study

Five grams of sample was dissolved in 100 ml of methanol for 24 h and filtered. 7.5 µl of the above sample was applied on percolated silica gel G on an aluminum plate to a bandwidth of 8 mm using CAMAG LINOMAT 5 thin layer chromatography (TLC) applicator. The plate was developed in chloroform: hexane: methanol (4.8:5:0.2) as solvent system. The solvent system ratio was designed. The developed plates were visualized at 254, 366, 500 and 520 nm in CAMAG high performance thin layer chromatography scanner 5. From the chromatogram, the number of spots and their R_f values were calculated.

Conceptual model for preparation of *Chandraprabha Vati*

For the preparation of *Chandraprabha Vati,* the conceptual model was prepared[7] which gives straight forward direction to manufacturing unit by reducing error in the manufacturing just like standard manufacturing practices. The conceptual model for *Chandraprabha Vati* is shown in Figures 2 and 3.

The model shows the short description of method of preparation for *Chandraprabha Vati*. The method deals with carrying out Quality characteristics of raw material (QCRM), Control parameter of mixing processes (CPMP), Quality characteristics of inter-mediatory product mixture (QCIPM), Control parameter of polishing process (CPPP) and finally Quality characteristics of final product- *Chandraprabha Vati* (QCFP).

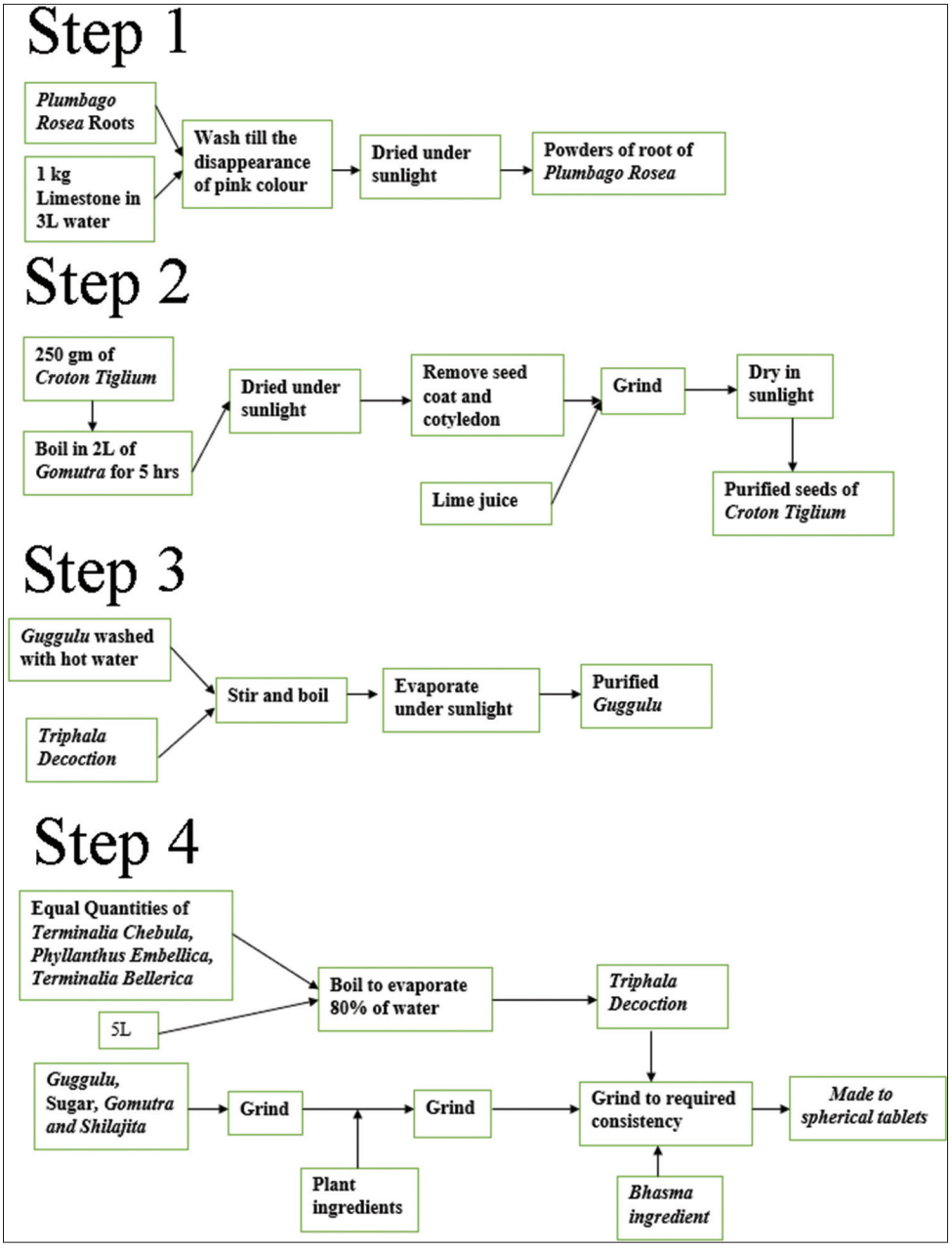


Figure 1: Method of preparation of *Chandraprabha Vati*

In the second conceptual model, detailed method of preparation of *Chandraprabha Vati* which deals with various matrices was prepared.

The matrices are as follows:

- M1 - QCRM1 × CPMP1
- M2 - QCRM2 × CPMP2
- M3 - QCRM3 × CPMP3
- M4 - QCRM4 × CPMP4
- M5 - IPM × CPRP (Control parameter of rolling process)
- M6 - CPRP × CPCP (Control parameter of cutting process).

M1 matrix depicts that raw materials are to be taken and mixed. M2 matrix deals with addition of *Guggulu* (*Commiphora mukul* (Stocks) Hook.) and *Shilajita* (*Asphaltum punjabianum)* in M1 matrix followed by mixing. In M3 matrix, there is an addition of *Loha Bhasma* (calx of iron) *Swarna Makshika* (Chalcopyrite) *Bhasma* ingredients in M2 matrix. In M4 matrix, there is an addition of sugar in M3 matrix. In M5 matrix, there is a rolling of intermediate product mixture. In M6 matrix, there is a cutting of *Vati* and then polishing of *Vati,* i.e., final product.

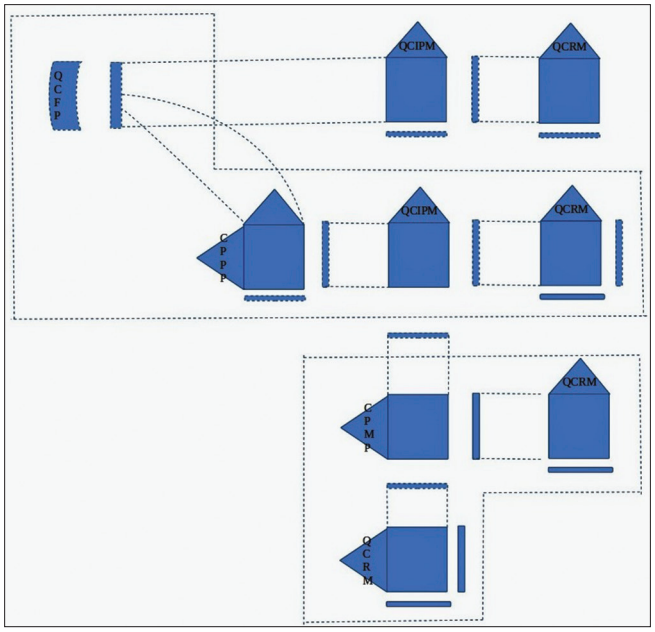


Figure 2: First conceptual model of preparation of *Chandraprabha Vati*

Survey study

The present study was carried out on a survey of university pharmacy product (2017/January/Batch 1) and market product (procured from local Ayurvedic medicine shop) by taking customer requirements and giving them rating for particular parameter (1–5 in which 1 is lower and 5 is highest). Twenty-five MD scholars were taken as volunteers for the present survey study for proper evaluation of both samples of *Chandraprabha Vati* prepared by university pharmacy and marketed *Chandraprabha Vati* samples. The survey study was divided into two parts as Survey 1 and Survey 2, in which Survey 1 is the survey study of university pharmacy product and Survey 2 is the survey study of marketed product.

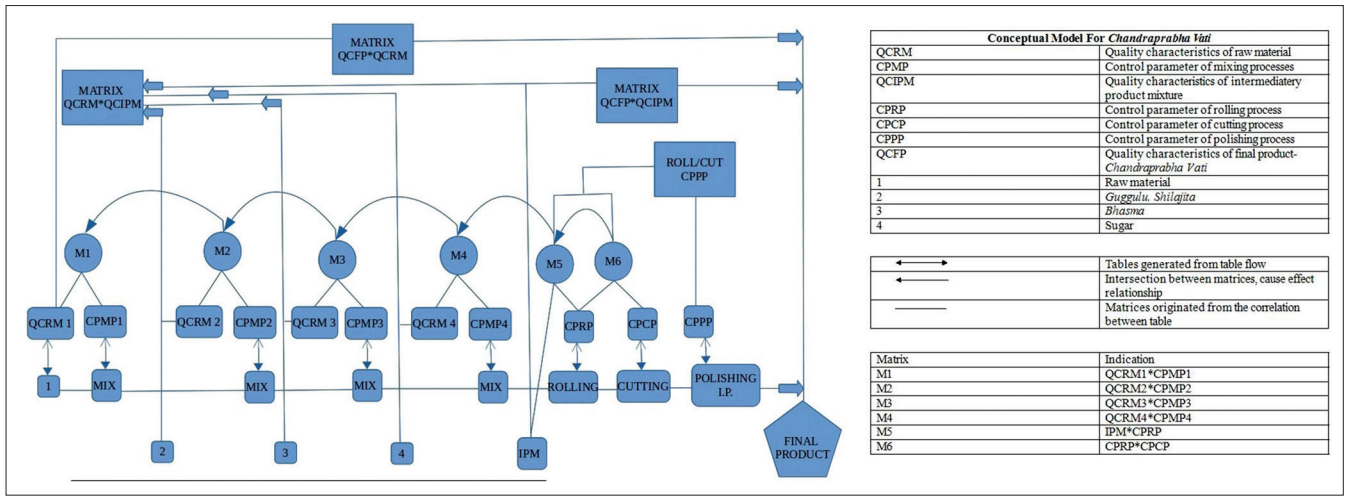
Principal component analysis

The result was pretreated using autoscaling and mean centering. Both university pharmacy product and marketed product were then submitted to the multivariate statistical data analysis and designing software using the Unscrambler version 9.7 package (CAMO software, USA).

Quality function deployment method

Steps to the house of quality

For the development of QFD matrix, 10-step procedures were followed.[8] The ten steps are as follows: Step first consist of customer requirements i.e., voice of the customer. Step second gives the regulatory requirement for the product. Step third gives the customer importance ratings. Step fourth gives the customer rating of the competition. Step fifth gives the voice of engineer i.e., technical description of the product. Step sixth gives the direction of improvement for the technical



Conceptual Model For *Chandraprabha Vati*	
QCRM	Quality characteristics of raw material
CPMP	Control parameter of mixing processes
QCIPM	Quality characteristics of intermediatery product mixture
CPRP	Control parameter of rolling process
CPCP	Control parameter of cutting process
CPPP	Control parameter of polishing process
QCFP	Quality characteristics of final product-*Chandraprabha Vati*
1	Raw material
2	*Guggulu, Shilajita*
3	*Bhasma*
4	Sugar

⟷	Tables generated from table flow
⟵	Intersection between matrices, cause effect relationship
——	Matrices originated from the correlation between table

Matrix	Indication
M1	QCRM1*CPMP1
M2	QCRM2*CPMP2
M3	QCRM3*CPMP3
M4	QCRM4*CPMP4
M5	IPM*CPRP
M6	CPRP*CPCP

Figure 3: Second conceptual model of preparation of *Chandraprabha Vati*

description. Step seventh in which relationship matrix were prepared. Step eight gives the organizational difficulties. Step nine gives the target values for technical descriptor. In the last step correlation matrix i.e., QFD chart were prepared.

Observation and Results

High performance thin layer chromatography of *Chandraprabha Vati*

Photo documentation of HPTLC profile is shown in Figure 4. HPTLC study was carried out using methanolic extract of *Chandraprabha Vati* and the spots were detected under 254 nm, 366 nm and visible light. Densitometric scan reveals 8 R_f values (0.05, 0.34, 0.38, 0.48, 0.55, 0.66, 0.85, and 0.94) at 254 nm and 8 R_f values (0.05, 0.10, 0.22, 0.32, 0.39, 0.56, 0.89, and 0.95) at 366 nm, being the peaks detected. HPTLC is an important tool in standardization and quality control of *Chandraprabha Vati* as there are more than one ingredient and qualitative HPTLC fingerprinting can be used for development of quality standards for the formulation.

Survey study

The survey data collected for both surveys are shown in Figures 5 and 6. Principal component analysis (PCA) of surveyed data was carried out. The survey data were tabulated in a two-way matrix form. One way is volunteer-needed parameter and another way is customer-needed parameter (dose, color, odour, taste, hardness, capping, lamination and sticking). The single data with respect to one survey were executed for PCA with the help of unscrambler software.

Survey 1

The survey data for university pharmacy product are shown in Figure 5. The PCA (biplot score and loadings) was applied on the given data. The data show that hardness and capping parameters are far away from the mid-region so there is likely some problem with both parameters.

The frequency data for given data show that hardness, capping, taste and odour have problem with the university pharmacy product. The frequency data were prepared using rating given by volunteer. With respective to the current data, a pareto chart was prepared.

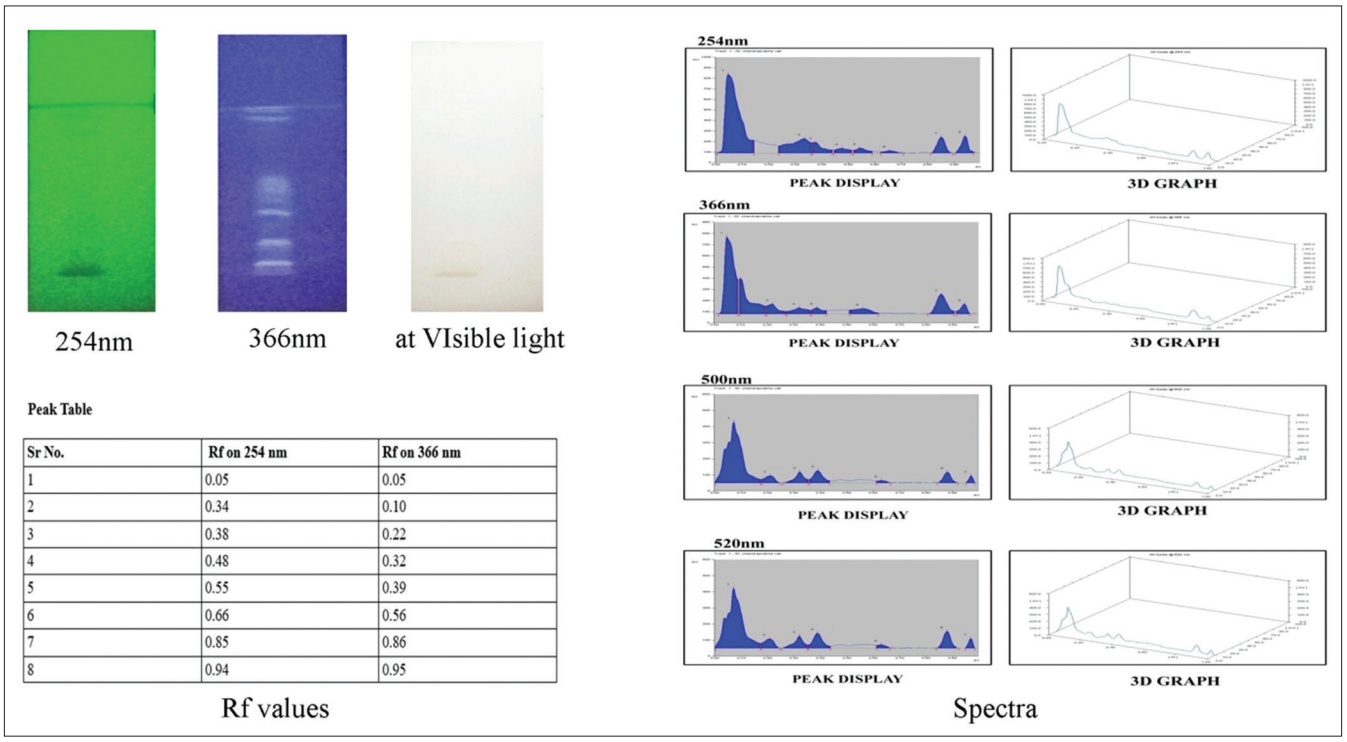
Survey 2

The survey data for marketed product are shown in Figure 6. The PCA (biplot score and loadings) was applied on the given data. The data show that hardness, taste, sticking and lamination parameters are far away from the mid-region so there is some problem with the above-mentioned parameters.

The frequency data for given data show that hardness, capping, sticking and lamination have problem with the marketed product. The frequency data were prepared using rating given by volunteer. With respective to the current data, a pareto chart was prepared.

The matrix of quality function deployment

The matrix of QFD is shown in Figure 7. The matrix is made up of customer requirements, i.e., Y-axis and technical requirement, i.e., X-axis. The matrix is made here to make relationship between customer requirements and technical requirement. The documentation must require for the



Sr No.	Rf on 254 nm	Rf on 366 nm
1	0.05	0.05
2	0.34	0.10
3	0.38	0.22
4	0.48	0.32
5	0.55	0.39
6	0.66	0.56
7	0.85	0.86
8	0.94	0.95

Figure 4: High performance thin layer chromatography data of *Chandraprabha Vati*

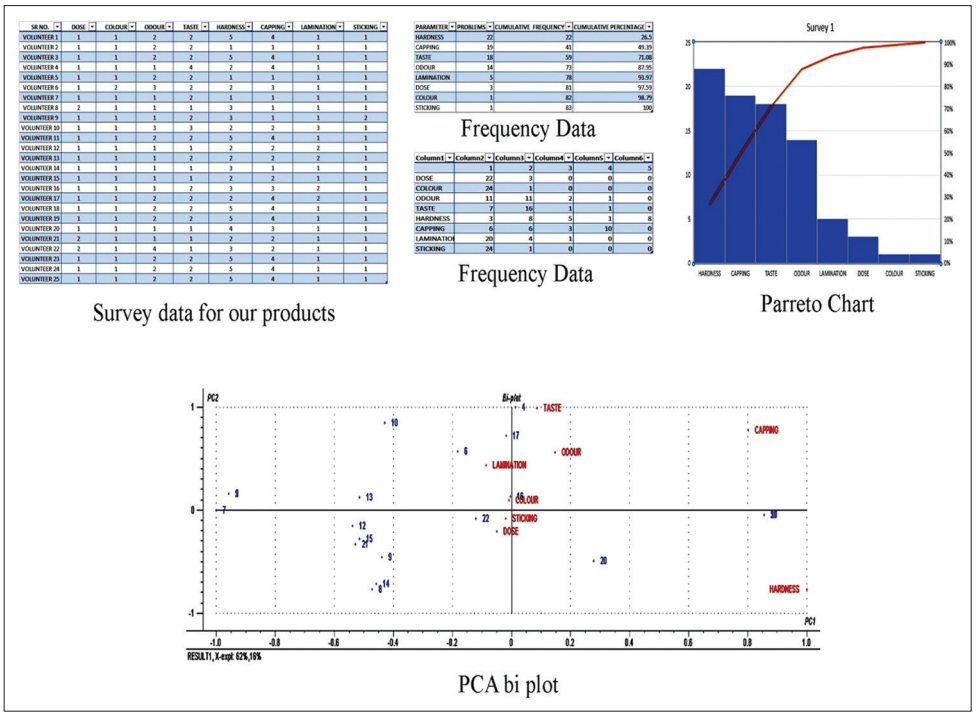


Figure 5: Survey 1 data

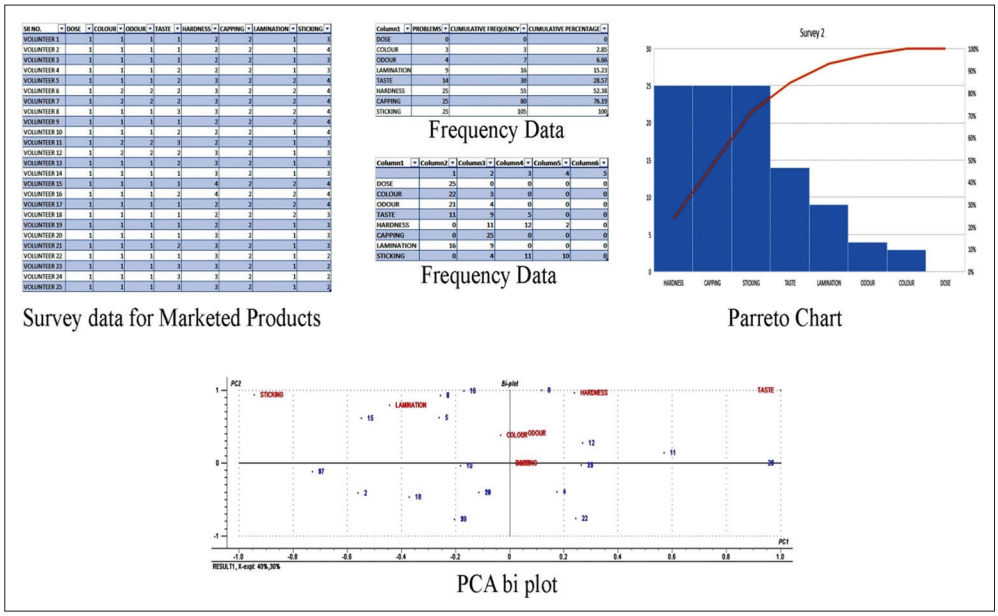


Figure 6: Survey 2 data

management of standard quality of the product. Customer ratings are taken for customer requirements.

After customer requirements, the voice of engineer should be taken as a technical descriptor. Then, for every technical description, give the direction of improvement as an upward direction or downward direction. The relationship matrix was made between X-axis and Y-axis for the improvement of product. The correlation matrix was made using the 10-step procedure for the improvement of product.

With the help of QFD matrix, the study reveals the product problem and with the help of technical requirement, there is a solution for that product problem. Hence, with the help of QFD method, product may go into zero defect concept.

Discussion

QFD is a multifunctional organizational tool that can effectively be used to inspire, organize and then communicate information within a company, effectively

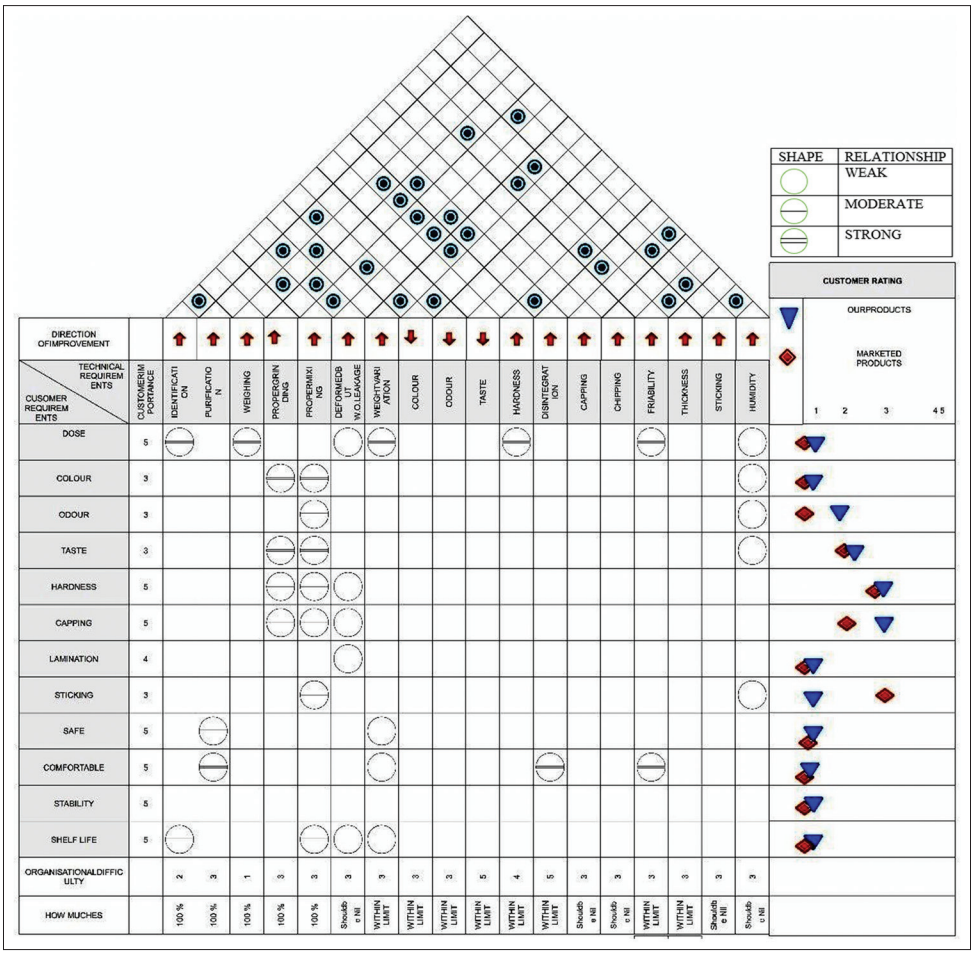


Figure 7: Quality function deployment chart for the *Chandraprabha Vati*

molding the different skills and mindsets with a company together.

Product quality as perceived by individual customers and by the market is critical to the economic success of a company. The easiest way found is to improve the quality to determine the needs of a product. The product determines the product parameters that satisfy the needs of customers.

Furthermore, it determines the conflicting product parameters that need to be optimized by the customer group. Moreover, to ensure a better level of communication between R and D, marketing, production and legal/standardization departments that a high-quality product can be made by applying QFD.

Conclusions

In high complexity environment quality function deployment is thus proved very important to control and optimize process in good manufacturing environment. Simultaneously the method is applicable with quantitative aspect also.

In short merit of the method is to adopt it in natural product (herbal, herbo-mineral) related complex manufacturing instead of regular process validation with respect to single variable. So QFD is a process as well as validation module for natural product.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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