IOCG 2025 Conference

The 1st International Online Conference on Gels

03–05 December 2025 | Online

MDPI

The Creation of A Docetaxel-Loaded Hydrogel Nanosponge for the Treatment of Malignant Melanoma

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INTRODUCTION & AIM

Clinical Challenge

- ✓ Metastatic melanoma: Stage 4 cancer with poor prognosis
- ✓ Docetaxel (BCS Class IV): Poor aqueous solubility - difficult formulation
- ✓ Severe dose-dependent side effects limit therapeutic efficacy
- ✓ Melanoma accounts for 80% of skin cancer deaths globally

Proposed Solution

- ✓ Nanosponges
- ✓ Hypercrosslinked polymer-based nanoparticles with tunable cavities for drug encapsulation

Hydrogel Vehicle

- ✓ Sustained-release topical delivery system for localized tumor targeting

Nanosponge Key Properties

- Porous 3D structure: 1-100 nm size with nanosized cavities
- Thermal stability: Stable up to 300°C; pH 1-11 stability
- Biodegradable, non-toxic, non-irritating formulation
- Extended release: Up to 12+ hours continuous action

MATERIALS & METHOD

Materials & Methods

- ✓ Drug: Docetaxel (CSC Pharmaceuticals)
- ✓ Polymer: β-Cyclodextrin (Sigma Aldrich)
- ✓ Crosslinker: 1,1-Carbonyldiimidazole (CDI)
- ✓ Method: Crosslinking reaction at 100°C for 4 hrs in DMF

Nanosponge Synthesis Procedure

Step 1: Dissolve β-cyclodextrin in anhydrous DMF

Step 2: Add CDI crosslinker in 1:2, 1:4, 1:8 ratios

Step 3: Reflux for 4 hrs at 100°C under oil bath

Step 4: Grind, filter, and wash with deionized water

Step 5: Soxhlet extraction with ethanol; vacuum dry at 25°C

RESULTS & DISCUSSION

Preformulation Findings: Solubility Studies: Table 1: Solubility analysis of Docetaxel

Solvent	Solubility	Solubility value(mg/ml)
Water	Poorly soluble	-
Ethanol	Soluble	1.14
Acetonitrile	Freely Soluble	2.57
DMSO	Highly soluble	4.71

Preformulation Findings: Compatibility (FTIR)

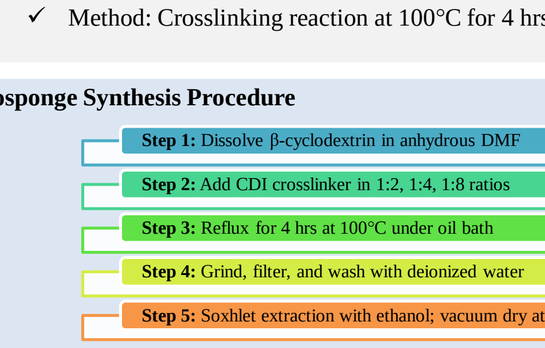


Fig.1: FT-IR studies showing functional group, B-Cyclodextrin and final formulation with Wave numbers

Functional group	β-Cyclodextrin	β-Cyclodextrin nanosponge
C-H, stretching	2928.53 cm^{-1}	2919.36cm^{-1}
-OH stretching	3370.72 cm^{-1}	3423.76 cm^{-1}
-C-C, stretching	1157.84 cm^{-1}	1035.41cm^{-1}
-C=C, stretching	1705.27 cm^{-1}	1723.68 cm^{-1}

Table 2: Showing functional group, B-Cyclodextrin and final formulation with Wave

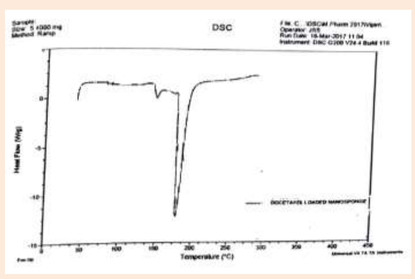


Fig.2: DSC Thermogram of Docetaxel

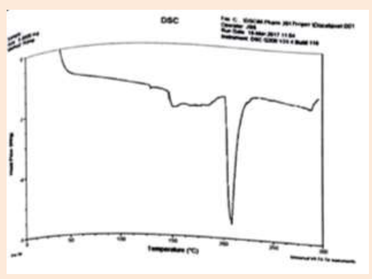


Fig.3: DSC thermogram of B-cyclodextrin nanosponge

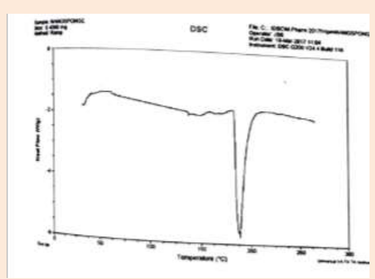


Fig.4: DSC thermogram of Docetaxel-loaded nanosponge

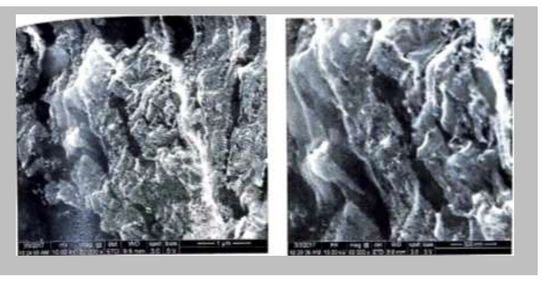
Formulation Optimization (F3: 1:8 Ratio)

Fig, 5 Size and PDI report for Docetaxel loaded nanosponge

Fig, 6 Zeta Potential report for Docetaxel-loaded nanosponge

Scanning electron microscopy (SEM):

Fig.17 scanning electron mierograph of Docetaxel loaded nanosponge



In Vitro Release Profile (24 hrs)

Table 3: The cumulative percentage drug release of F3 formulation and pure drug

S.No	Time (hrs)	% Cumulative Drug Release F3	% Cumulative Drug Release Pure Drug
1	0	0	0
2	0.5	10.2±0.05	20.11±0.06
3	1	14.22±0.09	49±0.14
4	2	20.18±0.1	60.62±0.2
5	4	32.92±0.1	77.81±0.1
6	6	36.32±0.05	86.37±0.05
7	8	51.22±0.1	
8	10	59.62±0.1	
9	12	67.92±0.1	
10	24	82.84±0.07	

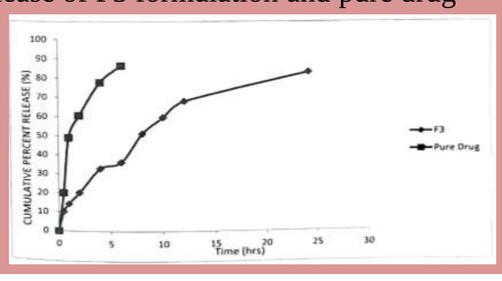


Table 4: Regression value for various kinetic models

Kinetic Model	R^2 Value	Slope (n)
Zero Order	0.8751	3.468
Peppas Model	0.9877	0.584
Higuchi	0.9781	18.329

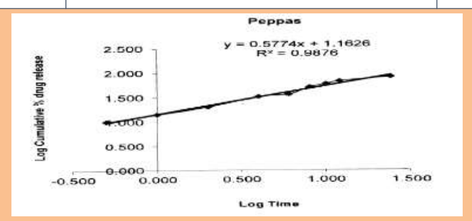


Fig 9: graph showing release kinetics

MTT Cytotoxicity Assay (Vero Cells)

Table 5: Determination of cytotoxicity by MTT assay

conc. (µg/ml)	% inhibition
500	82.92
250	54.25
125	32.54
62.5	12.25
IC_{50}	242.5 µg/ml

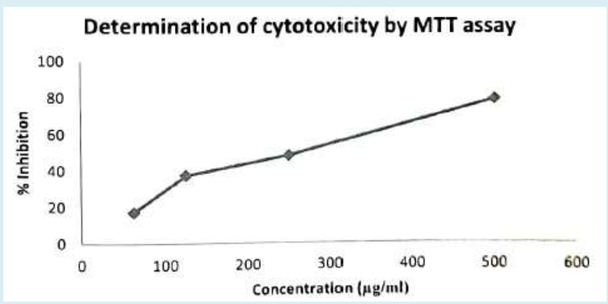
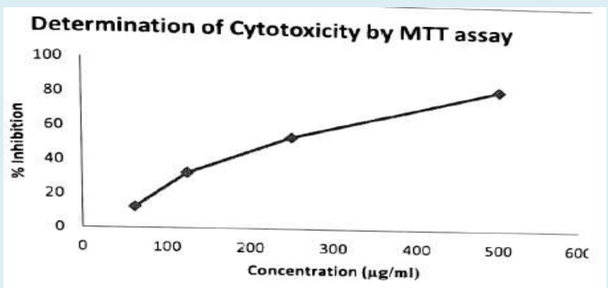


Table 6: Determination of cytotoxicity by MTT assay

Conc.(µg/ml)	% inhibition
500	78.92
250	48.25
125	37.56
62.5	17.45
IC50	275 µg/ml



CONCLUSION

- ✓ β-Cyclodextrin nanosponges successfully developed and optimized
- ✓ F3 formulation (1:8 ratio): 195 nm particles, 86% EE, 51.6% LC
- ✓ Sustained 24-hr drug release with non-Fickian diffusion mechanism
- ✓ Formulation safer & more efficacious than pure docetaxel

FUTURE WORK / REFERENCES

Five key research directions including in vivo pharmacokinetic studies, surface modification with targeting ligands, biodistribution tracking, combination therapy evaluation, and stability studies.

1.Rajpurohit D, Kakkar S, Sharma A, Kumar V. Cyclodextrin-based nanosponges for drug delivery: Formulation, characterization and therapeutic applications. Pharmaceutics. 2020;12(10):922. https://doi.org/10.3390/pharmaceutics12100922

2.Khunt D, Misra M, Shah S, Kacha M. Development and characterization of nanosponge-based hydrogel for topical delivery of terbinafine HCl. Pharmaceuticals. 2017;10(4):87. https://doi.org/10.3390/ph10040087

3.Quaglia F, Ostacolo C, Di Gaetano S, Nese G, Busetto R, De Rosa G. Delivery systems for poorly soluble drugs: cyclodextrins and nanosponges. Expert Opin Drug Deliv. 2018;15(12):1195-1205. https://doi.org/10.1080/17425247.2018.1533890