International Journal of Research in Pharmacy and Pharmaceutical Sciences
ISSN: 2455-698X; Impact Factor: RJIF 5.22
Received: 26-03-2020; Accepted: 15-04-2020; Published: 18-04-2020
www.pharmacyjournal.in
Volume 5; Issue 2; 2020; Page No. 10-16

Application of analytical hierarchy process (AHP) for the selection of an optimistic method to formulate nanosponges as controlled drug delivery systems

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Abstract
The recent advance in nanotechnology has led to the improvement of targeted drug delivery system by targeting a molecule to a particular site using specialized drug delivery system. The nanosponges are solid in nature and can be formulated to various dosage forms. For the oral administration, the complexes may be dispersed in a matrix of excipients, diluents suitable for the preparation of capsules or tablets**.** To achieve a better dissolution and bioavailability of poorly water insoluble drugs, it is necessary to select the best technique for the preparation of nanosponges for controlled drug delivery. This is influenced by a number of factors like Drug release (DR), Drug stability (DS) etc. The study was conducted using five alternatives to select the right decision for achieving the goal. The overall ranking of all techniques are selected based on priority ranking shows that Emulsion solvent evaporation technique is the most suitable method.

Keywords: controlled drug delivery, analytic hierarchy process, nanosponges, consistency index (CI)

1. Introduction
Nanosponges are porous small mesh like porous structures having size less than 1 µm. They can easily bind to wide range of drugs including both lipophilic and hydrophilic to achieve a better bioavailability and solubility [1]. The development of nanosponges is an emerging technology to overcome the numerous troubles in the formulation of conventional dosage form and can precisely control the release rate of controlled drug delivery. The various Nano drug delivery systems include nanoparticles nanoemulsions, nanosponges, solid lipid nanoparticles etc. All the above systems nanosponges is one of the most effective drug delivery system. These minute sponges can circulate until they reach definite target site to attach themselves to the surface and initiate the discharge of drugs in a predictable and controlled way. Nano drug delivery system has been developed one of the most capable aspect in the field of pharmaceutics [2]

The newer technological advances in various pharmaceutical formulations helps to overcome the limitations faced in conventional tablets. Development of bio adhesive controlled release dosage form leads to the formulation of vaginal tablet which is used for the treatment of topical and systemic diseases. Controlled tablet was prepared by incorporating drug loaded nanosponges containing ethyl cellulose (EC) and polymethylmethacrylate (PMMA) using emulsion solvent evaporation technique with different drug polymer ratios.

Ideal drug delivery system should steadily deliver a measurable and producible amount of drug the target site. This can be achieved by controlled drug delivery system which can provide a uniform concentration of drug at the absorption site. This helps to maintain the plasma concentration, minimises the side effect and helps to achieve the drug concentration within the therapeutic range. The development of a wide spectrum of nanoscale technologies, referred to as nanomedicines by the National Institutes of Health, have the potential to turn molecular discoveries arising from genomics and proteomics into prevalent benefit for patient. Biodegradable polymers have been studied extensively over the past few decades for the fabrication of drug delivery systems.

A number of technologies are available for the preparation of nanosponges which includes emulsion solvent evaporation (ESE), emulsion solvent diffusion method (ESD), Quassi-emulsion solvent diffusion method (QSD), solvent method (SM), Ultrasound assisted synthesis (UAS), salting out method (SOM) etc [3, 6].

The overall goal in the preparation of nanosponges is to achieve a targeted the delivery to the right place of the body to attain the controlled release of the drug and leads to better therapeutic efficacy. This is influenced by a number of factors like Drug release (DR), Drug stability, Method of formation (MF), Product yield (PY), Technical skill (TS), Preference to manufacturer (PM). The crucial design in the product development is the selection of appropriate design concept. Accuracy in decision made leads to redesigning or remanufacturing of the product. According to *Xu et al* implementing appropriate evaluation and decision tool should be considered at the conceptual design stage that involves many complex decision-making tasks [15]. One of the useful tools that can be employed at the conceptual design stage is analytic Hierarchy process (AHP). It is more rationale and appropriate to analyse both qualitative and quantitative parameters, to make a decision. When two or more alternatives are in hand and one has to select the best, then the appropriate approach is to use a multi-criteria decision making (MCDM) method, which involves all the factors that could influence nanosponges in decision making process while choosing technique.

Analytical Hierarchy Process (AHP)
Analytical Hierarchy Process (AHP) was developed by T L Saaty in 1980 at Wharton school of business [7]. AHP is a

powerful and a flexible tool in decision making process by setting priorities which helps to the researchers to make best decision. MCDM widely applied to solve the various alternatives in multicriteria for making a right decision in both academic research and industrial practice. There are various literatures are available with general methodology and excellent analytical mathematical treatments [8, 11]. AHP is widely applied to situations when a decision is characterized by a multitude of complementary and conflicting factors. The basic steps in analytical hierarchy process model are [12],

1. List the set of different alternatives.
2. Identify the factors that may be intrinsic as well as extrinsic, which may have an impact on the selection of alternatives for formulation of nanosponges. For each of these impacts identify the criteria and the quantifiable indicates to the criteria for a possible measure.
3. Develop a graphical representation to depict the hierarchy of the problem.
4. Assign weights to each alternative on the basis of its relative importance of its contribution to each criterion based on Saaty's nine-point scale.
5. Once the pair wise comparison matrix has been formed for a criterion, the normalized priority of each alternative is synthesized.

This is done as follows

- Sum the values in each column.
- Divide each element in the column by its column total which results in a normalized pair wise matrix.
- Compute the average of the elements in each row of normalized comparison matrix thus providing an estimate of the relative priorities of the alternatives. This result in a priority vector.

1. In addition to the pair wise comparison of the alternatives use the same pair wise comparison procedure to set priorities for all the criteria in terms of the importance of each in contributing towards the overall goal.
6. The priority vector is synthesized similar to step 5
7. Calculate the overall priority for alternatives
8. Choose the alternative that has the highest priority.

According to Saaty, a key step in the AHP model is the establishment of priorities through the use of pairwise comparison procedure and the quality of the ultimate decision relates to the consistency of judgments that the decision maker demonstrates during the pairwise comparisons. The consistency is determined using the eigen value ($M_W = \lambda_{max}$ W is solved). The eigenvector provides priority and eigen value measure of consistency index (CI) derived from the difference of λ_{max} from n is compared with corresponding average values for random entries yielding the consistency ratio (CR).

Here M = matrix; w=n dimensional eigenvector associated with the largest eigen value λ_{max} of the comparison matrix M.

Multiply each CI by the priority of the corresponding criterion and adding them together finds the consistency of the entire hierarchy. The result is then divided by the same type of expression using the random CI corresponding to the dimensions of each matrix weighted by the priorities as before. Figure 1 represents the flow chart of AHP methodology.

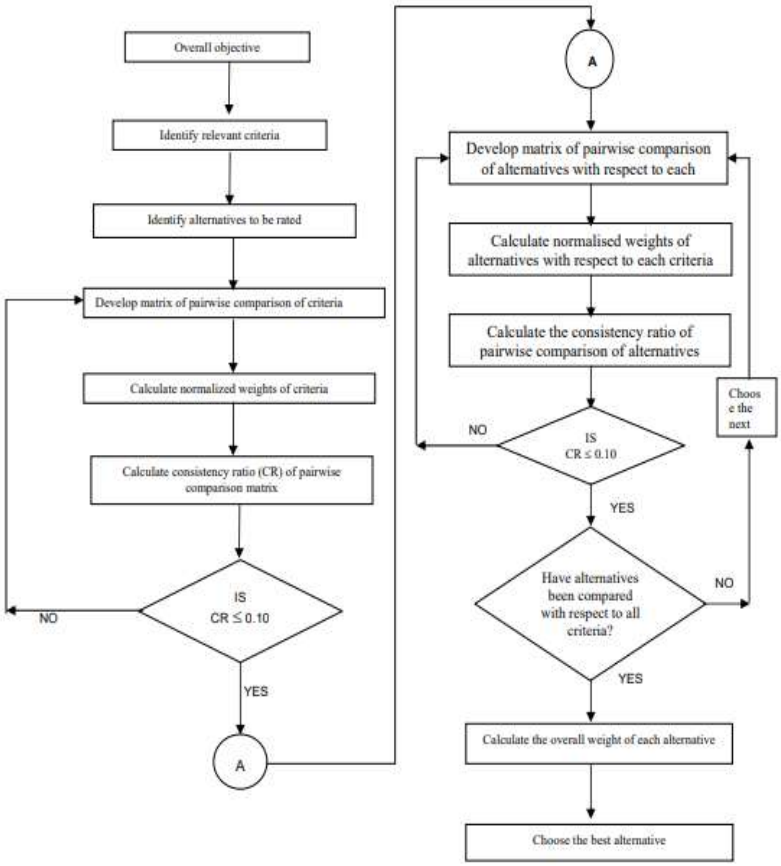

Fig 1: Flow chart for AHP methodology

Saaty has shown that λ_{max} is always greater than or equal to n, the closer the value of λ_{max} is to n, the more consistent are the observed values of matrix. A zero value of CR would indicate perfect consistency whereas large values indicating increasing levels of inconsistency. The CR should be about 10% or less to be acceptable, if not, the quality of the judgment should be improved, perhaps by revising the manner in which questions are asked in making pairwise comparisons. If this should fail to improve consistency then, it is likely that the problem should be more accurately structured; that is, grouping similar elements under more meaningful criteria. The CI for a matrix of size is given by the formula.

$CI = (\lambda_{max}-n/ (n-1)$

$CR= CI/RI$

Satty (based on large number of simulations runs) approximated random indexes (RI) for various matrix Sizes, n, as

Table 1: Random Index of Analytic Hierarchy Process.

n	1	2	3	4	5	6	7	8	9	10	11
RI	0	0	0.58	0.90	1.12	1.24	1.32	1.41	1.45	1.49	1.51

Table 2: Saaty's nine-point comparison scale.

Intensity of Importance	Definition	Explanation
1.	Equal importance	Two activities constitute equally to the objective
3.	Moderate importance	Experience and judgment of one over another slightly favour one activity over another.
5.	Essential or Strong importance	Experience and judgment strongly favour one over Another
7.	Very strongly demonstrated importance	An activity is favoured very strongly over another; its dominance demonstrated in practice
9.	Absolute importance	The evidence favouring one activity over another is of highest possible order of affirmation
2,4,6,8	Intermediate values between adjacent scale values. If activity ***i*** has one of the above non zero numbers assigned to it when compared with activity ***j***, then ***j*** has the reciprocal value when compared with ***i***	When compromise is needed

Table 3: Format of pair wise comparison matrix

Evaluation Criteria	C1	C2	C3	Cm
C1	1	Reciprocal of entries below the diagonal		
C2	Degree of preferences of C2 versus C1	1		
C3	C3 versus C1	C3 versus C2	1	
Cm	C3 versus C1	Cm versus C2	Cm versus C3	1

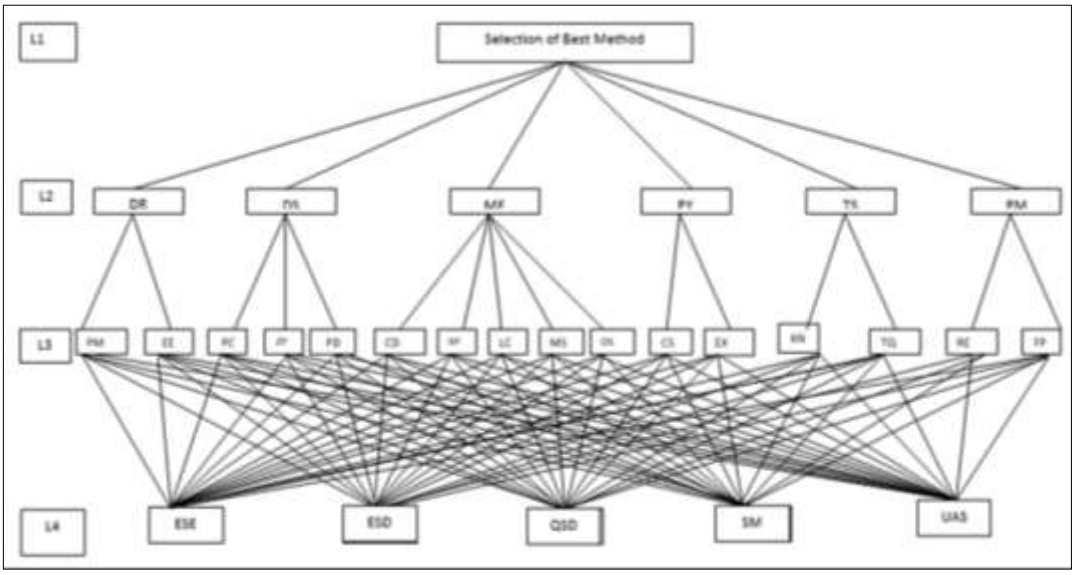

Fig 2: AHP Hierarchy structure for Nanosponge Formulation

2. Methodology and Experimental Work

The aim of the study is to select the best method for the preparation of nanosponges as a carrier for manufacturing of controlled release tablets. The different methods used are Emulsion Solvent Evaporation (ESE), Emulsion Solvent Diffusion Method (ESD), Quassi-Emulsion Solvent Diffusion Method (QSD), Solvent Method (SM), Ultrasound Assisted Synthesis (UAS), Salting out Method (SOM) etc.The following is the step by step description of the procedures used to select the best method. AHP employs a pairwise comparison method to arrive at a scale of preference among assertive alternative for a multi objective and multi criteria decision making problem

2.1 Step 1: Define the Problem [13]

A case study for this research is to select the best method for preparation of nanosponges with the most suitable method by using AHP.

2.2 Step 2: Develop a Hierarchy Model

The process is structured by four steps: -

- First step involves the decomposition of unstructured problem into different levels of elements in the hierarchy.
- Second step in includes determination of relative worth priorities of the factors through pairwise comparison scale.
- Third step synthesizes the priorities to realise the ultimate goal of the problem in hand. Thus in this study, at the top of hierarchy lies the main goal that is selection of best method for the formulation of nanosponges. The second level of hierarchy represent the factors affecting the preparation of nanosponges. The various factors affecting are Drug release (DR), Drug stability (DS), Method of formation (MF), Product yield (PY), Technical skill (TS), Preference to manufacturer (PM).
- Finally, the fourth step is the lowest level of hierarchy.
- The various three elements in the AHP hierarchy for the nanosponges in the present study are displayed in the figure 2

2.3 Step 3: Pair -Wise Comparison of Various Alternatives

Pair wise comparison using Saaty's scale which can evaluate the relative importance of criteria and compare the alternative of each criteria. The pair wise comparison starts with the comparing the relative importance of two selected items, which helps to derive accurate ratio scale priorities. A pair wise comparison matrix (nxn) is constructed for the lower levels with one Matrix in the level immediately above. This generate a matrix of relative rankings for each level of hierarchy. The explanation of sub-attributes are shown in table 4

Table 4: Explanation of sub-attributes.

Sl. No	Main Criteria	Sub-Criteria	Abbreviation	Explanation
1.	Drug release (DR)	Preparation method	PM	Application in laboratory, industry etc.
		Entrapment efficiency of polymers	EE	Polymer concentration and particle size
2.	Drug stability (DS)	Processing condition	PC	Ease in preparation, handling of machines, temperature solvent etc.
		Zeta potential in colloidal dispersion	ZP	Medium pH and temperature
		Protection from degradation	PD	Oxidation decomposition and polymer changes
3.	Method of formation (MF)	BCS Classification of drugs	CD	Aqueous solubility of drug based on pH range 1-7.5
		Refining process	RP	Purification procedure, use of solvent etc.
		Loading capacity of polymer	LC	Enhances the encapsulation efficiency
		Molecular size of drug	MS	Influences the drug absorption
		Operation skill	OS	Theoretical background of nanotechnology and expertise
4.	Product yield (PY)	Carrier selection	CS	Compatibility, processing and ease of solvent removal
		Experience	EX	Ease and skill in handling the machines
5.	Technical skill (TS)	Knowledge	KN	Training and depth of knowledge of theoretical information of nanosponges
		Technique	TQ	Formation of nanosponges
6.	Preference to manufacturer (PM)	Reproducibility	RE	Flexibility in operation
		Final product	FP	Stirring speed and surfactant used

2.4 Step 4 Perform Judgement for Pairwise Comparison [14]

There are nx (n-1) judgements required to develop a set of matrices in step 3. Table 2 shows relative scale pair wise comparison, helps the decision makers to compare or judge each element. These judgements are based on experience and knowledge of the decision makers. The scale is used for comparing is used for comparison in AHP, enables the decision maker to incorporate experience and knowledge intuitively. Reciprocals are automatically assigned to each pairwise comparison.

Table 5: Pair wise comparison with respect to overall goal

	DR	DS	MF	PY	TS	PM	Priority Vector
DR	1	3	5	5	8	9	0.434
DS	1/3	1	3	3	7	8	0.237
MF	1/5	1/3	1	3	5	7	0.151
PY	1/5	1/3	1/3	1	3	8	0.103
TS	1/8	1/7	1/5	1/3	1	5	0.052
PM	1/9	1/9	1/7	1/8	1/5	1	0.023

2.5 Step 5: Synthesizing the Pairwise Comparison

The average normalized two column (ANC) is used to

calculate the vectors of priority. The ANC is performed by dividing the elements of each column by the sum of the column and then the elements is resulting rows are added and this sum is divided by the number of elements in the row (n). This process is known as averaging over normalized column. In mathematical form, the vector priorities are calculated as follows: -

$$W_i = \frac{1}{n}\sum_{j=1}^{n}\frac{a_{ij}}{\sum_i^n a_{ij}}, i,j = 1,2,\ldots n$$

2.6 Step 6: Perform the Consistency

There are chances of occurrence of inconsistency in comparison due to the personal or subjective judgement. So, in order to overcome the inconsistency and ensure the consistency in judgement more concrete a final operation called as consistency verification performed. Consistency verification one of the most advantages feature of AHP, which can measure the degree of consistency among pairwise comparison by computing Consistency Ratio (CR). Consistency Ratio (CR) is determined by the ratio Consistency Index (CI) to random index (RI) for the same order of matrices.

The consistency is determined by the consistency ratio (CR) to random index (RI) for the same order matrices. To calculate the consistency ratio (CR), there are three steps to be implemented as follows:

6.1 Firstly, Calculate the Eigenvalue (λ_{max}) to calculate the eigenvalue (λ_{max}), multiply on the right matrix of judgments by the priority vector or eigenvector, obtaining a new vector.

6.2 Secondly, Calculate the Consistency Index (CI)

CI= (λ_{max}-n)/ (n-1)

Where n is the matrix size

6.3 Finally, Calculate the Consistency Ratio (CR). The CR can be calculated using the formula CR=CI/RI

Selecting the appropriate value of random index (RI), for the matrix size of five using Table 1. Then calculate the consistency ratio (CR), CR=CI/RI

As the value of CR is less than 0.1, the judgments are acceptable. If CR>0.1, the judgments are inconsistent. To obtain a consistent matrix, judgments should be reviewed and improved.

2.7 Step 7: Preformed for All Levels in the Hierarchy Model

The consistency tests for the sub-criteria and alternatives must be performed. As the value of CR for all sub criteria and alternatives in less than 0.1, the judgments are acceptable.

Table 6: Pair wise comparison for the sub criteria to drug release

	PM	PC	Priority Vector
PM	1	7	0.876
PC	1/7	1	0.124

Table 7: Pair wise comparison for the sub criteria to drug stability

	PC	ZP	PD	Priority Vector
PC	1	3	7	0.644
ZP	1/3	1	5	0.282
PD	1/7	1/5	1	0.073

Table 8: Pair wise comparison for the sub criteria to Method of formation

	CD	RP	LC	MS	OS	Priority Vector
CD	1	1	3	5	9	0.367
RP	1	1	3	5	7	0.353
LC	1/3	1/3	1	3	5	0.156
MS	1/5	1/5	1/5	1	5	0.090
OS	1/9	1/5	1/5	1/5	1	0.034

Table 9: Pair wise Comparison for the sub criteria to Product yield

	CS	EX	Priority Vector
CS	1	5	0.833
EX	1/5	1	0.167

Table 10: Pair wise Comparison for the sub criteria to Technical skill

	KN	TQ	Priority Vector
KN	1	7	0.876
TQ	1/7	1	0.124

Table 11: Pair wise Comparison for the sub criteria to Preference to manufacturer

	RE	FP	Priority Vector
RE	1	3	0.751
FP	1/3	1	0.249

2.8 Step 8: Priority Vector for All the Criteria to Sub Criteria

After the consistency calculation for all the levels is completed, the formation of matrix and further calculation of all the criteria to sub criteria is performed, its new vector is calculated, the consistency index and consistency ration is also estimated.

2.9 Step 9: Develop Overall Priority Ranking

The consistency calculation for all levels is completed, further calculation of overall priority vector is to select the best method for the preparation of nanosponges. Table 12 represents the overall rating of each method of preparation. The Figure 2 shows AHP for choosing the best technique for the preparation of nanosponges. It represents four levels of Hierarchy. The highest-level L-1 is the focus of the problem. This is in turn split into a set of attributes Drug release (DR), Drug Stability (DR), Method Of Formation (MF), Product Yield (PY), Technical Skill (TS) and Preference Manufacturer (PM).Corresponding to an intermediate level of hierarchy.L-2 represents another set of Sub attributes such as PM, EE etc. Corresponding to a lower level of hierarchy L-3, the last level hierarchy L-4 consists of the decision alternative, emulsion solvent evaporation (ESE),emulsion solvent diffusion method (ESD), Quassi-emulsion solvent diffusion method (QSD), solvent method (SM), Ultrasound assisted synthesis (UAS) Using the AHP model the priority weights, PRWT to the attributes and Sub-Attributes are calculated.

3. Results, Discussions & Its Investigations

In this study AHP is widely used as multi criteria decision making (MCDM) method that was applied for the selection of best method for the preparation of nanosponges for achieving controlled drug delivery. The Saaty's scale was used to assign weights of all pair wise comparisons. The following results shows the priorities of the alternative with

esteem to criteria and sub-criteria. From the general main concern of criteria, Drug release (DR) is given much significant pursued by Drug Stability (DS) and Method of Formation (MF) which are then pursued by Product Yield (PY), Technical Skill (TS) and Preference Manufacturer (PM). The general main concern of the alternative emulsion solvent evaporation (ESE), emulsion solvent diffusion method (ESD), Quassi-emulsion solvent diffusion method (QSD), solvent method (SM), Ultrasound assisted synthesis (UAS) as shown in figure 2.Asserting emulsion solvent evaporation (ESE) is a best procedure on the basis of criteria and sub-criteria pursued by emulsion solvent diffusion method (ESD), Quassi-emulsion solvent diffusion method (QSD), solvent method (SM), Ultrasound assisted synthesis (UAS).The selection procedure for the best suitable method is as follows. According to table 12 shows that emulsion solvent evaporation (ESE) has highest value of 0.501 of all the alternative methods which are applicable for the preparation of nanosponges. The second highest value is ESD having a values 0.286 and Quassi-emulsion solvent diffusion method (QSD) is 0.112. Subsequently Ultrasound assisted synthesis (UAS) solvent method (SM), having the lowest value.0.067 and 0.035 respectively, which can be assigned as the last choice method for the preparation of nanosponges. Emulsion solvent evaporation (ESE) is the most preferred method with highest value of the five alternatives.

In the present study, hierarchy was designed having a decision as a goal, the alternative for reaching the goal. The criteria for evaluating alternative and sub criteria for evaluating the criteria was performed. Based on the strength and relativeness, a priority was determined for each criteria and sub criteria. The priority values indicates the relative importance of each criteria and sub criteria in attaining the goal. According to Saatys, the alternative with highest priority is a more suitable method and the ratio of the method priorities would indicate the relative strength. The priority of the goal for selection of suitable method would be 1.00.

Table 12: Composite rating for techniques

SL.NO	Attributes	Notation	PR_WT	Sub Attributes	PR_WT	ESE	ESD	QSD	UAS	SOM
1	Drug Release	DR	0.434	PM	0.876	0.549	0.251	0.1	0.065	0.035
				EE	0.124	0.486	0.31	0.112	0.058	0.034
2	Drug Stability	DS	0.237	PC	0.644	0.479	0.307	0.12	0.062	0.033
				ZP	0.282	0.51	0.241	0.133	0.081	0.035
				PD	0.073	0.508	0.256	0.132	0.064	0.04
3	Method of Formation	MF	0.151	CD	0.367	0.466	0.314	0.116	0.07	0.033
				RP	0.353	0.421	0.393	0.078	0.073	0.035
				LC	0.156	0.400	0.376	0.123	0.068	0.033
				MS	0.090	0.447	0.347	0.078	0.075	0.053
				OS	0.034	0.385	0.346	0.151	0.084	0.034
4	Product Yield	PY	0.103	SM	0.833	0.479	0.29	0.131	0.062	0.039
				GS	0.167	0.447	0.302	0.138	0.07	0.043
5	Technical Skill	TS	0.052	PS	0.876	0.48	0.29	0.121	0.077	0.032
				CS	0.124	0.437	0.255	0.174	0.084	0.049
6	Preference to Manufacturer	PM	0.023	MS	0.751	0.458	0.328	0.114	0.07	0.03
				FP	0.249	0.444	0.335	0.117	0.074	0.03
	Composite Rating					0.501	0.286	0.112	0.067	0.035

From the table 5, the pair wise comparison with respect to overall goal the priorities of criteria for Drug release (DR), Drug stability, Method of formation (MF), Product yield (PY), Technical skill (TS), Preference to manufacturer (PM) are 0.434,0.237,0.151,0.103,0.052 and 0.023 respectively. Table 6 shows the priorities of sub criteria for drug release are Preparation method (PM) Entrapment efficiency of polymers (EE) having the priority values 0.879 and 0.124 respectively. The priority values like 0.644, 0.282 and 0.073 indicates the sub criteria priorities to Processing condition (PC), Zeta potential in colloidal dispersion (ZP) and Protection from degradation (PD) towards the criteria Drug stability is depicted in table 7.

BCS Classification of drugs (CD), Refining process (RP), Loading capacity of polymer (LC) Molecular size of drug (MS) and Operation skill (OS) are the sub criteria for the method of formation (MF) having the priority weights of 0.367,0.353,0.156,0.090 and 0.034 respectively. The pair wise comparison for sub criteria to method of formation is shown in table 8.

The pair wise comparison of sub criteria to product yield is shown in table 9. The attribute product yield represents the sub criteria Carrier selection (CS) and Experience (EX) with priority weight of 0.833 and 0.167 respectively.

The priority weights 0.876 and 0.124 towards the sub criteria Knowledge (KN) and Technique (TQ) corresponds to criteria technical skill is shown in table 10.

The priorities of sub criteria Reproducibility (RE) and Final product (FP) is leaded by the criteria preference to manufacturer having the priority weight 0.751 and 0.249 respectively is carried out in table 11.

The overall priorities are shown in the table 13 indicates the

highest score for Emulsion Solvent Evaporation Method (ESE) (0.501)

Table 13: Results of selection of best method from the overall priorities

Sl. No.	Best selection	Composite rating
1.	ESE	0.501
2.	ESD	0.286
3.	QSD	0.112
4.	UAS	0.067
5.	SOM	0.035

So, the alternatives with highest priority would achieve the goal as per Saaty. In this study the alternative with highest among all other alternatives is emulsion solvent evaporation method (ESE) with a score of 0.501.So by using Analytical Hierarchy process (AHP) technique, emulsion solvent evaporation method (ESE) is judged to be the most suitable method for the preparation of nanosponges to achieve controlled drug release for oral dosage forms.

4. Conclusion

Development of modified release dosage form as an effective that products have really come a long way in the last 40 years. Scientist are facing a lot of constraints in development of dosage form due to the complexity in framework for the formulation nanosponges. This case study is the presented AHP as multi criteria decision making a systematic approach which includes both qualitative and quantitative factors. The unsuitable selection of a method for the formulation of nanosponges, may result in the loss of material sources, financial resource and time of research. This can overcome by constructing hierarchy with six criteria, sixteen sub criteria and five alternatives. The AHP is a versatile decision, which can evaluate and select the most appropriate method for developing the best technique for the preparation of nanosponges as controlled release drug delivery. The preparation methods for are complicated so selection of best method is essential for the better application in pharmaceutical industry. The analysis reveals that emulsion solvent evaporation method (ESE) one is the most suitable method for preparation and this has got the highest value out of the other methods. This study resolves that MCDM should be used as a decision tool and can be widely applied to pharmaceutical and engineering applications for the formulation newer dosage forms.

5. Acknowledgments

The authors are expressing gratitude and gratefully acknowledge, Kerala State Council for Science, Technology and Environment (KSCSTE), Trivandrum for providing financial assistance in student project scheme to complete this project work successfully.

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