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Academia Open

Vol. 10 No. 2 (2025): December
DOI: 10.21070/acopen.10.2025.12834

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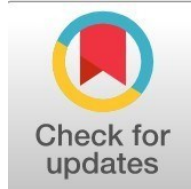
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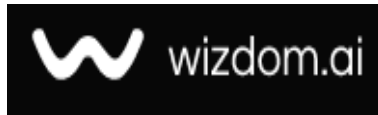
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Taste Masking of Prednisolone by Adsorption Method

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Abstract

General Background: Prednisolone, a synthetic glucocorticoid with potent anti-inflammatory and immunosuppressive properties, is widely used to treat conditions such as asthma, allergies, and rheumatoid arthritis. Specific Background: Despite its therapeutic benefits, prednisolone's intensely bitter taste negatively affects patient compliance, particularly in pediatric and geriatric populations. Knowledge Gap: Conventional taste-masking techniques often alter drug stability or release profiles, creating a need for simple, effective, and non-chemical masking approaches. Aims: This study aimed to mask the bitter taste of prednisolone using a physical adsorption method with Veegum® and Bentonite as adsorbents at varying concentrations. Results: Eight formulations were prepared and assessed for percentage yield, drug content, and in vitro taste masking. The optimal formula (F5, 1:5 drug-to-Veegum® ratio) achieved an 89% yield, 108.3% drug content, and reduced drug release in simulated saliva (pH 6.8) from 55% to 16.6% within one minute, without any detectable drug–excipient interaction by FTIR analysis. Novelty: This study demonstrates a successful use of physical adsorption as a straightforward and non-chemical method for prednisolone taste masking. Implications: The Veegum®-based adsorption approach offers a promising foundation for developing patient-friendly oral formulations of bitter drugs.

Highlight :

- ♦ The study aimed to mask the bitter taste of prednisolone using the adsorption method.
- ♦ Veegum® at a 1:5 drug-to-adsorbent ratio showed the best taste masking result.
- ♦ FTIR analysis confirmed no chemical interaction between prednisolone and the adsorbents.

Keywords : Prednisolone, Taste Masking, Adsorption Method, Veegum®, Bentonite

Published date: 2025-10-28

Introduction

Prednisolone (PRD) has a chemical formula $C_{21}H_{28}O_5$ (Figure-1) with molecular weight (360.44 g/ mole) and Melting point range is 240- 241 °C with decomposition ⁽¹⁾.

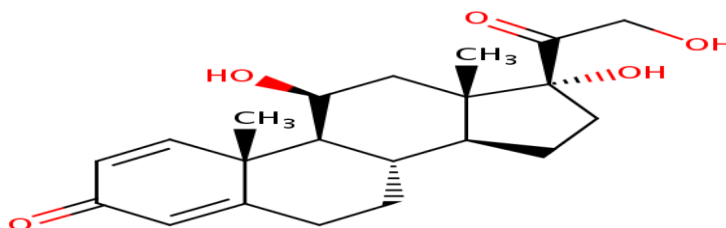


Figure (1): Prednisolone chemical structure ⁽¹⁾

PRD used in chronic obstructive pulmonary diseases, allergy, rheumatoid arthritis and asthma, it has strongly bitter taste and that's effect on patient compliance ⁽²⁾.

Adsorption method is the adhesion of drug on the surface of the adsorbent by weak bonds like van der Waals forces which called physical adsorption, or by strong bonds like ionic or covalent bonds called chemical adsorption ⁽³⁾. This adhesion leads to decreased the solubility of drug in the saliva and that's used as taste masking technique for unpleasant taste of drugs ⁽⁴⁾.

This study aimed to mask the bitter taste of the PRD by using physical adsorption technique Veegum® and Bentonite as adsorbent agents with different concentrations and comparison between the taste masked capacity of the prepared formulas with the taste of pure drug.

Material

Prednisolone (Samarra Pharmaceutical Company, Iraq), Veegum® and Bentonite (Hyperchemical comp. China).

Methodology

In this method, PRD and adsorbents were blend (Table-1) using mortar and pestle by geometric method, then placed the dry powder in a Petri- dish and added a small amount of distilled water drop by drop with continues manual mixing by spatula until a uniform gel was formed which was kept overnight for drying at room temperature. The solidified mass was then crushed by mortar and pestle and sieved by sieve with mesh #60 (250 micron) to get uniform powder mixture ⁽⁵⁾ as shown in the Figure (2).

Table (1) Composition of Taste Masked Formulas by Adsorption Method

Formula	F1	F2	F3	F4	F5	F6	F7	F8
Pred.: adsorbent	1:1	1:2	1:3	1:4	1:5	1:1	1:3	1:5
Pred. (mg)	250	250	250	250	250	250	250	250
Veegum® (mg)	250	500	750	1000	1250	-	-	-
Bentonite(mg)	-	-	-	-	-	250	750	1250

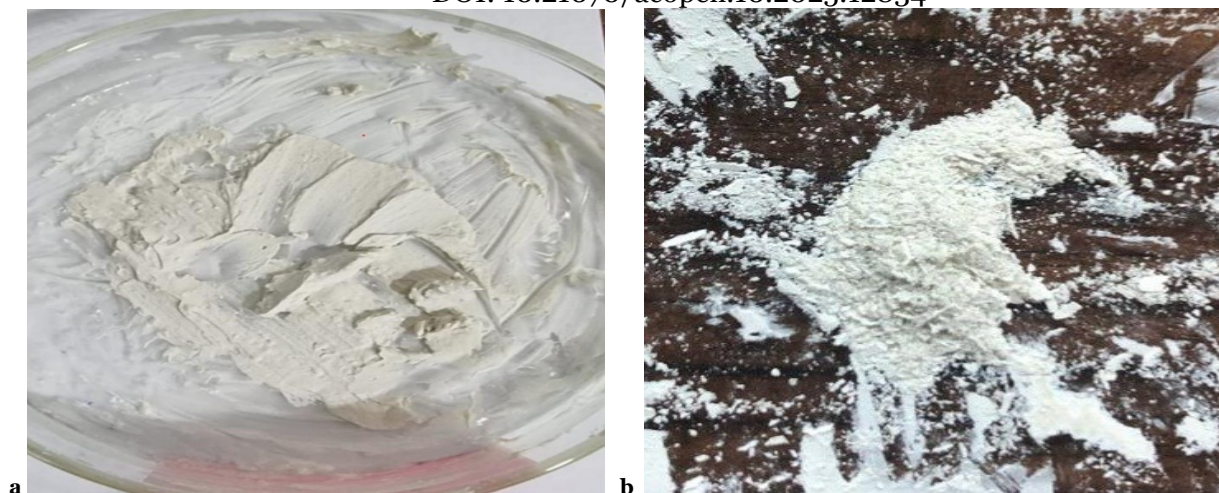


Figure (2): a- Photograph of F5 before drying, b- Photograph of F5 after sieving the dry powder mixture

Characterizations of adsorbates

Percentage yield

The percentage yield (Yield %) for each formula for was calculated as the ratio of actual weight of PRD- adsorbent dry mixture to theoretical weight of mixing materials by following equation ⁽⁶⁾:

$$\text{yield \%} = \frac{\text{actual weight of product}}{\text{theoretical weight of PRD and adsorbent}} * 100$$

Drug content

Drug content was evaluated by adding specific quantity from PRD- adsorbent powder equivalents to 5 mg of PRD to 30 ml ethanol and stirred by magnetic stirrer (Stuart. Prc) about 1 hour, then filtered through 0.45 µm membrane filter syringe and after appropriate dilutions the Pred. content was measured by using UV- spectrophotometer at 242 nm. The percentage for drug content was calculated by following equation ⁽⁷⁾:

$$\text{Drug content \%} = \frac{\text{Calculated drug content}}{\text{Theoretical drug content}} * 100$$

In- vitro taste evaluation

A specific amount of 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 °C separately and shaken for 60 second (the maximum time for the dosage form to stay in the mouth cavity). The quantity of the drug released was investigated by UV- spectroscopy at 247 nm. This taste was done in triplicate ⁽⁸⁾.

Factors affecting on percentage yield, drug content and taste masking of PRD

Type of adsorbent agent

Two different adsorbents agents were used in this study; Veegum® (F1-F5) and Bentonite (F6-F8) to determine their efficiency in the masking of the bitter taste of PRD were used as adsorbents as shown in Table (1).

Effect of drug: adsorbent ratio

Different ratios of drug: adsorbent was used to study the efficiency of their amount on taste masking of PRD.

From F1 -F5 were prepared using (PRD: Veegum®) ratio from 1:1, 1:2, 1:3, 1:4 and 1:5 respectively, while F6-F8 were prepared by using (PRD: Bentonite) in the ratio from 1:1, 1:3 and 1:5 respectively as shown in the Table (2).

Selected of the best formula

The selection of the best formula was depended on the best results of the percentage yield, drug content and *In- vitro* taste evaluation.

FTIR for selected formula

To show any chemical reaction between the drug and the adsorbent agent; FTIR spectrum (Shimadzu, Japan) for the pure drug, adsorbent agent, physical mixture (1:5) and the optimum formula was used. The sample were mixed with KBr separately and pressed on the discs then analyzed from 400 to 4000 cm⁻¹ ^(8,9).

ISSN 2714-7444 (online), <https://acopen.umsida.ac.id>, published by Universitas Muhammadiyah Sidoarjo

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Result and Discussion

Percentage yield

The percentage yield of PRD- adsorbent dry mixture was ranged from 80 to 91% as shown in the Table (2).

Drug content

All the formulas were within acceptable drug content according to USP (90- 110 %), since they were ranged from 93 to 108% as shown in the Table (2).

In- vitro taste evaluation

The release of the pure PRD in the phosphate buffer pH 6.8 at 37 °C was 55% $\pm$ 1.2 within one minute, which was considered as a control value for comparison the efficiency of the formulas.

The release of PRD- adsorbent dry mixture within 60 seconds ranged between 16.6 to 28.4 % (by using Veegum®) and 26.5 to 28 % (by using Bentonite) as shown in the Table (2).

Table (2): Properties of Formulas Prepared by Adsorption Method

Formulas	Yield %	Drug content % $\pm$ SD (n=3)	Drug release % in pH 6.8 $\pm$ SD (n=3)
Pure PRD	-	-	55 $\pm$ 1.2
F1	82	98.5 $\pm$ 1.2	28.1 $\pm$ 1.1
F2	82	95.1 $\pm$ 0.8	26 $\pm$ 3.2
F3	84	96.4 $\pm$ 1.2	28.4 $\pm$ 2.7
F4	80	109 $\pm$ 0.8	18 $\pm$ 2.1
F5	89	108.3 $\pm$ 1.2	16.6 $\pm$ 1.2
F6	91	93 $\pm$ 2.4	26.5 $\pm$ 1.4
F7	88	100.3 $\pm$ 0.98	26.8 $\pm$ 1.2
F8	83	95.3 $\pm$ 1.3	28 $\pm$ 1.2

Factors affecting on the percentage yield, drug content and taste masking of PRD

Type of adsorbent agents

As shown in the Table (2), two different types of adsorbent agents were used (Veegum® and Bentonite), both of them reduced the release of PRD in the phosphate buffer (pH 6.8) in comparison with pure PRD (control). The results were significantly ($p < 0.05$) less than that of pure PRD, indicating that, this method was efficient for reduction of the bitterness of PRD to about one half ⁽¹⁰⁾.

Effect of drug: adsorbent ratio

The results in the Table (2) showed that; as the amount of Veegum® increased, the amount of PRD, released in pH 6.8 was significantly decreased ($p < 0.05$) in comparison with control. This result can be attributed to the increased amount of adsorbent, which led to increased adsorption capacity of the PRD ^(10, 11). On the other hand, the release of PRD in phosphate buffer pH 6.8 was not significantly ($p > 0.05$) affected by increasing the amount of Bentonite and that's may be due to saturation of the interfacial layer of Bentonite with PRD ⁽³⁾.

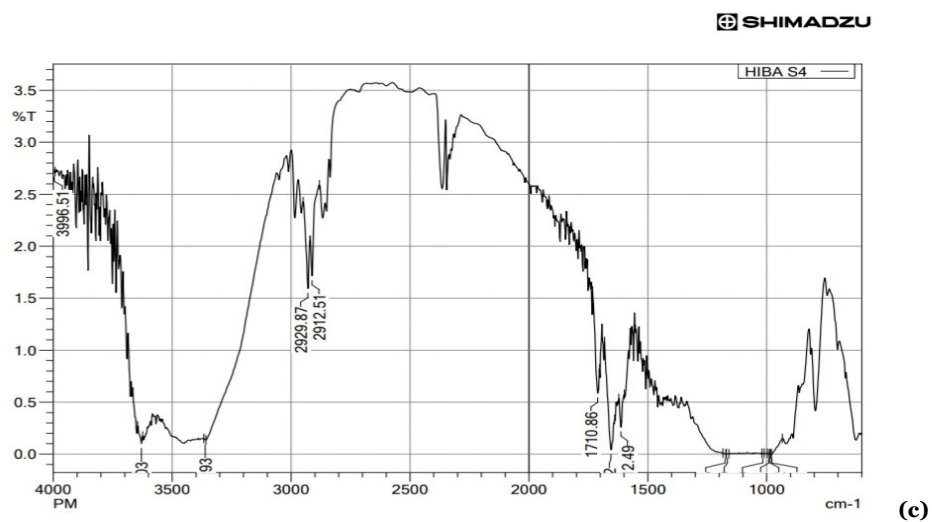
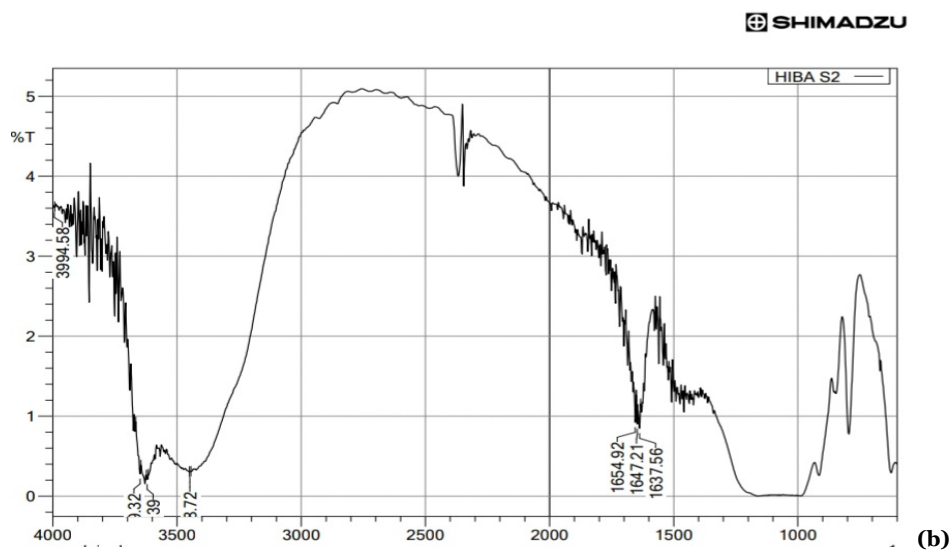
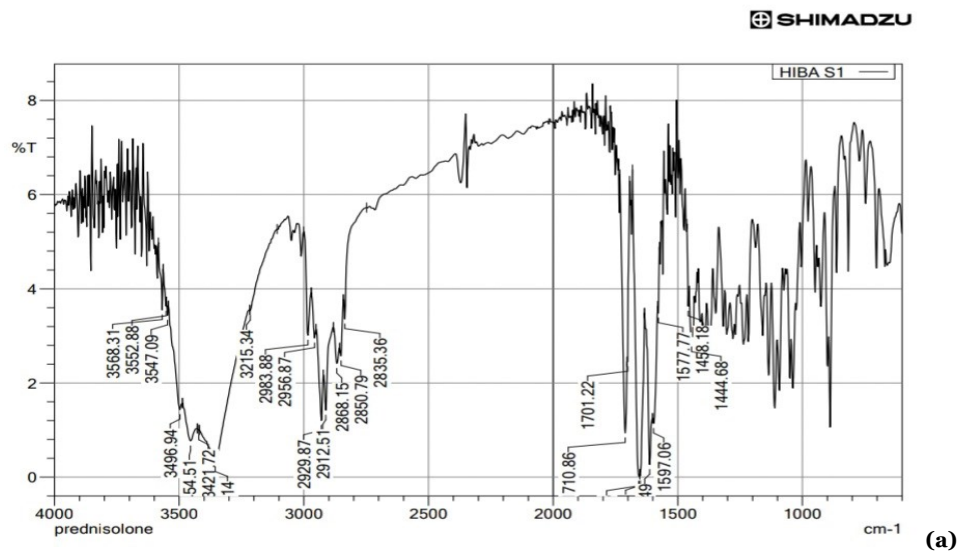
Selected of the best formula

The F5 (PRD: Veegum®) 1:5 ratio was selected as the optimum formula due to its acceptable percentage yield, drug content and it masks the taste more than the others formulas.

FTIR of the selected formula

The results of FTIR spectrum of PRD, Veegum®, physical mixture powder at ratio 1:5 (drug: adsorbent agent) and the optimum formula (F5)

are shown in Figure (3- a, b, c and d) respectively.



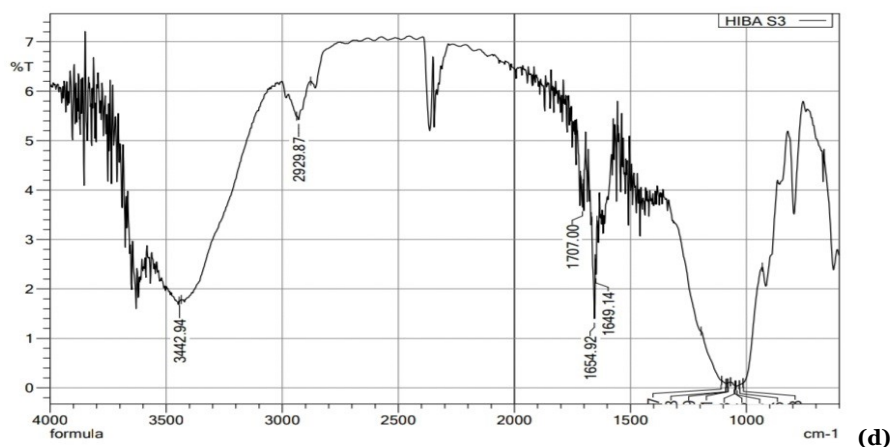


Figure (2): FTIR spectrum, a- Prednisolone, b- Veegum®, c- physical mixture and d- F5.

According to these figures, PRD spectrum (Figure -3a) shows the characteristic peaks at 3496 and 3354 cm^{-1} for OH (intermolecular bond) and 1710 cm^{-1} for stretching of (C=O) ⁽¹²⁾. Figure 3-b shows the strong of dry Veegum® at 3639 cm^{-1} for OH stretching of Si-OH, peak around 3440 cm^{-1} for OH stretching of hydrogen bonded water, 1637 cm^{-1} for OH bending and peak around 1000 cm^{-1} for Si-O-Si also peaks near 925, 800 and 525 cm^{-1} for bending vibration Al-Al-OH, Si-O and Al-Osi deformation respectively ^(13, 14, 15).

the FTIR spectrum of physical mixture (Figure 3- c) and that of the selected formula (Figure 3-d) showed no chemical interaction as the major peaks of PRD and Veegum® are still present with decreased intensity due to dilution effect. So; the FTIR spectrum showed no chemical interaction between them.

Conclusion

Adsorption technique using Veegum® in 1:5 ratio (PRD: Veegum®) was an efficient method for masking the bitter taste of PRD. Therefore, it is recommended to prepare and evaluate the above formula as tablet dosage form..

Recommendations

Raising a positive awareness about retirement and importance of using coping strategies in order to cope successfully with retirement through mass media and educational seminars. Create groups that are self-help and include new retired elderly to transit them smoothly to retirement with successful coping.

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