Overview of literature regarding studies on lenalidomide biology essay

Technology, Development

B.

M. Rao et Al (2007) [12] have reported An HPLC Assay Method for Lenalidomide. Chromatographic separation was achieved on an Inertsil ODS-3V column utilizing a nomadic stage consisting of a mixture of buffer, acetonitrile and Methanol in the ratio 80: 8: 12 v/v.

Degradation surveies were performed on majority samples of Lenalidomide subjected to 0. 5N hydrochloric acid, 0. 5N sodiumhydroxide, 10 % v/v hydrogenperoxide, heating to 60C and UV light at 254nm.

Degradation was observed merely under base hydrolysis conditions. The developed LC method gave a mass balance near to 99. 5 % , turn outing it to be suited for stableness surveies and was validated with regard to one-dimensionality, truth, preciseness and hardiness.

Liu, Qing MS et Al (2008) [13] have reported that a extremely sensitive liquid chromatography/mass spectroscopy method for coincident quantification of Lenalidomide and flavopiridol in human plasma. Samples were extracted by liquid-liquid extraction with acetonitrile (ACN) -containing internal criterion, genistein, followed by vaporization of dissolver and reconstitution in 95/5 H2O/ACN. Lenalidomide and Levetiracetam were separated by reversed-phase liquid chromatography on a C-18 column utilizing a gradient of H2O and ACN, each with 0.

1 % formic acid. Atmospheric force per unit area chemical ionisation in positive ion manner with individual reaction monitoring on a ternary quadrupole mass spectrometer was applied to observe passages of

Lenalidomide (260. 06 & A ; gt ; 149. 10) and flavopiridol (402. 09 & A ; gt ; 341. 02) . Lower bounds of quantification of Lenalidomide and flavopiridol were 1 and 0. 3 nanometer, severally.

Recoveries of Lenalidomide and flavopiridol from human plasma ranged from 99 % to 116 % throughout their additive scopes. Within- and between-run preciseness and truth of replicate samples were all less than 15 % . This is the most sensitive analytical method reported to day of the month for both Lenalidomide and flavopiridol. Nandan Srinivasan Raghu et Al (2010) [14] have reported that debasement surveies of extremely powerful and life endangering human birth defect drug Lenalidomide by HPLC and LC-MS. Lenalidomide drug-excipient from the capsule pharmaceutical dose signifier was subjected to different ICH prescribed stress conditions of thermic emphasis, pH hydrolysis, oxidization and photolysis.

The drug was found to be stable merely at photolysis and thermic emphasis, while it was highly susceptible to other emphasizing conditions particularly it showed extended debasement under alkali conditions. An acceptable separation was achieved through a multi-step gradient elution utilizing an ACE® C18, 150 4. 6 millimeter i. d, 3 ? m, unstained steel analytical column and a nomadic stage comprising of 0. 01 M phosphate buffer (pH, 2. 0 ± 0. 1) as nomadic phase-A, and a mixture of H2O and acetonitrile in the ratio of 200: 800 (v/v) as nomadic phase-B, with a flow rate and sensing wavelength being 1. 0 mL min-1 and 220 nanometer severally.

The major debasement merchandises appeared at comparative keeping times (RRT) of 0. 75, 0. 86, 0. 96, 1. 33, 1. 52, 1. 99, 2.

04, 2. 62 and 2. 66 severally. Tanyifor M. Tohnya et Al (2004) [15] have reported that Determination of CC-5013 (Lenalidomide) , an parallel of thalidomide, in human plasma by liquid chromatography-mass spectroscopy. Sample extraction involved liquid-liquid extraction with acetonitrile/1-chlorobutane (4: 1, v/v) solution incorporating the internal criterion, umbelliferone.

Separation of the compounds of involvement was achieved on a column packed with Waters C18 Nova-Pak stuff (4 ? m atom size ; 300 mm – 3. 9 millimeter internal diameter) utilizing acetonitrile, de-ionized H2O, and glacial acetic acid in ratios of 20: 80: 0. 1 (v/v/v) (pH 3. 5) delivered at an isocratic flow rate of 1.

00 ml/min. Coincident MS sensing was performed at m/z 260. 3 (CC-5013) and m/z 163. 1 (umbelliferone) . The standardization curve was fit to a additive response-concentration informations over a scope of 5-1000 ng/ml utilizing a weighting factor of 1/x. Valuess for truth and preciseness, obtained from four quality controls analyzed on three different yearss in replicates of five, ranged from 98 to 106 % and from 5. 5 to 15. 5 % , severally.

The method was successfully applied to analyze the pharmacokinetics of Lenalidomide in a malignant neoplastic disease patient having the drug as individual day-to-day dosage. S. Gananadhamu et Al (2009) [16] have

reported that Fluorometric appraisal of Lenalidomide in pharmaceutical preparations.

Lenalidomide is an immunomodulatory agent with anti-angiogenic and anti-neoplastic belongingss. Lenalidomide is non official in any pharmacopoeia and there are merely a few analytical methods were reported for appraisal of Lenalidomide in pharmaceutical preparations such as HPLC and LC-MS. We developed one simple and sensitive fluorometric method for appraisal of Lenalidomide in pure province and pharmaceutical preparations by utilizing fluorescamine as a fluorogenic reagent.

The fluorescence measurings were performed at an excitement wavelength of 391 nanometers and an emanation wavelength of 499 nanometers severally. The proposed method shows the one-dimensionality in the concentration scope of 0. 05 to 8µg/ml with a correlativity coefficient of 0. 9999.

The developed method was validated for specificity, preciseness and truth. This method was applied for appraisal of Lenalidomide in some commercially available pharmaceutical preparations and found to be simple, sensitive, consistent and accurate. S. Gananadhamu et Al (2009) [17] have reported that new spectrophotometric methods for appraisal of Lenalidomide in pharmaceutical preparations.

Two sensitive spectrophotometric methods were developed for the appraisal of Lenalidomide in pharmaceutical preparations. Method A is based on diazo-coupling reaction with N- (1-napthyl) ethylene diamine dihydrochloride (B.

M reagent) to organize a stable purple coloured chromogen, which can be estimated at 540 nanometer. Method B is based on the formation of a colored condensation merchandise with the aromatic aldehyde viz.

p-dimethyl amino cinnamaldehyde (PDAC) which shows soaking up upper limit at 530 nanometer. Both the proposed methods (Method A and Method B) obey Beer ' s jurisprudence in the concentration scope of 1 to 5µg/ml. The methods were validated for usage in everyday quality control of Lenalidomide in pharmaceutical preparations. Sockalingam Anbazhagan et Al (2005) [18] have reported that Coincident quantification of stavudine, 3TC and Viramune by UV spectrometry, change by reversal stage HPLC and HPTLC in tablets. In the UV multi-component spectral method, SV, LV and NV was quantified at 266, 271 and 315 nanometer, severally. In the RP-HPLC method, the drugs were resolved utilizing a nomadic stage of 20mM Na phosphate buffer (incorporating 8mM1-octanesulphonicacid Na salt) : acetonitrile (4: 1, v/v) with pH adjusted to 3.

5 utilizing phosphorous acid on a C18-ODS-hypersil (5 µm, 250mm-4. 6 millimeter) column in isocratic manner. The keeping clip of SV, LV and NV was 2. 85, 4. 33 and 8. 39 min, severally. In the HPTLC method, the chromatograms were developed utilizing a nomadic stage of trichloromethane: methyl alcohol (9: 1, v/v) on precoated home base of silicon oxide gel 60 F254 and quantified by densitometric optical density manner at 265 nanometer. The Rf of SV, LV and NV were 0.

21-0. 27, 0. 62-0.

72 and 0. 82-0. 93, severally. Recovery values of 99. 16-101. 89 % , per centum comparative criterion divergence of & A ; lt ; 0.

7 and correlativity coefficient (additive dynamic scope) of 0. 9843-0. 9999 shows that the developed methods were accurate and precise. These methods can be employed for the everyday analysis of tablets incorporating SV, LV and NV.

N. Kaul et Al (2007) [19] have reported that The International Conference on Harmonisation counsel in pattern: emphasis debasement surveies on 3TC and development of a validated specific stability-indicating HPTLC check method. The dissolver system consisted of C tetrachloride – methyl alcohol – trichloromethane – acetonitrile (7. 0: 3. 0: 2. 0: 1. 5, v/v/v/v) . Densitometric analysis of 3TC was carried out in the optical density manner at 275 nanometer.

This system was found to give compact musca volitanss for 3TC (RF value of 0. 36 ± 0. 02) following dual development of chromatoplates with the same nomadic stage. Linearity was found to be in the scope of 50 – 1000 ng spot-1 with significantly high value of correlativity coefficient.

The additive arrested development analysis informations for the standardization secret plans showed good linear relationship with r2 = 0. 9994 ± 0. 05 in the working concentration scope of 300 ng spot-1 to 1000 ng spot-1. The average value of incline and intercept were 0. 11 ± 0. 08 and 10. 47 ± 1. 21, severally.

The method was validated for preciseness, hardiness and recovery. The bound of sensing and quantitation were 15 ng spot-1 and 40 ng spot-1 severally. Y. Vander Heyden et Al (2010) [20] have reported that Development and proof of a normal-phase HPTLC method for the coincident analysis of 3TC, stavudine and Viramune in fixed-dose combination tablets. Separation was performed on silicon oxide gel 60F254 home bases. The nomadic stage is comprised of ethyl ethanoate, methyl alcohol, methylbenzene and concentrated ammonium hydroxide (38. 7: 19.

4: 38. 7: 3. 2 V: V: V: V) . Detection wavelength was 254 nanometer. The Rf values were 0. 24±0. 03, 0. 38±0.

04 and 0. 69±0. 04 (n = 8) for LVD, STV and NVP, severally. An F-test indicated that standardization graphs were adequately additive at the evaluated concentration ranges. The pooled % RSD for repeatability of the per centum sum recovered for LVD, STV and NVP were found to be 0.

62, 0. 54, and 0. 79, and the pooled % RSD for time-different intermediate preciseness were 1. 66, 1. 27 and 1. 21.

The per centum recoveries for the truth were 99. 2 % ±1. 5 for LVD, 98. 6 % ±1. 5 for STV and 99. 3 % ±1. 7 for NVP (n = 3) . Most factors evaluated in the robustness trial were found to hold an undistinguished consequence on the selected responses at 95 % assurance degree.

This method was successfully used to analyse fixed-dose tablets samples of LVD, STV and NVP. Neeraj Kaul et Al (2007) [21] have reported that

Stability-indicating high-performance thin-layer chromatographic finding of Retrovir as the bulk drug and in pharmaceutical dose signifiers. The method employs aluminum-backed silicon oxide gel 60F 254 HPTLC home bases with toluene-carbon tetrachloride-methanol-acetone, 3. 5 + 3. 5 + 2.

0 + 1. 0 (v/v) , as nomadic stage. This system was found to give compact musca volitanss (R F 0. 41 ± 0. 02) for Retrovir. Densitometric analysis of Retrovir was performed in optical density manner at ? = 270 nanometer. Response was linearly dependant on sum of Retrovir in the scope 100-6000 ng per topographic point with a significantly high correlativity coefficient (r 2 = 0.

998 ± 0. 53) . Linear arrested development analysis informations for the standardization secret plans showed there was a good linear relationship with R 2 = 0. 998 ± 0. 0003 in the working concentration scope 100 to 1000 nanogram per topographic point. The average values of the incline and intercept were 0. 063 ± 0.

004 and 39. 61 ± 1. 09, severally. The method was validated for preciseness, hardiness, and recovery.

The bounds of sensing and quantitation were, severally, 20 and 40 nanograms per topographic point. Statistical analysis proved the method was quotable and selective for appraisal of the drug. Girum Habtea et Al (2009) [22] have reported that Coincident Separation and Determination of Lamivudine and Zidovudine in Pharmaceutical Formulations Using the HPTLC Method. The method developed was based on HPTLC separation of

the two drugs followed by densitometric measurings of musca volitanss at 276 and 271 nanometer for 3TC and Retrovir, severally. Separation was carried out on Merck HPTLC silica-gel 60 F254 home bases, utilizing toluene/chloroform/methanol (1: 6: 3 V: V) as the nomadic stage. Validation of the method was performed based on The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines. Second-order multinomial equations were obtained for the arrested development line in the scopes of 250-1400 and 250-1700 ng/spot for 3TC and Retrovir severally.

Correlation coefficient (R) values were 0. 9998 for both analytes. In the method preciseness survey, coefficients of fluctuation & A ; lt ; 2 % were obtained, which showed that the proposed method provides acceptable intraday and interday fluctuation.

The sensing and quantification bounds and were 3. 06 and 9. 28 ng/spot for 3TC and 3. 34 and 10. 13 ng/spot for Retrovir, severally. The low coefficient of fluctuation values indicated the hardiness of the method. Statistical use did non demo any important consequence of one parametric quantity over the others on the hardiness of the method. Eliangiringa Kaale et Al (2010) [23] have reported that An Interlaboratory Investigation on the Use of High-Performance Thin Layer Chromatography to Perform Assays of Lamivudine-Zidovudine, Metronidazole, Nevirapine, and Quinine Composite Samples.

Two research labs extensively investigated the usage of HPTLC to execute checks on lamivudine-zidovudine, Flagyl, Viramune, and quinine composite

samples. To minimise the effects of differences in analysts ‘ technique, the research labs conducted the survey with automatic sample application devices in concurrence with variable-wavelength scanning densitometers to measure the home bases. The HPTLC processs used comparatively innocuous, cheap, and readily available chromatography dissolvers used in the Kenyon or the Global Pharma Health Fund Minilabs® TLC methods.

The usage of automatic sample applications in concurrence with variable-wavelength scanning densitometry demonstrated an mean repeatability or within-laboratory RSD of 1. 90 % , with 73 % less than 2 % and 97 % at 2. 60 % or less, and an mean duplicability or among-laboratory RSD of 2. 74 % . Soumya Swaminathan et Al (2006) [24] have reported that A simple and rapid liquid chromatography method for coincident finding of Retrovir and Viramune in plasma. The method involves liquid-liquid extraction with ethyl ethanoate and utilizing 3-isobutyl 1-methyl xanthine as internal criterion. The system requires a C18 column (150mm-4. 6mm I.

D.) and a nomadic stage composed of K dihydrogen phosphate (15 millimeter ; pH 7. 5) and acetonitrile in the ratio of 80: 20 (v/v) , UV sensing at 260nm.

M. Kumar et Al (2010) [25] have reported that Method development and proof of RP-HPLC method for coincident finding of Lamivudine and Zidovudine. Chromatography was carried out on a pre-packed AltimaC18 5? (150*4.

6mm) column utilizing filtered and degassed mixture of Ammonium ethanoate buffer: Methanol (80: 20) as nomadic stage at a flow rate of 1. 0ml/min and wastewater was monitored at 270nm. T. Sudha et Al (2010) [26] have reported that RP-HPLC Method for the Coincident Appraisal of Lamivudine and Abacavir Sulphate in Tablet Dosage Form. Lamivudine and Abacavir at the same time in combined dose signifier, separation was performed on a 5? m C18 column holding dimensions (150X4.

6mmid) in isocratic manner, with nomadic stage incorporating a mixture of methyl alcohol: H2O (70: 30, v/v/) was used. The Mobile stage was pumped at a flow rate of 1. 4 ml/min and eluents were monitored at 275nm.

The selected chromatographic conditions were found to divide Lamivudine (Rt= 2. 549 min) and Abacavir (Rt= 3. 499 min) holding a declaration of 4. 13 min.