

# Applying Quality by Design (QBD) Approach in Fluphenazine Decanoate(FLU-D) Nanoemulsion (NE) Optimization Using Design Expert®

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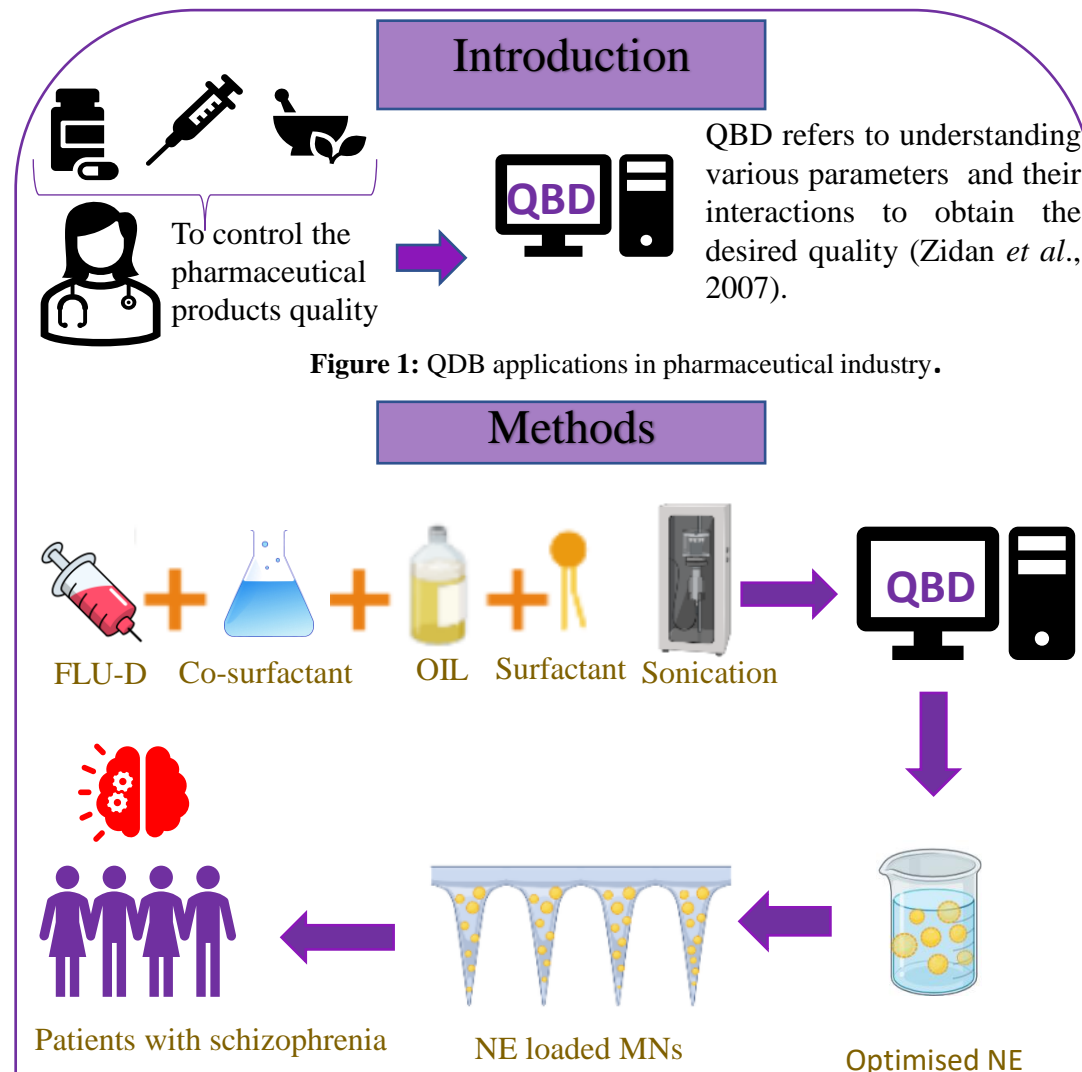


Figure 1: QBD applications in pharmaceutical industry.

Figure 2: FLU-D NE optimisation process using QBD approach.

Table 1: Design expert planning of FLU-D NE, including the selected factors with the selected ranges.

Factor	High level	Low level
Oil amount (mg)	500	100
Surfactant/oil (SOR) (mg/mg)	0.3	0.1
Co-surfactant amount (mg)	0.00	2000
Sonication Time (mins)	5	15

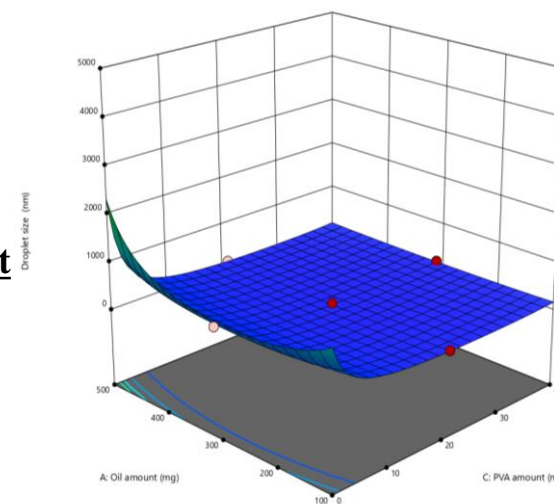
## Results and Discussion

The results revealed that the droplet size and PDI of FLU-D NE optimisation process followed the quadratic models. The F-values of droplet size analysis was 11.24. With respect to the PDI analysis, the F-values was found to 9.35. The p-value of < 0.001 was found in the case of droplet size and PDI analysis, indicating that the parameters exhibited significant effects on the droplet size and PDI of FLU-D NE.

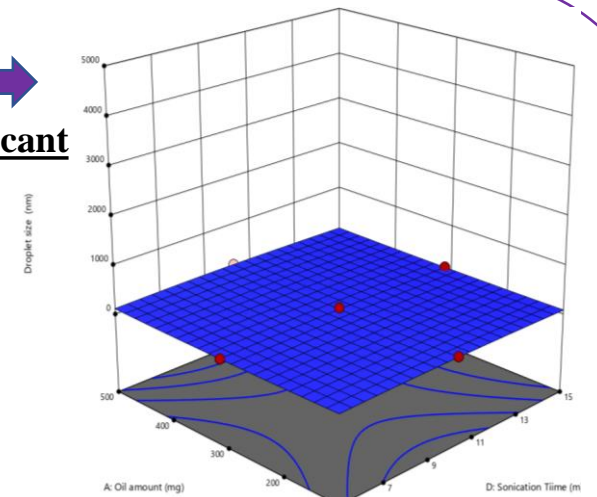
Table 2: Results of fit statistical analysis for responses of NE formulations

Factor	High level	Low level
Oil amount (mg)	500	100
SOR (mg/mg)	0.3	0.1
Co-surfactant amount (mg)	0.00	2000
Sonication Time (mins)	5	15

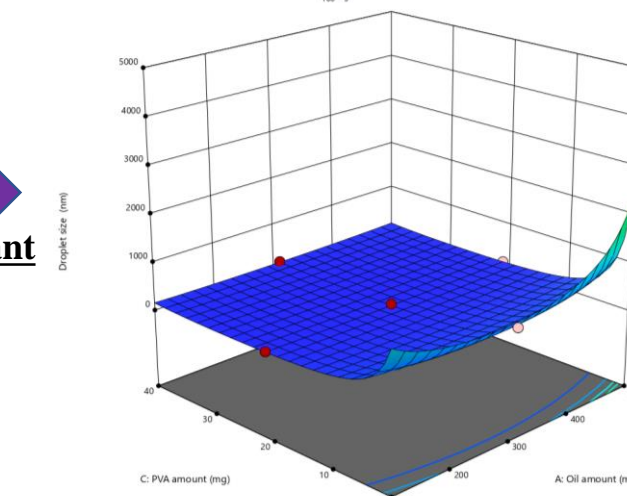
**Co-Surfactant** → **Significant**



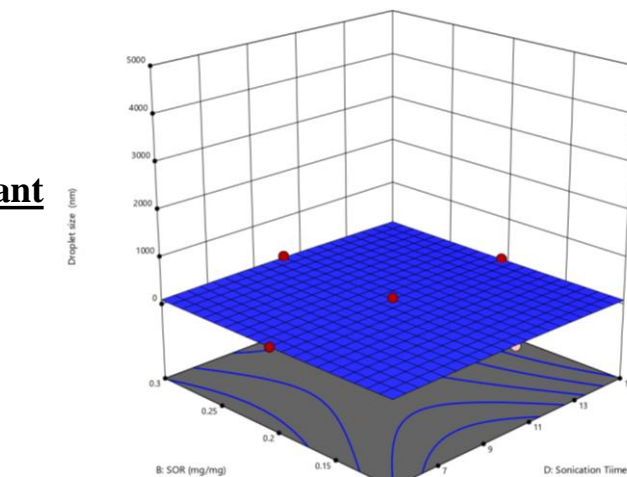
**Sonication Time** → **Insignificant**



**oil amount** → **Significant**



**SOR** → **Insignificant**



## Conclusion

From the response surface plots it can be concluded that with respect to parameters observed. QBD approach showed a significant role in time saving and successful development of NE, matching the established target product profile.