APPENDIX I: CASE RECORD FORM

Title of the Study: A Post Marketing Surveillance Study Of S-Amlodipine 2.5 Mg Drug Use Investigation (Switch 2.5).

Patient’s Initials: __________________________ Patient Number: __________________________

Patient’s Age: _________ years; Patient’s Gender: Male ☐ Female ☐

MEDICAL HISTORY:

Past History (Please Tick):

☐ Hypertension (Controlled), on Amlodipine ____ mg for ____ years _____ months

Personal History:

☐ Smoking / tobacco chewing

☐ Sedentary life style

Family History

☐ Hypertension

☐ Diabetes

☐ Dyslipidemia

☐ IHD

Other remarks (if any)
General & Clinical Examination

Weight: _____ kg

Height: ________ M

BMI: ___________

Treatment Administered:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablet:</td>
<td>S-amlodipine</td>
<td>Amlodipine</td>
</tr>
<tr>
<td></td>
<td>2.5mg</td>
<td>5mg</td>
</tr>
</tbody>
</table>

Other Concomitant Medications:

1. __________________________
2. __________________________
3. __________________________
4. __________________________

Office Blood Pressure Monitoring (Efficacy Evaluation)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline Visit (Visit 1)</th>
<th>After 4 weeks (Visit 2)</th>
<th>After 8 weeks (Visit 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td>_____ kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Height</td>
<td>________ M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td>__________</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Tick the relevant)</td>
<td>(Tick the relevant)</td>
<td>(Tick the relevant)</td>
</tr>
<tr>
<td>--------------------------</td>
<td>---------------------</td>
<td>---------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>SBP</td>
<td>mmHg</td>
<td>mmHg</td>
<td>mmHg</td>
</tr>
<tr>
<td>DBP</td>
<td>mmHg</td>
<td>mmHg</td>
<td>mmHg</td>
</tr>
<tr>
<td>Pulse</td>
<td>/min</td>
<td>/min</td>
<td>/min</td>
</tr>
<tr>
<td>Chest Pain</td>
<td>Nil</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>Diospnoea</td>
<td>Nil</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>Edema</td>
<td>Nil</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
</tbody>
</table>
SAFETY EVALUATION

Following are the keys to rating:

<table>
<thead>
<tr>
<th>ADVERSE EVENTS</th>
<th>Severity</th>
<th>Relation to the Drug (Tick Appropriate)</th>
<th>Action taken (Tick Appropriate)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
<td>Doubtful</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
<td>Doubtful</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
<td>Doubtful</td>
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<tr>
<td></td>
<td>Yes</td>
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<td>Doubtful</td>
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<td>Yes</td>
<td>No</td>
<td>Doubtful</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
<td>Doubtful</td>
</tr>
</tbody>
</table>

Severity: Mild +,
Moderate ++,
Severe +++

Action taken: [A] Same dose
[B] Dose reduced
[C] Drug discontinued
[D] Additional medication/ hospitalization required
Outcome (Tick Appropriate):  ☐ Recovered completely

☐ Recovered with sequelae

☐ Died

GLOBAL ASSESSMENT

Physician’s Assessment:  ☐ Very Good

☐ Good

☐ Fair

☐ Poor

Doctor’s comments (if any):

_____________________________________________________________________

_____________________________________________________________________

_____________________________________________________________________

_____________________________________________________________________

DATE:  DOCTOR’ STAMP & SIGNATURE
APPENDIX II: EC APPROVAL

ETHICLIN INDEPENDENT ETHICS COMMITTEE

This is to confirm that neither you nor any of your study team members were present during decision-making process for approval of the study proposal. All the 8 out of 11 members who reviewed the aforesaid documents gave favorable opinion and hence, committee pleased to grant approval for the conduct of the above mentioned reviewed clinical study subject to the following conditions:

1. You will conduct the clinical study in full compliance with all ethical requirements adhering to the Good Clinical Practice guidelines.

To,
Dr. Deepak B. Patel,
Director/Principal Investigator,
Sanjivani Hospital,
5 Aga Khan Road,
Sola Road, Ahmedabad,
Gujarat, India.

Re: Ethiclin-EC Approval

Subject: Approval of the study

Dear Dr. Patel,

We hereby certify that the protocol of the proposed study is approved by the Ethiclin-EC. Therefore, the study may proceed with the necessary modifications as per the guidelines to ensure the ethical conduct of the study.

The Ethiclin-EC would like to promptly notify in writing the following:
1. Clinical Study Protocol
2. Consent Forms
3. Case Report Form (CRF) for clinical study
4. Patient Information Sheet for clinical study
5. Informed Consent
6. Undertaking by Investigator

The following members of the Ethiclin Independent Ethics Committee were present at the meeting held on Sunday, September 18, 2011:

Member Secretary, Ethiclin IEC

1. Dr. Bhavesh Patel, Chairman
2. Dr. Parul B. Patel, Deputy Chairman
3. Dr. Deepak B. Patel
4. Ms. Rashmi Patel
5. Ms. Rupa Patel, Member Secretary
6. Dr. Vinay Dave, Scientist
7. Ms. Shambhata Patel, Social Scientist
8. Ms. Sunita Patel, Legal Expert

Member Secretary, Ethiclin IEC

Upp. 13, Marutideep Towers, Opp. C. P. Nagar, Ghatlodia, Ahmedabad 380001, Gujarat, India
Ph: 079-27440150, 151
E-mail: ethiclin@excelenza.in, ethiclin@excelenza.in, ethiclin@rediffmail.com

Upp. 13, MarutiDeep Towers, Opp. C. P. Nagar, Ghatlodia, Ahmedabad 380001, Gujarat, India
Ph: 079-27440150, 151
E-mail: ethiclin@excelenza.in, ethiclin@excelenza.in, ethiclin@rediffmail.com
I have been explained the possible risks and benefits and have understood the purpose for which my personal history are being sought by the Dept. of Pharmacy, J.J.T. University, Jhunjhunu, Rajasthan, India.

I will have the right to know the results of my data and I am not giving my consent for disclosure of any personal information either direct or derived from the analysis of my data to any one without my further consent.

Name of the Patient...................

Dated...........

Signature/Thumb impression

Name of the Investigator.............

Dated .............

Signature
APPENDIX IV: PUBLICATIONS

ARTICLE – 1

Obesity in India – The Omnipresent Influence

Bhargava Vyasa
Department of Pharmacy, Shri JIIT University, Vidyanagari, District Junghana, Rajasthan-333001.

ABSTRACT:
Obesity is an epidemic of the 21st century, and is a major causative factor for many other metabolic disorders. According to a global estimate by the World Health Organization (WHO), in 2005 there were about 1.6 billion overweight persons aged 15 years and above and among them at least 400 million adults were obese. The revision of definition of obesity to adjust for the racial differences, by the WHO, has resulted in a higher prevalence of 1.7 billion people classified as overweight. The WHO further projects that by 2015, approximately 2.3 billion adults will be overweight and more than 700 million will be obese. The obesity epidemic is not restricted to industrialized societies; this increase is often faster in developing countries than in the developed world. In India, obesity is emerging as an important health problem particularly in urban areas, paradoxically co-existing with undernutrition. In India, even childhood obesity is a latest epidemic with a very high magnitude. In this article the magnitude of obesity, other conditions and available management options has been reviewed.

KEYWORDS: Obesity, India.

1. MAGNITUDE OF OBESITY IN INDIA – THE EPIDEMIC:
Obesity is an epidemic of the 21st century, and is a major causative factor for many other metabolic disorders. According to a global estimate by the World Health Organization (WHO), in 2005 there were about 1.6 billion overweight persons aged 15 years and above and among them at least 400 million adults were obese. The revision of definition of obesity to adjust for the racial differences, by the WHO, has resulted in a higher prevalence of 1.7 billion people classified as overweight. The WHO further projects that by 2015, approximately 2.3 billion adults will be overweight and more than 700 million will be obese.5 The obesity epidemic is not restricted to industrialized societies; this increase is often faster in developing countries than in the developed world.6 In India, obesity is emerging as an important health problem particularly in urban areas, paradoxically co-existing with undernutrition. Almost 30-65% of adult urban Indians are either overweight or obese or have abdominal obesity.7 In India, even childhood obesity is a latest epidemic with a very high magnitude. In a recent article, Mohia et al.8 estimate that the prevalence of overweight to be 12.6% and that of obesity to be 3.4% among 92,862 Indian children.

ARTICLE – 2
Cardiovascular Death: Leading cause of death in Diabetes

Bhargava Vyasa
Department of Pharmacy, Shri JIT University, Vidyaganj, District-Jamnagar, Rajasthan-363001.

ABSTRACT:
Globalization, increase in the economy and the lifestyle has promoted cardiovascular deaths as the leading cause of death amongst all causes. Diabetes, a significant risk factor of Cardiovascular disease is associated with a great risk of morbidity and mortality accounting for up to two-thirds of all deaths in the diabetic population. Evidence suggests that hyperglycemia, the hallmark of diabetes, along with other associated factors contributes to myocardial damage after ischemic events and ultimately triggers the CV mortality and morbidity. Reducing coronary risk from diabetes requires a multifactorial approach to manage all atherogenic influences with change in the lifestyle manner.

KEYWORDS: Cardiovascular, mortality, diabetes

INTRODUCTION:
1. Introduction: Cardiovascular death incidence – A Global Scenario
The World Health Organization report on Global Burden of Disease in 2004 estimated 58.5 million deaths globally, of which 27.7 million were females and 31.1 million males. Death record by broad cause group reports that out of every 10 deaths, 6 are due to noncommunicable conditions; 3 to communicable, reproductive or nutritional conditions, and 1 to injuries. WHO report used 113 categories for disease and injury causes. The 20 most frequent causes of death are shown in Table 1. Ischemic heart disease and cerebrovascular disease are the leading causes of death, followed by lower respiratory infections (including pneumonia), chronic obstructive pulmonary disease and diarrheal diseases.

As may be expected from the very different distributions of deaths by age and sex, there are major differences in the ranking of causes between high and low income countries. In low-income countries, the dominant causes are infectious and parasitic diseases (including malaria), and perinatal conditions. In the high-income countries, 9 out of the 10 leading causes of death are noncommunicable conditions, including ischaemic heart disease as the leading cause with other four types of cancer. In the middle-income countries, the 10 leading causes of death are again dominated by noncommunicable conditions again leading by cerebrovascular disease and ischemic Heart disease as the leading ones.