



Formulation and in-vitro release study of vitamin B₁₂ from implant poly-lactic glycolic acid.

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DEDICATION

Knowledge, work and words are the outcome of years of my life that I

wrapped with my wish and hope to satisfy my God.

I dedicate this effort to my first teacher and master, my prophet

Mohammed (May peace be upon him) and to the reason behind my

success my mother Dr. Buthainah Al-Mahdawy with a wish of

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List of Abbreviations

adoB12	Adenosyl-cobalamin
API	Active pharmaceutical ingredient
CNS	central nervous system
CS	chitosan
DCM	dichloromethane
DDS	Controlled drug delivery systems
EC	ethyl cellulose
EtOH	ethanol
GC	Gas chromatography
GMO	glycerylmonooleate
GPC	Gel-permeation chromatography ()
HPLC	High-performance liquid chromatography
IF	Intrinsic factor
MeB12	Methylcobalamin
NA	denoted for not available.
NP	denoted for not performed

PCL	polycaprolactone
PEA	polyesteramide
PGA	Polyglycolic acid
PLA	polylactide
PLG	polyglycolide
PLGA	Poly Lactic-co-Glycolic Acid
PLL	Poly(L-lysine)
RBC	Red Blood Cell
SAM	S-Adenosylmethionin
SC	Subcutaneously
SiO	Silicone oil
TFA	Trifluoroacetic acid
Tg	Transition temperature

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Abstract

Vitamin B₁₂ (cyanocobalamin) is essential for normal RBC formulation, nerve, proteins in the body, certain enzyme reactions, and neurologic function. Vitamin B₁₂ is given both as an oral supplement and intramuscular single dose with multiple and consecutive treatment in an injections. The present research study was carried out to formulate a supplement vitamin B₁₂ in a controlled release dosage form as an implants biodegradable polymers, poly-lactic glycolic acid (PLGA) to increase bioavailability of drug in patients that have poor absorption of vitamin B₁₂ from oral route due to the decrease of intrinsic factor that is responsible for the absorption. Five different formulation of polymer implant and prepared in a twenty gram batch , according the USA patent **7612176**.

The dried and finished product implant weight 1 g contain 5mg of vitamin B₁₂ and characterized for drug content, molecular weight of the polymer, particle size of the embryonic particles, moisture contents and residual solvents (EtOH, DCM, Heptane, and SiO). In addition, the in vitro release study at blood simulated solution was also performed and samples analyzed throughout 38 day ,the release started ad 21- 24 days continuing to 38 day and release reached to 74.5%.