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SES/YTIP/lett./2019-03

20 March 2019

To
Principal
Oriental College of Pharmacy
Sanpada, Navi Mumbai

Sub.: No-Objection Certificate for pursuing PhD at OCP

Dear Mam,

We have no objection if Ms .Puja Gulabrao Vyawahare an employee of our organization/ institute, is admitted to the Ph.D. Programme in the Department of pharmaceutics at Oriental College of Pharmacy Sanpada, Navi Mumbai. It is certified that she has completed 8 year(s) of service in our organization/ institute as a regular employee. We shall give her leave of absence at our organization to attend classes of course work of Ph.D. programme.



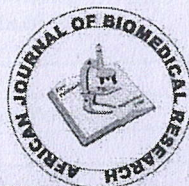
Puja
PRINCIPAL
PRINCIPAL

Yadavrao Tasgaonkar Institute of Pharmacy
S. K. Y. Tasgaonkar Education Complex
Sanpada, Navi Mumbai

Signature & Seal of head of the Organization/ Institute



SR
Dr. (Mrs.) Sudha Rathod
Principal
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Research Article

Systematic physicochemical characterization of potent anticancer drug paclitaxel loaded solid lipid nanoparticles with herbal adjuvants

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ABSTRACT:

The purpose of the study was to develop and analyze a solid lipid nanoparticle (SLN)-based Paclitaxel drug delivery system. The SLN's lipid & surfactant components were oleic acid & soy lecithin (Tween 80). Numerous batches of paclitaxel-containing solid lipid nanoparticles were produced using size-reduction methods, solvent emulsification by ultrasonication, and different drug and lipid doses. Excipients were employed in tests where the formulation characteristics were improved by varying the ratios of medicines, lipids, and surfactants. The created formulations underwent assessments in the areas of drug content, in-vitro drug release, particle size analysis, scanning electron microscopy, Fourier transform-infrared studies, differential scanning calorimetry, and stability. Additionally, it was discovered that the improved formulation performed well with each of the formulation's constituents as demonstrated by FTIR and DSC data. The solid lipid nanoparticles that were created have a size of 200.01 nm. After three months at 5±3°C and 25±2°C/60±5% RH, the improved formulation showed no significant modifications in appearance, drug content (%), drug entrapment efficiency (%), or in vitro drug release (%).

KEYWORDS: Drug Delivery, Paclitaxel, Solid Lipid Nanoparticles, Anticancer Medication, and Particle Size

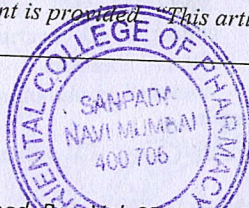
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Prof. Puja Vyawahare et al

Evaluation Parameter:	Initial	After 3 Months
Appearance:	Off-White Powder	Off
Drug Entrapment Efficiency (%):	89	88.6
Drug content (%):	87	86.1
In Vitro Drug Release (%):	98	97.8
MPS nm	228	286
Zeta Potential mv	-6.25	-3.2

Table 13.: Stability Studies for the Optimized Batch (Batch 5)

9. CONCLUSION:

According to a review of the literature, Paclitaxel-loaded solid lipid nanoparticles were prepared using Soy Lecithin and Oleic Acid as lipids and Papain as a herbal extract using an array of drug:lipid proportions via Solvent Emulsification, and the prepared nano-emulsion was lyophilized using Freeze Drying. Batch 5's drug:lipid ratio of 0.6 g Paclitaxel (drug), 1.2 g Soy Lecithin (lipid), and 0.6 g Oleic Acid (lipid) produced satisfactory results and was found to be more reproducible with the highest drug content (%), drug entrapment efficiency (%), and in vitro drug release (%), so it was considered the optimal formulation. Paclitaxel and Papain were shown to be pure by FTIR and DSC analysis. Pre-formulation experiments revealed that Paclitaxel and Papain have the highest solubility in methanol. The optimized formulation was also determined to be compatible with all of the formulation's constituents, as demonstrated by FTIR and DSC data. The size of the intended solid lipid nanoparticles was 300.01 nm. The optimized formulation (Batch 5) remained stable for 3 months at $5 \pm 3^\circ \text{C}$ and $25 \pm 2^\circ \text{C}/60 \pm 5\% \text{RH}$. There was no significant change in appearance, drug entrapment efficiency (%), drug content (%), or in vitro drug release (%).

10. REFERENCE:

- Peer D, Karp JM, Hong S, Farokhzad OC, Margalit R, Langer R. Nanocarriers as an emerging platform for cancer therapy. *Nano-Enabled Medical Applications*. 2020 Nov 23;61-91.
- Suri SS, Fenniri H, Singh B. Nanotechnology-based drug delivery systems. *Journal of occupational medicine and toxicology*. 2007 Dec;2(1):1-6.
- Cho K, Wang XU, Nie S, Shin DM. Therapeutic nanoparticles for drug delivery in cancer. *Clinical cancer research*. 2008 Mar 1;14(5):1310-6.
- Wilczewska AZ, Niemirowicz K, Markiewicz KH, Car H. Nanoparticles as drug delivery systems. *Pharmacological reports*. 2012 Sep 1;64(5):1020-37.
- Bhatia S. Nanoparticles types, classification, characterization, fabrication methods and drug delivery applications. In *Natural polymer drug delivery systems 2016* (pp. 33-93). Springer, Cham.
- Hasan S. A review on nanoparticles: their synthesis and types. *Res. J. Recent Sci*. 2015;2277:2502.
- Buabeid MA, Arafa ES, Murtaza G. Emerging prospects for nanoparticle-enabled cancer immunotherapy. *Journal of Immunology Research*. 2020 Jan 3;2020.
- Lingayat VJ, Zarekar NS, Shendge RS. Solid lipid

- nanoparticles: a review. *Nanoscience and Nanotechnology Research*. 2017 Apr;4(2):67-72.
- Awasthi R, Roseblade A, Hansbro PM, Rathbone MJ, Dua K, Bebawy M. Nanoparticles in cancer treatment: opportunities and obstacles. *Current drug targets*. 2018 Oct 1;19(14):1696-709.
- Ekambaram P, Sathali Aa, Priyanka K. Solid Lipid Nanoparticles: A Review
- Priyadarshini K, Keerthi AU. Paclitaxel in cancer treatment: a brief overview. *Med Chem*. 2012 Nov;2(7):139-41.
- Jones TM. *Preformulation Studies*.
- Savjani KT, Gajjar AK, and Savjani JK. Drug Solubility: significance and enhancement Techniques: International Scholarly Research Notices 2012;2012.
- Gannimitta, Arvind; Srinivas, Prathima. & A, Venkateshwar; Pedireddi, Sobhita. (2019). Preparation, Physical Characterization, And Pharmacokinetic Study Of Docetaxel Nanocrystals. *Asian Journal Of Pharmaceutical And Clinical Research*. 238-244. 10.22159/Ajpcr 2019.V12i6.32856.
- da Rocha MC, da Silva PB, Radicchi MA, Andrade BY, de Oliveira JV, Venus T, Merker C, Estrela-Lopis I, Longo JP, Bão SN. Docetaxel-loaded solid lipid nanoparticles prevent tumor growth and lung metastasis of 4T1 murine mammary carcinoma cells. *Journal of nanobiotechnology*. 2020 Dec;18(1):1-20.
- Devi TR, Gayathri S. FTIR and FT-Raman spectral analysis of Paclitaxel drugs. *Int J Pharm Sci Rev Res*. 2010;2(2):106-10.
- Pooja D, Tunki L, Kulhari H, Reddy BB, Sistla R. Optimization of solid lipid nanoparticles prepared by a single emulsification-solvent evaporation method. *Data in brief*. 2016 Mar 1;6:15-9.
- Mukherjee S, Ray S, Thakur RS. Solid lipid nanoparticles: a modern formulation approach in drug delivery system. *Indian journal of pharmaceutical sciences*. 2009 Jul;71(4):349.
- Yang T, Cui FD, Choi MK, Lin H, Chung SJ, Shim CK, Kim DD. Liposome formulation of Paclitaxel with enhanced solubility and stability. *Drug delivery*. 2007 Jan 1;14(5):301-8.
- Nandini PT, Doijad RC, Shivakumar HN, Dandagi PM. Formulation and evaluation of gemcitabine-loaded solid lipid nanoparticles. *Drug delivery*. 2015 Jul 4;22(5):647-51.
- Zhang JQ, Liu J, Li XL, Jasti BR. Preparation and characterization of solid lipid nanoparticles containing silibinin. *Drug delivery*. 2007 Jan 1;14(6):381-7.

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22. Agubata CO, Chime SA, Kenekwkwu FC, Nzekwe IT, Onunkwo GC. Formulation and characterisation of hydrochlorothiazide solid lipid microparticles using lipid matrices: Irvingia fat; International Journal of Pharmaceutical Investigation, 2014. Oct;4(4):189.
23. [23]. Venishetty V.K., Parikh N., Sistla R. Ahmed FJ and Diwan PV. Application of Validated RP-HPLC Method for The simultaneous determination of docetaxel and ketoconazole in solid lipid nanoparticles. Journal of chromatographic science. 2011 Feb 1;49(2):136-41.
24. Sharma M, Kohli S, Dinda A. In-vitro and in-vivo evaluation of repaglinide loaded floating microspheres prepared from different viscosity grades of HPMC polymer. Saudi pharmaceutical journal. 2015 Nov 1;23(6):675-82.
25. Devi TR, Gayathri S. FTIR and FT- Raman spectral analysis of Paclitaxel drugs. Int J Pharm Sci Rev Res. 2010;2(2):106-10.
26. Raza K, Singh B, Singal P, Wadhwa S, Katare OP. Systematically optimized biocompatible isotretinoin-loaded solid lipid nanoparticles (SLNs) for topical treatment of acne. Colloids and Surfaces B: Biointerfaces. 2013 May 1;105:67-74.



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