5.6.7 Accelerated Stability Study

Stability study of the selected formulation was carried out as per ICH accelerated conditions of 60 ± 2°C and 75 ± 5 % RH for a period of 6 months. The results of stability study of selected formulation was shown in Table 5.16.

Table 5.16 Stability Study

<table>
<thead>
<tr>
<th>Tests</th>
<th>Parameters</th>
<th>Time (Months)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Leak test</td>
<td>No Leakage</td>
<td>No</td>
</tr>
<tr>
<td>Spray pattern (cm)</td>
<td>2.6</td>
<td>2.59</td>
</tr>
<tr>
<td>Valve discharge rate (mg/spray)</td>
<td>1.24</td>
<td>1.27</td>
</tr>
<tr>
<td>Droplet size determination (µm)</td>
<td>19</td>
<td>24</td>
</tr>
<tr>
<td>Dose uniformity (mg)</td>
<td>88.96</td>
<td>93.37</td>
</tr>
<tr>
<td>In-vitro diffusion study (%)</td>
<td>83.56</td>
<td>81.81</td>
</tr>
</tbody>
</table>

The stability study indicated that the formulation H3 was physically and chemically stable with no significant changes in any of the evaluated parameters when stored at the 60 ± 2°C and 75 ± 5 % RH conditions. There was no as such difference in the results shown in the table 5.16. Thus it was concluded that the buccal spray of Gymnema sylvestre was stable.
Conclusion and Future scope

Conclusion:

Good health is an important dimension of the quality of life. But today prevalence of diabetes is increasing at an alarming rate with increasing urbanization and changing lifestyle pattern. Diabetes mellitus is a chronic disease with complex underlying etiology. It was characterized by hyperglycemia and other metabolic abnormalities due to glucose intolerance.

Apart from insulin and oral hypoglycemic agents, phytotherapy are the most alternative therapy which includes a variety of herbal medicinal plants and they are evaluated and believed to be an outstanding candidates for diabetes and have been recommended as non-toxic efficient and with less or no side effects by the world Health Organization. *Gymnema sylvestre* is a traditional medicinal plant belonging to family Asclepiadaceae. Mainly leaves of *Gymnema sylvestre* have been used for the treatment of madhu meha. Or “honey urine” for more than 2,000 years in India. In market *Gymnema sylvestre* is available in the form of crude plant, powder, extract paste and solid in standardized form. The plant material is also available in the form of capsule or tablets in combination with other herbal plants. Recently novel dosage forms have gained significant popularity in the treatment of diabetes like buccal spray, nasal spray, buccal film etc. due to its outstanding characteristics.

*Gymnema sylvestre* leaves were collected, dried and powdered which were subjected to continuous and exhaustive Soxhlet apparatus using different solvents like petroleum ether, chloroform and methanol. This methanolic extract were used in the novel formulation. Preformulation study were carried out in order to establish the compatibility between the drug and polymers by FT-IR. The study revealed that drug and polymers are satisfactorily compatible. The present investigation was aimed to develop buccal spray of *Gymnema sylvestre* for the treatment of diabetes mellitus. Buccal spray of *Gymnema sylvestre* was prepared using different concentration of penetration enhancers and co-solvents. All the prepared formulations were evaluated...
for different evaluation parameters like leak test, spray pattern, valve discharge rate, content uniformity, drug diffusion study, droplet size measurement and stability study.

The prepared herbal formulations for buccal spray were taken for spray pattern studies. In that data, the H3 formulation shows uniform spray pattern having an average diameter of 2.6 cm. The data of characterization of valve discharge rate shows that among all formulations, H3 batch provides desired discharge rate from the container. The droplet size measurement revealed that H3 and H6 formulations provide minute size of the droplet from the device but the H3 gives 24 µm whereas H6 gives 26 µm and that prove that H3 is better than H6 because they are more permeable than other formulation due to smallest droplet. The % diffusion data revealed that H3 and H6 show the highest cumulative amount of drug diffused nearly 84-85 %, whereas other formulations give lower diffusion than that. Thus the most effective batch H3 considered as the best formulation in this study. Stability study revealed that the maximum stability of buccal spray at 60° C ± 2° C and at 75% RH for 6 months.

**Scope for the Future Work**

Clinical studies of the developed formulations could be carried out to optimize the desired effect associated with the buccal spray which may prove very promising and useful in future.
Chapter 7

References


Ayurvedic pharmacopoeia of India, 2008. the Ayurvedic Pharmacopoeia of India. , II.


Kahn, S.E., 2003. The relative contributions of insulin resistance and beta-cell


Liu, H.M., Kiuchi, F. & Tsuda, Y., 1992. Isolation and structure elucidation of


sylvestre leaf extract,


Dekker. Available at: https://books.google.co.in/books?id=Jwx-10FmsBUC.


