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QUALITY BY DESIGN (QbD) BASED APPROACH FOR DEVELOPMENT OF FAST DISSOLVING TABLETS

Bhukya Yamuna ¹, Thadipatri Reshma ¹ and Nawaz Mahammed ^{* 2}

Department of Pharmaceutical Quality Assurance ¹, Department of Pharmaceutics ², Raghavendra Institute of Pharmaceutical Education and Research, K. R. Palli Cross, Anantapur - 515721, Andhra Pradesh, India.

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Correspondence to Author:

Dr. Nawaz Mahammed

Associate Professor,
Department of Pharmaceutics,
Raghavendra Institute of Pharmaceutical
Education and Research, K. R. Palli
Cross, Anantapur - 515721, Andhra
Pradesh, India.

E-mail: drnawaz@riper.ac.in

ABSTRACT: Background: Oral disintegrating tablets are strong dosage forms comprising medications that disintegrate throughout the oral cavity in less than 1 minute. Quality by design is a modern approach to pharmaceutical quality. Pharmaceutical Quality Design and discusses the use of Quality Design to maintain the quality of Pharmaceuticals. **Methods:** The frequent screening design, such as 3² factorial design, Box-Behnken, placket-Burman, optimization designs, 2³ factorial design, and Central composite designs, including analysis of variance, are used. **Conclusion:** Quality by Design can be used to develop and evaluate methodological methods. Critical analytical variables are defined in an approach that is consistent with the process improvement referred to in ICH Q8 and Q9. This latest quality-by-design mechanism would incentivize even greater regulatory stability in the future. Formulations of Oral disintegration tablets were optimized with the help of quality by design. In the present article, an effort was made to review different screening designs employed in optimization formulations of oral disintegrating tablets.

INTRODUCTION: The formulation of drugs in the presentable form is a basic requirement and necessity today. The dosage form is the mean of the drug delivery system used for the administration of the drug to a living body. Various varieties of dosage formulations are available, such as pills, syrups, suspensions, suppositories, implants, transdermal patches of a particular type of medication distribution system. The improvement of the optimal system for the conveyance of drugs is a big test for the drug expert in the current scenario.

To achieve the optimal effect, the medicinal substance should be shipped to its site of operation at such a pace to produce the greatest restorative effect and the least unfavourable impact. Intensive reporting of the required measuring structure activities should be suppressed by the physicochemical laws that give rise to a particular drug schedule ¹.

Oral substance organization classes provide a wide knowledge of up to 50-60% of all measurement schemes. Good dosage systems are common for ease of organization, efficient dosage, self-medication, pain evasion and, in particular, patient continuity. The discomfort in swallowing is an important downside of this dosage type for some patients. People feel difficulty swallowing conventional medications, such as pills where water is unavailable in case of motion sickness and

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unexpected bouts of coughing during the common cold, respiratory illness and bronchitis². The problem with swallowing is a common phenomenon in geriatric patients due to fear in shock, hand tremors, dysphasia in young people due to immature strong and sensory systems, and schizophrenic patients adding to the adherence of poor patients. Pediatrics and geriatrics had trouble swallowing poor conformity with oral tablet therapy, leading to the reduced overall effectiveness of treatment³. For this cause, tablets that are it may quickly disintegrate in the oral cavity, which has attracted much publicity.

USFDA about FDT: United States Food and Drug Administration (USFDA) has described a fast-dissolving tablet (FDT) as "a solid dosage type containing a medicinal substance or active ingredient that normally disintegrates easily within seconds when put on the tongue". In the late 1970s, a fast-dissolving drug delivery system was first developed as an alternative to traditional dosage formulations for paediatric and geriatric patients. These tablets are generally designed to disintegrate quickly in less than 60 seconds of saliva⁴.

Pharmaceutical goods technicians have developed novel oral dosage forms known as oral disintegrating tablets or fast-dissolving tablets or oral dissolving tablets, immediate-release tablets that disintegrate quickly in saliva, usually in seconds, without the need for water. Recent industry surveys have shown that more than half of the patients in the population favour FDT over other dose types. Mouth-dissolving tablets are usually formulated using two methods, with the first using super disintegrates such as sodium croscarmellose, sodium starch glycolate, and crospovidone. Another approach is optimizing tablet pore structure for freeze drying and vacuum drying⁴. Direct compression is preferred in all methods due to its effortlessness, speed, and cost-efficiency.

Quality by Design (QbD): ICH QbD describes a structured approach to production that starts with predefined goals and focuses on the knowledge of goods, procedures, and process regulation, based on good science and quality risk management (ICH Q9) as shown in Fig. 1⁵.

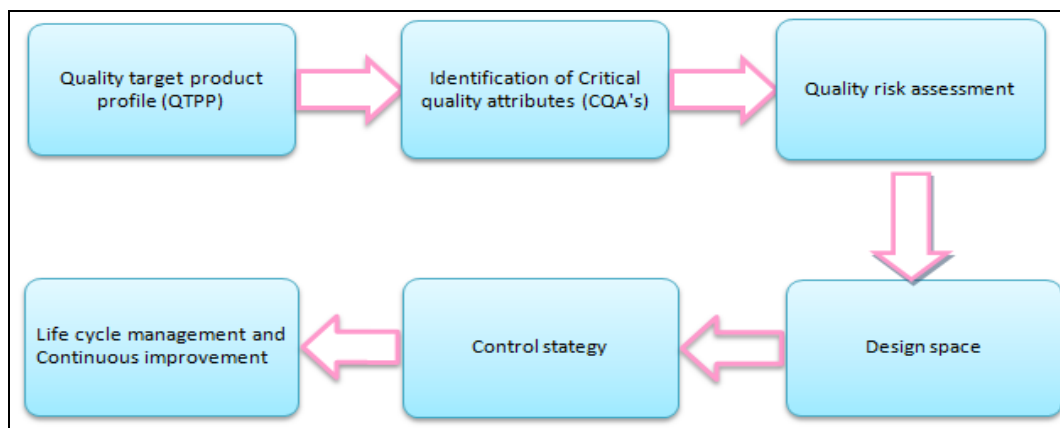


FIG. 1: ELEMENTS OF QbD

Elements of QbD:

Quality Target Product Profile (QTPP): It is described as 'a prospective description of the quality attributes of a drug product that is preferably accomplished to achieve the desired quality, taking into consideration the safety and effectiveness of the drug substance.

Critical Material Attributes (CMA): This involves the input material's physical, chemical, biological or microbiological characteristics. CMA must be within the acceptable limit spectrum of

delivery to ensure the desired consistency of the drug product, excipient or process product.

Critical Quality Attributes (CQA): Physical, chemical, biological or microbiological features that should be beyond the acceptable boundaries, spectrum or delivery to maintain the optimal consistency of the substance. *E.g.*, dissolution.

Critical Process Parameter (CPP): Variables tracked before or during the process greatly affect

the appearance, impurity and output of the finished product.

Design Space: Multi-layered mixture and association of input variables (e.g., material attributes) and processing parameters that have been shown to provide quality assurance.

Design of Experiments (DoE): A Structured study of which inputs are modified and the variance in outputs is calculated to determine the extent of the influence of each input or mixture of inputs.

Risk Assessment: It is a team used to define the overall mechanism or approach when determining

the danger and risk variable that may cause harm (risk assessment), analyzing and evaluating the risk's impact (risk identification and risk assessment).

Fast Dissolving Tablet Dosage forms with QbD

Approach: A tablet is a prescription oral dosage form or a solid unit dosage form of a medication or medical substance with sufficient excipients. It consists of a combination of drug products and super disintegrates, usually in fine powder, squeezed or compacted from a powder to a firm dosage, as shown in **Table 1**.

TABLE 1: A WORK DONE ON FAST-DISSOLVING TABLETS

S. no.	Author	Drug	Excipients	Method	Inference
1	Omprakash G. Bhusnure, et.al (2015)	Montelukast Sodium	Gum guar, CCS, MCC, Mg. Stearate, Talc, Peppermint, Sodium saccharine, Mannitol	Factorial design	Excipients-compatible drug. By introducing excipients, the time of decay is delayed. It thus proves to be safe and efficient dosage form the Oro-dispersible tablets ⁶
2	Dev Asish, et.al (2019)	Aceclofenac	CCS, MCC Sodium Saccharine Mg. Stearate Lactose	Factorial design	Aceclofenac more dissolving tablet was disintegrated rapidly & show fast action on inflammatory conditions ⁷
3	M.A. EL-Nabarawi, et.al (2013)	Aceclofenac & Ranitidine HCL	Super disintegrates, Aspartame, Mg.stearate, Aerosil	IV – Optimal design Factorial design	This study aims to decrease the disintegration time of all variables & significantly the disintegration time was significantly decreased from 4.56 mins to 40 sec. More than 85% drug dissolved after 5min in simulated saliva fluid (SSF) & after 15min in simulated gastric fluid (SGF). No significant change upon storage for 1 year ⁸
4	Santosh D. Borde, et.al (2016)	Paliperidone HCL	Avicel PH 102, Indion 234, Aerosil, Aspartame, SLS, Mg. stearate, Pearlitol SD200	Factorial design	Avicel102 & Indion 234 plays an important role in formulation & which disintegrates and disperses in mouth within 30 sec & used in treatment of Schizophrenia ⁹
5	Birajdar Shivprasad M., et al., (2014)	Losartan potassium	MCC, Talc, Sodium starch glycolate, Mannitol, Mg. Stearate, Isabgol seeds/ mucilage	Factorial design	The disintegration time was shown within the limit of 46 to 75 sec. Increase in concentration of excipients it decreases the disintegration time ¹⁰
6	Saurabh M. Mishra, Bhagwan D.Rohera. (2017)	Carbamazepine	Mannitol, CCS, PVP K30, Sodium starch glycolate, Crospovidone, Camphor, Menthol, Ammonium bicarbonate	Box- Behnken response surface methodology	The poorly water-soluble drug was developed into ODTs by using Box-Behnken surface methodology. It is evident that combined use of QbD tools, that facilitates understanding of the role of formulation & process parameters on the Quality attributes of ODTs ¹¹
7	Shehla Khan, et al., (2018)	Methylphenidate Hydrochloride	Avicel PH 102 Indion 234 Aerosil Aspartame SLS Mg. Stearate Pearlitol SD200	Factorial design	The drug which disintegrates & disperse in saliva within 30 sec & is a promising approach for the treatment of Attention deficit hyperactivity disorder (ADHD) ¹²
8	Omprakash	Nifedipine	Mannitol, PVP K30,	Factorial	The <i>in-vitro</i> disintegration time of

	G. Bhunure, et al., (2015)		PEG 4000 & 6000, CCS, MCC, Talc, Urea, Crospovidone, Lactose, Sucrose, Mg. Stearate, Citric acid	design	tablets ranges from 5 to 11 sec ¹³
9	Desai. S. R., et al., (2018)	Aspirin	Povidone Crospovidone Mg stearate	Factorial using Box-Behnken design	Among 9 formulations 7th formulation, the peak with no impurities was observed at wave length 275nm & DSC & XRD studies shows a sharp peak. It is summarized that the formulation & evaluation of FDT of Aspirin by QbD approach was successfully prepared ¹⁴
10	Ahmad Ainurofiq & Syaiful Choiri, (2016)	Meloxicam / β -cyclodextrin complexes	Avicel PH 102, Sodium starch glycolate type A(Primojel), CCS, pearlitol 200SD, Sodium stearyl fumarate, β - Cyclodextrin.	QbD statistical analysis	The spray drying method was the best for solubility & dissolution rate enhancement. According to QbD paradigm a less friable ODT formulation & rapid disintegration time were obtained at low crushing strength ¹⁵
11	Alhussain H. Aodah, et al., (2020)	Metformin Hydrochloride	D- Mannitol Starch & Starch 1500, Colloidal silicon dioxide, Aerosil 200, Sodium stearyl fumarate	Factorial design	It is concluded that an acceptable ODT of high dose drug was successfully developed based on the MDAG technique & it showed high mechanical strength, short oral disintegration acceptable release ¹⁶
12	Omaima A. Sammour, et al., (2010)	Indomethacin	Mannitol Polyvinyl pyrrolidone K25, Avicel PH 101, Dichloromethane, Chloroform, Mg. Stearate	Factorial design	The drug polymer interaction a long with the partial amorphous state of the dispersion was responsible for dissolution improvement. Hardness was the most important factor controlling the disintegration & dissolution ¹⁷
13	Andrei catalin muntean, et al., (2020)	Paracetamol	Mannitol, Isomalt 720, Ludiflash, CCS, Crospovidone, Mg. Stearate, Colloidal silicon dioxide, Sodium saccharine, Natural orange flavour.	D-optimal experimental design	It is concluded that high level of disintegrate had no impact on the needy factors & good responses were obtained at low disintegrate content. Using sodium croscarmellose led to better result than using crospovidone ¹⁸
14	Emine Tashan, et al., (2020)	Ziprasidone hydrochloride monohydrate	Standardized taurocholate – lecithin powder, Mannitol, PVP K30,	Factorial design	It is concluded that by using nanocrystals for the preparation of ODTs has improved the bioavailability and enhances the solubility and dissolution rate ¹⁹
15	Stefana suciu, et al., (2018)	Ibuprofen	Methyl cellulose, Xanthan gum, Rhodigel 200, Gelatine 7& sodium alginate, carbopal, polycarbophyl, PVP, HPMC methocel, Polyox, Mannitol, Sucrose	D-optimal experimental design	It is concluded that sodium alginate as an appropriate matrix-forming agent that yields good disintegration and dissolution properties and the study worked on developing oral lyophilizes with bio-adhesive agents which shows prolonged disintegration and dissolution to overcome this problem fillers where highly beneficial for fast disintegration ²⁰
16	Sonia Iurian, et al., (2017)	Meloxicum	Mannitol, PEG 4000, PVP K25, Ploxamer 188, CSS, Alginic acid sodium salt	Quality by Design	It is concluded that, this study approaches study of different variables influencing the oral lyophilisate preparation with high versatility and also further study of nano suspension ²¹ .

17	Sheshank sethi, et al., (2018)	Cinnarizine	Citric acid, Glycine, Mg. Stearate, sodium bicarbonate, HPMC K4M, Spray dried lactose, A corn fibre gum	Quality by Design	It is concluded that the use of p-CFG has quick swelling characteristics, which helps to avoid the buoyancy lag time and maintains a longer duration of time for the floating of the tablet in the gastric fluid ²²
18	Kapil josh, et al., (2015)	Amlodipine & Ramapril	Sodium starch glycolate, Mg. Stearate	Factorial design	Factorial designs were used to refine the Oro-dispersible Amlodipine - Ramipril tablet mixture with less disintegrating time and maximum hardness ²³ .
19	Gozde guncan, et al., (2017)	Alfuzosin hydrochloride	Avicel PH 101, Ludiflash, sodium stearyl fumarate, sodium starch glycolate, mannitol	Quality by design	This study explains to understand the relationship between input and output attributes with multiple experiments and the results are evaluated by using GEP and ANN software which helps to develop models based on the known results to estimate the unknown results ²⁴
20	E.Bhargav, et al., (2017)	Piroxicam	Croscarmellose sodium, Sodium starch glycolate, Aspartame, Crospovidone, Sodium saccharin, Mannitol, PVP, Talc, Mg.Stearate.	Central composite design	It was concluded that the usage of different concentrations of super disintegrates observed with interactive effect on dispersion time and drug release, this model can be successfully applied for the development of piroxicam ODTs ²⁵
21	Roy, et al., (2020)	Piroxicum	CCS, Spary dried lactose, HPMC K4M	QbD & Box-Behnken	By using a large no.of variables and responses development of piroxicam ODTs was successfully prepared and responses are evaluated by using Box-Behnken design ²⁶
22	Yetin N Dholariya, et al., (2014)	Hydrochlorothiazide	CCS, HPMC K4M, HPMC K100M, MCC, PVP K30, Sprays dried lactose, tartazine	Factorial design, surface response plot	It was concluded that HCTZ bilayered tablets were prepared successfully by applying QbD. The one layer of tablet shows immediate release followed by sustained release, it indicates the potential dosage form when compared to the conventional dosage form ²⁷
23	Brahmaiah Bonthagarala, et al., (2019)	Pioglitazone	MCC, lactose, colloidal silicon dioxide, CCS, Mg. Stearate, Dibasic calcium phosphate, Glycerine, Tween 20, Tween 80, PEG 200, PEG 400, Propylene glycol	Liquisolid technology, Kawakita analysis, DoE	It was concluded that a poorly water-soluble drug was developed with improved solubility by using liquisolid method with application of QbD and the dissolution rate of tablet was increased due to mechanism of wetting, surface area of particles improvement and conversion of crystalline to amorphous form ²⁸
24	Preena Shrimal, et al., (2019)	Telmisartan	Poloxamer 407, Avicel PH 101, Sodium starch glycolate, Talc,	Box - Behnken design	By using microchannel precipitation with the approach of QbD telmisartan nano particles are successfully prepared with increased solubility and bioavailability ²⁹
25	Chintan parmar, et al., (2018)	Mesalamine	HPMC K4M, HPMC K15M, PVP K30, Eudragit ® S100, Eudragit ® RLPO, Eudragit ® RSPO, MCC, Aerosil, Mg.stearate	Response surface methodology	The different grades of HPMC polymers were the major excipients which affect the drug release so they are optimizes by central composite design and formulation of mesalamine bilayered tablet was successfully prepared ³⁰

Process of QbD for FDTs: As shown in Fig. 2.

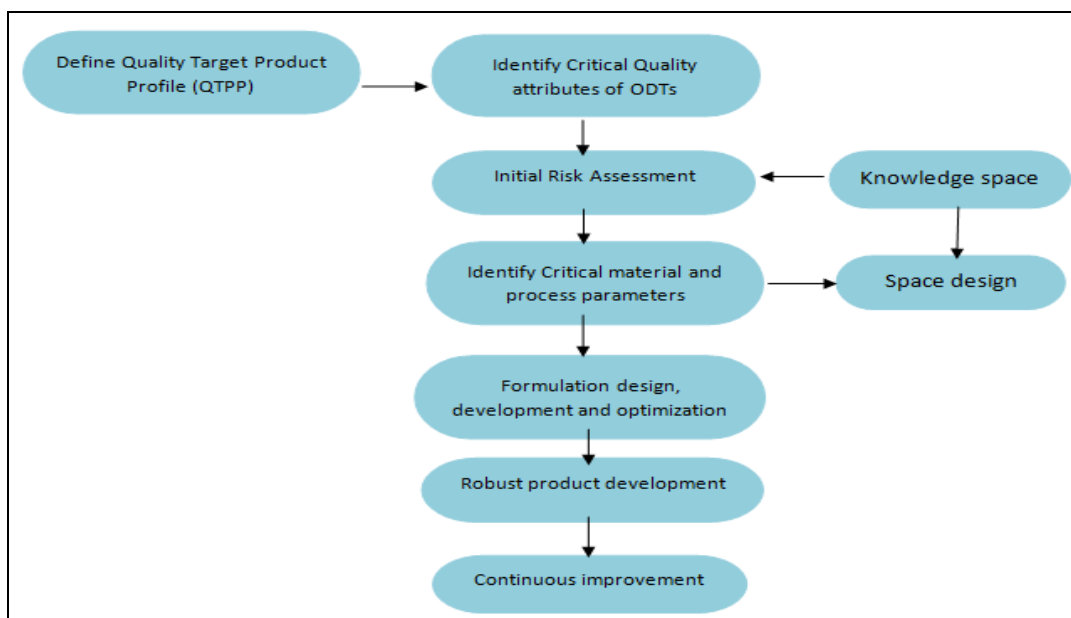


FIG. 2: QUALITY BY DESIGN (QbD) APPROACH FOR THE FORMULATION DEVELOPMENT OF FDTs

Process of Direct Compression: The process involved in the direct compression tablets are as shown in Fig. 3.

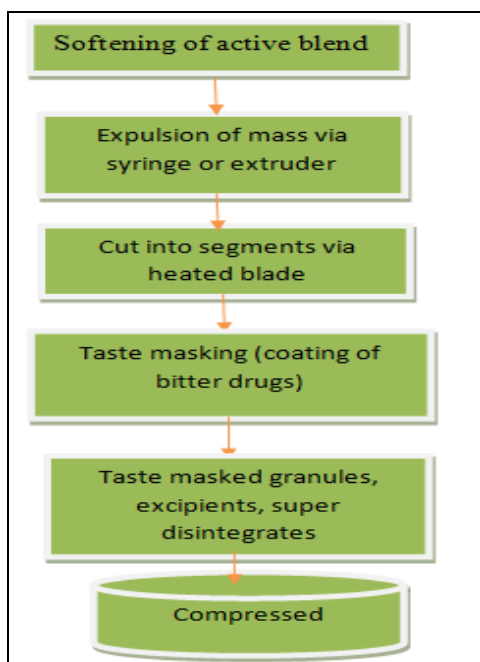


FIG. 3: SCHEMATIC FLOW CHART OF DIRECT COMPRESSION METHO

CONCLUSION: The importance of FDTs has risen significantly over the last decade. Based on the literature surveyed, it can be inferred that Oro-dispersible tablets are of special interest to paediatric, geriatric, bedridden and bipolar patients afflicted by dysphagia. These fast-dissolving tablets are converted into a suspension of salivary fluid in the oral cavity, which indicates a fast onset of

action with increased bioavailability, increased approval of the patient, and excellent protection relative to traditional oral dosage formulations. QbD can be used to develop and analyse analytical approaches. All possible variables and critical analytical responses are analysed during the system's production to determine the relationship. Critical analytical variables are defined in an approach that fits what is mentioned for process improvement in ICH Q8 and Q9. This new QbD process provides an opportunity for much increased regulatory flexibility in the future. The success parameters of the process may theoretically be recorded instead of the system itself. According to my analysis, several fast-dissolving tablets were prepared using a direct compression process. So, based on my analysis, I concluded that the direct compression method is mainly used for formulating FDTs with a QbD-based approach.

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