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Formulation and In Vitro Evaluation of Taste- Masked Prednisolone Orodispersible Tablets

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Abstract:

Background: prednisolone is a corticosteroid with a very bitter taste acts as anti- anti-inflammatory and immune suppressant drug and it is used at any age.

Objective: To improve patient compliance by masking the bitter taste of the drug to be delivered as an orodispersible tablet.

Methods: External ionic gelation using sodium alginate (0.5%w/v) and calcium chloride (1% w/v) in the presence of 0.5% w/v carbopol 940 was used to prepare taste-masked beads loaded with prednisolone to be compressed as orodispersible tablets.

Results: The bitter taste was masked by preparing beads composed of 1:1:1 (sodium alginate: Carbopol 940: prednisolone) which released only 0.77 % of the drug in pH 6.8 (pH of the oral cavity). The ODT prepared by direct compression using taste-masked beads equivalent to 5 mg PRD, 3% crospovidone, 2% PVP, 1% talc, 1% magnesium stearate and a combination of Avcil® PH 102 and mannitol at (1:1) ratio was the optimum formula (T6) with a hardness of 3.9± 0.32 kg, friability 0.45%, thickness 2.5 ± 0.05 mm, % drug content 98.2% ± 1.8, wetting time 18.7 ± 1.3 sec, water absorption 41 ± 2.1%, disintegration time 15.3 ± 0.5 sec. and released only 0.75% ± 0.01 of PRD in an oral pH of 6.8 within one minute (indicating good taste masking). Its release in the stomach (pH 0.1N HCl) and intestine (pH 6.8) was continued for up to two hours.

Conclusion: it can be concluded that the external ionic gelation method was successful in masking the bitter taste of prednisolone and also can be formulated as taste-masked orodispersible tablets by direct compression method.

Keywords: External ionic gelation method, oro- dispersible tablets, prednisolone, sodium alginate-beads, taste masking.

Introduction

Prednisolone (PRD) is a synthetic corticosteroid that acts as anti- inflammatory and immunosuppressant, used in several diseases like arthritis, allergy Crohn's disease, myasthenia gravis and ocular myasthenia (1). It has a bitter taste which affects patient compliance, especially in children (2). External ionic gelation is one of the taste mask techniques used to improve patient compliance by encapsulating the active ingredient by forming an insoluble gel which decreases the drug released in the oral cavity (3). In this method sodium alginate (S. Alg) as polymer reacts with bivalent metal ions like calcium chloride (CaCl2) to form calcium-alginate beads which are loaded with PRD (4). An oral route of drug administration has wide acceptance capable of 50 to 60 % of overall dosage forms. Solid dosage forms are popular due to easy administration, self-medication, accurate dosage, pain avoidance, and improved patient compliance. So, one of these dosage forms is an orodispersible tablet (ODT) which is defined as "a solid dosage form containing medicinal substances, which disintegrates rapidly usually within a matter of seconds, when placed upon the tongue" (5).

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Such tablet is easy to be taken by a patient of any age, regardless of time or place, and by patients who have difficulties swallowing tablets or capsules. These tablets are also named mouth-dissolving tablets, quick-disintegrating tablets, fast-dissolving tablets, and porous tablets (6). Thus, this study aimed to formulate the taste-masked PRD (PRD-beads) as ODT to improve patient compliance, especially in pediatric and geriatric patients by delivering the drug orally without the need for water, through time less than one minute, and with palatable taste.

Methods

The Preparation of masked PRD (PRD- beads)

By using the external ionic gelation method; S. Alg (0.5 % w/v) with PRD dispersion was prepared in distilled water at a 1:1 ratio with continuous stirring by magnetic stirrer (500 rpm) for about 1 hour at 40 oC with 0.5% w/v carbopol 940 as viscosity agent. Later the prepared dispersion was added dropwise to 100 ml of 1% CaCl2 solution using a needle (23-G). The calcium-alginate beads were then separated, rinsed with distilled water, and kept for 24 h in an oven for drying at 40 oC, after that stored in a sealed container (7). The resultant beads were then spread either directly on a Petri- dish (Beads A) or on a Petri- dish covered by filter paper (Beads B), and

then they were kept for 24 h in an oven for drying at 40 oC.

The preparation of PRD-beads as ODT

Taste-masked ODT of PRD was prepared by direct compression and wet granulation methods using crospovidone as super-disintegrant, mannitol and Avicel® PH 102 as diluents, talc as a glidant and magnesium stearate as a lubricant as shown in Table (1). The beads-powder blend was evaluated for its flow properties before compression. After that, the blend with accepted flow properties was compressed into tablets.

Direct method: PRD beads were added with diluents, super-disintegrant, and binder in a mortar and mixed for 20 minutes, then the glidant and the lubricant were added and mixed for 2 minutes, finally, the prepared powder was compressed by a manual tablet machine (China) (8).

Wet granulation method: In this method super-disintegrant and diluent were mixed in mortar then a sufficient quantity of binder (alcoholic solution 2% w/v of PVP) was added until wet mass was obtained. Then this mass was sieved by sieve no. 10 and dried by oven 40oC for about 30 minutes to get dry granules. After that the dry granules were mixed with PRD beads by mortar for 20 minutes then the glidant with lubricant was added and mixed for 2 minutes, then compress the dry mixture by tablet machine (9).

Table (1): Formulation of PRD- Alginate Beads blend for ODT

Formula	Method of mixing	*Beads (mg)	PVP	Cross povidone (mg)	Talc (mg)	Magnesium stearate (mg)	Avcil 102 (mg)	Mannitol Qs. (mg)
Beads (A)								
T1	Dry	15	2mg	3	1	1	-	100
T2	Dry	15	2mg	3	2	1	-	100
T3	Wet	15	1.3 ml	3	1	1	-	100
T4	Wet	15	1.3 ml	3	2	1	-	100
Beads (B)								
T5	Dry	15	2mg	3	1	1	-	100
T6	Dry	15	2mg	3	1	1	39mg	100

*Beads (15 mg) which equivalent to 5 mg of PRD

Evaluations of PRD- beads

General appearance: The general appearance of PRD- alginate beads like shape and size before drying.

In vitro taste evaluation: Take 15 mg from the prepared formulas equivalents to 5 mg of PRD and 5mg of pure PRD (as control) was added to 10 ml phosphate buffer (pH 6.8) at 37 oC separately and shaked for 1 minute. The quantity of the drug released was determined at 248 nm. This taste was done in triplicate (10).

Evaluation of PRD-beads as ODTs

Pre- compression parameter of beads- powder mixture

Determination angle of repose: The angle of repose was determinate for pure PRD (as control), beads, and a blend of beads with excipient of ODT by using a fixed funnel technique. It was measured by allowing the powder or beads to flow through a funnel and fall easily onto the surface. The height (h) of the subsequent cone with its radius (r), was measured and the angle of repose was calculated (11, 12):

Tan (θ) = h/r.

Bulk density The bulk density was determined by pouring a weighed amount of each powder composite into a graduated cylinder and bulk volume was determined. The bulk density was calculated by following equation (13):

$$\text{Bulk density} = \frac{\text{Weight of sample (gm)}}{\text{Bulk volume (ml)}}$$

Tapped density The tapped density was determined by tapping the measuring cylinder containing the accurate amount of powder until a fixed volume was obtained and then recorded. The tapped density was intended by subsequent equation (14):

$$\text{Tapped density} = \frac{\text{Weight of sample (gm)}}{\text{Tapped volume (ml)}}$$

Carr's index: Carr's index (compressibility) was measured by consuming the values of bulk density and tapped density and calculated by the following equation (15):

$$\text{Carr's index} = \frac{(\text{Tapped density} - \text{Bulk density})}{\text{Tapped density}} * 100$$

Hausner ratio: The Hausner ratio indirectly shows powder flowability. It characterizes powder resistance against flow due to the particle interaction, shape, and size of particles, moisture content, plus powder cohesiveness. It is calculated by using tapped and bulk density values by using the following equation (16):

$$\text{Hausner ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Post-compression parameters of ODTs

General appearance: The general appearance of tablets including tablet odor, color, and surface texture was determined (17).

Weight variation: Twenty tablets were randomly taken from each formula and weighed individually, and their average weight (Wt) was then calculated (18).

Hardness: The hardness test is used to measure the crushing strength of the tablet and how it withstands the handling and transportation conditions. Three ODTs were selected randomly from the prepared formula and their hardness (Kg) was determined by

a hardness tester (YD-1, China). Results were expressed as mean (±S.D) (19).

Friability % test: The friability of tablets was determined via the Roche Fribilator USP test apparatus. Randomly ten ODTs were chosen from prepared formulas and their initial weight was determined. The ODTs were placed in a fribilator and rotated at 25 rpm for 4 minutes. The tablets were removed, and cleaned from dust and their final weight was determined. After that, calculate the friability by using the next equation (18):

$$\text{Fribility} = \frac{\text{Intial Wt} - \text{Final Wt}}{\text{Final Wt}} * 100$$

The tablets pass the friability test, if the percentage added in weight loss of uncoated tablets is < 1% (18).

Thickness: The thickness (mm) of the tablets was determined via a digital caliper. Results were reported as the mean (± SD) of three measurements (20).

Drug content: Three tablets were chosen randomly from the prepared formula and crushed by mortar and pestle, then the powder was added to 30 ml of ethanol and stirred by magnetic stirrer for 1 hour at 400- rpm at room temperature then the drug content was detected by UV- spectrophotometer at 242- nm after dilution and filtration by filter syringe (0.45- µm). The percentage for drug content was calculated by following equation (21):

$$\text{Drug content \%} = \frac{\text{calculated drug content}}{\text{theoretical drug content}} * 100$$

In vitro taste evaluation: One tablet placed in 10 ml phosphate buffer (pH 6.8) at 37 oC and shaked for 1 minute. The quantity of the drug released was determined at 248- nm. This taste was done in triplicate (10).

Wetting time and water absorption: To determine the wetting time of ODTs, a part of filter paper was folded twice and site in Petri- dish with a diameter = 9.5- cm2 of containing about 10- ml of distilled water then ODT placed on filter paper. The time necessary for wetting of ODT was determined. Percentage of water absorption was determined after measuring the wetting time, and that's by transferring the moistened tablets carefully and removing the excess water with filter paper then weighing directly. The water absorption % was calculated by subsequent equation (22):

$$\text{Water absorbtion\%} = \frac{\text{Wa} - \text{Wb}}{\text{Wa}} * 100$$

Where Wa: Weight of ODT after absorption of water

Wb: Weight of ODT before absorption of water

Disintegration time: Disintegration time was detected by using a modified disintegration method. For this determination, a Petri- dish was full with 10- ml of phosphate buffer pH 6.8 at 37±0.5ºC. The tablet was placed in the middle of the dish and the time for the total disintegration of the tablet into well particles was recorded (10).

In vitro dissolution study: The dissolution profile of PRD- ODT was detected by using a USP type II dissolution test apparatus (paddle method) (18). The dissolution test was achieved by placing one ODT (5mg PRD) in 900- ml of in 0.1 N HCl and phosphate buffer pH 6.8 as dissolution medium at 37 ± 0.5°C and 50- rpm separately. A sample (5 ml) of the solution was withdrawn from the dissolution apparatus at 15, 30, 45, 60, 75, 90, 105, and 120 minutes (in each medium) and replaced by a fresh dissolution medium. The samples were filtered by a 0.45µm membrane filter syringe. The absorbance of these solutions was measured by UV- UV-spectroscopy 248 nm (20). The resultant dissolution profile was compared and statistically evaluated by similarity factor.

Selection of the best formula as PRD-ODT

The selection of the best formula was based on all physical properties including friability, disintegration time and dissolution (10).

Results

PRD- beads evaluations

General appearance

The wet beads productions (before drying) were uniform in shape and size as shown in Figure (1).

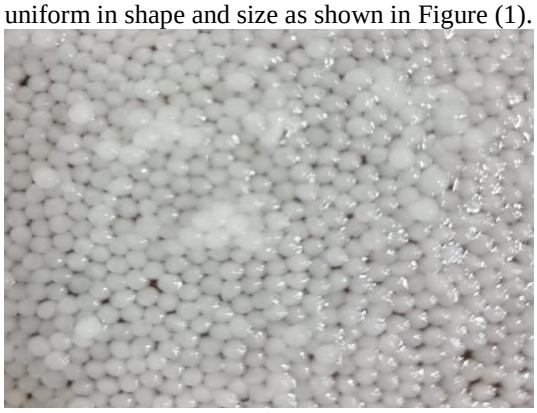


Figure (1): Photograph of PRD- Alginate Beads before Drying.

In vitro taste evaluation

The release of the pure PRD in the phosphate buffer pH 6.8 at 37 oC was 55% ±1.2 within 60 seconds, which was considered a control value for comparison of the efficiency of the taste masking. While the release of PRD from PRD- beads was only 0.77% ±0.19, and that indicates very good masking.

Pre- compression parameter of beads- powder mixture

The results of the angle of repose, Carr's index, Hausner ratio, and the type of flow for pure PRD, beads A, beads B, and all the prepared formulas are shown in Table (2). The prepared beads (A and B) improved the flowability of pure PRD; very poor flowability was obtained by T1 and T2 so they were excluded from other studies. The flowability of PRD- beads powder mixture was affected by talc concentration, method of preparation, and drying technique of beads as will be discussed.

Table (2): Flow Properties of PRD- Beads Powder Mixture

Formula	Angle of repose	Type of flow	Carr's index	Hausner ratio	Type of flow
PRD	26±1	Excellent	41±0.8	1.7±0.03	Very, very poor
Beads A	8.7±1.2	Excellent	33.4±1.2	1.5±0.05	Very poor
T1	38.5±0.9	Fair	33.4±1.9	1.5±0.02	Very poor
T2	29±1.4	Excellent	33.4±1.3	1.5±0.05	Very poor
T3	12.5±0.5	Excellent	18.1±1.7	1.22±0.03	Fair
T4	12.5±0.9	Excellent	18±1.4	1.22±0.07	Fair
Beads B	13±0.8	Excellent	9.8±0.8	1.11±0.03	Excellent
T5	25±1.8	Excellent	14±1	1.16±0.6	Good
T6	19.4±1.3	Excellent	15±1.4	1.18±0.05	Good

Data were expressed as Mean ± SD for n=3

Post- compression parameter of ODTs

General appearance: The appearance of ODTs that prepared from beads- powder mixture that pass the flowability test was affected by drying technique as it will be discussed.

Weight variation: As shown in Table (3), formulas T3 -T6 were within the accepted range of the standard requirement of USP (18).

Hardness: The hardness of the prepared tablets ranged from 2.7- 3.9 kg as shown in the Table (3).

Friability % test: As shown in the Table (3), formulas T3, T4, and T5 failed to pass this test according to USP (18) as the percentage of their weight loss was >1% and only T6 passed this test so it was subjected to further studies.

Thickness: The thickness of formula T6 was 2.5 ± 0.05 as presented in the Table (3).

Drug content: The drug content % of formula T6 was 98.2 ± 1.8 which is within accepted range of drug content concerning the USP standards (90 -110 %) as shown in Table (3) (18).

In- vitro taste evaluation: The taste masking of PRD was preserved and not affected by compression or the process of tablet formation as shown in Table (3).

Wetting time and water absorption: Wetting time is a meaning of internal building of the tablet and reflects the hydrophilicity of the excipients (23). The wetting time of the T6 was 8.7 seconds as shown in Table (3) which may be considered as a good result.

It is commonly required for ODTs to be quickly absorb water, swell and disintegrate. Thus, water absorption abilities of ODTs act as an indicator of their disintegration capacity (24). The water absorption ratio for T6 was 41 ± 2.1% as shown in the Table (3).

Disintegration time: As shown in the Table (3) the disintegration time of T6 was 15.3±0.5 seconds, which was within acceptable time ≤ 1minute of disintegration time of ODTs according to USP (18).

In vitro dissolution study: The rate of dissolution of PRD-ODTs in 0.1 N HCl and phosphate buffer pH 6.8 was shown in Figure (2).

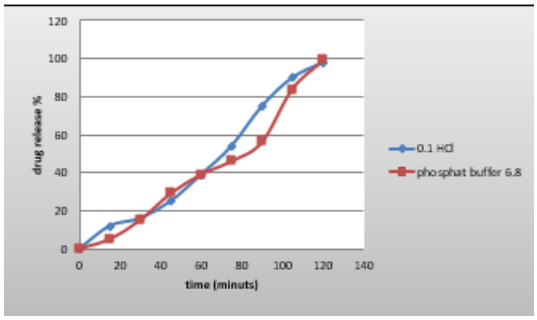


Figure (2): Dissolution profile of PRD from T6-ODT in 0.1 N HCl and phosphate buffer pH 6.8 at 37.5 ºC±0.5 after two hours.

Table (3): Post- Compression parameters of the prepared PRD-ODTs

Hardness (kg)	3.1±0.4	2.7±0.5	3.5±0.57	3.9± 0.32
Weight (mg)	98±3.5	98±2.7	98.1±3.5	99.4± 1.9
Friability %	Failed	Failed	Failed	0.45
Thickness (mm)				2.5 ± 0.05
Drug content %	-	-	-	98.2 ± 1.8
Wetting time (sec.)	-	-	-	18.7 ± 1.3
Water absorption %	-	-	-	41 ± 2.1
Disintegration time (sec.)	-	-	-	15.3 ± 0.5
% Release in buffer pH 6.8 at 37 oC	-	-	-	0.75± 0.01

Effect of drying technique on size and morphology of PRD- beads

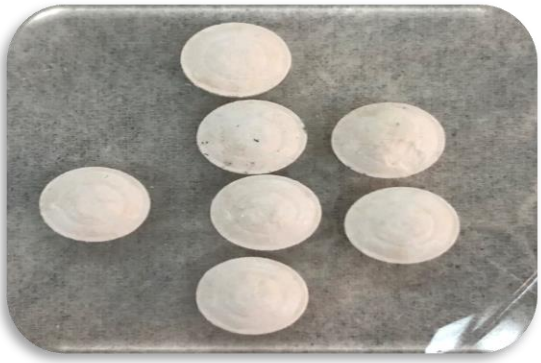
Wet beads were all spherical irrespective of the experimental processing factors. However, during drying, the beads shrank significantly and changed in size and shape. Dry beads had a usual shape with subsequent characteristics: they look like to flattened, completely flattened and some had regular or irregular spherical shape (29).

After drying of beads, different shapes and sizes were obtained according to the drying technique.

Beads A (spread directly on a Petri- dish) is characterized by a large and flat or flack-like shape which may be referred to inefficient drying technique. Beads B (dried on filter paper) were smaller and irregularly spherical in shape in comparison to Beads A (Figure 3) indicating that filter paper improved the drying process.

Figure (3): Visual PRD-bead shape, Beads A at the left side and Beads B at the right side of the picture.

The improvement in shape, size of Beads B resulted in uniform tablets with smooth surface compare to tablets prepared from Beads A as shown from Figure (4 a- & b).



(a)

(b)

Figure (4): (a) Beads A- ODTs formulation by wet granulation (T3), (b) Beads B- ODTs formulation by direct compression method (T6).

Discussion

Factors affecting pre-compression parameters

Effect of talc concentration on flowability of beads- powder mixture

As shown the Table (2- Beads A), although the angle of repose of T2 was decreased by increasing talc concentration in comparison with T1 because of the anti-adherent effect of talc (25), the overall flow properties of T1 and T2 were bad so these formulas were canceled from further studies.

In contrast, increasing the talc concentration had no effect on the blend prepared by the wet granulation method (T3 and T4), indicating that the method of preparation of the blend had more effect than the talc concentration on the flowability (26).

Effect of the preparation method of beads-powders mixture

As shown in Table (2), the flow ability of formulas prepared by the dry method was very poor, while the flowability of the formulas prepared by wet granulation was improved and that's because the enlargement of the particles which reduced the inter-particle friction and improved flow ability (27, 28).

Effect of drying technique on size and morphology of PRD- beads

Dry beads had a usual shape with subsequent characteristics: they look like to flattened, completely flattened and some had regular or irregular spherical shape (29). After drying of beads, different shapes and size were obtained according to drying technique. In general, both Beads A and B improved the flowability of the drug as shown in Table (2) mainly due to reduce the inter-particle friction and improved flowability as they have larger size than the pure PRD powder. In addition, more improvement in flow properties was obtained by Beads B compared to Beads A as they have spherical shape compared to flake like shape of Beads A (12).

The improvement in shape, size of Beads B resulted in uniform tablets with smooth surface compare to tablets prepared from Beads A as shown in Figure (4 a &b).

Effect of diluent combination

Combination of Avcil® PH102 with mannitol at 50% (w/w) from total weight of diluent (T6- ODT) improved the friability of tablets prepared using mannitol alone (T5), since Avicel® PH102 had good compactibility and binding action compared to mannitol (25, 30).

The rapid disintegration can be attributed to the presence of super-disintegrant (crospovidone) which have high capacity of hydration disintegrate rapidly (25).

The rate of dissolution of PRD-ODTs in 0.1 N HCl is shown in Figure (2), complete release of drug was obtained within 120 minutes which can be explained to be due to the formation of alginic acid from alginate which form a gel layer that retard the release of the drug up to 120minutes (31, 32).The release of PRD-ODTs in phosphate buffer (pH 6.8) was also prolonged for two hours, in spite of the high swelling of beads at this pH (due to the strong affinity of the phosphate anion to Ca+2 that hold the alginate- polymer chain together in the beads) and the high solubility of alginate in this media and that's due to the rigid gel coat of carbopol 940 at this pH retarding the drug release (31, 33, 34). Therefore, a similar dissolution profile (f2= 61) was obtained in both media Selection of the best formula as PRD-ODT from the previous outcomes; T6 can be selected as the best formula since it had the best flow, good appearance, rapid disintegration, and reasonable dissolution.

Conclusion

The bitter taste of PRD can be masked by external ionic gelation technique using S. Alg (0.5% w/v) with CaCl2 to form beads loaded PRD. In addition, successful ODTs (T6) were obtained from the prepared beads as they have an elegant appearance, good taste masking, rapid disintegration, and complete release of the drug within two hours.

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Author contributions

Hiba Mohammed S A Data collection.

Hiba Mohammed S A and Eman B. H. Al-Khedairy writing, reviewing and approved the final version of the manuscript.

Author Declaration

We confirm that this work has not been sent to any other Journal. The figures and tables in the manuscript are for our results and we are responsible for its content.

References:

1. BNF. BNF81 for other requests email : Br Natl Formul. 2021;1500.

2. Celebioglu A, Wang N, Kilic ME, Durgun E, Uyar T. Orally Fast Disintegrating Cyclodextrin/Prednisolone Inclusion-Complex Nanofibrous Webs for Potential Steroid Medications. Mol Pharm. 2021; 18(12):4486-500. https://doi.org/10.1021/acs.molpharmaceut.1c00677

3. Suza H, Al-Khedairy E. Formulation and Evaluation of Prednisolone -Loaded Alginate Beads for Taste Masking. ejhm. 2023; 90(2): 2178-2186. https://doi.org/10.21608/ejhm.2023.285683.

4. Leong J, Lam W, Ho K et al. Advances in fabricating spherical alginate hydrogels with controlled particle designs by ionotropic gelation as encapsulation systems. Particuology. 2016; 24: 44-60. https://doi.org/10.1016/j.partic.2015.09.004.

5. Hazzaa S, Abd-Alhameed S. Formulation and evaluation of optimized zaltoprofen lyophilized. Iraqi J Pharm Sci, 2017;.26(1): 40-49. https://doi.org/10.31351/vol26iss1pp40-49.

6. Mali R, Pawar H, Mali K, Dias R. Fast disintegrating tablets of olmesartan medoxomil using solid dispersion technique. Asian J Pharm. 2017;11(2):S425-433.

7. Ghumman S, Mahmood A, Noreen S, Rana M, Hameed H, Ijaz B, et al. Formulation and evaluation of quince seeds mucilage - sodium alginate microspheres for sustained delivery of cefixime and its toxicological studies. Arab J Chem. 2022;15(6):1- 16. https://doi.org/10.1016/j.arabjc.2022.103811.

8. Alhagiesa A, Ghareeb M. Formulation and evaluation of nimodipine nanoparticles incorporated within orodispersible tablets. Int J Drug Deliv Technol. 2020;10(4):547-552.

9. Ehaasn M, Abd Al Hamid S. Formulation and evaluation of rosuvastin orodispersible tablet. Int J Pharm.2013, 5(12): 339-346.

10. Abdulqader A, .Al-Khedairy E. Formulation and Evaluation of Fast Dissolving Tablets of Taste-Masked Ondansetron Hydrochloride by Solid Dispersion. Iraqi J Pharm Sci. 2017;26(1):50-60. https://doi.org/10.31351/vol26iss1pp50-60.

11. Abed K, Hussein A, Ghareeb M and Abdulrasool A. Formulation and Optimization of Orodispersible Tablets of Diazepam. AAPS PharmSciTech. 2010;11(1): 356- 361. https://doi.org/10.1208/s12249-010-9387-y.

12. Aulton M, Taylor K. Powder flow. In: Aulton's Pharmaceutics: The Design and Manufacture of Medicines. 5th ed. London: Elsevier Ltd; 2018.

13. Rada S, Kumar V. A review on Fast Dissolving Tablets: A new era of water less orally administered dosgeform. Ymer. 2022;21(8):1317-1342.

14. Abouzeid A, Essa E and Eldin E. Formulation and evaluation of mouth dispersible tablets of simvastatine using novel excipents. Biomedical European of and Pharmaceutical sciences .2019;6(6):532-541.

15. Nikam V, Shete S, Khapare J. Most promising solid dispersion technique of oral dispersible tablet. Beni-Suef Univ J Basic Appl Sci. 2020; 9(1). https://doi.org/10.1186/s43088-020-00086-4.

16. Trisopon K, Kittipongpatana N, Wattanaarsakit P, Kittipongpatana O. Formulation study of a co-processed, rice starch-based, all-in-one excipient for direct compression using the sedem-odt expert system. Pharmaceuticals. 2021; 14(10). https://doi.org/10.3390/ph14101047.

17. Driany R, Anwar E, Andrajati R, Hanafi M. Formulation of orodispersble tablet of luffa acutangula (L) roxb using co-processed via spray dried excepient. Innovare Academic Sciences. 2015;7(1).

18. The United State Pharmacopeia (USP) 37 NF 32. 2014.

19. Muhsin Z, Ghareeb M. Preparation and characterization of Oro-dispersible tablets of Bromhexine hydrochloride. J. Pharm. Sci. & Res. 2018;10(9): 2258- 2262.

20. Chen Y etal . Development of oral dispersible tablets containing prednisolone nanoparticles for the management of pediatric asthma. Dovepress. 2015;9:5815-5825. https://doi.org/10.2147/DDDT.S86075.

21. Pratap R, Kumar S. Formulation and Evaluation of Prednisolone Loaded Microsponges for Colon Drug Delivery: in-Vitro and Pharmacokinetic Study. Int J Pharm Sci Res. 2014;5(5):1994-2005.

22. Dave V, Yadav R, Ahuja R, Sahu A. Formulation and evaluation of orally dispersible tablets of Chlorpheniramine maleate by fusion method. Marmara Pharm J. 2017; 21: 67-77. https://doi.org/10.12991/marupj.259883.

23. Sivadasan D, Sultan M, Madkhali O, Javed S, Jabeen A. Formulation and in vitro evaluation of orodispersible tablets of fexofenadine hydrochloride. Trop J Pharm Res. 2020;19(5):919-25. https://doi.org/10.4314/tjpr.v19i5.2.

24. Akdag Y, Gulsun T, Izat N, Cetin M, Oner L, Sahin S. Evaluation of preparation methods for orally disintegrating tablets. Med Sci. 2020; 9(1):259 . https://doi.org/10.5455/medscience.2019.08.9167.

25. Rowe R, Sheskey P and Quinn M. Handbook of pharmaceutical excipients. sixth edition, london, shigago, 2009.

26. Elgahmi S, Alrishei N, Algaraboly R, Altrablesy A, El-Mahdi I. The redesign of amoxicillin capsules as a tablet dosage form using direct compression. Libyan. Int Med Univ J. 2019;04(01):33-38. https://doi.org/10.4103/LIUJ.LIUJ_45_18.

27. Apeji Y, Olowosulu A. Quantifying the effect of glidant on the compaction and tableting properties of paracetamol granules. J Res Pharm. 2020;24(1):44-55. https://doi.org/10.35333/jrp.2020.112.

28. Chen P, Ansari M, Bokov D, Suksatan W, Rahman M, Sarjadi M. A review on key aspects of wet granulation process for continuous pharmaceutical manufacturing of solid dosage oral formulations. Arab J Chem. 2022;15:1-9. https://doi.org/10.1155/2022/1799772.

29. Smrdel P, Bogataj M, Mrhar A. The influence of selected parameters on the size and shape of alginate beads prepared by ionotropic gelation. Sci Pharm. 2008;76(1):77-89. https://doi.org/10.3797/scipharm.0611-07.

30. Nofrerias I, Nardi A, Sune-Pou M, Sune-Negre J, García-Montoya E, Perez-Lozano P, et al. Comparison between Microcrystalline Celluloses of different grades made by four manufacturers using the SeDeM diagram expert system as a pharmaceutical characterization tool. Powder Technol. 2019; 342: 780-788. https://doi.org/10.1016/j.powtec.2018.10.048.

31. Fernandes R, Regina M, Glenn G. Thermal, microstructural and spectroscopic analysis of Ca +2 alginate/ clay nanocomposite hydrogel beads. j.molliq. 2018; 265: 327-336. https://doi.org/10.1016/j.molliq.2018.06.005.

32. Thomas L, Khalil Y. Preparation and Evaluation of Atenolol Floating Beads as a Controlled Delivery System. Iraqi J Pharm Sci. 2011; 20(1):70-80. Available from: http://bijps.com/LionImages/News/70-80.pdf https://doi.org/10.31351/vol20iss1pp70-80.

33. Patel N, Lalwani D, Gollmer S, Injeti E, Sari Y, Nesamony J. Development and evaluation of a calcium alginate based oral ceftriaxone sodium formulation. Prog Biomater. 2016;5(2):117-133 https://doi.org/10.1007/s40204-016-0051-9.

34. Chakraborty S, Dinda SC, Patra CN, Khandai M. Fabrication and characterization of algino-carbopol microparticulate system of aceclofenac for oral sustained drug delivery. Int J Pharm Sci Rev Res.2010;4(2):192-199

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تصييغ و تقييم خارج الجسم للبريدنيزولون كقرص متشتت بالفم مكسو الطعم

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ألخلاصة

ألخلفية: ألبريدنيزولون هو كورتيكوستيرويد ذو طعم شديد ألمرارة يعمل كدواء مضاد للإلتهاب و مثبط للمناعة يستعمل في أي مرحلة عمرية.

ألهدف: لتحسين تقبل ألمريض للدواء بواسطة إكساء ألطعم ألمر للدواء ليتم إيصاله كقرص متشتت بالفم.

ألطريقة: طريقة ألتبلور الأيوني ألخارجي, حيث إستخدم ألجينات ألصوديوم (0.5%) و كلورايد ألكالسيوم (1%) بوجود (0.5%) غم/ مل من ألكاربابول 940 لتحضير خرز مكسوة ألطعم محملة بالبريدنيزولون ليتم كبسها كأقراص متشتتة بالفم.

ألنتائج: تم إكساء ألطعم ألمر للبريدنيزولون بواسطة تحضير خرز متكونة من 1:1:1 (ألجينات ألصوديوم, كاربابول 940, بريدنيزولون) والتي حررت فقط 0.77% من ألبريدنيزولون في وسط يشبه ألوسط ألفموي.

تم تحضير ألقرص ألمتشتت في ألفم بواسطة طريقة ألكبس ألمباشر بأستعمال كمية من ألدواء ألمكسو ألطعم المكافئ ل 5 ملغم من ألبريدنيزلون, 3% كروسبوفيدون, 2% بولي فينيل ألكحول, 1% تالك, 1% سترات ألمغنيسيوم ومزيج من ألأفسيل PH 102 وألمانيتول بنسبة 1:1 وكان ألتصييغ ألمختار T6 يملك صلابة 3.9± 0.32, هشاشة 0.45%, سمك 2.5 ± 0.05 mm, نسبة محتوى ألدواء 98.2% ± 1.8, ألوقت ألللازم للترطيب 18.7 ± 1.3 ثانية, نسبة امتصاص الماء 41 ± 2.1%, ألوقت ألللازم للتشتت15.3 ± 0.5 ثانية وكانت نسبة تحرر ألدواء في ألوسط ألمشابه للوسط ألفموي هي فقط .75% ± 0.010 من ألبريدنزلون خلال دقيقة واحدة (وهذا يدل على ألإكساء ألجيد) بينما إستمر تحرر ألدواء في ألوسط ألحامضي ألمشابه لوسط ألمعدة وألوسط ألقاعدي ألمشابه لوسط ألأمعاء لمدة ساعتين لكل وسط.

ألأستنتاج: يمكن ألإستنتاج بنجاح طريقة ألتبلور ألايوني ألخارجي في إكساء ألطعم ألمر للبريدنيزولون وأيضا يمكن تصييغه كقرص متشتت بالفم مكسو ألطعم بواسطة طريقة ألكبس ألمباشر.

الكلمات المفتاحية: طريقة التبلور الأيوني ألخارجية, اقراص متشتتة بالفم, بريدنيزولون, خرز الجينات الصوديوم, اكساء الطعم