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ASSAY OF NEW FORMULATIONS OF ISOSORBIDE MONONITRATE BY USING UV SPECTRO-PHOTOMETER

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Abstract- A rapid, simple, accurate, and economical spectrophotometric method has been developed and validated for the assay of isosorbide mononitrate in new tablet formulation and compare with different brand available in the market. The analysis is based on the UV absorbance maxima at about 405nm wavelength of isosorbide mononitrate, using glacial acetic acid as solvent. A sample of drug was dissolved in glacial acetic acid to produce a solution containing isosorbide mononitrate. Similarly, a sample of ground tablets of different brand were extracted with glacial acetic acid and diluted with the same glacial acetic acid. The absorbance of sample preparation was measured at 405 nm against the solvent blank and the assay was determined by comparing with the absorbance of a similarly prepared standard solution of isosorbide mononitrate. The method can be applied for the routine QC quantitation of isosorbide mononitrate in tablet formulation.

Keywords- isosorbide mononitrate, dry granulation method, UV pectrophotometry

Introduction

The objective of the present study was to develop new formulation of Isosorbide Mononitrate by dry granulation method. Isosorbide mononitrate [Fig-1] is a drug used principally in the treatment of angina pectoris [1] and acts by dilating the blood vessels to reduce the blood pressure. The rate of absorption is slowed by food but overall bioavailability is unchanged. Kinetics are not significantly influenced by advancing age [2], hepatic [3], or renal disease [4] The drug is mainly indicated for the treatment of stable and unstable angina pectoris, acute (MI) myocardial infarction and heart failure. The tablets were prepared by dry granulation method. The tablets were analyse by uv spectrophotometer and compare with different brand available in the market.

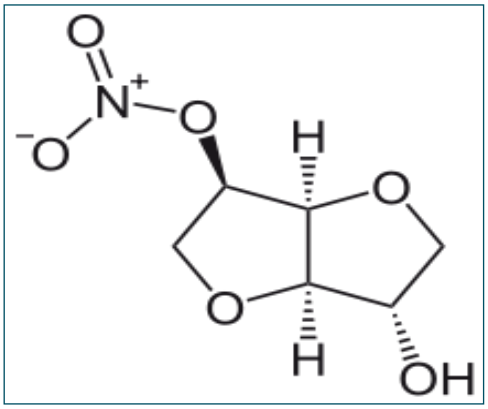

Fig. 1- Isosorbide-5- Mononitrate

The dry granulation process is used to form granules without using a liquid solution. Forming granules without moisture requires compacting and densifying the powders. This method is referred to as-dry granulation, precompression or double compression [5]. In the new formulation of Isosorbide mononitrate by dry granulation method during manufacturing magnesium stearate was replaced by Talc because it is cheaper and requires less blending time as compared to magnesium stearate. Mixing time differences of as little as two minutes can significantly alter the dissolution pattern of Isosorbide mononitrate tablets [6].

Materials and Methods

UV visible 1601 Shimadzu double beam spectrophotometer was used to record the spectra. The solvent used for the assay was spectroscopic-grade glacial acetic acid.

Wavelength Selection

About 100ppm of Isosorbide mononitrate was accurately prepared in spectroscopic-grade glacial acetic acid solvent. This preparation was then scanned in the 200-400 nm UV region. The wavelength maxima (λ_{max}) was observed at 405nm and this wavelength was adopted for absorbance measurement.

Standard Stock solution

Accurately weighed 0.2 gm of Isosorbide mononitrate standard was transferred to a volumetric flask and add 5 ml water and add sufficient glacial acetic acid to produce 25 ml. This was sonicated 5 min to dissolve it.

Standard Preparation

Dilute 5.0ml of standard stock solution to 50.0 ml with glacial acetic acid.

Sample Preparation

20 tablets of four different brand of Isosorbide mononitrate from the marketed sample were weighed and crushed uniformly with the help of a mortar and pestle. Accurately weighed sample powder equivalent to 0.2gm of Isosorbide mononitrate was transferred into a volumetric flask containing 20mL glacial acetic acid solvent. The contents were sonicated for about 5 min and than make up volume upto 25 ml with water than filter it, discard the first few ml and collect the clear filtrate.

Procedure

Transfer 1.0 ml each of standard preparation and sample preparation and glacial acetic acid yo provide blank to separate 100ml volumetric flasks. To each flaskadd 2.0 mlof phenoldisulfonic acid solution, mix and allow to stand for 20 minutes. To each flask, add 50 ml of distilled water and make alkaline with ammonia solution (10-15)ml. Cool, dilute to volumewith distilled water and mix well concomitantly determine the absorbance of the sample preparation and standard preparation in 1cm cell at the wavelength of maximum absorbance at about 405nm, using a spectrophotometer, using the blank solution. Calculate the quantity in mg, of isosorbide-5- mononitrate per tablet.

Result and Discussion

Pharmaceutical assay was carried out by using spectrophotometer on all brands and new formulations of Isosorbide mononitrate tablets during the study. Table-1 to Table-4 show potencies in accordance of required specification.

The proposed method for the assay of Isosorbide mononitrate of new formulation and in the commercially available tablet formulation is simple, economical, accurate and rapid. It can be easily adopted for routine quality control for monitoring the assay in the API, in-process samples and tablet formulation. The method can be used for studying the dissolution profile.

Table 1- Drug's Specifications

S.no	Code no.	Batch no.	Potency (%)	BP/USP Specification	Deviation from BP/ USP Specification
ISM-1	1624	B322	106.98%	Between 90 - 110%	Within specified limit
ISM-2	6484	OOK654	96.51%		Within specified limit
ISM-3	5903	9B121	108.96%		Within specified limit
ISM-4	14820	O25	101.74%		Within specified limit
ISM-5	11168	O24	98.28%		Within specified limit
ISM-6	18563	01M0098	107.21%		Within specified limit
ISM-NEW	110	T-2	108.12%		Within specified limit

Table 2- ANOVA

	Sum of Squares	Df	Mean Square	F	Sig.
Between Groups	688.002	6	114.667	261.586	0
Within Groups	12.274	28	0.438		
Total	700.276	34			

Table 3- Descriptive using SPSS

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
ISM1	5	106.956	0.03975	0.01778	106.907	107.005	106.89	106.99
ISM2	5	96.648	0.1813	0.08108	96.4229	96.8731	96.5	96.9
ISM3	5	108.828	0.17181	0.07684	108.615	109.041	108.6	109
ISM4	5	102.348	1.16855	0.52259	100.897	103.799	101	104
ISM5	5	98.616	0.2651	0.11856	98.2868	98.9452	98.28	99
ISM6	5	106.842	0.8543	0.38205	105.781	107.903	106	108
New Formulation	5	107.424	0.9159	0.4096	106.287	108.561	106	108.12
Total	35	103.952	4.53832	0.76712	102.393	105.511	96.5	109

Table 4- Comparison of new formulation with different brand

Drugs		Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
New Formulation	ISM1	0.468	0.41874	0.273	-0.3897	1.3257
	ISM2	10.77600*	0.41874	0	9.9183	11.6337
	ISM3	-1.40400*	0.41874	0.002	-2.2617	-0.5463
	ISM4	5.07600*	0.41874	0	4.2183	5.9337
	ISM5	8.80800*	0.41874	0	7.9503	9.6657
	ISM6	0.582	0.41874	0.176	-0.2757	1.4397

**The mean difference is significant at the 0.05 level.*

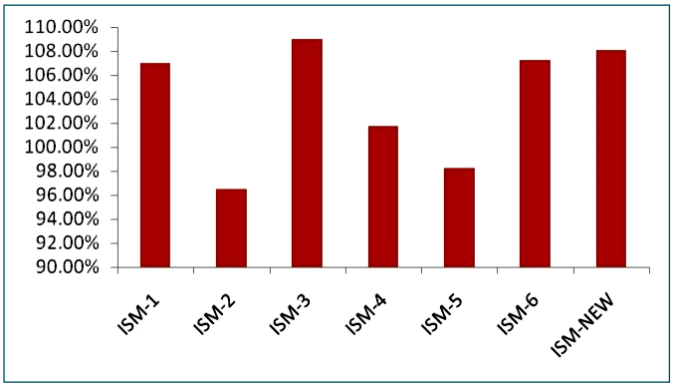

Fig. 2- % Assay of drugs

Conflicts of Interest: None declared.

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