COPYRIGHT AND CITATION CONSIDERATIONS FOR THIS THESIS/DISSERTATION

o Attribution — You must give appropriate credit, provide a link to the license, and indicate if changes were made. You may do so in any reasonable manner, but not in any way that suggests the licensor endorses you or your use.

o NonCommercial — You may not use the material for commercial purposes.

o ShareAlike — If you remix, transform, or build upon the material, you must distribute your contributions under the same license as the original.

How to cite this thesis
The Production of the Antibody to the Surface Antigen of Hepatitis B (anti-HBs) due to Hepatitis B 12cH Nosode Administration

A dissertation submitted to the Faculty of Health Sciences, University of Johannesburg, as partial fulfilment for the degree of Master of Technology of Homeopathy.

By
Sarah Caldwell
(Student Number: 820300532)

(Supervisor): _____________________________ _____________________________
Dr N. Gower
MTech Hom (UJ) CML (UNISA)  Date

(Co-Supervisor): _____________________________ _____________________________
I. Van der Westhyzen
MDip Tech (TWR)  Date

Johannesburg, 2014
DECLARATION

I declare that this dissertation is my own, unaided work. It is submitted for the Degree of Masters of Technology at the University of Johannesburg, Johannesburg. It has not been submitted before for any degree or examination in any other Technikon or University.

______________________________
(Signature of Candidate)

g__ day of February 2014
AFFIDAVIT

AFFIDAVIT: MASTER'S AND DOCTORAL STUDENTS TO WHOM IT MAY CONCERN

This serves to confirm that I ________________________
(Full Name(s) and Surname)

ID Number ________________________

Student number ________________________ enrolled for the

Qualification ________________________

Faculty ________________________

Herewith declare that my academic work is in line with the Plagiarism Policy of the University of Johannesburg which I am familiar with.

I further declare that the work presented in the __________ MINOR DISSERTATION __________ (minor dissertation/dissertation/thesis) is authentic and original unless clearly indicated otherwise and in such instances full reference to the source is acknowledged and I do not pretend to receive any credit for such acknowledged quotations, and that there is no copyright infringement in my work. I declare that no unethical research practices were used or material gained through dishonesty. I understand that plagiarism is a serious offence and that should I contravene the Plagiarism Policy notwithstanding signing this affidavit, I may be found guilty of a serious criminal offence (perjury) that would amongst other consequences compel the UJ to inform all other tertiary institutions of the offence and to issue a corresponding certificate of reprehensible academic conduct to whomever request such a certificate from the institution.

Signed at ________________________ on this ________________________ day of __________ FEBRUARY __________ 20__.

Signature ________________________ Print name ________________________

STAMP COMMISSIONER OF OATHS

Affidavit certified by a Commissioner of Oaths

This affidavit conforms with the requirements of the JUSTICES OF THE PEASE AND COMMISSIONERS OF OATHS ACT 16 OF 1963 and the applicable Regulations published in the GG GNR 1258 of 21 July 1972; GN 903 of 10 July 1998; GN 109 of 2 February 2001 as amended.
ABSTRACT

According to the World Health Organisation (2008), an estimated two billion individuals globally, are infected with Hepatitis B (HBV). South Africa reported 864 notified new cases between 2001 and 2004 (Department Of Health, 2005), with an estimated 3-4 million chronic HBV infected black South Africans (Kew, 2008). Kwa-Zulu Natal and Free State were the most affected provinces; while 20-39 years was the most affected age group as of 2005 (Department Of Health, 2005). Workers in the health industry, intravenous drug users and children of women who have Hepatitis B are at the most risk for contracting this disease from blood products and body fluids (Immunization Action Coalition, 2007; Boon et al., 2006), where contraction of the disease can lead to liver cirrhosis, fibrosis and hepato-cellular carcinoma (Highleyman, 2008).

The Expanded Program on Immunization (EPI) of the South African Department of Health (2009) suggests vaccination for Hepatitis B should be administered at six, ten and fourteen weeks, or a dose every month for 3 months. Adverse reactions associated with the vaccine include “Guillain-Barre Syndrome, arthritis, demyelinating nervous system disease” (Pratt, 2008) and anaphylaxis (Danis & Halm, 1997). Alternatives that may assist in avoiding such symptoms include: waiting until adolescence to vaccinate (Slonim et al., 2005); only vaccinating high risk groups (Francois et al., 2002); or researching an alternative (Romm, 2001).

Homeoprophylaxis is the use of homeopathy to prevent the contraction or development of disease (Zoltan, 2000) and its successful use has been recorded in various disease types and locations. There have been very few studies to show the effect of individual homeopathic nosodes used as prophylactic treatment in their related diseases, with almost none of these utilising any means of serological testing (Bevan-Jones, 2009; Frost et al., 2003; Sheffield, 2006).

The aim of this study was to determine the production of the antibody to the surface antigen of Hepatitis B (anti-Hbs) due to Hepatitis B 12cH nosode administration.
Forty-three participants ranging, in ages 18 to 65 years, who tested negative for the presence of anti-HBs, took part in this four week long, double-blind, placebo controlled study. Participants were randomly placed into either the Verum or Placebo group, each group receiving four lactose powders to be taken weekly for four weeks. The Active group received lactose powders medicated with *Hepatitis B* 12cH, whereas the Placebo group received lactose powders medicated with 96% alcohol. Participants underwent a repeat of the serum/plasma antibody testing at the conclusion of the study to determine if there were anti-HBs present in their blood.

The results were then statistically analysed using nonparametric testing: Chi-squared independent test, Mann-Whitney test and Sign test. These showed that there was no change measurable effect on the surface antigen of hepatitis B (anti-HBs) of either the Verum (active medication) or Placebo group.

Primary preventative medicine is becoming increasingly popular (Kuehlein et al., 2010). Both vaccination and homeoprophylaxis are examples of primary preventative medicine, where the aim is to prevent future disease. Vaccinations encourage the production of antibodies via the activation of T-helper cells and B-lymphocytes, thus providing a template for immunity against future infections (Miller, 2000; Janeway et al., 2001). While the mechanisms of vaccination are well understood, those of homeoprophylaxis are still being investigated. One theory is that nosodes enable the body to overcome diseases. Several studies have been conducted on the effects of nosodes (Bracho et al., *Prophylactic vaccination against human papilloma virus infection and disease in women: a systemic review of randomized control trial*.; Gosavi et al., 2012; Shuller, 2010) and have shown favourable results in the prevention of diseases associated with those homeopathic nosodes. However, only two studies have investigated the effects that nosodes have on the antibodies of the immune system (Hoover, 2006; Neustaedter, 2002) showing the need for further studies conducted in this area.

The study showed that homeopathically prepared *Hepatitis B* 12cH nosode is not capable of eliciting an immune response that would result in the production of the antibody to the surface antigen of Hepatitis B, and thus not able to provide immunity against Hepatitis B.
DEDICATION

To all nearly insane research students and their long suffering supervisors.
ACKNOWLEDGEMENTS

Dr Neil Gower:
For all his help, support and seemingly endless supply of patience.

Ms Ingrid van der Westhuyzen:
For agreeing to co-supervise the study through unusual circumstances of an absent student

Nick and Margi Caldwell:
For their love over all the years, their patience through all the tears, and their support through all the fears.

Dr Gloria Braum:
For inspiration to follow the road less travelled.

Dr Yolande Olivier
For all the strings you pulled and favours you agreed to.

My friends and soul mates:
For all the laughter and life long memories.
TABLE OF CONTENTS

DECLARATION ........................................................................................................ ii
AFFADAVIT ............................................................................................................. iii
ABSTRACT .............................................................................................................. iv
DEDICATION .......................................................................................................... vi
ACKNOWLEDGEMENTS ..................................................................................... vii
TABLE OF CONTENTS .................................................................................... viii
LIST OF APPENDICES ...................................................................................... xii
LIST OF TABLES .................................................................................................. xiii
LIST OF FIGURES ............................................................................................... xiv

CHAPTER ONE .................................................................................................... 1
   Introduction ........................................................................................................... 1
     1.1 Problem Statement ....................................................................................... 1
     1.2 Aim of the Study ......................................................................................... 1
     1.3 Benefits of the Study ................................................................................... 1

CHAPTER TWO .................................................................................................. 2
   Literature Review ............................................................................................... 2
     2.1 Hepatitis B .................................................................................................... 2
       2.1.1 Epidemiology .......................................................................................... 3
       2.1.2 Clinical Features ..................................................................................... 4
       2.1.3 Diagnosis ................................................................................................ 4
       2.1.4 Treatment ............................................................................................... 5
     2.2 Immunity, Prophylaxis and Vaccination ...................................................... 7
       2.2.1 Immunity and Propylaxis ........................................................................ 7
       2.2.2 Vaccines ................................................................................................. 7
         2.2.2.1 Types of Vaccines ................................................................................. 8
     2.3 Hepatitis B Vaccine ..................................................................................... 11
     2.4 Homeopathy ............................................................................................... 12
2.4.1 Homeoprophylaxis ................................................................................................................................. 13
2.4.2 Homeopathic Nosodes ............................................................................................................................ 14
2.4.3 Related Research ..................................................................................................................................... 15

CHAPTER THREE ............................................................................................................................................. 18
Methodology ...................................................................................................................................................... 18
3.1 Study Design ............................................................................................................................................... 18
3.2 Recruitment of Participants .................................................................................................................... 18
3.3 Research Procedure .................................................................................................................................. 19
3.3 Data Analysis and Statistical Methods .................................................................................................... 20
3.3.1 Chi-square Tests .................................................................................................................................... 21
3.3.2. Mann-Whitney Test ............................................................................................................................ 21
3.3.3 Sign Test ................................................................................................................................................ 21
3.3.4 The P-Value .......................................................................................................................................... 21

CHAPTER FOUR .............................................................................................................................................. 22
Results ............................................................................................................................................................... 22
4.1 Introduction to Results ............................................................................................................................... 22
4.2 Patient Health ............................................................................................................................................ 24
4.3 Demographic Studies ................................................................................................................................ 26
4.3.1 Gender .................................................................................................................................................. 26
4.3.2. Age ....................................................................................................................................................... 26
4.4 Results ....................................................................................................................................................... 26

CHAPTER FIVE ............................................................................................................................................... 28
Discussion .......................................................................................................................................................... 28
5.1 Introduction ................................................................................................................................................ 28
5.2 Demographic Studies ................................................................................................................................ 28
5.3 Physical examination and Vital Signs ...................................................................................................... 29
5.4 Adverse events and Side Effects ............................................................................................................ 29
5.5 Critical Analysis ....................................................................................................................................... 29
## CHAPTER FIVE

### 5.5.1 Preventative Medicine

### 5.5.2 Expanded Programme on Immunisation (EPI) in South Africa

### 5.5.3 Vaccination

#### 5.5.3.1 Pertussis Vaccination

#### 5.5.3.2 Streptococcus pneumoniae Vaccine

#### 5.5.3.3 Human Papilloma Virus (HPV) Vaccine

#### 5.5.3.4 *E-Coli* Vaccine

#### 5.5.3.5 Measles, Mumps, and Rubella (MMR) Vaccine Controversy

### 5.5.4 Homeoprophylaxis

#### 5.5.4.1 Application

### 5.6 Conclusion

## CHAPTER SIX

### conclusions and Recommendations

### 6.1 Conclusions

### 6.2 Recommendations

## REFERENCES

## APPENDIX A

### Interpretation of Hepatitis B Serum Tests

## APPENDIX B

### Procedure for Hepatitis B Serum Testing

## APPENDIX C

### Advertisement

## APPENDIX D

### Flyer

## APPENDIX E

### Brochure

## APPENDIX F

### Participant Health Survey and Case Taking Form
LIST OF APPENDICES

APPENDIX A  
Interpretation of Hepatitis B Serum Tests................................................................. 53

APPENDIX B  
Procedure for Hepatitis B Serum Testing................................................................. 54

APPENDIX C  
Advertisement............................................................................................................. 55

APPENDIX D  
Flyer............................................................................................................................ 56

APPENDIX E  
Brochure..................................................................................................................... 57

APPENDIX F  
Participant Health Survey and Case Taking Form.................................................... 58

APPENDIX G  
Participant Consent and Information Form................................................................. 62

APPENDIX H  
Patient Medication Information Leaflet....................................................................... 65
LIST OF TABLES

Table 4.1 Participant Vital Signs at Commencement of Study ............................................25
Table 4.2 A Cross Tabulation of Gender Comparison between Verum and Placebo Groups.................................................................................................................................26
Table 4.3 T-Tests for Age Comparison and Average between Verum and Placebo Groups.................................................................................................................................................26
Table 4.4 Results of Serum Antibody Testing for Verum and Placebo Groups.................27
Table 4.5 Frequencies and P-values of Sign Test................................................................27
LIST OF FIGURES

Figure 2.1 Schematic Diagram of Hepatitis B (Boon et al, 2006) ........................................ 2
Figure 2.2 Flow Diagram of Vaccine Manufacture (Nelson and Williams, 2007) ........... 10
Figure 4.1 Summary of Eligible Participants by Location ................................................. 22
Figure 4.2 Flow of Participants through Study ................................................................. 23
Figure 5.5.1 Revised EPI in South Africa (Department of Health, 2009) ...................... 31
CHAPTER ONE
INTRODUCTION

1.1 Problem Statement
There are an estimated two billion individuals affected by Hepatitis B (World Health Organization, 2008). This potentially deadly disease most commonly affects healthcare workers, as transmission is via infected blood or body fluids (Immunization Action Coalition, 2007; Boon et al., 2006). These high risk individuals are therefore advised to receive the Hepatitis B vaccine, which may expose recipients to side effects such as Guillain-Barre syndrome, demyelinating nervous system diseases (Pratt, 2008), as well as anaphylaxis, bronchospams and tachycardia (GlaxoSmithKline, 2008). This has led to the need for a possible safer alternative (Romm, 2001). Homeopathy may be used in the form of nosodes, which are homeopathic medications made from killed disease cultures, disease organs or body fluids (German Homeopathic Pharmacopeia, 2003) to provide prophylactic efficacy to prevent the contraction of disease, referred to as homeoprophylaxis (Zoltan, 2000). The effect of homeoprophylaxis on the immune system’s antibodies has not been well researched. In 1932, Patterson and Boyd elicited Diphtheria antibodies on Schick Tests after the administration of Diptherium nosode (Hoover, 2006). Smits administered homeopathically prepared Diphtheria, Tetanus and Polio (DTP) vaccine to 10 children. One month after this administration, Smits conducted an antibody test on this group and found no rise in the serum antibodies in any of the children (Neustaeder, 2002).

1.2 Aim of the Study
The aim of the study was to determine the production of the antibody to the surface antigen of Hepatitis B (anti-HBs) due to Hepatitis B 12cH nosode administration.

1.3 Benefits of the Study
It was anticipated that the Hepatitis B 12cH would cause a measurable increase of the antibody to the surface antigen of Hepatitis B, thus showing it to be an effective form of prophylaxis against Hepatitis B.
CHAPTER TWO
LITERATURE REVIEW

2.1 Hepatitis B

Hepatitis B virus or HBV is classified as a *Hepadnavirus* or a DNA virus of the family *Hepadnaviridae* (Alcomo, 2001). Hepatitis is an inflammation of the liver that may result in areas of necrosis or dying tissue. It is caused by an infection by one of several viruses including: Hepatitis A, Hepatitis B, Hepatitis C, Hepatitis D and Hepatitis E (Beers *et al.*, 2006).

Hepatitis B consists of a core and surface envelope, making up a sphere known as a Dane particle (Timbury, 1997). The core consists of potentially double stranded DNA, with certain sections being made of a single strand of DNA, DNA polymerase and the core protein (HBcAg) (Kumar and Clark, 2005; Timbury, 1997). The core is surrounded by a surface protein that expresses the Hepatitis B surface antigen (HBsAg). The surface envelope also includes a lipid derived from the host’s cells and a carbohydrate. The surface coat can exist independently from the core as it is expressed by infected hepatocytes, thereby increasing the amount of surface antigen in the blood (Rubin, 2001; Kumar and Clark, 2005). The surface coat is often seen on a microscopic level as particles and tubules that outnumber the Dane particles (Rubin, 2001).

![Figure 2.1 Schematic Diagram of Hepatitis B (Boon et al., 2006)](image-url)
2.1.1 Epidemiology

According to the World Health Organization (2008) there are an estimated two billion individuals, globally, who are infected with Hepatitis B. In South Africa, the Department of Health (2005) reported 864 notified cases between 2001 and 2004. Out of these cases the disease seemed most prevalent in the age group of 20-39 years, most likely due to the nature of the spread of the disease (Department of Health (2005). Kew (2008) stated that there were an estimated 3 to 4 million black South Africans who were currently in a chronic Hepatitis B infection state.

There are two types of transmission of the Hepatitis B virus. The first type, Vertical Transmission, takes place from an infected or HBsAg-positive mother to her child during birth or breast feeding (Norris and Mohsen, 2006; Boon et al., 2006). The second type, Horizontal Transmission, is the spread from person to person by “physical contact” rather than by “inheritance” (Boon et al., 2006), and occurs through contact with infected blood or body fluid such as semen, saliva and serum (Strol et al., 2001).

According to the Department of Health (2001) the number of reported cases of Hepatitis B totalled 2077 between 1998 and 2007; however there are no current statistical figures available.

With the increasing HIV/AIDS infection rates in South Africa, estimated at around five million individuals, it has caused the infection rates of Hepatitis B to rise (Mphahlele, 2008). This is due to the similar entry routes that each infection has into the human body, through body fluids and blood. The mortality rate rises when these two diseases are combined, particularly from damaged caused by chronic Hepatitis B (Hoffman and Thio, 2007).

Certain groups of individuals are at higher risk for contracting the disease due to the work environment, home environment or their lifestyle. These groups include:

- Healthcare workers;
- Intravenous drug users;
- Sexually active individuals with multiple partners, or those seeking treatment for a sexually transmitted disease;
- Individuals who reside with infected persons; and
• Individuals who reside in or travel to high risk areas (Immunization Action Coalition, 2007).

2.1.2 Clinical Features
An acute infection is initially characterized by headaches, malaise, myalgia, loss of appetite and nausea, followed by vomiting, diarrhoea and abdominal pain in the later stages (Boon et al., 2006). These symptoms are found throughout all the types of viral hepatitis, but a rash, or urticaria, and joint pains, known as arthralgia, are more prevalent in Hepatitis B (Beers et al., 2006). Within a week of the onset of symptoms, the patient starts to appear jaundiced, a yellow colouring to the mucous membranes, but may feel respite from the previous symptoms with the onset of the jaundice (Beers et al., 2006). Hepatomegally (enlargement of the liver) and mild splenomegaly (enlargement of the spleen) may occur as the disease progresses. Most patients make a full recovery from all their symptoms (Beers et al., 2006; Boon et al., 2006), with 10 to 20 percent of these cases becoming the chronic form of disease, thus increasing the risk of hepatoma two hundred fold (MIMS, 2007). Fifteen percent of these chronic infections are fatal (Boon et al., 2006).

When an acute infection does not resolve completely and the infected individual fails to develop immunity to the initial infection, a “chronic carrier state” is sustained (Rubin, 2001). These individuals show no signs of liver disease and are not highly infective, but it may take them years to develop immunity to the disease that eventually resolves this state (Kumar and Clark, 2005; Rubin, 2001).

Fulminant hepatitis is a rare complication of a Hepatitis B infection, which causes cell death and necrosis within the liver leading to shrinkage of this organ, hepatic failure and death (Rubin, 2001; Beers et al., 2006). Other complications include cirrhosis, fibrosis, hepatocellular carcinoma (Highleyman, 2008), cholestatic hepatitis, aplastic anaemia and disease relapses (Boon et al., 2006).

2.1.3 Diagnosis
Testing of blood serum can determine if an individual has an acute or chronic infection, acquired immunity from a previous infection or acquired immunity from a vaccine (American Association for Clinical Chemistry, 2005) (Appendix A).
The presence of the surface antigen (HBsAg) is the earliest indicator of an acute infection of Hepatitis B, along with an increased IgM, level and is also positive in chronically infected individuals (American Association for Clinical Chemistry, 2005).

The antibody to the core antigen (anti-HBc) is present in an acute infection, chronic infection and in immunity acquired from an infection of Hepatitis B (Wallach, 2007).

The antibody to the surface antigen (anti-HBs) is the only level that is raised when immunity is acquired through vaccination, and the presence of more than 10mU/ml usually indicates a successful prophylaxis as long as no other serological markers are present. This is also known as a serum titre test (Wallach, 2007).

Viral load testing measures the number of RNA copies of the virus, which is useful for the determination of the severity of a chronic Hepatitis B infection and the efficacy of the treatment being administered (Wallach, 2007; Cutler, 2008).

Serum titer testing for antibodies measures the amount of antibodies present in a sample of serum after there has been exposure to an antigen. Titer testing is useful in the determination of sero-conversion after vaccination has taken place, the possible need for further vaccination and investigation into recent infections. However, it does not distinguish between antibodies generated by vaccination and those generated by natural exposure to disease agents through infection (Henochowicz, 2009).

Modern testing methods include rapid serum titre testing, which can test for the presence of the antibody to the surface antigen of Hepatitis B (anti-HBs) in under 20 minutes using a small amount of serum, with a 99.5% reliability rating (Labstix CC, 2006) (Appendix B).

**2.1.4 Treatment**

There is no specific treatment recommended for the acute form of the Hepatitis B infection (Conte, 2002). Palliative measures of total bed rest until recovery, adopting a low protein and alcohol free diet, and treating the associated symptoms such as vomiting and dehydration are recommended (Kumar and Clark, 2005;).
Drugs that are processed by the liver, such as aspirin and non-steroidal anti-inflammatory drugs, must also be avoided (Beers et al., 2006).

Chronic Hepatitis B sufferers, and those that are co-infected with HIV/AIDS, are treated with interferon and anti-virals (Lalezin and Moyle, 2001).

Alfa-interferon suppresses the viral replication and enhances the T lymphocyte response (Lalezin and Moyle, 2001). Doses of 2.5 to 5 million u/m³ are given three times a week for four to six months (MIMS, 2007). Side effects can include: depression, suicidal behaviour, anxiety, insomnia, headaches, confusion, myalgia, bone marrow depression, arthritis, epistaxis, and flu-like symptoms (MIMS, 2007). Alfa-interferon has a 40 percent efficacy rate of eliminating chronic Hepatitis B infections, but is usually unsuitable for the majority of HIV co-infected patients, due to toxicity (Conte, 2002; Lalezain and Moyle, 2001).

The most common anti-viral used is Lamivudine which is used in chronic Hepatitis B and HIV co-infected patients (Lalezain and Moyle, 2001). The goal of anti-viral therapy is to stop the viral replication thus stopping the virus. Unfortunately there have been reports of resistance forming in patients (Lalezain and Moyle, 2001). The prescribed dose is 100mg daily for twelve weeks (MIMS, 2007). Side effects may include: headaches, nausea, vomiting, diarrhoea, abdominal pain and insomnia (MedicineNet, 2010).

Adefovir dipiovixl has proven to have no ‘cross-resistance with Lamivudine’ and possess both anti-HBV and anti-HIV properties (Lalezain and Moyle, 2001). The dosage of this anti-viral is 10mg daily (MIMS, 2007). Side effects may include: headaches, nausea, vomiting, diarrhoea and fever (MedicineNet, 2010).

Alternative or complementary treatments are available. High doses of Vitamin C, between 10 and 50 grams four times daily, are taken during the acute phase of the disease and helps clear jaundice. Glycyrrhiza Glabra, a herb, has 'anti-hepatotoxic effects', anti-viral properties and enhances the immune system when taking 500mg three times daily. It is advised that when taking this herb that the blood pressure is measured regularly. Silybum marianum, 120 - 140 mg three times daily, is a strong liver
protector which inhibits liver damage due to its anti-oxidant effects and it helps stimulate hepatocyte, or liver cells, regeneration (Pizzorno et al., 2002).

2.2 Immunity, Prophylaxis and Vaccination

2.2.1 Immunity and Propylaxis
There are two types of immunity within the human body: innate and adaptive.

Innate immunity is mediated by cells like phagocytes, natural killer cells and plasma proteins from the complement system. These work by creating a defence line that blocks microbes from entering the system (Abbas and Lichtman, 2011).

Adaptive immunity is further divided into humoral and cell-mediated immunity. Cell-mediated immunity is mediated by T-lymphocytes, which kill host cells that contain infectious material within their cytoplasm (Abbas and Lichtman, 2011; Playfair; 2006). Humoral immunity is controlled by antibodies produced by B-lymphocytes (Abbas and Lichtman, 2006).

Vaccination mechanisms work by introducing a small amount of a specific antigen into the body where B-lymphocytes produce antibodies to the antigen. A certain aggregate of these B-lymphocytes will go on to act as memory cells, retaining the information to produce these antibodies should the body encounter the disease (Playfair, 2006).

Prophylaxis is defined as “any means taken to prevent disease, such as immunisation” (Ed. Martin, 2007).

2.2.2 Vaccines
In 1798, Edward Jenner introduced the theory of vaccination by inoculating individuals against the dreaded disease of the time, smallpox (Bloom and Lambert, 2003). He used pus from a cow pox lesion, usually found on the hands of milkmaids, and inoculated James Phipps, an eight year old boy, which protected him against the subsequent infection of smallpox that Jenner introduced into his body (Stern and Markel, 2003).
Louis Pasteur developed the next vaccine in 1885 to counteract the Rabies virus (Stern and Markel, 2003). In 1886 the first true killed-virus vaccine, to hog cholera, was produced by Salmon and Smith, which lead to great advancements in vaccination against cholera and typhoid (Bloom and Lambert, 2003).

In the 1930s a vaccine boom produced the diphtheria, yellow fever, tetanus and pertussis vaccines (Bloom and Lambert, 2003).

The discovery of tissue culturing in the 1940s started the advent of the polio vaccine, which was eventually perfected in 1955 (Bloom and Lambert, 2003). This vaccine has been cited as the cause for the successful eradication of poliomyelitis in the United States of America (CDC National Immunization Programme, 1999).

The modern quest for vaccination focuses on the plagues of Sub-Saharan Africa: malaria and HIV, but as yet there has been little success (Stern and Markel, 2003).

Dr Baruch Blumberg developed the first Hepatitis B vaccine in 1965. The first commercial Hepatitis B vaccine, introduced in 1981, was developed from the blood of donors who were infected by the virus. This blood was then put through a series of steps in order to ‘inactivate the virus’. The recombinant vaccine, still used today, was introduced in 1986 and still remains due to the fact that there are no blood products used in the production of the vaccine (The Hepatitis B Foundation, 2009).

2.2.2.1 Types of Vaccines
There are several types of vaccination that are manufactured in different ways.

Live Attenuated Vaccines
The attenuated processes are achieved by growing the cultures in abnormal conditions so that virulence is lost (Walker and Rapley, 2009). These attenuated pathogens still retain the ability to replicate in the host but should not cause disease (Waldor, 2007). Live attenuated vaccines, such as the BCG vaccine for tuberculosis, are not safe in immunocompromised patients, (Nelson and Williams, 2007). The upside, however, is the stronger immune reaction these vaccines produce provide life-long immunity by
inciting humoral and cell-mediated responses. Examples of these vaccines include: BCG for tuberculosis; MMR for measles, mumps and rubella; OPV for polio and the yellow fever vaccine (Nelson and Williams, 2007).

**Inactivated/Killed Vaccines**

Inactivated vaccines are produced using the whole organism, usually bacteria or viruses, that are then deactivated using heat or chemicals, like formalin or formaldehyde, both of which are known carcinogens (Nelson and Williams, 2007; Decker, 2006). The advantage of this method is that the organism will not revert to its virulent form so it is safe to use in immunocompromised patients. Inactivated/killed vaccines produce a good immune response but unfortunately it is significantly weaker than the response, produced by a live vaccine (Walker and Rapley, 2009). Examples of these vaccines include the influenza vaccines and Haemophilus influenza B vaccine (Nelson and Williams, 2007).

**DNA Vaccines**

The newest form of vaccination uses ‘gene guns’ to shoot DNA-coated gold beads into the body causing, both humoral and cell-mediated immunity. Only the desired genes are located, isolated and replicated (Decker, 2006; Nelson and Williams, 2007).

**Subunit Vaccines**

Subunit vaccines do not contain the whole organism, but rather antigens from that organism (Walker and Rapley, 2009). The effectiveness of these vaccines is increased by adding adjuvants to slow the antigen release (Decker, 2006). These substances include aluminium and mercury, in the form of thiomerosal, both which can cause adverse reactions (White, 2001). Subunit vaccines are divided into 3 categories: conjugated vaccines, toxoid vaccines and recombinant Vaccines (Decker, 2006).

Conjugated vaccines, also known as polysaccharide vaccines or protein carrier vaccines, use organisms that are naturally protected from phagocytosis and link them to polysaccharides, so that infant immune responses are enhanced (Decker, 2006). Examples include: DPT for diphtheria, pertussis and typhoid; *Nesseria meningitidis* and Haemophilus influenza B (Nelson and Williams, 2007; Decker, 2006).
With toxoid vaccines, there is immunisation against the exotoxin produced by the organism, rather than against the active bacteria, as in tetanus (Walker and Rapley, 2009).

Recombinant vaccine is the category that the Hepatitis B vaccine falls into, being the first DNA recombinant vaccine to be produced (Walker and Rapley, 2009). The surface antigen genes to Hepatitis B (HBsAg) are bound to yeast genes, able to make proteins, via a process known as “transvected” as the yeast acts as a vector (Nelson and Williams, 2007). The advantage of this process is that there are no harmful products used in the production of the vaccine (Decker, 2006).

---

**Figure 2.3 Flow Diagram of Vaccine Manufacture (Nelson and Williams, 2007)**
2.3 Hepatitis B Vaccine

The Hepatitis B vaccine is a recombinant DNA vaccine (GlaxoSmithKline, 2008). The current “second generation” vaccines (Zanetti et al., 2008) work by using Saccharomyces cerevisiae, a yeast, as a vector or replication unit, for the Hepatitis B surface antigen (HBsAg) which is then purified and injected into an individual as a vaccine (Zanetti et al., 2008; Roitt and Delves, 2001). Once injected into the human body, the individual undergoes sero-conversion, meaning they have more than 10μL/mL of the antibody to the surface antigen of Hepatitis B (anti-HBs) and are therefore immune to the disease (Immunization Action Coalition, 2007; White, 2001).

According to Decker (2006), by using the recombinant method it is possible to choose a vector that is “safe and easy to store” so that large amounts of the vaccine may be made, but the cost of the genetic development are much higher than with attenuated vaccines.

South Africa makes use of Engerix B®, a recombinant vaccine that eliminates a possible transfer of disease like HIV/AIDS from human donor blood (Alcamo, 2001; GlaxoSmithKline, 2008). Engerix B® became the Hepatitis B vaccine in South Africa in 1999 as Hepaccine-B®, used from 1995 to 1998, was a plasma derived vaccine which not only increased the risk of adverse side effects, but was also the more expensive option (Tsebe et al., 2001; Mphahlele et al., 2002). Engerix B® is administered to infants at six, ten and fourteen weeks of age; to adults it is given at zero, one, two and six months (GlaxoSmithKline, 2008).

It is recommended that individuals within the high risk groups, who may be at risk of contracting Hepatitis B, should receive the vaccination (White, 2001). These include:

- Healthcare workers;
- Intravenous drug users;
- Sexual partners of infected individuals;
- Persons residing with infected individuals;
- Persons receiving treatment for a sexually transmitted disease;
- Infants born to infected mothers;
- Persons residing in high risk area;
• Persons travelling to high risk areas;
• Persons receiving haemodialysis;
• Persons with chronic liver disease; and
• Persons with HIV (Immunization Action Coalition, 2007).

In 2001, the Department of Health’s EPI introduced an active surveillance system for reporting Adverse Effects Following Immunisation (AEFIs), which could range from redness and pain at the injection sight, to severe allergic reactions. Engerix B®, the Hepatitis B vaccine used in South Africa uses aluminium hydroxide as its suspension substance (GlaxoSmithKline, 2008). Aluminium hydroxide has been implicated in brain damage, Alzheimer’s disease and other neurological symptoms (Vaccine Information Service, 1999). The prescribing information for Engerix B® (GlaxoSmithKline, 2008) states that 1-10% of patients who received the injection experienced fever, dizziness and a headache. In 1% or less of patients the following symptoms were seen: erythema, lymphadenopathy, hypotension, chills and puritis amongst others. Post-marketing reports warn of the following symptoms notified by doctors who had given the vaccine to patients: anaphylaxis and angioedema, bronchospasms, tachycardia, abnormal liver function tests, Guilliane-Barre Syndrome, visual disturbances and Bell’s palsy (White, 2001; GlaxoSmithKline, 2008). It has been recommended that children born to mothers who are not infected with Hepatitis B should wait until the infant is between two and six months old, because their larger size can reduce the risks associated with vaccination (American Academy of Paediatrics and the United States Health Service, 1999).

2.4 Homeopathy

Homeopathy is a “formal therapeutic system” founded by the German physician, Dr Samuel Hahnemann (1755-1842), on the principle of simila similibus cures like” (Wells, 2002). The literal translation of the term homeopathy is derived from “homios” meaning similar and “patho” meaning suffering (Bloch and Lewis, 2002).

There are several principles that homeopathy is based on, the most important being simila similibus cures like”, referring to the principle that when a
substance is given in homeopathic potency, it will cure the same symptoms the substance would elicit in a healthy individual during a proving (Wells, 2002).

The vital force, also known as the life force, creates balance within the body in order to maintain health. When a disease enters the body it creates a reaction which the vital force must resist, following the law that every action causes an equal but opposite reaction, and results in the symptoms of the disease. The homeopathic medication that is administered brings the vital force back into balance and helps the body heal (Vilthoulkas, 2002).

In order to find this medication, originally, a medicinal proving needed to be completed. During a remedy proving, a substance in raw form is taken by a healthy volunteer, in order to determine what physical and mental symptoms this substance may elicit. These symptoms are collected, correlated and placed in the *Materia Medica*. These symptoms are the same symptoms the substance will cure when administered to a sick individual in homeopathic form (Bloch and Lewis, 2002; De Schepper, 2007).

When this single homeopathic medication is given to a sick individual whose presenting symptoms match a remedy picture, it is termed the “similimum”. The similimum is given in the lowest dose possible and only repeated when the symptoms return (Wells, 2002; De Schepper, 2006).

In order to lessen the harmful effects of the substances administered to his patients, Hahnemann began diluting and succussing i.e. vigorously shaking and banging, the raw material. He found that this also increased the curative powers of his medications (Wells, 2002; De Schepper, 2006).

### 2.4.1 Homeoprophylaxis

The origin of homeopathic prophylaxis or homeoprophylaxis seems to have originated when Dr Samuel Hahnemann used *Atropa belladonna* in small quantities to treat an epidemic of scarlet fever that had broken out in Koningslutter in 1799 (Bradford, 2004). Hahnemann, in the addition to the thirty-third aphorism in his 5th Edition of the Organon of Medicine, states that he found this mode of treatment effective again in 1801 and that
“all of the treated children that took the dose remained unaffected by this highly infectious disease”.

De Schepper (2007) states that homeoprophylaxis can be used to protect patients from “contracting a certain disease” and goes on to explain three ways in which this prophylactic effect might be achieved: by giving the constitutional remedy or the remedy based on what the patient is normally like in order to strengthen the vital force; by giving the remedy that is the almost specific to the disease; or by giving the nosode (potentised pathological material) of the disease which can be given either as a prophylactic or to combat the effects of “lingering” disease.

### 2.4.2 Homeopathic Nosodes

The German Homeopathic Pharmacopeia GHP (2003) defines nosodes as “preparations derived from products of human or animal processes, pathogen or their metabolic products or from the decomposition products of animal organs”. Nosodes are made from “killed-cultures”, animal organs and from body fluids through the processes of titration (German Homeopathic Pharmacopeia GHP, 2003).

The *Hepatitis B* 12cH nosode is made from disease tissue according to method 44 of the German Homeopathic Pharmacopeia GHP (2003) and is as follows:

- The culture is adjusted to contain $1 \times 10^7$ microorganisms per gram.
- The organisms are heated with steam for twenty minutes at a pressure of $3 \times 10^2$ kPa until the core temperature is 133°C.
- The mother tincture is prepared by taking 1 part of the heat-treated raw material with 9 parts of 85% glycerol.
- It is left to stand for 5 days and then filtered. This mix is equivalent to a tenth potency or D1.
- To make C1 (centesimal dilution) 10 parts of D1 is mixed 90 parts of alcohol 30% ($m/m$), followed by 100 succussions.
- C2 potency is made by taking 1 part C1 and 99 parts 43% alcohol ($m/m$), followed by 100 succussions.
- Subsequent potencies are made in the above way until the 12th potency or C12 is reached.
The nosode contains no trace of active viral material and has no known contraindications (Kayne, 2006).

2.4.3 Related Research
There have been several successes with the use of homeopathic treatment as a prophylactic. In Brazil in 1974, during a meningitis outbreak, *Menginococcinum* 10C was given to 18,640 children, while 6,340 children remained untreated. In the “protected” children’s group there were 4 cases of meningitis reported while in the “unprotected” group there were 34 cases (Sheffield, 2006).

Golden (2004) performed a 15 year clinical study where he outlined a purely homeopathic prophylaxis protocol, substituting traditional vaccines, from the age of 1 month to 7 years. He found in a treatment group of 1305 children (Post, 2004), that he had a 90.4% success rate where the majority of the children had not developed childhood diseases at all, and the small group that contracted a childhood disease experienced a shorter duration and recovered fully with no lasting sequelae.

*Leptospirosis*, a water-borne bacterium, causes pneumonitis, hepatitis, nephritis, meningitis and hemorrhagic-crisis, and it has become an epidemic in Cuba during the rainy season. In 2007, a study was undertaken to use homoeopathically prepared Leptospirosis nosode as prophylactic treatment. At the start of the study, there was enough conventional vaccine to cover 0.6% of the population while the homeopathic prophylaxis was given to 92% of the population. The prophylaxis was given initially as *Leptospirosis* 200cH, 5 drops as a dose, as first dose that was repeated 7-9 days later. Ten to twelve months later *Leptospirosis* 1M was given as a 5 drop dose, and then repeated 7-9 days later. After this prophylactic treatment there was a significant decrease of the disease in the regions that received the homeoprophylaxis (Bracho *et al*., 2010).

Dr Smits conducted tests on children after they received the DTP 30cH and 200cH nosode which was made from Diptheria, Tetanus and Polio Vaccine. He tested for the antibody before giving the homeoprophylactic treatment and one month after, but he found “no rise in antibody levels” (Neustaedter, 2002). This is the only published study
were there have been antibody titre test conducted when giving homeopathic prophylaxis.

Engystol®, a homeopathic OTC medication available in tablets and injectables, used for boosting the immune system, was tested *in vitro* in 30 volunteers aged 20 to 56 years in order to determine if the medication had any effect on the interferon-γ production by T-lymphocytes. Lymphocyte suspensions were treated with different solutions of Engystol®, ranging from 100% to 2% dilution. Results showed an increase in the number of lymphocytes regardless of the percentage of Engystol® used in solution (Enbergs, 2006).

Homeopathic dilutions of Silica 3X, 6X, 30X and 200X were used on human polymorphonuclear (PMN) cells, also known as phagocytes. It was found that the homeopathic dilutions increased the phagocytosis of PMN cells in the presence of the foreign cells of *Candida albicans*. It was proposed that it was due to changes in the oxidative process increasing chemotaxis, but the exact mechanism could not be clearly determined (Patoll and Mahaja, 2010).

Lemos *et al.* (2011) conducted an *in vitro* study using a live nosode of *Mycoplasma gallisepticum* prepared from a non-inactive culture in order to access the safety of its use to immunise domesticated fowls. They used six homeopathic dilutions (1D, 10D, 11D, 12D, 20D, 30D). They found that the 11D, 12D, 20D, 30D treated cultures had no growth, while the 1D and 10D still had growth of the micro-organism. It was concluded by the researchers that the 30D *Mycoplasma gallisepticum* was safe to use as prophylaxis.

It was proposed by Walchliii *et al.* (2006) that homeopathic potencies of *Cadmium* could have an effect on both normal and cancerous lymphocytes. *Cadmium* is usually prescribed for diseases that are progressing quickly towards death. The homeopathic potencies had a significant stimulatory effect on the normal T-cell lymphocytes yet, failed to provoke a response in the cancerous lymphocytes. The researchers concluded that, while they thought that the *Cadmium* would have a greater effect on the cancerous cells due to the “similis principle”, the effect was not large enough within the closed cellular system for the cancerous cells to “recognise the information” from the homoeopathically prepared *Cadmium*. 
Chikramane et al. (2010) tested pre-prepared homeopathic medications to discover if the metals in a 30cH and 200cH homeopathic potency were still present in any form. They found nanoparticles of the substances still present, which suggested that the starting substances of homeopathic remedies did survive past Agravado’s number. Upadhyay and Nayak (2011) found the nanoparticles became smaller with serial dilutions, but their study only went as high as 15cH homeopathic potency. Nandy et al. (2011) found that with repeated dilutions, not only did the nanoparticles decrease in size but also the membrane anisotropy thus allowing more of the nanoparticles to cross the membrane.

Research conducted at the Technikon Witwatersrand (TWR) from May until August 2003 compared the effectiveness of Influenzinum 7cH in the prevention of influenza compared to the influenza vaccination. The randomized double-blind placebo study included 30 participants placed into either Group A, receiving the influenza vaccination in a single dose, and Group B, receiving Influenzinum 7cH in 14 doses over thirteen weeks. When compared, both groups showed similar efficacy in the prevention of influenza (Frost et al., 2003).
CHAPTER THREE
METHODOLOGY

3.1 Study Design

The study was conducted according to the randomised, double-blind method. The study included participants between the ages of 18 and 65 years of age. Participants needed to meet specific inclusion criteria, exclusion criteria and have a negative result for the rapid testing for the anti-body to the surface antigen of Hepatitis B (anti-HBs).

Participants were recruited via advertisements (Appendix C), flyers (Appendix D) and brochures (Appendix E) placed around the UJ Doornfontein campus and several external locations. The research participants represented a random sample of the population. The study was conducted from June 2010 until July 2012 at the University of Johannesburg Health Clinic in Doornfontein; The Campus, Dimension Data, Bryanston; and Linden Presbyterian Church, Linden, Johannesburg.

3.2 Recruitment of Participants

Due to the vaccine protocol among Health Sciences students, there were very few participants recruited from the University of Johannesburg as most students had received their Hepatitis B vaccination at the end of their first year of study. Permission was requested, and granted, by the Head of the Department of Homeopathy to recruit and screen participants off the campus at two external locations: Dimension Data’s The Campus in Bryanston and Linden Presbyterian Church. Initial participant screening was conducted under the supervision of the research supervisor.

Participants recruited for the study were selected after an initial interview was conducted and a case form (Appendix F) was completed for each participant. Several criteria were considered for inclusion into study.
**Inclusion Criteria**

Individuals were included in the study if:

- They were in good general health without chronic disease;
- They were not taking any form of chronic medication, and
- A plasma titre test yielded a negative result to the antibody of the surface antigen of Hepatitis B (anti-HBs).

**Exclusion Criteria**

Individuals were excluded from the study if:

- They reported a previous history of a Hepatitis B infection;
- They had received a Hepatitis B vaccine within the previous 3 to 5 years;
- A positive plasma titre test was obtained, indicating that they had immunity to Hepatitis B; or
- They were pregnant or breast feeding.

The participants had the process and the aim of the study explained to them in the Patient Consent and Information form (Appendix G) which they, and the researcher, were required to sign.

**3.3 Research Procedure**

All volunteers had 5ml of whole venous blood collected, by a registered nurse, which was labelled and allowed to stand for 20 minutes in order for the blood to separate into blood components and plasma. Using the recommendations of the rapid plasma test (Appendix H) approximately 120uL or 3 drops of plasma was added to the sample well of the rapid test cassette using the pipette provided within the kit. The results were then read after ten minutes or as long as the background remained clear. The cassettes were labelled with the volunteer’s participant number and the results were recorded. Volunteers who had a positive plasma test were excluded from the study.

The participants that fulfilled the inclusion criteria, and who had given their consent, were randomly placed into two groups, namely the Verum Group and the Placebo Group. During the study neither the participants nor the researcher were aware of which group the participants were allocated to. At the completion of the medication
period, which was four weeks, all the participants returned to have 5mls of venous blood drawn and tested. The plasma titre test was performed, as before, and results were recorded in order to determine if the participants had undergone sero-convertion.

3.3.1 Medication

The Hepatitis B 12cH nosode and the lactose powders were manufactured by Natura Laboratories according to method 44 of the German Homeopathic Pharmacopeia (German Homeopathic Pharmacopoeia GHP, 2003). The researcher then manufactured the lactose powders under sterile conditions in the Homeopathic Dispensary of the Homeopathic Clinic. The active powders were medicated with one drop of Hepatitis B 12cH, while the placebo powders were medicated with 1 drop of 96% alcohol. This ensured that the lactose powders, between the two groups, had the same consistency and were visually uniform. The Homeopathic Dispenser at the time, Dr Bianca de Canha, then randomly assigned the active and placebo powders to a participant number. A record of the randomisation was kept in the Homeopathic Dispensary. Neither the researcher, nor supervisor, was aware of which participant received the active or placebo powders. The powders were numerically marked and taken by the participants in that order. Instructions (Appendix H) on how to take the powders were as follows:

- One powder was one dose of the medication and was to be taken sub-lingually, or under the tongue, in the morning.
- One powder was to be taken on the same day every week so that one dose a week was taken.
- The medication was to be taken 20 to 30 minutes before eating or drinking.
- The medication was not be taken with food, coffee, tea or juices or soon after brushing the teeth.
- The medication was to be stored out of direct sunlight and away from any strong smelling substances like menthol, camphor or coffee.

3.3 Data Analysis and Statistical Methods

After completion of the study, all data was collected from the participants and analysed by the researcher with the aid of a statistician. The variables between the two groups were analysed using Chi-tests and Sign Tests, while comparison of the two groups over time was done using Mann-Whitney Tests and T-Tests.
3.3.1 Chi-square Tests
There are two types of Chi-squared tests. Chi-square Goodness of Fit test is used to compare two populations or groups. Chi-square Test for Independence is used to compare 2 groups that have 2 or more variables within them (Pallant, 2007).

3.3.2 Mann-Whitney Test
This nonparametric test is used to analyse differences between two groups of equal size. Unlike parametric T-tests that use means, Mann-Whitney tests use medians to calculate any statistical differences between the two groups (Pallant, 2007).

3.3.3 Sign Test
This is a simple test that calculates any differences between the two groups by counting the positive, negative and zeros (Norussis, 2003).

3.3.4 The P-Value
In order to prove that a research trial is statistically significant the researcher must show that the hypothesis is a more plausible outcome that the null-hypothesis. This measurement of probability is termed the p-value. The p-value must be <0.05 in order to deem that the null-hypothesis is false. A p-value that is 0.10 or higher shows that there is no evidence against the null-hypothesis and thus the null-hypothesis must be accepted as true (Mendenhall et al., 2012).
CHAPTER FOUR
RESULTS

4.1 Introduction to Results

This randomised double-blind placebo controlled study aimed to discover the effect the Hepatitis B 12cH nosode would have on the antibody to the surface antigen of Hepatitis B (anti-HBs). A total of 60 individuals were interviewed to assess eligibility into the study. Four individuals did not meet the required inclusion criteria; one due to medication-dependent type II diabetes and the other three individuals due to their positive serum titre tests, indicating immunity to Hepatitis B.

Out of the 56 eligible participants, 31 were on active medication and 25 on placebo. 13 participants failed to undergo the final serum test and had to be eliminated from the final analysis. The final analysis showed that there were 25 participants on active medication and 18 participants on the placebo, whose data was evaluated in the final analysis (Figure 4.1).

![Figure 4.1 Flow of Participants through Study](image-url)
Fifty six eligible participants were recruited from the University of Johannesburg (n = 11); Dimension Data’s The Campus in Bryanston (n = 33); and Linden Presbyterian Church in Linden (n = 12). The study was carried out at the above mentioned locations (Figure 4.2).

![Figure 4.2 Summary of Eligible Participants by Location]

Participants were recruited between June 2010 and July 2012. After initial interviews and health screen, each participant was screened for the antibody to the surface antigen of Hepatitis B (anti-HBs) and was included in the study on the basis of the negative result. Participants were randomly assigned according to participant number to either the Verum or Placebo group, taking one lactose powder weekly. Participants returned to have a second blood sample taken four weeks later. Following completion of the study, the participant numbers were unblinded and data collected.

Statistical analysis of this study was made using non-parametric testing. These types of tests allow for smaller sample groups and do not make “assumptions about the population” that parametric testing does. Chi-square Test for Independence, Sign Test
and Mann-Whitney test were used to analyse the data (Devy, 2012; Pallant, 2007; Corder & Foreman, 2009).

Ideally a good representation of the population was needed in order to give a firm basis for the study, as well as making statistical analysis simpler. However, this proved to be difficult as participants were not assigned to two groups, such as Group A and Group B, but rather given participant numbers and therefore it was difficult to split participants with similar demographics equally between the active and placebo groups. Once the participant allocation was unblinded at the conclusion of the study, participants who received the Hepatitis B 12cH nosode were placed in the Active group and participants who received the placebo were placed in the Placebo group. This was done so that statistical analysis was simpler.

It was hypothesised that the participants in the Verum group would undergo seroconversion, under the influence of Hepatitis B 12cH, to produce anti-HBs which would be measurable in the serum taken from participants at the end of the study. The null hypothesis was that participants would not produce anti-HBs in response to Hepatitis B 12ch and thus have negative serum results at the end of the trial.

4.2 Patient Health
At their commencement in the study, participants had their vital signs taken and an abdominal exam performed (Table 4.1). The vital signs included blood pressure, pulse rate, breathing rate and oral temperature. None of the participants presented with vitals readings outside of the normal ranges.
Table 4.1 Participant Vital Signs at Commencement of Study

<table>
<thead>
<tr>
<th>Participant Number</th>
<th>Pulse Rate</th>
<th>Respiratory Rate</th>
<th>Temperature</th>
<th>Blood Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>32</td>
<td>16</td>
<td>36</td>
<td>122/80</td>
</tr>
<tr>
<td>2</td>
<td>60</td>
<td>24</td>
<td>36.4</td>
<td>132/80</td>
</tr>
<tr>
<td>3</td>
<td>68</td>
<td>20</td>
<td>36.4</td>
<td>131/82</td>
</tr>
<tr>
<td>4</td>
<td>88</td>
<td>24</td>
<td>36.4</td>
<td>110/80</td>
</tr>
<tr>
<td>5</td>
<td>80</td>
<td>20</td>
<td>35.4</td>
<td>116/80</td>
</tr>
<tr>
<td>6</td>
<td>80</td>
<td>24</td>
<td>36</td>
<td>120/80</td>
</tr>
<tr>
<td>7</td>
<td>80</td>
<td>20</td>
<td>36</td>
<td>140/100</td>
</tr>
<tr>
<td>8</td>
<td>80</td>
<td>20</td>
<td>36.4</td>
<td>118/90</td>
</tr>
<tr>
<td>9</td>
<td>72</td>
<td>28</td>
<td>36.4</td>
<td>120/79</td>
</tr>
<tr>
<td>10</td>
<td>80</td>
<td>20</td>
<td>36.4</td>
<td>130/80</td>
</tr>
<tr>
<td>11</td>
<td>96</td>
<td>20</td>
<td>36.4</td>
<td>120/100</td>
</tr>
<tr>
<td>12</td>
<td>80</td>
<td>20</td>
<td>36.4</td>
<td>110/80</td>
</tr>
<tr>
<td>13</td>
<td>88</td>
<td>20</td>
<td>36.4</td>
<td>110/70</td>
</tr>
<tr>
<td>14</td>
<td>80</td>
<td>24</td>
<td>37</td>
<td>120/80</td>
</tr>
<tr>
<td>15</td>
<td>80</td>
<td>24</td>
<td>36.7</td>
<td>120/80</td>
</tr>
<tr>
<td>16</td>
<td>80</td>
<td>24</td>
<td>36.7</td>
<td>160/100</td>
</tr>
<tr>
<td>17</td>
<td>80</td>
<td>20</td>
<td>36.4</td>
<td>120/80</td>
</tr>
<tr>
<td>18</td>
<td>84</td>
<td>22</td>
<td>36.7</td>
<td>130/90</td>
</tr>
<tr>
<td>19</td>
<td>80</td>
<td>24</td>
<td>36.4</td>
<td>120/80</td>
</tr>
<tr>
<td>20</td>
<td>80</td>
<td>20</td>
<td>36.7</td>
<td>122/80</td>
</tr>
<tr>
<td>21</td>
<td>80</td>
<td>20</td>
<td>36.7</td>
<td>110/80</td>
</tr>
<tr>
<td>22</td>
<td>80</td>
<td>20</td>
<td>36.7</td>
<td>110/60</td>
</tr>
<tr>
<td>23</td>
<td>80</td>
<td>20</td>
<td>36.7</td>
<td>100/70</td>
</tr>
<tr>
<td>24</td>
<td>80</td>
<td>20</td>
<td>36.4</td>
<td>122/80</td>
</tr>
<tr>
<td>25</td>
<td>80</td>
<td>20</td>
<td>36.7</td>
<td>120/80</td>
</tr>
<tr>
<td>26</td>
<td>78</td>
<td>18</td>
<td>36.7</td>
<td>110/70</td>
</tr>
<tr>
<td>28</td>
<td>80</td>
<td>20</td>
<td>36.7</td>
<td>117/70</td>
</tr>
<tr>
<td>29</td>
<td>74</td>
<td>18</td>
<td>36.7</td>
<td>100/60</td>
</tr>
<tr>
<td>35</td>
<td>80</td>
<td>18</td>
<td>36.7</td>
<td>129/80</td>
</tr>
<tr>
<td>36</td>
<td>80</td>
<td>21</td>
<td>36.5</td>
<td>110/70</td>
</tr>
<tr>
<td>37</td>
<td>80</td>
<td>20</td>
<td>36.5</td>
<td>110/70</td>
</tr>
<tr>
<td>43</td>
<td>70</td>
<td>18</td>
<td>36.7</td>
<td>120/80</td>
</tr>
<tr>
<td>44</td>
<td>80</td>
<td>20</td>
<td>36.7</td>
<td>120/80</td>
</tr>
<tr>
<td>45</td>
<td>78</td>
<td>18</td>
<td>36.7</td>
<td>120/80</td>
</tr>
<tr>
<td>46</td>
<td>80</td>
<td>20</td>
<td>36.6</td>
<td>110/60</td>
</tr>
<tr>
<td>47</td>
<td>80</td>
<td>20</td>
<td>36.7</td>
<td>110/60</td>
</tr>
<tr>
<td>48</td>
<td>80</td>
<td>20</td>
<td>36.7</td>
<td>120/80</td>
</tr>
<tr>
<td>51</td>
<td>80</td>
<td>20</td>
<td>36.7</td>
<td>120/80</td>
</tr>
<tr>
<td>53</td>
<td>80</td>
<td>19</td>
<td>36.5</td>
<td>110/70</td>
</tr>
<tr>
<td>54</td>
<td>70</td>
<td>20</td>
<td>36.7</td>
<td>100/70</td>
</tr>
<tr>
<td>55</td>
<td>80</td>
<td>20</td>
<td>36.7</td>
<td>123/83</td>
</tr>
<tr>
<td>56</td>
<td>80</td>
<td>20</td>
<td>36.7</td>
<td>120/80</td>
</tr>
<tr>
<td>57</td>
<td>80</td>
<td>20</td>
<td>36.8</td>
<td>110/70</td>
</tr>
<tr>
<td>58</td>
<td>76</td>
<td>18</td>
<td>36.7</td>
<td>90/80</td>
</tr>
<tr>
<td>60</td>
<td>80</td>
<td>21</td>
<td>36.7</td>
<td>118/70</td>
</tr>
</tbody>
</table>
4.3 Demographic Studies

4.3.1 Gender
Gender comparisons between the Verum and Placebo group (Table 4.2) showed that there was an even distribution of male and females within the groups (p=0.897).

Table 4.2 A Cross Tabulation of Gender Comparison between Verum and Placebo Groups

<table>
<thead>
<tr>
<th>Gender</th>
<th>Group</th>
<th>Placebo</th>
<th>Verum</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>Count</td>
<td>9</td>
<td>9</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>% within group Placebo or Active</td>
<td>40.9%</td>
<td>42.9%</td>
<td>41.9%</td>
</tr>
<tr>
<td>Female</td>
<td>Count</td>
<td>13</td>
<td>12</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>% within group Placebo or Active</td>
<td>59.1%</td>
<td>57.1%</td>
<td>58.1%</td>
</tr>
<tr>
<td>Total</td>
<td>Count</td>
<td>22</td>
<td>21</td>
<td>43</td>
</tr>
<tr>
<td></td>
<td>% within group Placebo or Active</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

4.3.2. Age
The average age of the participants in the Placebo group was 40.73 years whereas the average age of the participants in the Verum group was 42.24 years (Table 4.3). It was found that the age distribution between the groups was even (p=0.65).

Table 4.3 T-Test for Age Comparison and Average between Verum and Placebo Groups

<table>
<thead>
<tr>
<th>Group Placebo or Verum</th>
<th>N</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age Agee</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Placebo</td>
<td>22</td>
<td>40.73</td>
<td>13.382</td>
<td>2.853</td>
</tr>
<tr>
<td>Active</td>
<td>21</td>
<td>42.24</td>
<td>13.597</td>
<td>2.967</td>
</tr>
</tbody>
</table>

4.4 Results
A score of zero was given to participants that had a negative serum test result thus indicating that they had no antibody to the surface antigen of Hepatitis B (Anti-HBs). A score of one was given to participants who had a positive blood result indicating that their serum had Anti-HBs present in it and consequently providing them with immunity to Hepatitis B.
On commencing the study all participants from both Placebo and Verum Groups had no antibody to the surface antigen thus giving them a score of zero (Table 4.4)

**Table 4.4 Results of Serum Antibody Testing for Active and Placebo Groups**

<table>
<thead>
<tr>
<th>VERUM GROUP</th>
<th>Participant Numbers</th>
<th>Presence of anti-HBs in Serum at Start of Trial</th>
<th>Presence of anti-HBs in Serum at End of Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>7 9 11 13 18 22 23 24 25 28 30 31 37 39 44 46 51 54 58 59 60</td>
<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PLACEBO GROUP</th>
<th>Participant Numbers</th>
<th>Presence of anti-HBs in Serum at Start of Trial</th>
<th>Presence of anti-HBs in Serum at End of Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 2 4 5 10 12 14 15 16 19 21 29 32 35 36 40 43 47 48 52 53 56 57</td>
<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
</tr>
</tbody>
</table>

Due to the negative blood results at the end of the study, all participants from both Active and Placebo groups were given a score of zero (Table 4.5). However since this dependant variable became a constant no comparison could be made and thus the p-value is 1.

**Table 4.5 Frequencies and P-Value of Sign Test**

<table>
<thead>
<tr>
<th>Frequencies</th>
<th>Test Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Result at End</strong></td>
<td><strong>Result at End</strong></td>
</tr>
<tr>
<td><strong>– Result at Start</strong></td>
<td><strong>Result at End – Result at Start</strong></td>
</tr>
<tr>
<td><strong>Negative Differences</strong></td>
<td><strong>Asymp. Sig. (2-tailed)</strong></td>
</tr>
<tr>
<td><strong>Positive Differences</strong></td>
<td><strong>1.000</strong></td>
</tr>
<tr>
<td><strong>Ties</strong></td>
<td><strong>a. Sign Test</strong></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>p=1</strong></td>
</tr>
</tbody>
</table>

In conclusion, it must be observed that there is no evidence against the null hypothesis, thus making the null hypothesis previously stated true (p-value = 1).
CHAPTER FIVE
DISCUSSION

5.1 Introduction

This research study was undertaken to determine what effect *Hepatitis B 12cH* nosode had on the production of the antibody to the surface antigen of Hepatitis B when given in vitro.

Sixty participants, aged between 18 to 65 years of age were interviewed for the study. Of these initially interviewed, 4 did not meet the inclusion criteria and were thus excluded from the study. 56 participants were included in the study from 3 locations: The University of Johannesburg (n = 11), Dimension Data’s The Campus in Bryanston (n = 33) and Linden Presbyterian Church (n = 12). 45 participants completed the study while 13 participants failed to complete the study. Of those who did not complete the study, 2 participants failed to complete their medication schedule while the remaining 9 withdrew from the study after the initial blood tests. Reasons for withdrawal included lack of clarity over what the blood would exclusively be used for, that was not mitigated by explanation of the discarding of the blood by the researcher once tested

5.2 Demographic Studies

Comparison of the distribution of gender between Verum and Placebo groups shows that there was no significant difference in proportion between the two groups. There was an equal number of men (Placebo: n=9, Verum: n=9) in each group, and a near equal split between the female participants (Placebo: n = 13, Verum: n = 12).

The average age of participants in the placebo group was 40.73 years while in the Active group it was 42.24 years of age. This meant that there was no significant difference in average age between the two groups. The higher average age, when considering the target age range, may be explained by the fact that the younger potential participants had received the Hepatitis B vaccine in high school or in university; and the EPI adding the Hepatitis B vaccine into the immunization schedule in 1995.
5.3 Physical Examination and Vital Signs

After obtaining informed consent, all participants underwent a physical examination. During this examination the following vital signs were assessed: pulse rate, respiratory rate, temperature, and blood pressure. A deviation of any of these from the normal ranges would have resulted in participants no longer being eligible for inclusion into the study. An abdominal examination was also performed in order to assess if there was any palpable changes to the liver, which would also have excluded participants from the study.

5.4 Adverse Events and Side Effects

Participants were encouraged to report any side effects that they may have experienced during the period in which they were taking the research medication. Only one participant reported any unusual symptoms during the study. They experienced an increase in physical energy, however this participant was later found to be part of the placebo group.

5.5 Critical Analysis

5.5.1 Preventative Medicine

Prophylactic medication is defined as initiating ‘measures to protect a person from attack of a disease’ to which ‘they have a reasonable chance of being exposed’ (Stegman, 2008).

Preventive medicine is divided in four different stages (Kuehlein et al., 2010):

- Primary prevention
  - No disease yet exists in the body, but medical intervention like vaccinations and lifestyle changes are used in order to prevent any from occurring in the future.

- Secondary prevention
  - A definable disease has been diagnosed, such as hypertension. Here the goal is to prevent this disease from escalating to a more serious condition like myocardial infarction. These preventive measures can include lifestyle changes and medication.
Tertiary prevention

- The risk factors have now increased to the degree where the primary disease has developed into a more serious form. The risk factors now need to be addressed, eliminated and prevented from occurring again in the future.

Quaternary prevention

- The patient is suffering from unexplainable symptoms without being diagnosed with a definitive disease. Causes could include psychosomatic illness or a last resort diagnosis like fibromyalgia, where all other explanations have been exhausted.

Primary prevention is increasing in popularity. Medical Schemes in South Africa offer better rates for their customers who actively participate in primary prevention (Discovery, 2013). Primary prevention strategies may include, amongst others:

- attending a gym on a regular basis;
- radiographic mammograms to detect breast cancer at early stages;
- annual prostate examination for the early detection of prostate cancer;
- attending gynaecologist for a sexual health screening;
- blood pressure and cholesterol monitoring in order to prevent atherosclerosis;
- joining a weight loss support group to prevent obesity and the diseases that occur alongside it;
- smoking cessation and counselling to prevent lung cancer;
- glucose monitoring to detect adult-onset diabetes;
- and annual influenza vaccinations. It has even found its way into everyday life in the form of fluoride in toothpaste and drinking water, which prevents the cariogenic bacteria from creating dental caries and increases the recovery of lost tooth enamel (Kohn et al., 2001).

Preventive medicine has become an important focus in the modern medical practice, be it conventional or alternative therapies. However, in the conventional GP practice it isn’t always feasible for doctors to dedicate the time needed to conduct the relevant screening and counselling (Yarnall et al., 2003). Other barriers to preventive medicine included patient ignorance to the benefits of prevention, cost of the services, lack of physician knowledge, physician attitude and poor record keeping (Susman, 2002). It was found that single interventions, such as vaccination, were far more effective than multiple modalities. Alternative therapies, like homeopathy, are far more attuned to primary preventive medicine based on its principles and the practitioners time spent with the patient.
5.5.2 Expanded Programme on Immunisation (EPI) in South Africa

The expanded programme on immunisation (EPI) set out the guidelines for a vaccination schedule country wide (Figure 5.2.2) (Department of Health, 2009).

**Figure 5.5.2 Revised EPI for South Africa (Department of Health, 2009)**

The South African Department of Health introduced the Hepatitis B vaccination into the EPI in 1995 (Burnett et al., 2012). Infants receive the vaccine at 6 weeks, 10 weeks and 14 weeks. Infant infections for Hepatitis B generally occur before 5 years of age due to vertical transmission from mother to child. After that, infections generally occur through sexual contact or from exposure to infected blood products. It is therefore recommended that the following individuals also receive the Hepatitis B vaccination (Immunization Action Coalition 2007; White, 2001), if they have not already, or update their booster shots:

- Healthcare workers;
• Intravenous drug users;
• Sexual partners of infected individuals;
• Persons residing with infected individuals;
• Persons receiving treatment for a sexually transmitted disease;
• Infants born to infected mothers;
• Persons residing in high risk area;
• Persons travelling to high risk areas;
• Persons receiving haemodialysis;
• Persons with chronic liver disease; and
• Persons with HIV

5.5.3 Vaccination
Almost everyone, globally, receives at least one vaccine in their life time. Vaccinations actually work using the immune system’s humoral response to antigens. By introducing a small amount of antigen into the blood stream, the antigen is ingested and broken down by presenting cells like macrophages (Miller, 2000; Janeway et al., 2001). Once broken down into peptides, the antigen can be presented to the T-lymphocytes, who in turn secrete autocrines. These autocrines then activate T-helper cells, also known as CD4 cells. The T-helper cells then activate the B-lymphocytes to produce antibodies. B-lymphocytes can go onto to differentiate into plasma cells, which produce large amount of antibodies to eliminate an infection, and memory cells which store the antibodies against specific antigens (Playfair, 2006).

Vaccination protocols have been a major contributing factor in the decrease in the incidence of infectious diseases (Ed. Jamison et al., 2009). Since the time of Edward Jenner and his smallpox vaccine (Riedel, 2005) immunisation has become ever popular in the medical community. However, in recent years, anti-vaccination information has gained popularity in the media. The internet is a fertile ground for anyone with a theory to share and for anyone looking for reasons not to vaccinate. The theories and arguments against vaccination range from conspiracy theories about regulating bodies covering up the true side effects, to the elimination of freedom of choice by schools forcing vaccinations on students (Kata, 2010).
Vaccinations are simple, quick to administer and their efficacy is assured by many clinical trials. Even though vaccines have been around for decades, advances in modern medicine has seen their further development (Andre et al., 2008).

5.5.3.1 Pertussis Vaccination
Pertussis vaccination has had great success in reducing the incidence of whooping cough. A new acellular pertussis vaccine, introduced in 1997, replaced the whole cell vaccine as it was thought to have better efficacy. Vickers et al. (2006) compared the whole cell vaccine to the acellular vaccine by comparing data collected between 1995 and 2005. Their results showed that the acellular vaccine may not be as effective in the long term prevention of whooping cough, especially in children under the age of five. It does however have fewer adverse events associated with it compared to the whole cell vaccine. The decline in efficacy may not be solely due to the change in vaccine components. A change in the antigen, as a result of immunization, could be the cause of the increase in whooping cough incidence.

5.5.3.2 Streptoccus pneumoniae Vaccine
Streptococcus pneumoniae has gained new prevalence, mainly due to lowered immune systems caused by HIV. The polysaccharide pneumococcal vaccine is given to adults who are at risk of developing pneumococcal disease. However there have been conflicting results in clinical trials on the efficacy of this vaccine. A meta-analysis of 22 trials revealed that the introduction of the polysaccharide vaccine was based more on observational studies rather than on clinical trials. Although the polysaccharide vaccine has some efficacy there needs to be more research, particularly clinical trials, on the long-term effects and the cost-effectiveness of this inadequate vaccine (Huss et al., 2009).

5.5.3.3 Human Papilloma Virus (HPV) Vaccine
The latest vaccine to be added to the schedule is the HPV (human papilloma virus) vaccine. HPV is one of the leading causes of cervical cancer, primarily found in women in their 30s. A systemic review of 9 randomised control trials, narrowed down from 457, were analysed to find the effects of the vaccine on women who received it. The analysis showed the vaccination reduced the incidence of “high-grade cervical lesions” when compared to the control groups. By decreasing the prevalence of the cell
changes caused by these lesions, the risk of cancer may also decrease (Rambout et al., 2007).

5.5.3.4 *Escherichia Coli* Vaccine

While travelling, it is often recommended that sources of *Escherichia coli* contamination, such as tap water, be avoided particularly in countries like India, Mexico and the Philippines. However this isn’t always possible but the introduction of a vaccination against the organisms, like *E.coli i*, that cause traveller’s diarrhoea, seems to be a good solution. The most common vaccine of this type is the whole cell/recombinant B subunit oral vaccine. It acts on the mucosa-secreted IgA immunological response, rather than B-cells, to initiate inflammatory responses. The vaccine contains colonization factors (C56) and heat-labile toxin (LT) which causes the mucosa in the intestinal system to produce antibodies. Studies showed that participants who received the vaccines containing C56 only experienced a 68% immune response compared to the participants who received a mixture of LT and C56 who had a 100% immune response (Steffan et al., 2005).

5.5.3.5 Measles, Mumps, and Rubella (MMR) Vaccine Controversy

In 1998, Wakefield et al. presented a study in which they concluded that there was a link between the MMR (measles, mumps and rubella) vaccination and the development of autism. However, the study only consisted of 12 children, of which only 8 children had any symptoms develop after receiving the MMR vaccine. Following this, several studies were conduct in order to confirm or disprove the results. Smeeth et al. (2004) matched case control studies of pervasive developmental disorders, including autism, pulled from the UK General Practice Research Database using age, sex and general practices. 1294 cases and 4469 controls where included in the analysis. When the cases and controls where analysed it was concluded that there was no link between the development of a pervasive developmental disorder, like autism, and receiving the MMR vaccine. Lancet, the original journal in which the Wakefield study was published, was forced to print a partial retraction of the study (Editors of Lancet Retraction, 2010).

5.5.4 Homeoprophylaxis

Homeopathic medication is often used to prevent various diseases, like headaches and asthma, and infectious epidemics, also known as homeoprophylaxis. Samuel Hahnemann, the father of homeopathy, first discovered that homeopathic remedies
could be used to protect against disease (Dudgeon, 2004). He found that Atropa belladonna, commonly known as deadly nightshade, normally used to treat Scarlet fever could also be used to prevent it. During an outbreak of the disease during 1801 in Germany, he successfully treated many affected individuals. He then went on to use the remedy as prophylactic treatment against the disease, saying “this preventative remedy never fails”. Kent (2004) agreed with Hahnemann concerning the choice of preventive remedies. He agreed that the remedy used as prophylactic treatment should also cure the disease. Many studies have been conducted in order to establish the validity of the prophylactic effects of these medications.

5.5.4.1 Application
Sixty three migraine sufferers, with or without aura, were included in a randomised double blind placebo trial to determine the efficacy of homeopathic remedies on the prophylaxis of migraine. All participants were placed in the placebo group for the first month, during which there were 3 participants who exited the study. Participants were then placed on homeopathic treatment, individualised according to their symptoms. The study concluded that the treatment reduced the number of moderate to severe attacks but that there was a reduction on mild attacks on both placebo and treatment. The overall conclusion was that there was no significant difference between homeopathic treatment and placebo but it could not conclude that the homeopathic treatment was without effect (Whitmash et al., 1997).

Heal-Well VT6® is a homeopathic complex containing Phytolacca decandra, Calcaera fluorica, Silica, Atropa belladonna, Bryonia alba, Arnica montana, Conium and Ipecachuana. This preparation was used to treat 96 dairy cows with clinical mastitis. 67 cows had non-fibrosed mastitis and 29 cows had fibrosed mastitis. This group was compared to a group containing 96 cows, all with non-fibrosed mastitis, that were treated with antibiotics. The study found that the antibiotically treated cows showed a 59.2% recovery rate compared to the homoeopathically treated cows that had an 86.6% recovery rate. However the homoeopathically treated cows had a longer recovery period than those treated with antibiotics (Varshney and Naresh, 2005).

Karazn et al. (2011) used a complex prepared from Staphylococcus aureus and Streptococcus dysgalactiae in order to prevent subclinical mastitis in dairy cows. Three hundred lactating cows were randomly assigned to Group A (160) and Group B (140).
They were pulled from a population of cows in Tehran. All animals showed no signs of clinical mastitis, had California mastitis test less than 1 and somatic cell counts less than $10^5/ml$. Group A received 5 mls of the homeopathic complex daily, while Group B received 5 mls of water daily by mouth. Milk samples were taken on day 0, 21, and 28. Milk tests conducted on days 21 and 28 showed significant decreases in *Streptococcus* and *Staphylococcus* levels in Group A when compared to Group B. It was concluded that the homeopathic preparation was effective in the prevention of clinical mastitis with the added benefit that there were no residue of medication left in the milk.

*Poumon histamine* complex is obtained from the lung extract of a guinea pigs killed by anaphylactic shock. This complex was used in a trial that enlisted 182 children, aged 2-8 years, with asthmatic conditions such as 3 or more asthma attacks; or a family history of asthma. Before receiving the treatment, both the placebo and treatment groups had an incidence of asthma 1.68 times per month. This dropped to 0.39 times in the treatment group whereas the control group incidence remained the same (Boucinhas and de Madeiros, 1990).

Nosodes are homeopathic remedies made from diluted and potentised diseased tissues. Boenninghausen was the earliest homeopath to use nosodes as a way to prevent diseases (Little, 2007). He used *Variolinum* to prevent smallpox and is reported as saying, “Variolinum 200th is far superior to the crude vaccination and is absolutely safe’. Dr Wheeler, an eminent homeopath of his time, together with Dr Bach wrote ‘Chronic Disease’. He stated that ‘in epidemics the corresponding nosode in the 30th potency will protect for two weeks’ (Little, 2007).

Individualised electronically-stored nosodes, made from the tooth and joints of patients, were used to treat subjects who had a rheumatic degenerative disease. 42 participants were recruited, 21 in the placebo group and 21 in the verum group. T40 values were obtained by electropuncture, or the amount of deviation from the standard reading of the 40 electropuncture points. After treatment, the verum group showed that the T40 readings improved toward the mean. The placebo group showed improvement but not improvement that was statiscally significant. The study showed that individually prepared nosodes could improve readings in individuals with degenerative rheumatic diseases (Schuller, 2010).
Helicobacter pylori is classified as the primary cause of gastric carcinoma and is prevalent in individuals who suffer with gastric ulceration. Gosavi et al. (2012) used six groups of rats, with 8 individuals in each. Group one contained non-infected and non-ulcerated rats which were given 2 mls/kg of distilled water per day. The remaining five groups consisted of infected and ulcerated individuals. Group two were given 2mls/kg of distilled water per day, and these acted as the placebo group. Group three were given the standard conventional treatment of Clarithromycin (25mg/kg per day), Amoxicillin (50mg/kg per day) and Omeprazole (20mg/kg per day). Group four received H. pylori 3X 2mg/kg daily for 4 weeks. Group five received H.pylori 6X 2mg/kg for 4 weeks. Group six received H. pylori 12X 2mg/kg for 4 weeks. The study looked at several parameters, such as ulceration area, inflammation, TNF markers, and bacterial load. It was concluded that the H. pylori homeopathic potencies showed a decrease in ulceration and initiated infection resistance in the homoeopathically treated groups, without the side effects caused by conventional remedies.

Bracho et al. (2010) conducted a study using Leptospirosis 200cH and Leptospirosis 1M as prophylactic treatment against the water-borne bacterium of the same name. The infection caused by this bacterium becomes epidemic during a season of high rainfall. The Cuban government only had enough conventional vaccine for 0.6% of their population, but the homeoprophylaxis showed significant results in the prevention of the disease. However, the study came under some attack by critics who claimed the decrease in infection rate seen after the administration of the homeopathic remedies was actually caused by the decrease in rainfall that directly followed (Lipson, 2010).

The validity of the use of nosodes using antibody testing has not been explored in great detail.

In 1932, Patterson and Boyd used Schick testing to demonstrate diphtheria antibodies in children treated with Diphtherium (Hoover, 2006). They treated 45 children, all who became Schick test negative which showed that they had produced antibodies to diphtheria. They repeated the test in 1941 on 33 children, 20 of whom became Shick test negative.

Smits conducted antibody testing in ten children who were given DTP (diphtheria, Tetanus and Polio vaccine) in 30cH and 200cH. Their antibody levels were tested
before the remedy and one month after receiving the remedy. He found no rise in antibody levels in these children (Neustaedter, 2002). However it can be argued that the treatment group was too small to argue statistically significance.

Homeoprophylaxis has show great short-term effectiveness in the prevention of disease, especially during epidemics. However, none of the clinical trials mentioned conducted antibody testing in order to show that there had been a long-lasting immune response. It is still unclear whether nosodes will provide the same long-term protection as that given by a vaccine.

5.6 Conclusion
The results of certain research studies have shown homeoprophylaxis to have been successful in the prevention of particular diseases, both infectious and non-infectious, with the results of some studies potentially demonstrating greater efficacy than conventional treatment. It has been hypothesised that in order for homoeoprophylaxis to stand as a valid means of prophylaxis, its biochemical explanation would have to be similar to vaccination, i.e.: creating a measurable antibody response. Like the study of Smits (Neustaedter, 2002), this study demonstrated no rise in antibody levels in any of the participants over a four week period. When considering similar results from other studies (Neustaedter, 2002; Hoover, 2006) it can be concluded that homeopathic nosodes appear to not have a similar mechanism to that of vaccines.

The mechanism behind homeoprophylaxis is still poorly understood and some research studies into the subject have been criticised. When considering the studies with positive effect it appears there still exists potential for more evidence-based studies to be conducted into the effects, both long and short-term, as well as the mechanisms of homeoprophylaxis.
CHAPTER SIX
CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

The aim of the study was to determine if Hepatitis B 12cH had any measurable effect on the antibody to the surface antigen of hepatitis B (anti-HBs). As a means to demonstrate whether the mechanism of action of homoeoprophylaxis would be similar to vaccination, it was hypothesised that one powder of Hepatitis B 12cH administered once weekly for 4 weeks would induce a measurable rise in the antibodies to the surface antigen of hepatitis B (anti-HBs), thus showing a acquired immunity to Hepatitis B.

The results of the serum antibody testing showed that of 31 participants who received active medication (n = 0) had any measurable rise in anti-Hbs levels. Although this study was conducted on a small scale, the failure to elicit a single antibody response during the study would suggest that the underlying mechanism of homeopathic nosodes, if indeed present, is not similar to the antibody response elicited of vaccination.

Despite numerous studies using homeopathic remedies as prophylactic treatment having been undertaken, the number of positive effects may warrant further evidence-based research into homeoprophylaxis and its mechanisms of action. Unless another measurable theory suggestive of its prophylactic mechanism of action is offered, any further positive claims related to homeoprophylaxis would need to be supported by measurable factors or large scale observational studies.

6.2 Recommendations

For further research into homeopathic nosodes and their efficacy as prophylactic treatment the following recommendations could be made:

- The use of a lower potency, such as a 6cH or lower, when administering nosodes could provide different results.
- Along with lower potency, increasing the frequency over a longer period of time may render a positive result.
The use of a higher potency, such as a 200c, as this potency showed efficacy in the prevention of epidemic in previous research studies.

- As alcohol is a more stable than lactose it should be considered as the vehicle medication administration.
- Various forms of haematological testing to verify any results should be used.
- The consideration of the use of a larger sample group may impact the statistical validity of any particular findings and should be considered.
REFERENCES


# APPENDIX A

## INTERPRETATION OF HEPATITIS B SERUM TESTS

<table>
<thead>
<tr>
<th>Tests</th>
<th>Results</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hepatitis B surface antigen (HBsAg)</td>
<td>Negative</td>
<td>No immunity to Hepatitis B</td>
</tr>
<tr>
<td>2. Antibody to the Hepatitis B core antigen (anti-HBcAg)</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>3. Antibody to the Hepatitis B surface antigen (anti-HBsAg)</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>1. Hepatitis B surface antigen (HBsAg)</td>
<td>Negative</td>
<td>Immunity to Hepatitis B through previous infection.</td>
</tr>
<tr>
<td>2. Antibody to the Hepatitis B core antigen (anti-HBcAg)</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td>3. Antibody to the Hepatitis B surface antigen (anti-HBsAg)</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td>1. Hepatitis B surface antigen (HBsAg)</td>
<td>Negative</td>
<td>Immunity to Hepatitis B through vaccination.</td>
</tr>
<tr>
<td>2. Antibody to the Hepatitis B core antigen (anti-HBcAg)</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>3. Antibody to the Hepatitis B surface antigen (anti-HBsAg)</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td>1. Hepatitis B surface antigen (HBsAg)</td>
<td>Positive</td>
<td>Acute current infection of Hepatitis B.</td>
</tr>
<tr>
<td>2. Antibody to Hepatitis B core antigen (anti-HBcAg)</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td>3. IgM antibodies to Hepatitis B</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>4. Antibody to the Hepatitis B surface antigen (anti-HBsAg)</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>1. Hepatitis B surface antigen (HBsAg)</td>
<td>Positive</td>
<td>Chronic infection of Hepatitis B.</td>
</tr>
<tr>
<td>2. Antibody to Hepatitis B core antigen (anti-HBcAg)</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td>3. IgM antibodies to Hepatitis B</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>4. Antibody to the Hepatitis B surface antigen (anti-HBsAg)</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>1. Hepatitis B surface antigen (HBsAg)</td>
<td>Negative</td>
<td>1. Recovery from Hepatitis B infection</td>
</tr>
<tr>
<td>2. Antibody to the Hepatitis B core antigen (anti-HBcAg)</td>
<td>Positive</td>
<td>2. Immunity not sensitive enough for test</td>
</tr>
<tr>
<td>3. Antibody to the Hepatitis B surface antigen (anti-HBsAg)</td>
<td>Negative</td>
<td>3. False positive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Chronic Infection but low levels of hepatitis B surface antigen</td>
</tr>
</tbody>
</table>
APPENDIX B
PROCEDURE FOR HEPATITIS B SERUM TESTING

One Step Cassette Style Anti-HBs Serum/Plasma Test

INTRODUCTION
The One Step Cassette Style Anti-HBs Test is a rapid, direct binding test for the visual detection of antibodies to hepatitis B surface antigen (Anti-HBs) in serum/plasma. It is used as an aid in the diagnosis of hepatitis B infection. The One Step Anti-HBs Test is based on the principle of sandwich immunocassette for determination of Anti-HBs in serum/plasma. Purified recombinant antigens are employed to identify Anti-HBs specifically. This one test is very sensitive and only takes 10-20 minutes. Test results are read visually without any instrument.

SPECIMEN COLLECTION & PREPARATION
Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolized specimens.

If the specimen cannot be tested on the day of collection, store the specimen in a refrigerator or freezer. Stir and bring the specimen to room temperature before testing. Do not freeze and thaw the specimen repeatedly.

TEST PROCEDURE
1. When you are ready to begin testing, remove the test device from its protective pouch. Once the test kit is taken out from the pouch, use it as soon as possible.
2. Label the device with patient or control identifications.
3. Add 4 drops (~120 µL) of specimen into the sample well by using the pipettes provided. For each sample or control, use a separate pipette and device.
4. Wait 10-20 minutes and read results. It is important that the background is clear before the result is read. And do not read results after 30 minutes.

PRECAUTION
1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.
4. Do not compare results from a different device.

5. Serum/plasma specimens may be infectious; ensure proper handling and disposal of all used reaction devices into a biohazard container.
6. Using a new specimen collection container and specimen pette for each sample to avoid cross-contamination of samples.

STORAGE AND STABILITY
The test kit can be stored at temperatures between 2 to 30°C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

INTERPRETATION OF RESULTS
- Negative: Only one colored band appears on the control region. No apparent band on the test region.
- Positive: In addition to a pink colored control band, a distinct pink colored band will also appear in the test region.
- Invalid: None of line appears or no line appears in the control (C) region. An invalid result may be due to improper testing procedures, or deterioration of the kit components. Repeat the assay sequence using a new device.

(2) (3) (4)

LIMITATIONS
1. Only test serum and plasma samples.
2. As with all diagnostic tests, all results must be considered with other clinical information available to the physician. A definite clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated.
3. This test is for in vitro diagnostic use only.
4. Interfering substance in the sample and technical error will affect the results; further testing is required.

(Labstic CC, 2006)
DO YOU KNOW IF YOU ARE PROTECTED AGAINST HEPATITIS B?

If you are unsure, come find out.

If you have not been vaccinated against Hepatitis B, then you may be eligible to take part in a homeopathic research trial on Hepatitis B 12ch nosode and Homeoprophylaxis.

For information please contact:

Sarah Caldwell

083-321-3910

Hepatitis.research@gmail.com
DO YOU KNOW IF YOU ARE PROTECTED AGAINST HEPATITIS B?

If you are unsure, come find out and you may be eligible for an exciting Homeopathic Study.

For more information please contact

Sarah Caldwell 084-362-8969
APPENDIX E
BROCHURE

Researcher Contact Details
SARAH CALDWELL
CELL: 084-362-8969
EMAIL: hepatitis.research@gmail.com

DO YOU KNOW IF YOU ARE IMMUNE TO HEPATITIS B?
Come find out and you could participate in a research project!

What is Hepatitis B and How Do I Become Immune?
Hepatitis B is an infectious disease that is acquired through infected blood or other body fluids and causes inflammation and swelling of the liver. The virus itself is surrounded by a surface protein that your body’s immune system can detect and form antibodies to in order to protect you from the infection. The antibodies to the surface protein are made when you have immunity or protection against hepatitis B, for example after you receive a vaccine.

What Is The Study About?
The research aim is to determine the production of the antibody to the surface antigen of hepatitis B (anti-HB) as a result of hepatitis B vaccine or having received the hepatitis B vaccine in previous three or more years.

What Will Happen During The Study?
It will consist of an initial consultation at which the researcher will help you complete the patient information and consent form. A general health survey and physical examination will be performed. A small quantity of your venous blood will be collected from a vein in your arm by a qualified nurse registered with the Nursing Council of South Africa. This will be tested for the presence of antibodies to the surface antigen (anti-HB). If the plasma test is positive, then you will be excluded from the trial as you have some immunity to hepatitis B. If none are present, you will be placed at random into either the placebo group or the experimental group. Neither the researcher nor the supervisor will know which participants are in the placebo group or the experimental group. Each participant will receive four loose powders that contain the medication and a medicine information leaflet. The placebo group will receive powders that have been medicated with plain ninety-six percent alcohol while the experimental group will receive powders medicated with the homoeopathic medicine hepatitis B 12x c.h.. Once the medication has finished, a blood sample will be collected and tested again.

Are There Side Effects?
There are no anticipated side effects from the medication, however, there may be some discomforts experienced during the collection of the blood samples.

Should I Be Vaccinated AFTER The Trial?
Once you have been released from the trial it is advised that you receive the vaccination.

Anything Else I Should Know?
If you choose to participate in this study you are free to withdraw at anytime as you are participating on a voluntary basis. All information supplied to the researcher is confidential and participant numbers rather than names will be used to protect your anonymity.

How Can I Take Part?
You are invited to take part in this study if you:
• Are between the ages of 18 and 65.
• Have never received the hepatitis B vaccine or have not received the hepatitis B vaccine in previous three or more years.
• You are negative for the antibody to the surface antigen of hepatitis B (anti-HB).
• Have no chronic diseases, like chronic medication or pregnancy.

How Long Will The Study Be?
The study will be approximately 7 weeks in length. It will be conducted at the University of Johannesburg Health Clinic in Johannesburg.

SARAH CALDWELL
CELL: 084-362-8969
EMAIL: hepatitis.research@gmail.com

UNIVERSITY
OF JOHANNESBURG
# APPENDIX F
PARTICIPANT HEALTH SURVEY AND CASE TAKING FORM

Date: ______________

<table>
<thead>
<tr>
<th>Participant Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>Occupation:</td>
</tr>
<tr>
<td>Marital Status:</td>
</tr>
<tr>
<td>Address:</td>
</tr>
<tr>
<td>Contact Number 1:</td>
</tr>
<tr>
<td>Contact Number 2:</td>
</tr>
</tbody>
</table>

**What is your general state of health?**

---

**Past Medical Health**

1. **Chronic Diseases**:

<table>
<thead>
<tr>
<th></th>
<th>Own</th>
<th>Maternal</th>
<th>Paternal</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Epilepsy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rheumatic Heart Disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tuberculosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart Disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Liver Disease</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. **Vaccinations**
### Vaccination

<table>
<thead>
<tr>
<th>Vaccination</th>
<th>Childhood</th>
<th>Adolescence</th>
<th>Adult</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis A</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. **Assessment of Hepatitis B Risk**

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are you sexually active? If yes do you use adequate protection?</td>
<td>Are you involved in a health care profession?</td>
</tr>
<tr>
<td>Do you make use of intravenous drugs?</td>
<td>Are you ever exposed to blood or body fluids?</td>
</tr>
<tr>
<td>Have you recently travelled or do you resided in a high risk area for Hepatitis B?</td>
<td></td>
</tr>
</tbody>
</table>

4. **Hepatitis Symptoms Currently**

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you had a loss of appetite recently?</td>
<td>Have you been experiencing bouts of nausea or vomiting recently?</td>
</tr>
<tr>
<td>Have you had a loss of weight recently?</td>
<td>Have you been experiencing fever: like sweating, feeling of warmth etc?</td>
</tr>
<tr>
<td>Do you currently have abdominal pain or discomfort?</td>
<td></td>
</tr>
</tbody>
</table>

5. **Medications**

6. **Hospitalizations and Operations**

7. **Childhood Diseases**
Social History

1. Diet

2. Smoking?

3. Alcohol?

4. Drugs?

5. Occupational Hazards?
## PHYSICAL EXAMINATION

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Pressure</td>
<td></td>
</tr>
<tr>
<td>Pulse Rate</td>
<td></td>
</tr>
<tr>
<td>Respiratory Rate</td>
<td></td>
</tr>
<tr>
<td>Temperature</td>
<td></td>
</tr>
</tbody>
</table>

## CAJCOLD

## Abdominal Examination
APPENDIX G
PARTICIPANT CONSENT AND INFORMATION FORM

Dear Participant

My name is Sarah Caldwell and I am currently working towards my Masters Degree in Homeopathy at the Faculty of Health Science at the University of Johannesburg.

The research aim is to determine the production of the antibody to the surface antigen of Hepatitis B (anti-HBs) as a result of Hepatitis B 12cH nosode use. Hepatitis B is an infectious disease that is acquired through infected blood or other body fluids and causes inflammation and swelling of the liver. The virus itself is surrounded by a surface protein that your body’s immune system can detect and form antibodies to in order to protect you from the infection. The antibodies to the surface protein are made when you have immunity or protection against Hepatitis B, for example after you receive a vaccine. Homeoprophylaxis is the use of a homeopathic remedy to induce immunity from disease. This study will try and elicit the above antibody response using a homeopathic medication.

You are invited to take part in this study if you are between the ages of 18 and 65, have never received the Hepatitis B vaccine or haven’t received the Hepatitis B vaccine in previous three or more years and you are negative for the antibody to the surface antigen of Hepatitis B (anti-HBs). You should not have any chronic disease, be on chronic medication or be pregnant.

The study will be approximately seven weeks in length. It will consist of an initial consultation at which the researcher will help you complete the patient information and consent form. A general health survey and physical examination will be performed. A small quantity of your venous blood will be collected from a vein in your arm by a qualified nurse registered with the Nursing Council of South Africa. This will be tested for the presence of the antibodies to the surface antigen (anti-HBs). If the plasma test is positive, then you will be excluded from the trial as you have some immunity to Hepatitis B. If none are present, you will be placed at random into either the placebo group or the experimental group. Neither the researcher nor the supervisor will know which participants are in the placebo group or the experimental group. Each participant will
receive four lactose powders that contain the medication and a medicine information leaflet. The placebo group will receive powders that have been medicated with plain ninety-six percent alcohol while the experimental group will receive powders medicated with the homeopathic nosode *Hepatitis B 200 cH*.

One powder is taken weekly, under the tongue twenty to thirty minutes before eating or drinking. On the day that the medication will be taken each participant will receive a SMS to indicate the time it should be taken. Once the medication has finished, a blood sample will be collected and tested again.

There are no anticipated side effects from the medication however there may be some discomfort experience during the collection of the blood samples.

If you have chosen to take part in the trial and you are employed in a high risk occupation, such as the health care sector, it is advised you should receive a full course of Hepatitis B vaccination.

Should you choose to participate in this study you are free to withdraw at anytime as you are participating on a voluntary basis.

All information supplied to the researcher is confidential and participant numbers rather than names will be used to protect your anonymity, every participant will receive a signed copy of the participant information and consent form. The contact details of the researcher and supervisor will be supplied to each participant and they can be contacted with any queries.

Your participation will help further the understanding of how homeopathic nosodes work.
I, _________________________ (The Participant Name) have been fully informed of all procedures of the study. I agree to the method of the study and understand that I am free to withdraw from the study at any time. I understand that the researcher will answer all my queries and that I am free to contact the supervisor of the study should I have further queries.

_________________________   ______________________________
Date       Signature

_________________________
Cell Number

I, Sarah Caldwell, as the researcher have fully explained the methods and purpose of the study. I will answer any questions that may arise during the study to the best of my ability.

_________________________   ______________________________
Date       Signature
APPENDIX H
PATIENT MEDICATION INFORMATION LEAFLET

**MEDICATION INFORMATION LEAFLET**

**Scheduling Status:** S0 (unscheduled)

**Dosage Form:** 30 Homeopathic Lactose Powders

**Directions for Use:**
- Take one powder in the morning weekly, under the tongue (sublingual)
- Take 20 – 30 minutes before eating and drinking
- Do not take with:
  - Food
  - Coffee
  - Tea
  - Juices
- Do not take before after brushing your teeth

**Contraindications:** None Known

**Interactions:** None Known

**Storage:**
- Keep out of direct sunlight
- Store below 25˚C
- Store away from strong smelling substances such as menthol, camphor, spices and coffee

KEEP OUT OF REACH OF CHILDREN