DEVELOPMENT AND OPTIMIZATION OF PHYTOCONSTITUENT LOADED CHITOSAN NANOPARTICLES USING QUALITY BY DESIGN APPROACH

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Introduction

Phytoconstituents like curcumin, quercetin etc are natural products derived from various plant sources and have high medicinal values. These are gaining lot of attention in research field due to their several properties like antioxidant, antiseptic, anti inflammatory, anti apoptotic, anticancer activities etc and are utilized in treatment of several diseases like Alzheimer's, cancers, arthritis etc. Most of the phytoconstituents are susceptible to external environmental factors like pH, temperature, oxidation and light and in presence of these factors may get degraded or loss their activity and stability. To protect the activity of these phytoconstituents, several natural polymer based systems were developed. In the present research phytoconstituent loaded chitosan nanoparticles were developed and optimized using quality by design approach. Chitosan nanoparticles prevent degradation of phytoconstituent and also enhance its stability. For optimization of chitosan nanoparticles various formulation and process variables were identified and optimized on the basis of different quality attribute of nanoparticles like particle size, PDI, zeta potential and encapsulation efficiency of phytoconstituent.

Aim and Objective

The main objective of work was to perform risk analysis of process so as to efficiently design the formulation batches of phytoconstituent loaded nanoparticles for better quality of product.

Methodology

Chitosan nanoparticles were prepared by ionic gelation method using TPP as cross linker. Nanoparticles were prepared by adding TPP solution in the chitosan solution in different concentrations. Various factors like concentration of chitosan and TPP solution, pH of chitosan and TPP solution, rate of addition, chitosan: TPP ratio, stirring rate etc were optimized using screening design. Critical parameters identified by screening design will be further optimized by response surface methodology. The nanoparticles were optimized on basis of particle size, zeta potential, PDI and encapsulation efficiency.
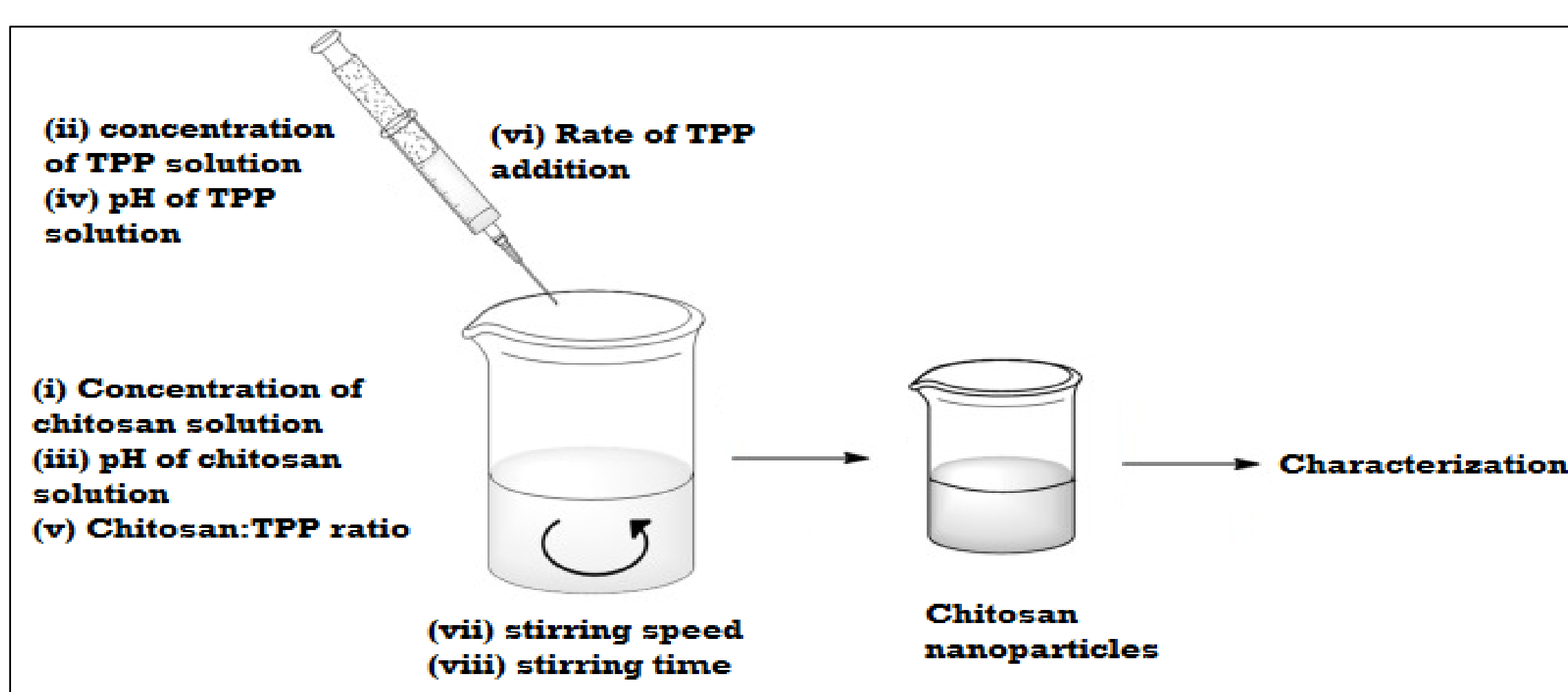

Figure 1: Ionic gelation method

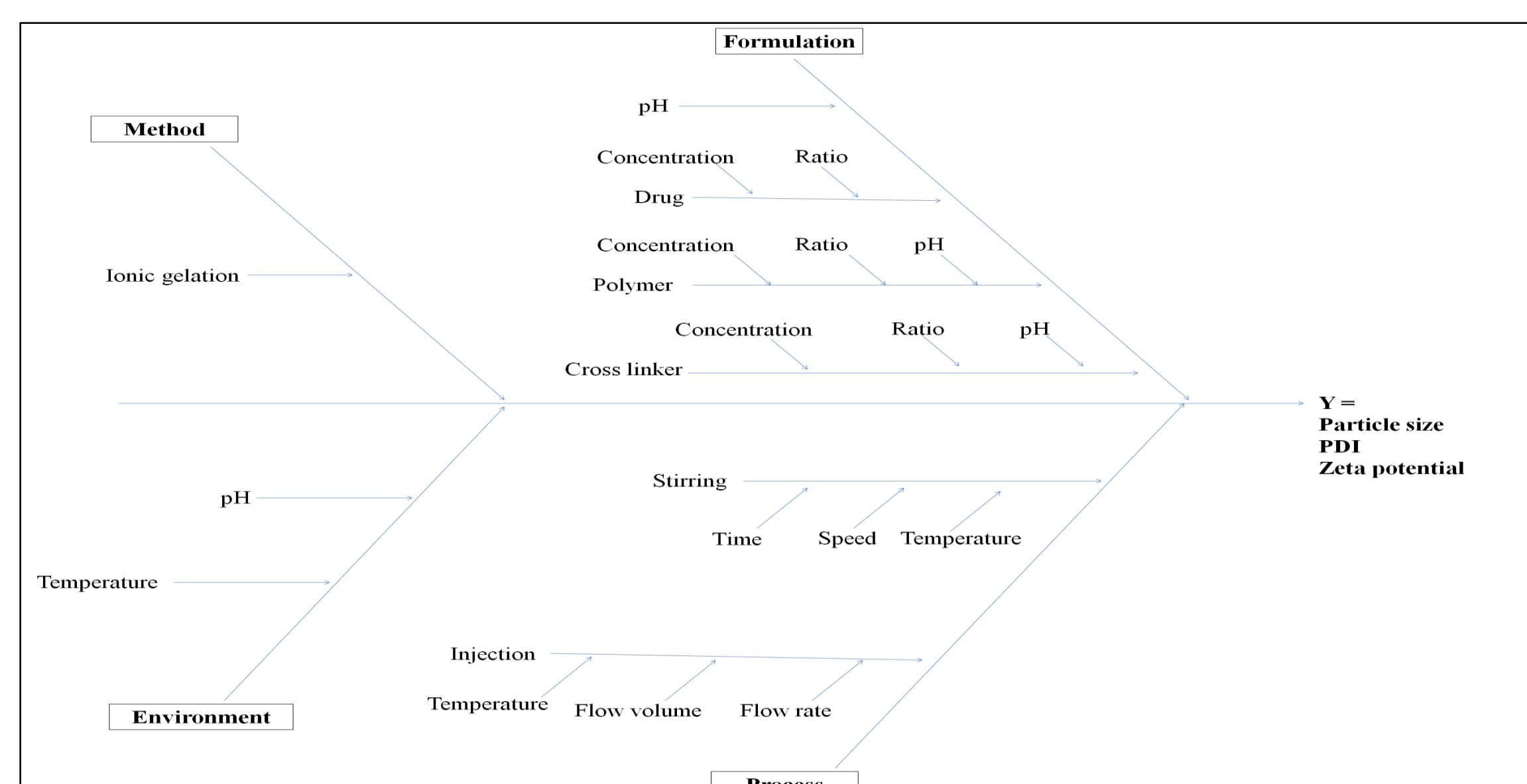### Ishikawa diagram for qualitative measure of Risk analysis

Figure 2: Ishikawa diagram

Screening of factors

| Sr. No.	Factor	Factor Type	Range
1	Concentration of chitosan solution	Formulation	0.05% - 0.25% w/w
2	Concentration of TPP solution	Formulation	0.05% - 0.15% w/w
3	Chitosan: TPP volume ratio	Formulation	1:1 – 5:1
4	Rate of addition of TPP solution	Process	1ml/min – 8ml/min
5	pH of chitosan solution	Formulation	4-6
6	pH of TPP solution	Formulation	4-6
7	Stirring speed	Process	600 – 1000 rpm
8	Stirring time	Process	15 min – 90 min

Screening of process factors
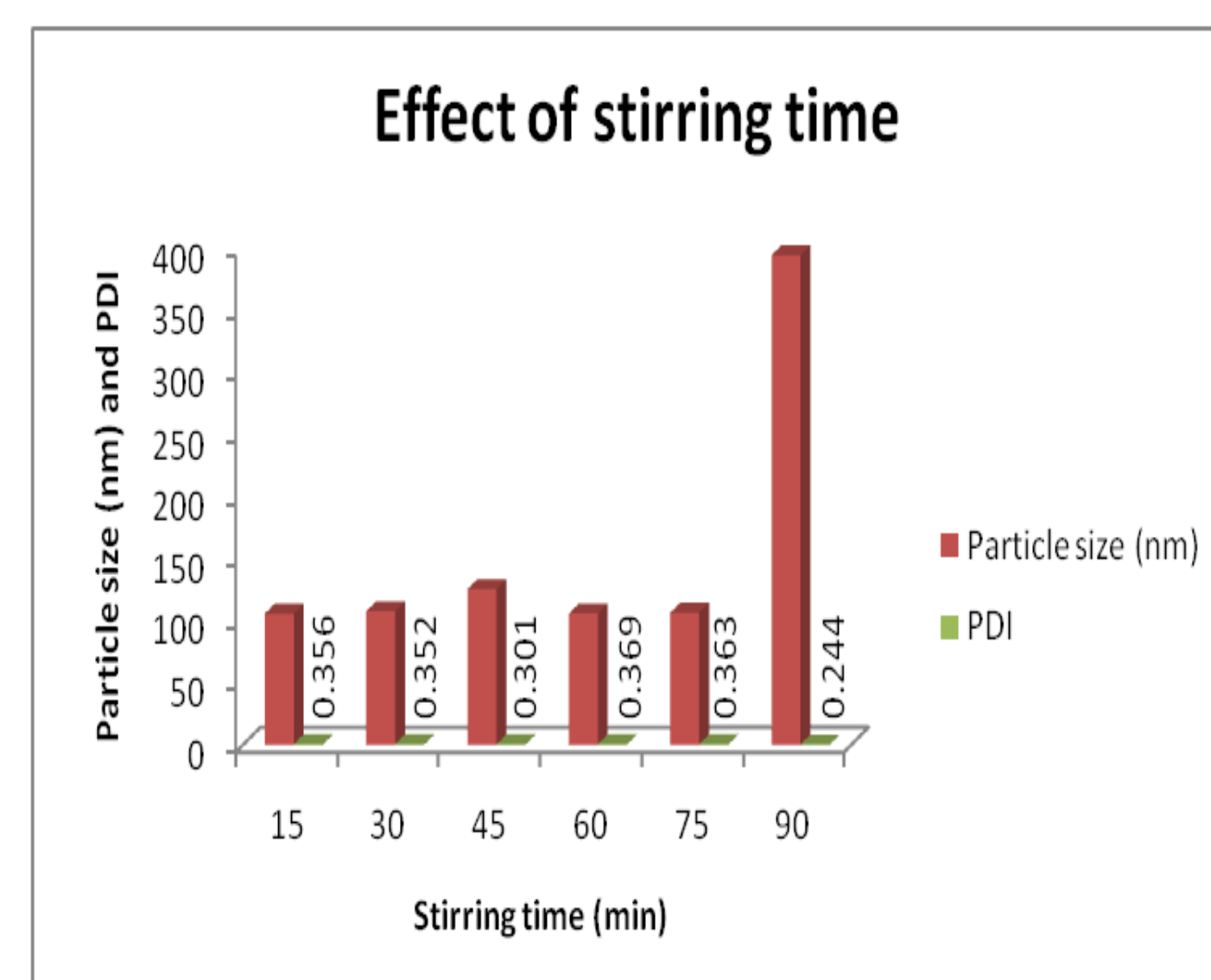
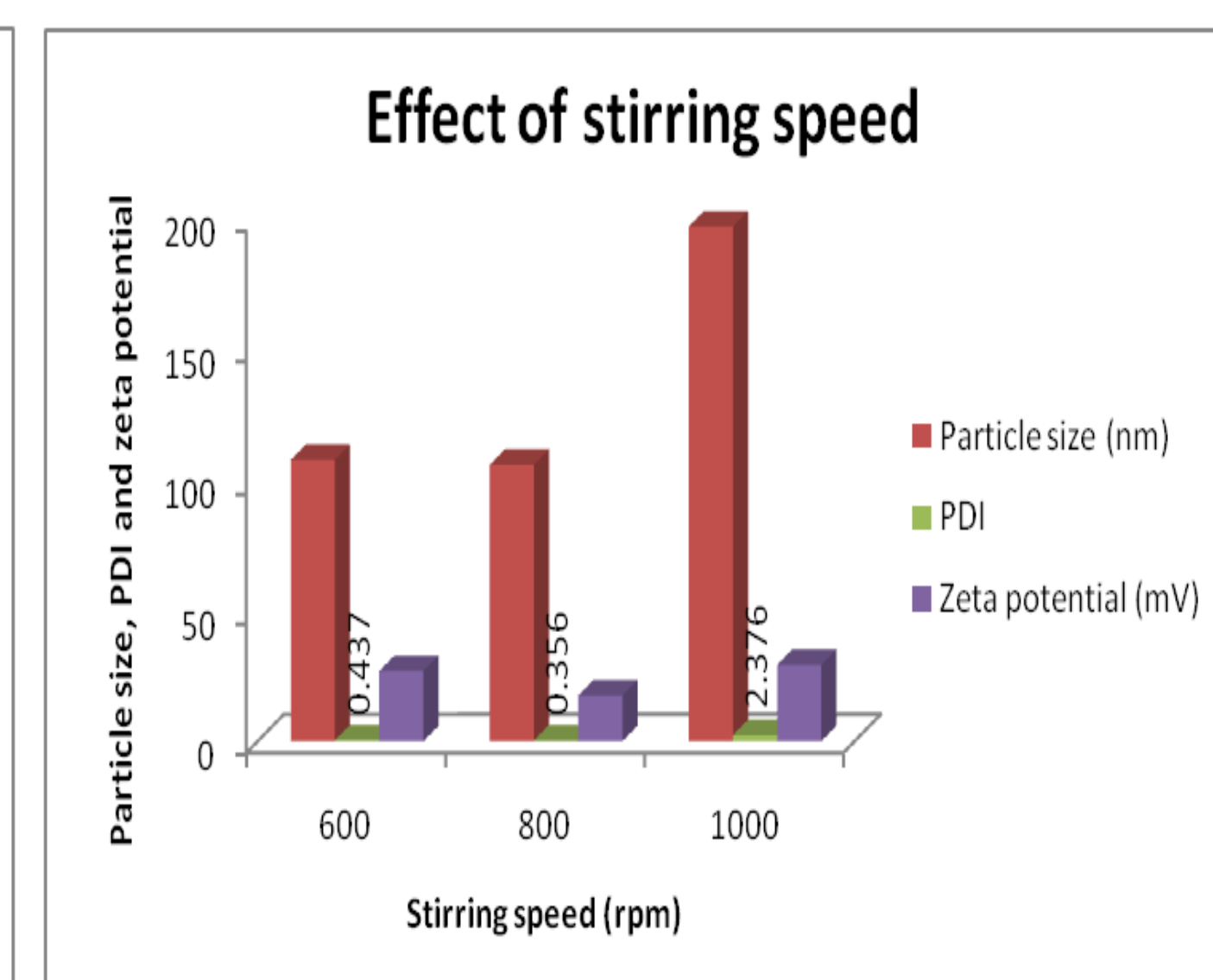Figure 3: Effect of stirring time

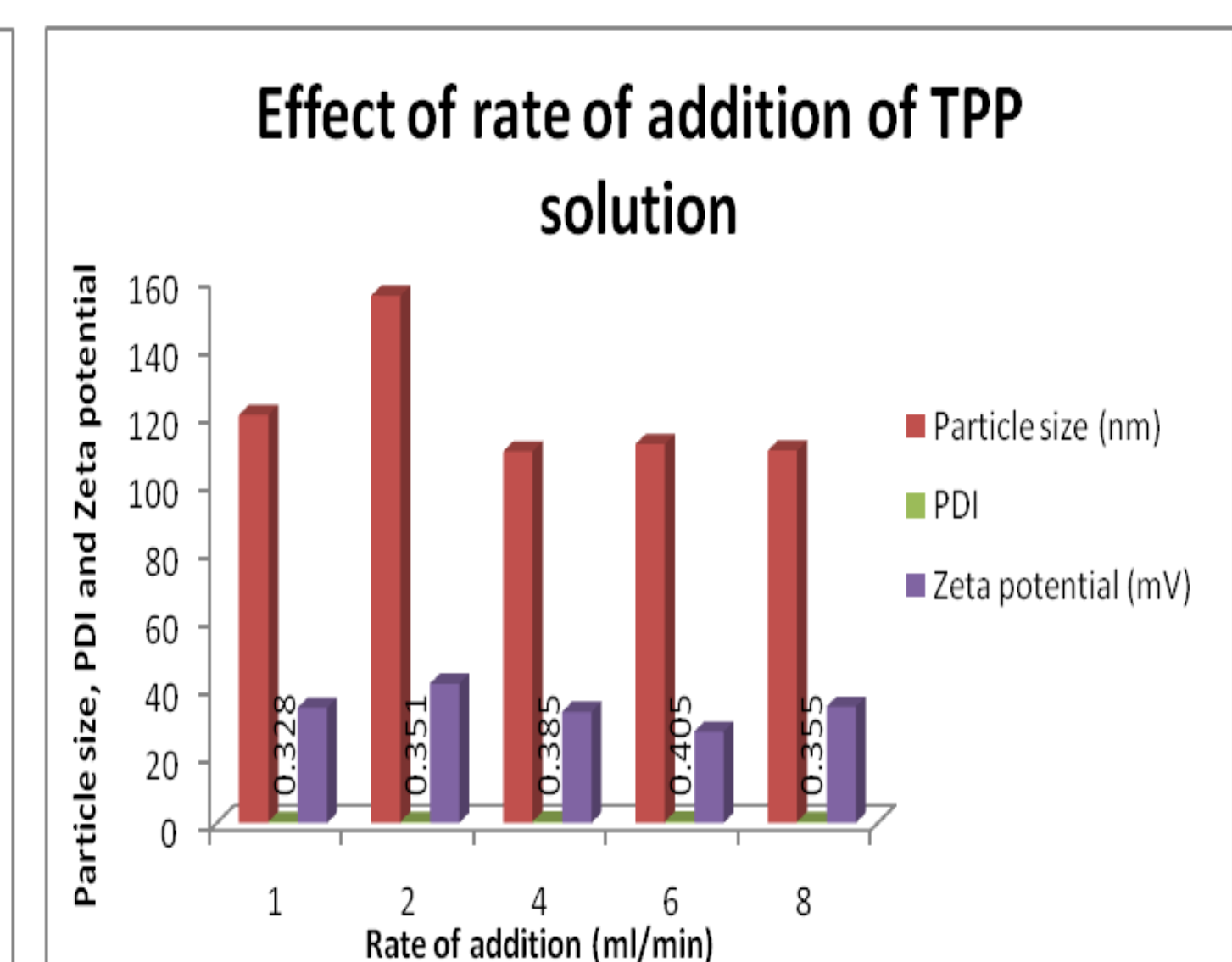Figure 4: Effect of stirring speed

Figure 5: Effect of rate of addition
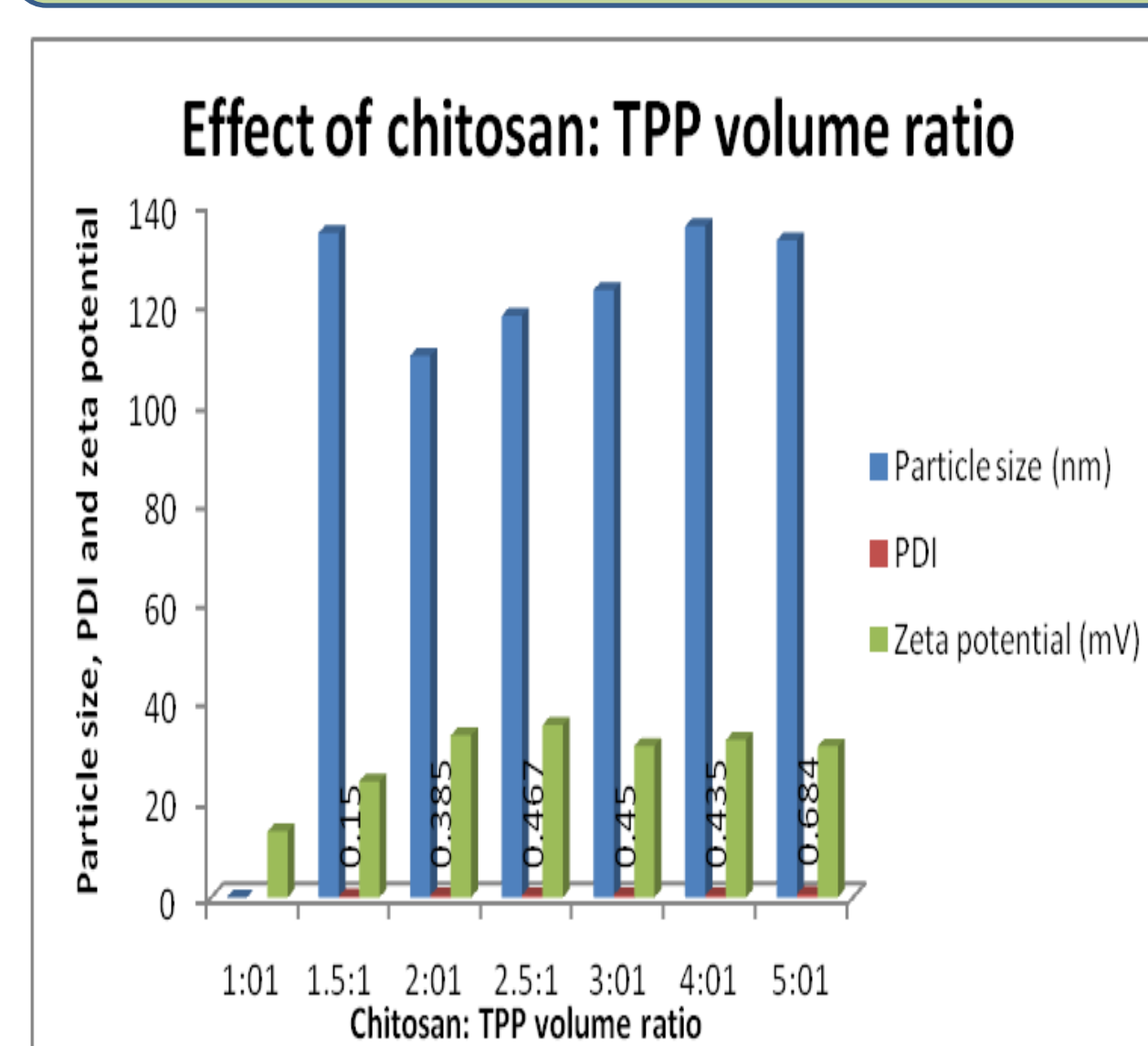
Screening of formulation factors

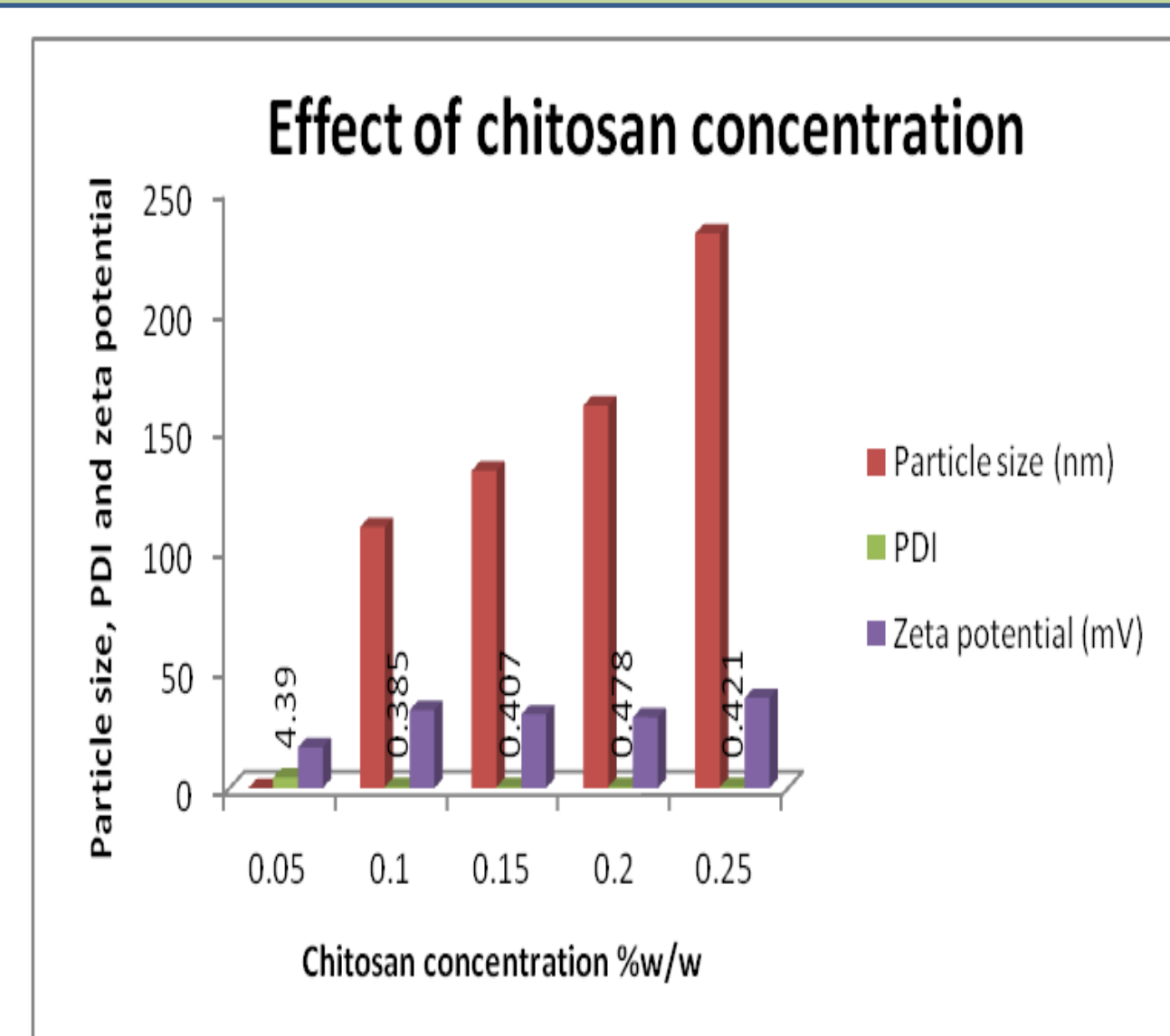Figure 6: Effect of chitosan: TPP ratio
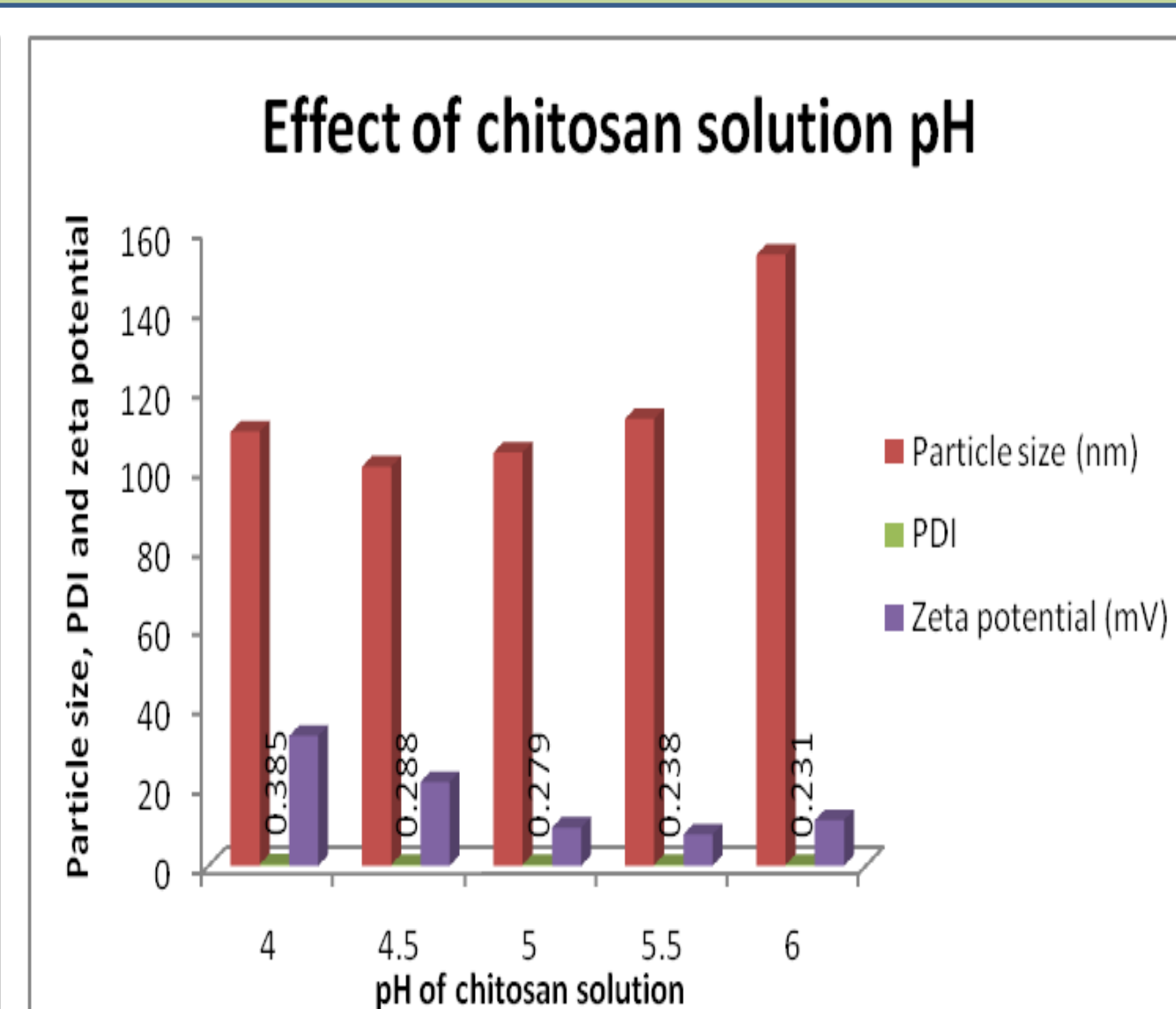

Figure 7: Effect of chitosan concentration

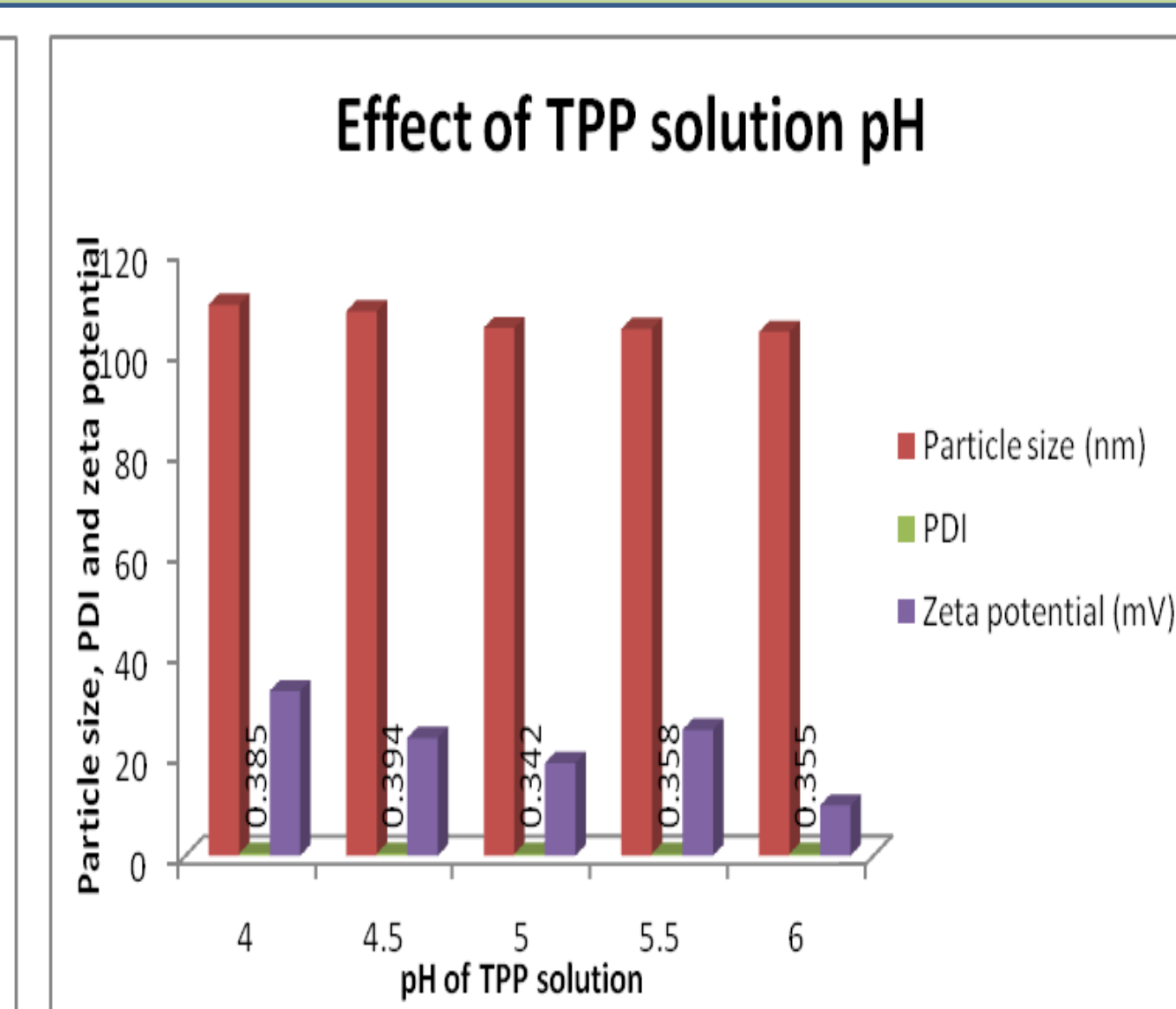Figure 8: Effect of chitosan Solution pH
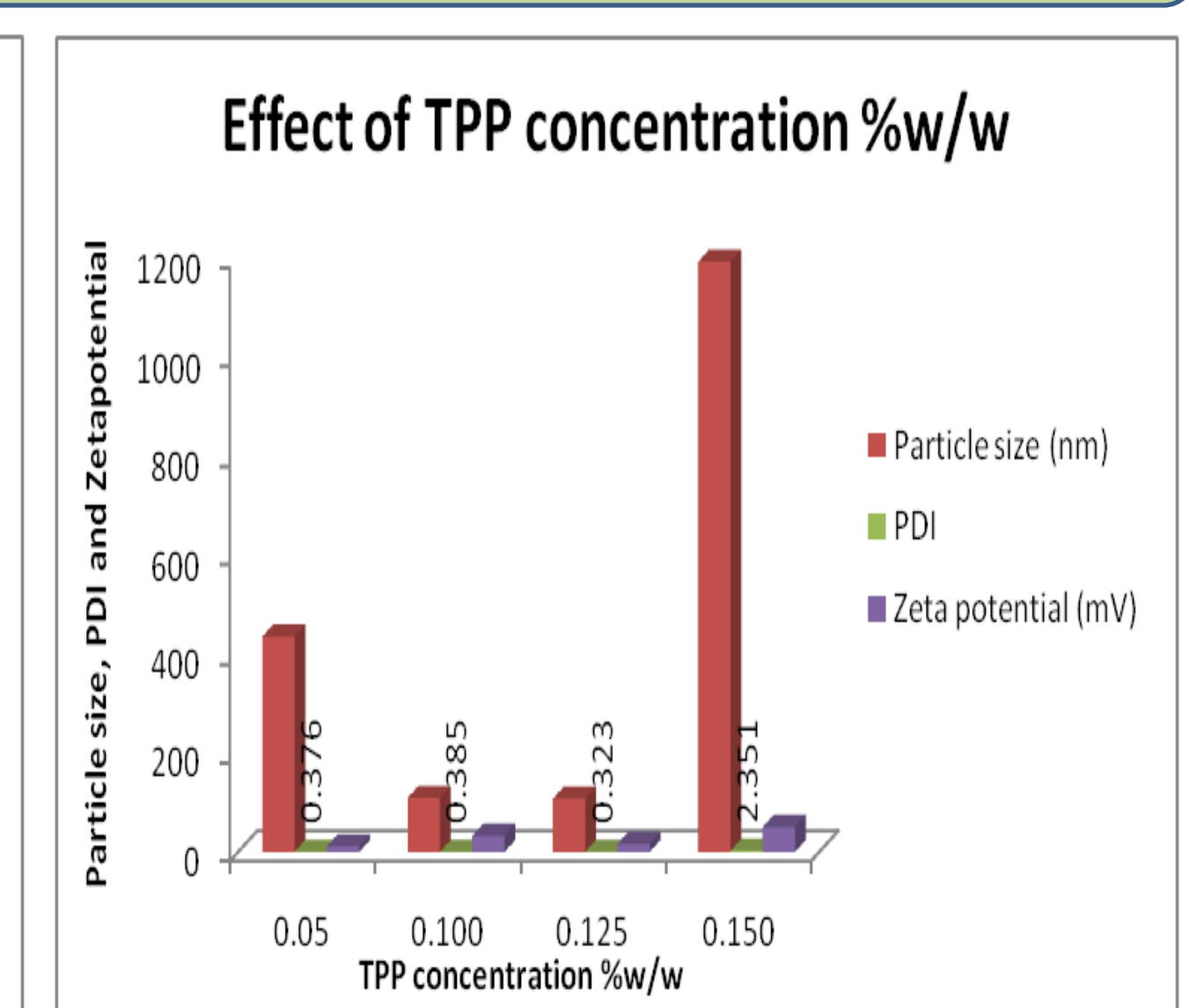

Figure 9: Effect of TPP Solution pH

Figure 10: Effect of TPP Concentration %w/w

Result and discussion

Results showed that concentration of chitosan and TPP along with chitosan: TPP volume ratio affect final particle size of chitosan nanoparticles to great extent. Zeta potential is mainly affected by concentration of TPP solution. Apart from these, pH also played significant role in formation of chitosan nanoparticles and their stability

Future perspective

Further optimization using response surface methodology, characterization and evaluation of developed phytoconstituent loaded chitosan nanoparticles.

References

1. Hassani, S., et al., *Colloids and surface A: Physicochemical Enginerring Aspects* 482.34 (2015).
2. Pandey, A., P., et al., *Artificial Cells, Nanomedicine, and Biotechnology* 45.1 (2016).

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