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A Review on Analytical Methods for Estimation of Isosorbide Dinitrate and Hydralazine Hydrochloride in Bulk and Pharmaceutical Dosage Form

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Abstract : Pharmaceutical drug products play a major role on human lives which help in curing the various diseases. Now a day's many of the drugs are synthesized oftenly shows many therapeutic effect in their pharmaceutical formulations. At finally the biologically active substances are formulated into different formulations such as tablets, capsules, suspensions, ointments and injectables. This drug delivers the drugs and shows the therapeutic effect. Various analytical methods used for the estimation of Isosorbide dinitrate and Hydralazine hydrochloride has been reviewed in this paper. These include Ultraviolet spectrometry, High performance liquid chromatography, and Dissolution method to determine the amount of Isosorbide dinitrate and hydralazine hydrochloride in single dosage form as well as in combination with other drugs. These analytical methods can be used for qualitative and quantitative estimation of Isosorbide dinitrate and hydralazine hydrochloride in single dosage form as well as in combination with other drugs.

Introduction:

Isosorbide dinitrate, chemically 1,4:3,6-dianhydro-D-glucitol-2,5-dinitrate[1] is antianginal agent. Isosorbide dinitrate is converted to nitric oxide (NO), an active intermediate compound which activates the enzyme guanylyl cyclase (atrial natriuretic peptide receptor A). Isosorbide dinitrate is well absorbed from buccal mucosa, intestines and skin. It can be used sublingually at the time of attack as well as orally for chronic prophylaxis. [2]

Hydralazine hydrochloride, chemically 1-hydrazinophthalazine hydrochloride[3] is antihypertensive agent. Hydralazine apparently lowers blood pressure by exerting a peripheral vasodilating effect through a direct relaxation of vascular smooth muscle. Hydralazine is well absorbed orally and is subjected to first pass metabolism in liver. Hydralazine is completelv metabolized both in liver and plasma; the metabolites are excreted in urine, $t_{1/2}$ is 1-2 hours.[4]

Analytical Methods for Isosorbide Dinitrate

Hasson KJ, et al.[5] developed and validated Comparative study for the dissolution of Isosorbide dinitrate tablets in commercial products using 0.1 M HCl as dissolution medium. The analysis was carried out on ODS C18 (250 x 4.6 mm, 5µm) reversed-phase column, using a mixture of Methanol: water (50:50) as the mobile phase with flow rate at 1.0ml/min at 222 nm using UV detector.

Carlson M et al.[6] developed and validated a simple, rapid, accurate and precise RP-HPLC method for determination of Isosorbide dinitrate in pharmaceutical products using ODS C18 column (250 cm × 4.6 mm i.d., 5 µm particle size) as a stationary phase required for separation with Methanol: Water: Acetate buffer pH 4.7 (55:35:10 v/v/v) as mobile phase at flow rate 1.0 ml/min using UV detector at 220 nm. The proposed method is applicable to the analysis of the diluted bulk drug and dosage forms, including sublingual, oral, chewable, and timed-release preparations.

Liu WY et al.[7] reported a method for determination of isosorbide dinitrate and its degradation products in pharmaceuticals by gradient RP-HPLC using Nucleosil C18, 150 X 4.6 mm, 5 microns, column. Solution A (70% methanol) and solution B (5% methanol) were used as mobile phase at a flow rate of 1.0 ml/min in gradient elution and detection was carried out at 220 nm.

Pillai A, et al,[8] developed a new Spectrophotometric Method for the Estimation of Isosorbide Mononitrate in Bulk and Tablet Formulation. The method was based on reduction of nitrate group of Isosorbide mononitrate to nitrite ion by zinc/sodium chloride. Then this nitrate ion formed a diazotized salt with sulphanilamide in presence of hydrochloric acid and diazotized salt was then coupled with n-(1-naphthyl) ethylene-diamine dihydrochloride to form a colored product which was measured at 540 nm.

Analytical Methods for Hydralazine Hydrochloride

Siddappa K et al.[9] reported sensitive spectrophotometric methods for quantitative determination of Hydralazine Hydrochloride in pure and pharmaceutical formulation. The developed methods were based on the formation of blue colored chromogen due to the reaction of hydralazine hydrochloride with Folin Ciocalteu reagent in presence of alkali, which exhibits λmax at 640 nm (Method A). The Method B was based on reduction of ferric ions to ferrous ions in presence of drug produces greenish blue colored complex measured at 720 nm against reagent blank.

Adegoke OA et al.[10] developed a Spectrophotometric method for determination of Hydralazine using P-dimethylaminobenzaldehyde. The procedure was based on a condensation reaction between alcoholic solution of hydralazine and acidic solution of p-dimethylaminobenzaldehyde to generate an instant greenish-yellow coloured product. The hydrazone formed absorbed visible light strongly at a wavelength of 470 nm.

Gonsalves AA, et al.[11] developed an alternative spectrophotometric method for determination of total iron using flow injection analysis (FIA). The analysis was based on the coordination reaction between hydralazine and Fe2+ ions, which results in the formation of a purple complex monitored at 538 nm.

Patel RM, et al.[12] reported RP–HPLC method for simultaneous estimation of Hydralazine hydrochloride and Propranolol in pharmaceutical dosage form. The analysis was performed on RP Phenomenex C18 column (250 mm x 4.6 mm i.d., 5 µm particle size) using Acetonitrile -0.25mlTriethylamine -Water (35:65%) pH adjusted to 3.5 with O- phosphoric acid as mobile phase at a flow rate of 1.0 ml/min and the detection wavelength was 273 nm.

Fatmi AA, et al.[13] developed and validated a method for determination of Hydralazine hydrochloride and Hydrochlorothiazide in dosage forms by High Performance Liquid Chromatography using radialpak cyanopropylsilane cartridge with a mixture of methanol, water and dibutylamine phosphate as mobile phase and detection at 254 run.

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