

Formulation and Evaluation of Hydrogel-Based Dexamethasone Mouth-Dissolving Oral Film

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Abstract

Background: Dexamethasone is a potent synthetic glucocorticoid used for its anti-inflammatory and immunosuppressive effects. A mouth-dissolving oral film may offer a convenient unit-dose option for people who experience difficulty swallowing conventional solid dosage forms. This study describes the formulation and evaluation of dexamethasone-loaded hydrogel-based oral films prepared using hydrophilic polymers.

Methods: Dexamethasone was examined by FTIR spectroscopy and thermal/melting-point assessment, and drug-polymer compatibility was considered for hydroxypropyl methylcellulose (HPMC), pullulan, polyvinyl alcohol (PVA), sodium alginate, and a combined polymer system. A UV-visible calibration curve was reported over 0–10 µg/mL. Nine film formulations (F1–F9) were evaluated for physical and mechanical characteristics, surface pH, folding endurance, drug content, disintegration time, in-vitro release, release kinetics, and stability-related parameters.

Results: The supplied thesis data report film weights of 18.15 ± 0.28 to 23.20 ± 0.37 mg and thicknesses of 0.039 ± 0.012 to 0.050 ± 0.012 mm. Tensile strength ranged from 0.78 ± 0.08 to 2.26 ± 0.07 kg/cm², folding endurance from 214 to 256, surface pH from 6.43 to 6.92, and disintegration time from 11 ± 0.2 to 37 ± 0.5 s. Drug content ranged from $96.40 \pm 0.50\%$ to $99.60 \pm 0.60\%$. F5 showed the highest reported drug content ($99.60 \pm 0.60\%$), highest folding endurance (256), shortest disintegration time (11 ± 0.2 s), and highest reported cumulative drug release at 10 min (99.10%). The reported first-order correlation coefficient for F5 was $R^2 = 0.998$. During the reported three-month stability assessment, drug content declined under each listed storage condition.

Conclusion: On the basis of the supplied results, F5 was the most promising of the nine evaluated films for drug content, folding endurance, disintegration, and early drug release. The manuscript should be finalized only after the original laboratory records, formulation composition, full dissolution dataset, and stability protocol have been checked for consistency.

Keywords: Dexamethasone; oral dissolving film; hydrogel; HPMC; pullulan; PVA; sodium alginate; disintegration; drug release.

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Introduction

Inflammation is a protective biological response to tissue injury, infection, and other harmful stimuli. When excessive or persistent, it can contribute to tissue damage and disease progression. Glucocorticoids modify inflammatory and immune responses through intracellular glucocorticoid receptors and regulation of gene transcription. Dexamethasone is a potent synthetic glucocorticoid used in a range of inflammatory and immune-mediated conditions; however, its clinical use requires appropriate dosing and consideration of adverse effects. Conventional tablets and capsules are established oral dosage forms, but swallowing

can be difficult for some pediatric, geriatric, or otherwise vulnerable patients. Oral dissolving films are thin polymeric dosage forms intended to hydrate and disintegrate in the oral cavity. Their performance depends on polymer type and concentration, plasticizer and other excipients, film thickness, mechanical integrity, moisture behaviour, and drug distribution. Hydrogel-forming and hydrophilic polymers such as HPMC, pullulan, PVA, and sodium alginate can contribute to film formation and hydration. A formulation must balance sufficient strength for handling with rapid disintegration after administration. In addition,

because dexamethasone is a potent drug, uniform drug distribution and reliable drug-content measurement are important quality attributes. The supplied thesis investigates dexamethasone-loaded hydrogel-based mouth-dissolving oral films using nine formulations (F1–F9). This article reorganizes the reported methods and results into a research-paper format without introducing unreported experimental results.

Materials and Methods

Materials: Dexamethasone was the active pharmaceutical ingredient. The polymer systems described in the supplied chapters included HPMC, pullulan, polyvinyl alcohol (PVA), and sodium alginate, together with other pharmaceutical excipients used in the formulation. The complete grade, supplier, batch number, and exact quantity of each ingredient should be inserted from the original materials register and formulation table before submission.

Preformulation and drug–polymer compatibility: FTIR spectroscopy was used to consider characteristic dexamethasone functional-group regions and the corresponding bands in drug–polymer combinations. The thesis describes assessment of O–H, C=O, C=C, C–O, and C–F-related bands, with the reported interpretation

indicating compatibility for dexamethasone with HPMC, pullulan, PVA, sodium alginate, and the combined polymer system. The reported reference melting point was approximately 262°C, while 260–263°C was listed as an adapted working range; the actual experimental observation must be verified against the laboratory notebook.

UV-visible calibration curve: A calibration curve for quantitative estimation of dexamethasone was reported over a working concentration range of 0–10 µg/mL. The reported absorbance increased from 0 to 0.3568, and the coefficient of determination was approximately $R^2 = 0.9992$.

The wavelength, solvent/buffer, regression equation, and validation parameters should be confirmed from the full experimental record before journal submission.

Formulation and evaluation of oral films: Nine formulations (F1–F9) were prepared using the polymer/excipient combinations described in the thesis. The supplied results report evaluation of film weight, thickness, tensile strength, percentage elongation, folding endurance, surface pH, drug content, disintegration time, in-vitro drug release, release-kinetic models, and selected stability parameters.

Table 1: Formulation Table

Ingredients (mg/batch)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Dexamethasone	100	100	100	100	100	100	100	100	100
HPMC E5	500	750	–	–	–	–	–	–	–
HPMC E15	–	–	500	750	–	–	–	–	–
Pullulan	500	250	–	–	500	250	–	–	–
PVP K30	–	–	500	250	–	–	500	250	–
PVA	–	–	–	–	–	–	–	–	500
Sodium alginate	–	–	–	–	–	–	–	–	250
Sodium CMC	–	–	–	–	500	750	500	750	250
Glycerin	200	200	200	200	200	200	200	200	150
Citric acid	50	50	50	50	50	50	50	50	50
SLS	25	25	25	25	25	25	25	25	25
Sodium saccharin	50	50	50	50	50	50	50	50	50
Mannitol	500	500	500	500	500	500	500	500	500
Vanillin	10	10	10	10	10	10	10	10	10
Purified water	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

Evaluation parameters: Physical and mechanical characteristics included weight, thickness, tensile strength, percentage elongation, folding endurance, and surface pH.

Drug content was measured to assess drug distribution. Disintegration behaviour was evaluated under the conditions specified in the thesis. In-vitro release was compared across F1–F9, including cumulative release at 10 min and the reported times to 25%, 50%, 70%, and 90%

release. The data were examined using zero-order, first-order, Higuchi, and Korsmeyer–Peppas models.

Stability Assessment: The thesis reports stability-related observations for appearance, pH, tensile strength, percentage elongation, folding endurance, and drug content under refrigerated (4–5°C), room-temperature, and elevated-temperature (37 ± 5°C) conditions over three months.

These conditions are reproduced as reported; they should not be described as ICH-compliant accelerated stability conditions unless the actual protocol supports that claim.

Results and Discussion

Drug identification and compatibility: The supplied FTIR interpretation considered characteristic functional groups of dexamethasone and selected polymer combinations.

Compatibility was reported for HPMC, pullulan, PVA, sodium alginate, and the combined polymer system. FTIR interpretation alone does not

establish complete long-term compatibility; the claim should be supported by the spectra and, where available, complementary thermal or stability data.

Identification of Drug: Dexamethasone was considered for identification by FTIR spectroscopy. The characteristic functional-group bands were retained as reference features for interpretation.

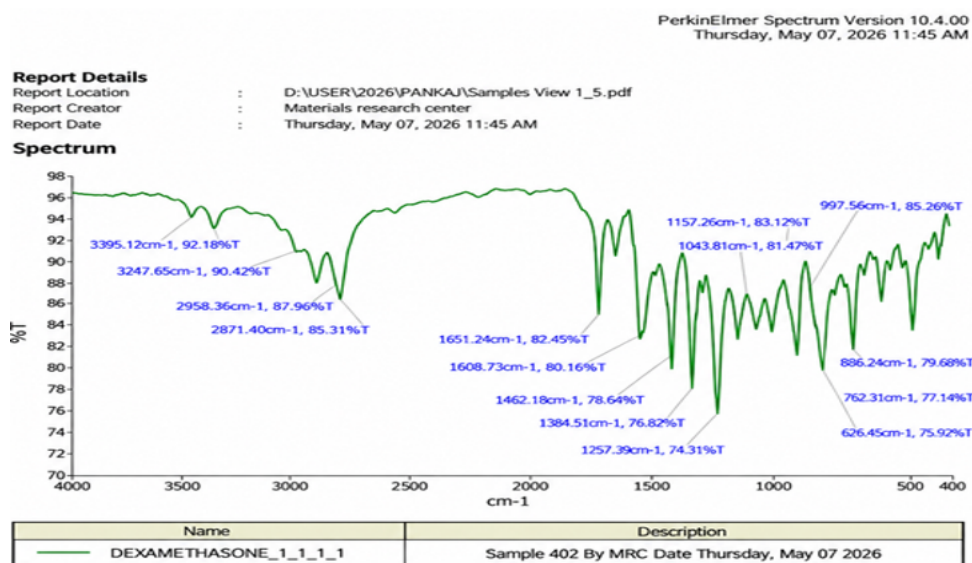


Figure 1: FTIR Spectra of Pure drug Dexamethasone

Table 2: Pure drug Identification

Functional group / vibration	Expected/reference region (cm ⁻¹)	Working interpretation
O–H stretching	3600–3200	Hydroxyl functionality
C=O stretching	1750–1650	Carbonyl-containing groups
C=C stretching	1650–1600	Conjugated unsaturation
C–F stretching	1400–1000	Fluorinated functionality
C–H stretching	3000–2850	Aliphatic C–H groups

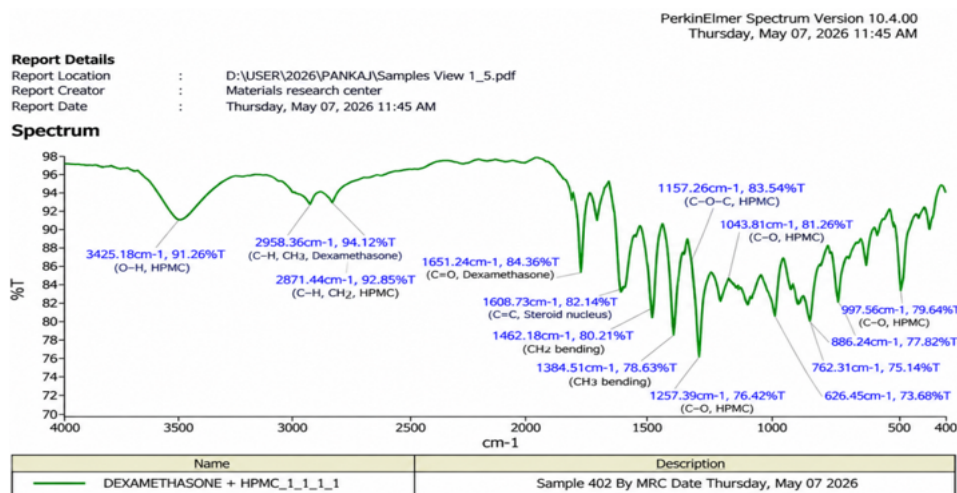


Figure 2: FTIR Spectra of Pure drug Dexamethasone+ HPMC

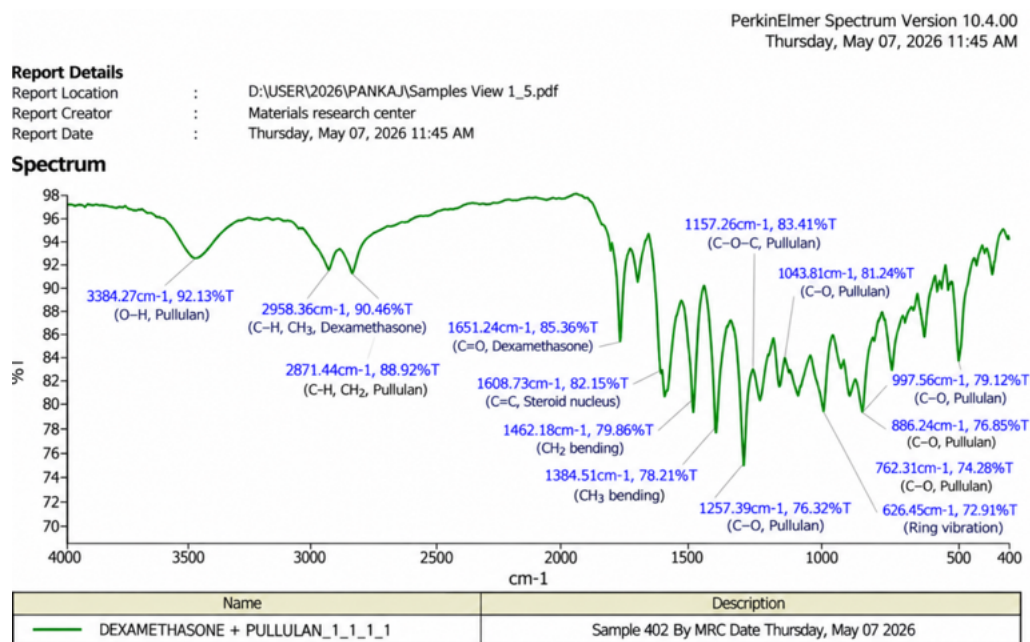


Figure 3: FTIR Spectra of Pure drug Dexamethasone+ Pullulan

Table 3: FTIR compatibility study of Dexamethasone with polymers

S. No.	Drug-polymer combination	functional groups to examine by FTIR	Compatibility
1	Dexamethasone (pure drug)	O-H, C=O, C=C, C-O and C-F	Compatible, No Interaction
2	Dexamethasone + HPMC	Drug carbonyl and hydroxyl bands; HPMC O-H, C-H and C-O-C bands	Compatible
3	Dexamethasone + Pullulan	Drug C=O and C-O bands; Pullulan O-H, C-H and glycosidic C-O-C bands	Compatible
4	Dexamethasone + PVA	Drug C=O and O-H bands; PVA O-H, C-H and C-O bands	Compatible
5	Dexamethasone + Sodium alginate	Drug C=O and O-H bands; alginate COO ⁻ asymmetric/symmetric stretching and O-H bands	Compatible
6	Dexamethasone + HPMC + Pullulan + PVA + Sodium alginate	Characteristic bands of the drug and all four polymers	Compatible

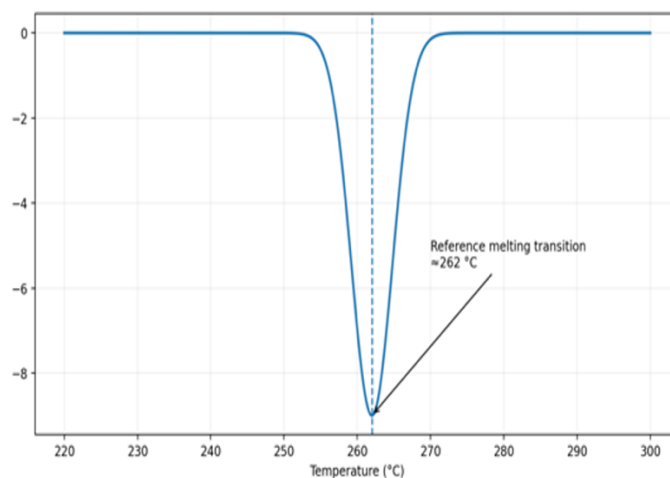


Figure 4: DSC of Dexamethasone

Calibration curve: The reported dexamethasone calibration curve covered 0–10 µg/mL, with absorbance values increasing to 0.3568 and R² of approximately 0.9992. This indicates strong reported linearity across the

presented range. The regression equation and individual calibration points were not reproduced here because they must be transcribed and checked from the original calibration dataset.

Table 4: Calibration Curve

S. No.	Concentration ($\mu\text{g/mL}$)	Mean absorbance $\pm$ SD
1	0	0
2	2	0.0812 ± 0.0004
3	4	0.1501 ± 0.0002
4	6	0.2190 ± 0.0002
5	8	0.2881 ± 0.0003
6	10	0.3568 ± 0.0003

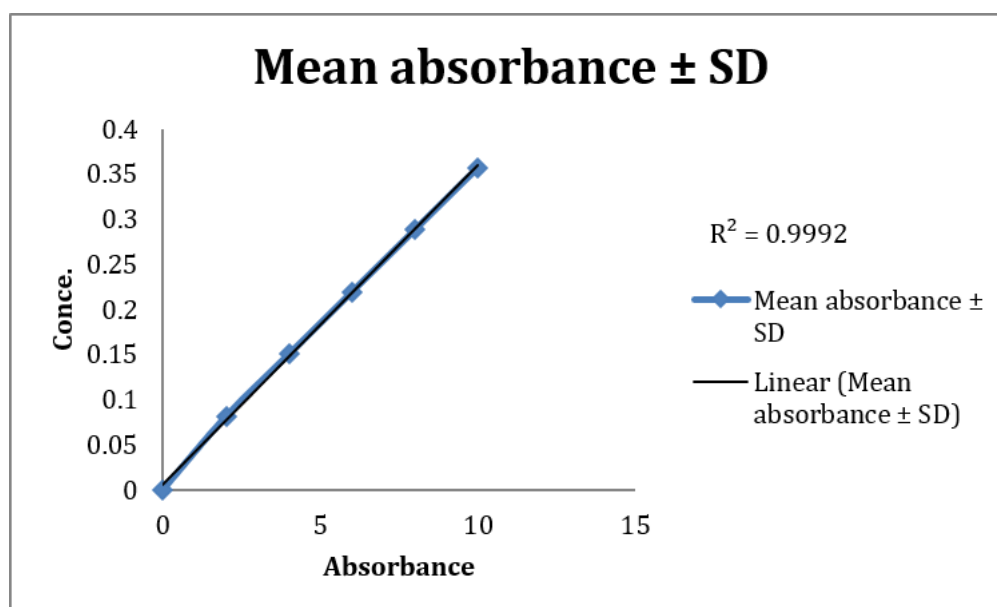


Figure 5: Calibration Curve

Physical and mechanical properties

Table 5: Evaluation of Dexamethasone Hydrogel Oral Films

Code	Weight (mg)	Thickness (mm)	Tensile strength (kg/cm^2)	Elongation (%)	Disintegration (s)
F1	19.45 ± 0.30	0.041 ± 0.010	0.78 ± 0.08	2.48	29 ± 0.5
F2	21.85 ± 0.28	0.045 ± 0.011	0.89 ± 0.06	2.44	25 ± 0.3
F3	20.55 ± 0.30	0.039 ± 0.012	1.01 ± 0.07	2.46	19 ± 0.4
F4	21.60 ± 0.34	0.049 ± 0.012	2.02 ± 0.10	2.41	23 ± 0.5
F5	23.20 ± 0.37	0.048 ± 0.010	2.19 ± 0.12	2.51	11 ± 0.2
F6	18.15 ± 0.28	0.046 ± 0.011	2.26 ± 0.07	2.39	34 ± 0.3
F7	22.45 ± 0.23	0.047 ± 0.012	1.51 ± 0.06	2.35	37 ± 0.5
F8	19.15 ± 0.33	0.048 ± 0.010	1.57 ± 0.05	2.31	30 ± 0.4
F9	20.55 ± 0.21	0.050 ± 0.012	1.68 ± 0.08	2.34	27 ± 0.6

Drug content and disintegration

Table 6: Drug content of Dexamethasone Hydrogel Oral Films

Formulation Code	Drug Content (%)
F1	96.50 ± 0.40
F2	98.40 ± 0.70
F3	97.40 ± 0.35
F4	96.70 ± 0.50
F5	99.60 ± 0.60
F6	98.70 ± 0.55
F7	98.40 ± 0.30
F8	96.40 ± 0.50
F9	97.20 ± 0.35

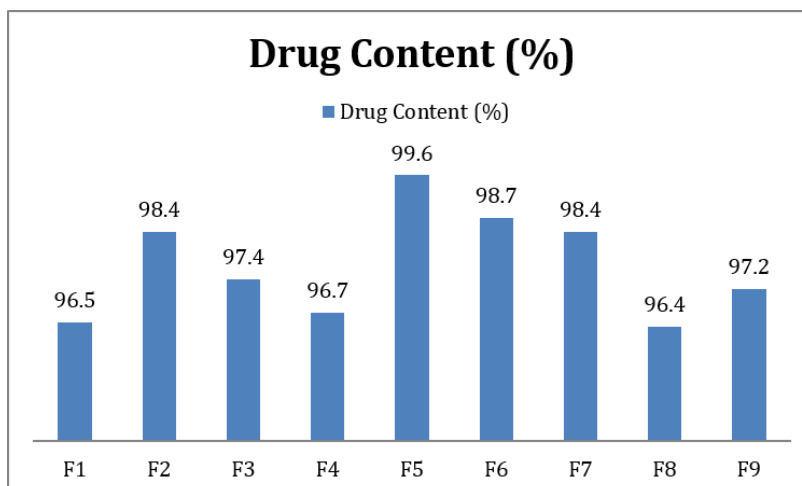


Figure 6: Drug content of Formulations F1-F9

Table 7: Drug Content and Disintegration Time

Parameter	Reported result	Formulation noted in thesis
Drug content	96.40 $\pm$ 0.50% to 99.60 $\pm$ 0.60%	F5 highest: 99.60 $\pm$ 0.60%; F6: 98.70 $\pm$ 0.55% reported as next highest.
Disintegration time	11 $\pm$ 0.2 to 37 $\pm$ 0.5 s	F5 shortest: 11 $\pm$ 0.2 s; F3: 19 $\pm$ 0.4 s; F7 longest: 37 $\pm$ 0.5 s.

F5 combined the highest reported drug content with the shortest disintegration time. These results make F5 a promising candidate among the evaluated formulations.

For a low-dose potent drug, however, mean drug content should be supplemented by content-uniformity data and the number of replicate units tested.

In-vitro drug release: The reported cumulative drug release at 10 min ranged from 80.20% to

99.10%. F5 showed the highest reported release (99.10%) and the reported $t_{25\%}$, $t_{50\%}$, and $t_{70\%}$ values were 0.95, 1.90, and 2.00 min, respectively. F6 showed the lowest reported cumulative release at 10 min (80.20%). The rapid release reported for F5 is consistent with its short disintegration time, although the full dissolution profiles and replicate variability are needed to substantiate comparative claims.

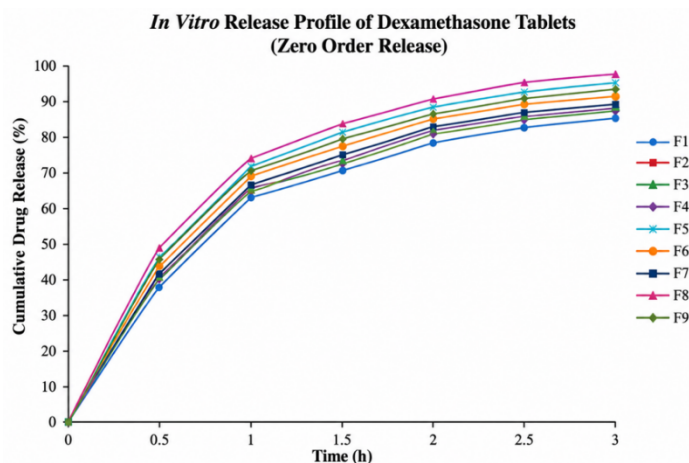


Figure 7: In vitro release data of Dexamethasone tablet -Zero Order Release

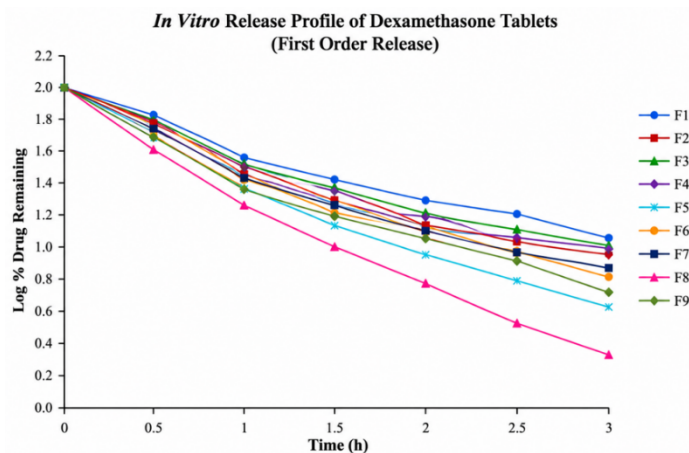


Figure 8: In vitro release data of Dexamethasone tablet -First Order Release

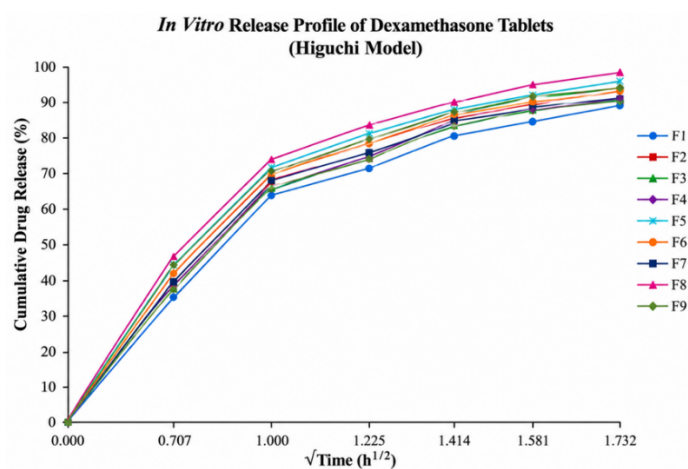


Figure 9: In vitro release data of Dexamethasone tablet –Higuchi Model

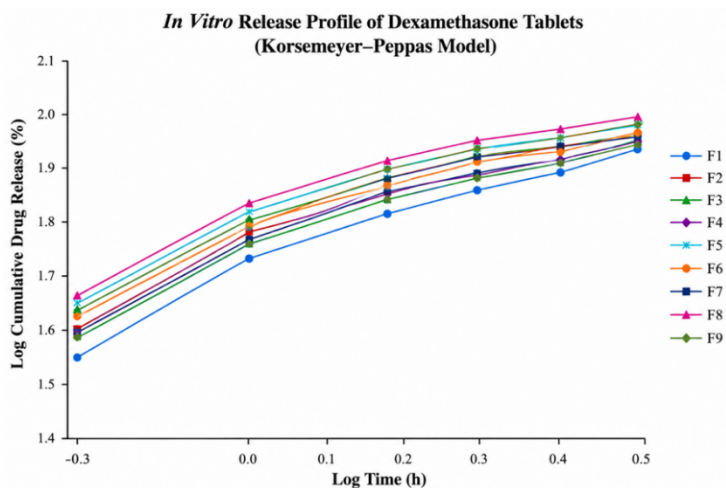


Figure 10: In vitro release data of Dexamethasone tablet –Korsmeyer

Table 8: Kinetic Value for F5

Release parameter	F5 reported result
Cumulative release at 10 min	99.10%
t25%	0.95 min
t50%	1.90 min
t70%	2.00 min
First-order model R ²	0.998
Zero-order model R ²	0.670

Release-kinetic analysis

Table 9: Kinetic Value Obtained from In Vitro Release

Formulation Code	Zero Order		First Order	
	Ko (mg/h)	R ²	K1 (hr ⁻¹)	R ²
F1	7.510	0.575	0.488	0.960
F2	7.545	0.495	0.490	0.979
F3	7.600	0.465	0.486	0.971
F4	7.455	0.470	0.405	0.973
F5	8.650	0.670	0.482	0.998
F6	8.080	0.555	0.455	0.860
F7	7.760	0.535	0.268	0.993
F8	6.520	0.475	0.295	0.947
F9	7.890	0.615	0.382	0.912

Stability observations

Table 10: Stability Study (pH, Tensile Strength, Elongation, Folding Endurance)

Condition	Appearance	pH	Tensile strength (kg/cm ²)	Elongation (%)	Folding endurance
Room temperature	White, smooth	6.91	2.20	2.50	255
37 ± 5 °C	No significant change	6.88	2.19	2.48	253
4–5 °C	No significant change	6.90	2.21	2.49	254

Chemical Stability / Drug Content

Table 11: Stability Study of drug content

Storage condition	0 month	1 month	2 months	3 months
4–5 °C	99.10	98.60	98.05	97.55
Room temperature	99.05	98.70	98.20	97.80
37 ± 5 °C	99.10	98.55	97.95	97.40

Conclusion

Hydrogel-based dexamethasone mouth-dissolving oral films were described using nine formulations (F1–F9). Based on the reported data, F5 showed the highest drug content (99.60 ± 0.60%), highest folding endurance (256), shortest disintegration time (11 ± 0.2 s), and highest cumulative drug release at 10 min (99.10%). The reported first-order model fit for F5 was R² = 0.998. Therefore, F5 may be considered the most promising formulation among those evaluated in this dataset. Confirmation requires checking the original formulation composition, full analytical and dissolution data, content uniformity, and stability protocol.

References

- Dixit RP, Puthli SP. Oral strip technology: Overview and future potential. *Journal of Controlled Release*. 2009;139(2):94–107. doi:10.1016/j.jconrel.2009.06.014.
- Cilurzo F, Cupone IE, Minghetti P, Selmin F, Montanari L. Fast dissolving films made of maltodextrins. *European Journal of Pharmaceutics and Biopharmaceutics*. 2008;70(3):895–900. doi:10.1016/j.ejpb.2008.06.032.
- Borges AF, Silva C, Coelho JFJ, Simões S. Oral films: Current status and future perspectives: I—Galenical development and quality attributes. *Journal of Controlled Release*. 2015;206:1–19. doi:10.1016/j.jconrel.2015.03.006.
- Bala R, Pawar P, Khanna S, Arora S. Orally dissolving strips: A new approach to oral drug delivery system. *International Journal of Pharmaceutical Investigation*. 2013;3(2):67–76. doi:10.4103/2230-973X.114897.
- Preis M, Knop K, Breitzkreutz J. Mechanical strength test for orodispersible and buccal films. *International Journal of Pharmaceutics*. 2014;461(1–2):22–29. doi:10.1016/j.ijpharm.2013.11.033.
- Preis M. Orally disintegrating films and mini-tablets—innovative dosage forms of choice for pediatric use. *AAPS PharmSciTech*. 2015;16:234–241. doi:10.1208/s12249-014-0249-6.
- Salawi A. An insight into preparatory methods and characterization of orodispersible film—A review. *Pharmaceutics*. 2022;15(7):844. doi:10.3390/ph15070844.
- Gupta MS, Kumar TP. Characterization of orodispersible films: An overview of methods

- and introduction to a new disintegration test apparatus using LDR–LED sensors. *Journal of Pharmaceutical Sciences*. 2020;109(10):2925–2942. doi:10.1016/j.xphs.2020.06.012.
9. Khalid GM, Selmin F, Musazzi UM, Gennari CGM, Minghetti P, Cilurzo F. Trends in the characterization methods of orodispersible films. *Current Drug Delivery*. 2021;18(7):935–946. doi:10.2174/1567201818999201210212557.
 10. Boateng JS, Matthews KH, Stevens HNE, Eccleston GM. Wound healing dressings and drug delivery systems: A review. *Journal of Pharmaceutical Sciences*. 2008;97(8):2892–2923. doi:10.1002/jps.21210.
 11. Peppas NA, Bures P, Leobandung W, Ichikawa H. Hydrogels in pharmaceutical formulations. *European Journal of Pharmaceutics and Biopharmaceutics*. 2000;50(1):27–46. doi:10.1016/S0939-6411(00)00090-4.
 12. Caló E, Khutoryanskiy VV. Biomedical applications of hydrogels: A review of patents and commercial products. *European Polymer Journal*. 2015;65:252–267. doi:10.1016/j.eurpolymj.2014.11.024.
 13. Rowe RC, Sheskey PJ, Quinn ME, editors. *Handbook of Pharmaceutical Excipients*. 6th ed. London: Pharmaceutical Press; 2009.
 14. Rowe RC, Sheskey PJ, Cook WG, Fenton ME, editors. *Handbook of Pharmaceutical Excipients*. 8th ed. London: Pharmaceutical Press; 2017.
 15. Aulton ME, Taylor KMG, editors. *Aulton's Pharmaceutics: The Design and Manufacture of Medicines*. 5th ed. Edinburgh: Elsevier; 2018.
 16. Allen LV Jr, Ansel HC. *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems*. 10th ed. Philadelphia: Wolters Kluwer; 2014.
 17. Banker GS, Rhodes CT, editors. *Modern Pharmaceutics*. 4th ed. New York: Marcel Dekker; 2002.
 18. Siepmann J, Peppas NA. Modeling of drug release from delivery systems based on hydroxypropyl methylcellulose (HPMC). *Advanced Drug Delivery Reviews*. 2001;48(2–3):139–157. doi:10.1016/S0169-409X(01)00112-0.
 19. Higuchi T. Mechanism of sustained-action medication: Theoretical analysis of rate of release of solid drugs dispersed in solid matrices. *Journal of Pharmaceutical Sciences*. 1963;52(12):1145–1149. doi:10.1002/jps.2600521210.
 20. Korsmeyer RW, Gurny R, Doelker E, Buri P, Peppas NA. Mechanisms of solute release from porous hydrophilic polymers. *International Journal of Pharmaceutics*. 1983;15(1):25–35. doi:10.1016/0378-5173(83)90064-9.
 21. Peppas NA. Analysis of Fickian and non-Fickian drug release from polymers. *Pharmaceutica Acta Helvetica*. 1985;60(4):110–111.
 22. United States Pharmacopeial Convention. *United States Pharmacopeia and National Formulary (USP–NF)*. General chapter <905>, Uniformity of Dosage Units. Rockville, MD: USP.
 23. International Council for Harmonisation. *ICH Q1A(R2): Stability Testing of New Drug Substances and Products*. Geneva: ICH; 2003.
 24. International Council for Harmonisation. *ICH Q2(R2): Validation of Analytical Procedures*. Geneva: ICH; 2023.
 25. United States Food and Drug Administration. *Dexamethasone tablets: Prescribing information*. Silver Spring, MD: FDA. Consult the current approved product label.
 26. National Center for Biotechnology Information. *PubChem Compound Summary for CID 5743, Dexamethasone*. Bethesda, MD: National Library of Medicine.
 27. Schimmer BP, Funder JW. ACTH, adrenal steroids, and pharmacology of the adrenal cortex. In: Brunton LL, Hilal-Dandan R, Knollmann BC, editors. *Goodman & Gilman's The Pharmacological Basis of Therapeutics*. 13th ed. New York: McGraw-Hill; 2018.
 28. Rhen T, Cidlowski JA. Antiinflammatory action of glucocorticoids—new mechanisms for old drugs. *New England Journal of Medicine*. 2005;353(16):1711–1723. doi:10.1056/NEJMr050541.
 29. Cain DW, Cidlowski JA. Immune regulation by glucocorticoids. *Nature Reviews Immunology*. 2017;17:233–247. doi:10.1038/nri.2017.1.
 30. European Medicines Agency. *ICH Q1A(R2): Stability testing of new drug substances and drug products—scientific guideline*. Amsterdam: EMA; 2003.