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A CASE STUDY USING THE QUALITY-BY-DESIGN METHOD FOR DEVELOPING FORMULATIONS OF DISPERSIBLE TABLETS

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Abstract:

In ICH Q8, the application of QbD is explained. To create stabiliser suspension, a thickening agent is used. To avoid the practical pleasant mouth feel, it has been added. The benefits of dry and liquid formulations are mixed with dosages. Both technologies allow for substantial medication loading while maintaining a pleasant flavour. In order to carry out this research, ibuprofen is used as a depreciable component. Ibuprofen is used to treat depression when combined with polyacrylic depression medications. This research also makes use of the target product profile. It is crucial as a goal for the effectiveness and safety of medication development initiatives. The creation of dispersible tablets and their design are crucial in the early stages of performing the research.

Keywords: ICH, ObD, Stabilizer suspension, Polyacrylic depression, Ibuprofen

Introduction:

Elderly patients and children have difficulty swelling conventional tablets. Consequently, medical science focused on developing dispersible tablets. There are two types of dispensable tablets using ibuprofen. It is directed as a model drug that develops to facilitate the administration of tablets for patients. It is primarily considering patients with oesophageal problems. The disintegrated Instantaneous tablets are easily dispersible in the mouth with the interaction of saliva (Nayak *et al*. 2019). It does not require any drinking water to swallow. There are other kinds of tablet formulations that can be dispersed in water.

Literature Review:

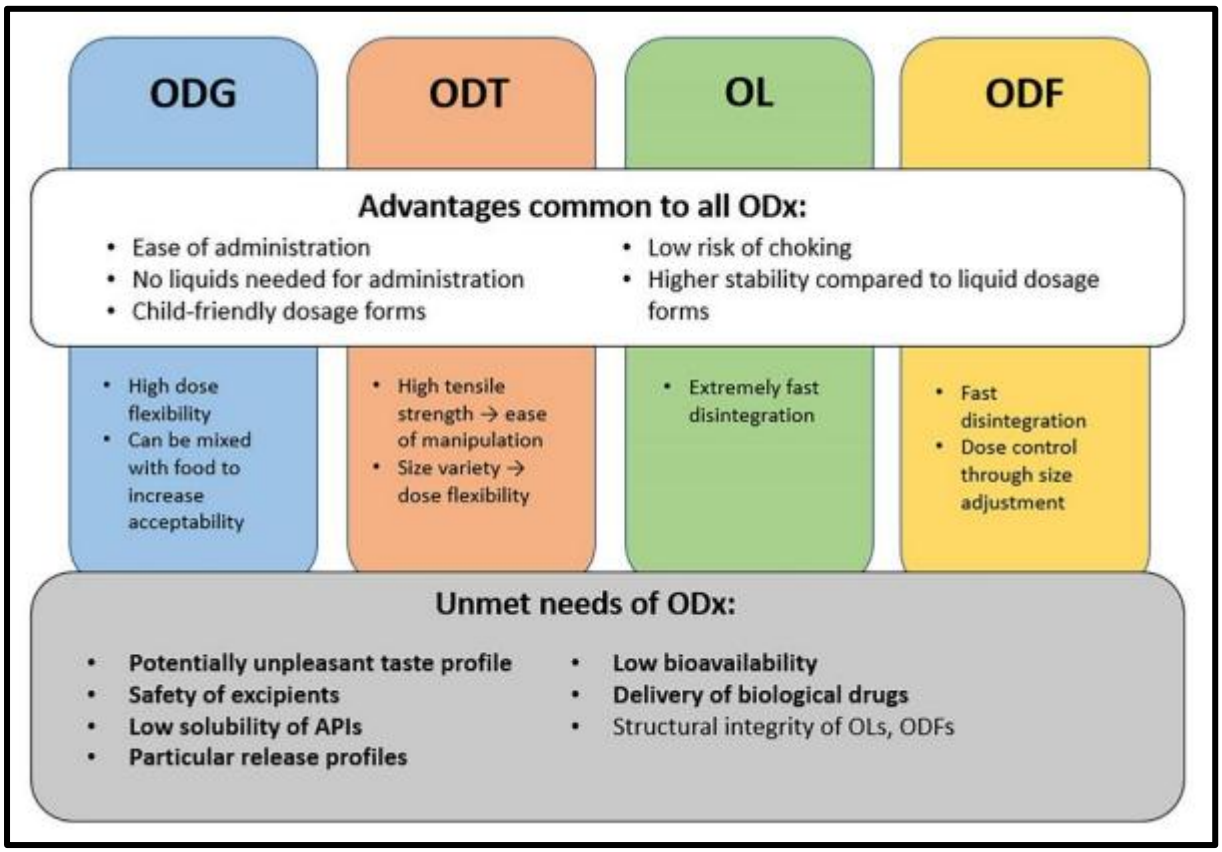

Figure 1: Advantages of orally dispersible tablet
(Source: Cornilă*et al.* 2022)

The utilisation of QbD is described in ICH Q8. The thickening agent is utilised to generate stabiliser suspension. It is added to avoid the practical pleasant mouth feel. The doses are combined with the advantages of the dry and liquid formulations. In the case of both the technology, It allows high drug loading with an acceptable taste (Ter Horst *et al.* 2021).

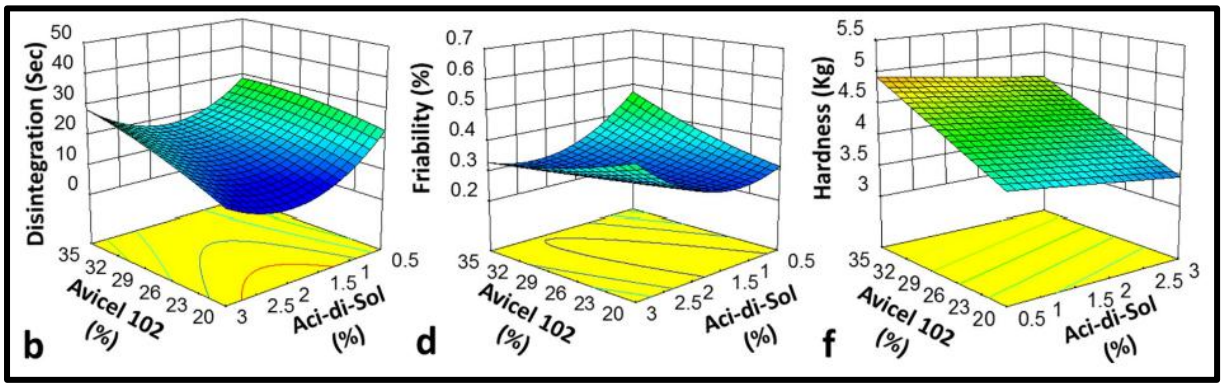

Figure 2: Disintegration formula of dispersible tablet
(Source: Yasmin *et al*. 2020)

The advantages of dispersible tablets are identified by patients and organisations. There are three consecutive Technologies, applied in producing the displaceable tablets. The freeze-drying strategy is followed to mould the dust chemicals into a form. It comes under direct compression to form the tablets. Another form of producing displaceable tablets is Lyophilized tablets. It has very porous which causes a quick penetration of saliva.

Methods:

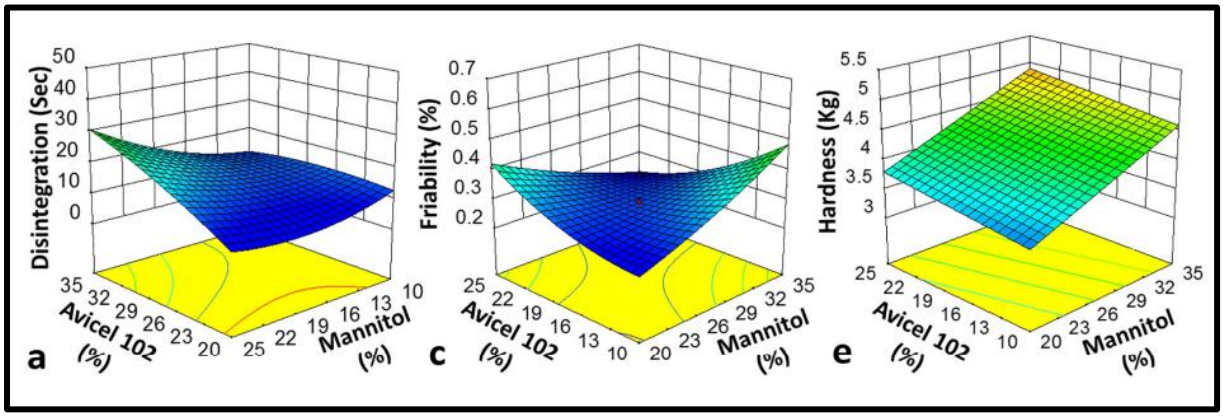

Figure 3: Dispersible tablet formulation
(Source: Yasmin *et al*. 2020)

Ibuprofen is utilised as a depreciable component in order to conduct this research. Ibuprofen is used to court medicines with a poly acrylic depression element (Abdelkader *et al*. 2021). The target product profile is also utilised to conduct this research. It is important as an objective of the safety and efficiency of drug development programs. In the initial stage of conducting the research, the formation of dispersible tablets and their design is essential. The potential interaction between drugs and various unit operations is carried out in this research (Abdelkader *et al*. 2021). There are certain components utilised in this research which are water-depreciable and mouth depressible.

	Water dispersible tablet	Mouth dispersible tablet
Coated ibuprofen	160.0	50.0
Meyprofin M-175	104.0	
Avicel PH 102		6.5
Avicel PH 105	94.0	
Mannitol DC		30.0
Crospovidone	32.0	13.0
Citric acid	6.0	
Aerosil 200	2.0	
Calcium arachidonate	2.0	0.5
Flavour	5.2	0.1
Saccharin sodium	1.6	0.2
Sodium cyclamate	0.8	0.1
SicovitTartrazine 85E102	0.2	
Batch size (g)	407.8	100.4
Tablet weight (mg)	2340	1200
Content of ibuprofen	600	400

The experimentation design is also considered in this research where the pharmaceutical product development has improvised the material and process attribute for dispensable tablets.

Findings and Discussion:

The formulation and process development identified displaceable tablets after conducting the research. It has a better process of understanding and controlling the vital product waste in the formation of dispensable tablets. It is also found that Enteric coated ibuprofen is utilised for tabletting the formulation. However, it has been found that ibuprofen has a better taste. It may sometimes cause gastric irritation.

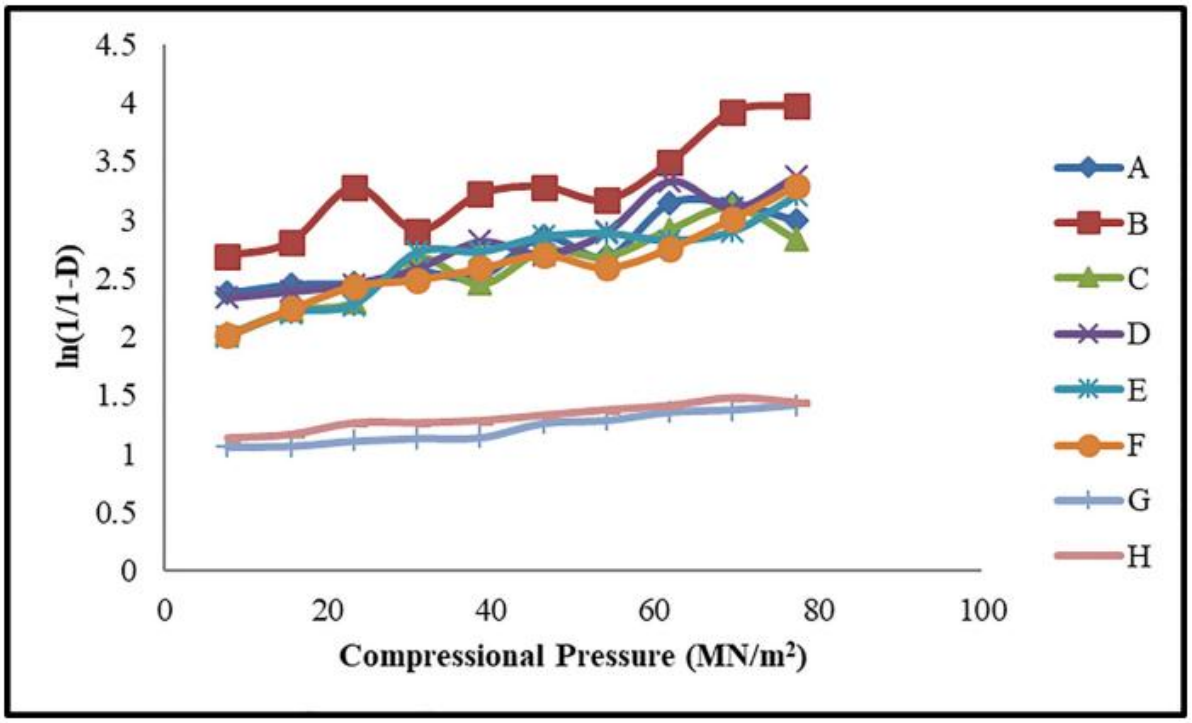

Figure 4: Heckel plots of fast dispersible Aceclofenac tablets

(Source: Yasmin et al. 2020)

The coating material uses Eudragit FS 30 D to make it suitable. It also increases the pH level by 7.0. It also causes a cavity in the mouth (Luo *et al.* 2020). There are certain disadvantages found in these doses such as the cost-intensive production process. It has a lack of physical resistance in the standard blister pack of the medicine. In the primary cases disintegration of such tablets is found to be essential for rapid dispersion. The expansion of the predesigned quality of the medicine is found with robust and stable depreciable components. The suitable depreciable tablets have the utilisation of BCS class II analogistic drugs. It is identified as diclofenac. In this medicine, the use of elements like QBD is identified (Javed*et al.* 2019). The dispensable tablets provide some advantages in the administration of drugs to paediatric and dysphagic patients. It exhibits a high mechanical elasticity for sweetening tablets that are coated with sucrose crystals. Packaging materials with a stability range have also been found in this research. It has provided careful protection from the merchandiser in nature.

Conclusion:

In conclusion it can be stated that Innovation approaches with a quality management perspective in the

pharmaceutical industry have improvised. The possible preparation of dispersible tablets is directed with a compression method. Conventional solid dosages are facing competition with dispensable tablets. It has become easy to access children and aged people.

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