Review of Literature

Chapter 2

2.1 Atorvastatin

There have been several reports for the estimation of proposed drugs individually and in combination with other drugs. On literature survey it was found that ATOR can be estimated independently or in combination with the other drugs by several methods, including HPLC[1-7] LC-MS[8, 9] spectrophotometric methods[10] FT-Raman spectroscopy[11] and electrochemical methods[11] in pharmaceutical formulations, in bulk, in plasma, also determined its impurities, enantiomers, intermediates and metabolites.

2.2 Fenofibrate

FENO is determined by spectrophotometry,[12] square-wave voltametry,[13] HPLC, nuclear magnetic resonance (NMR),[14-16] in pharmaceutical formulations, raw materials, plasma, serum, its impurities, and bioactive metabolites. There is no report for the simultaneous estimation of this combination in synthetic mixture or pharmaceutical formulations.

2.3 Amlodipine besylate

AMLO is found in combination with many other drugs. Quantitative analysis of the samples containing AMLO is achieved by many methods which include, RP-HPLC,[17-22] HPTLC,[23] fluorimetry[24] and various spectrophotometric methods[25-31].

2.4 Ramipril

An assortment of techniques has been described to the quantitation of RAMP alone and in combination with other drugs is reported by various methods which includes HPLC[32-35], LC-MS[36-38], GC-MS[39], spectrophotometri[40-42], fluorimetric[43],

voltametric[44, 45], capillary electrophoresis[46, 47] and atomic absorption spectrophotometry[48, 49].

2.5 Ezetimibe

Quantitation of EZET alone and in combination with other drugs is reported by various methods which include RP-HPLC[50-52] and spectrophotometric methods[53, 54].

2.6 Nebuvolol

Very few methods appeared in the literature for the determination of NEB. Ramakrishna, N.V.S. et al. reported quantification in human plasma by liquid chromatography coupled with electrospray ionization tandem mass spectrometry[55], Patel, L.J et al. reported estimation of NEB by RP-HPLC and HPTLC in tablet dosage forms[56] and Kamila, M.M. et al. reported spectrophotometric method in bulk and in formulation[57]. Mario, T. et al. in urine samples[58], Selvan, P. S et al.[59] and Hans, H. M. et al.[60] in human blood plasma determined NEB in combination with other β- blocker by LC/MS.

2.7 Hydrochlorathiazide

There have been several reports on the determination of HCTZ individually or in its combination with other drugs, including the use of liquid chromatography[61-70] spectrophotometry[71-79], and fluorimetric methods[80].

Notably, no spectrophotometric, (including chemometrics), HPLC and HPTLC methods for the simultaneous determination of above mentioned drugs in pharmaceutical formulations has been reported till date. In view of the need for a suitable method for routine analysis of proposed combinations in formulations,

attempts are being made to develop simple, precise and accurate analytical methods for simultaneous estimation of these drugs and extend it for their determination in formulation. This prompted us to disclose our work consisting of new and accurate methods for the simultaneous determination of proposed combinations in synthetic samples and pharmaceutical formulations. As chromatographic method of analysis is a pre-requisite for the marketing of most of the formulation, one HPLC, HPTLC method along with the four spectrophotometric methods namely Simultaneous equation method (Vierodt's method), First derivative zero crossing method, Ratio derivative Spectrophotometry, and four chemometric techniques CLS, PCR and PLS were developed and validated for the simultaneous determination of proposed drugs. These methods provide means to separate the individual components of a mixture and simultaneously characterize and quantify the components.

The chemometric HPTLC and HPLC assay presents convenience, rapidity and the ability to separate substances quantitatively without prederivation. Especially chemometric methods appear to be reasonable and in fact are the best when dealing with well behaved systems (linear responses, no interfering signals, no analyte-analyte interaction, low noise and no collinearities). The chemometric methods have been successfully applied to the quantitative analysis in spectrophotometric[81-84], chromatographic[85, 86] and electrochemical data[87, 88]. Chemometric calibration techniques are discussed in more detail elsewhere [89-95]. To achieve those method characteristics, the developed methods must be validated according to the well-recognized analytical parameters established by the official compendiums, scientific

literature and Pharmacopeias, obtaining experimentally the linearity, specificity, accuracy, precision and limits of detection and quantification.

References

(1) Sıdıka, E.; Armalmagean, O.; Sevil, M. C. *J. Chromatogr. B* 2003, *793*, 193-205.

(2) Mann, E. E.; Palmer, C. W.; Hagen, S. R. *J. Liq. Chromatogr. Relat. Technol* 1997, *20*, 2441-2449.

(3) Gholamreza, B.; Bahareh, M.; Shahla, M.; Amir, K. *J. Chromatogr. B* 2005, *826*, 41-45.

(4) Alaa, K. *J. AOAC INTERNATIONAL* 2007, *90*, 1547-1553.

(5) Bharat, G. C.; Natvarlal, M. P.; Paresh, B. S.; Laxman, J. P.; Vipul, P. P. *J. AOAC INTERNATIONAL* 2007, *90*, 1539-1546.

(6) Mohammadi, A.; Rezanour, N.; Ansari, D. M.; Ghorbani, B. F.; Hashem, M.; Walker, R. B. *J. Chromatogr. B* 2007, *846*, 215-221.

(7) Thanikachalam, S.; Rajappan, M.; Chandrasekharan, M.; Kannappan, V. *J. Sep. Sci.* 2007, *30*, 3143 - 3153.

(8) Ramakrishna, N.; Koteshwara, M.; Vishwottam, K. *J. Pharm. Biomed. Anal.* 2007, *44*, 379-387.

(9) Xiu-Sheng, M.; Chris, D. M. *J. Chromatogr. A* 2003, *998*, 133-141.

(10) Nevin, E. *Anal. Letters* 2003, *36*, 2699 - 2711.

(11) Nevin, E. *Critical Rev. Anal Chem* 2004, *34*, 1-7.

(12) El-Gindy, A.; Emara, S.; Mostafa, K.; Mesbah; Ghada, M. H. *Il. Farmaco.* 2005, *60*, 425-438.

(13) Yardimci, C.; Ozaltin, N. *Anal. Bioanal. Chem.* 2004, *378*, 495-498.

(14) Ji, X.; Ye, C. *Zhongguo.Yaoke. Daxue. Xucbao.* 1987, *18*, 284-286.

(15) Pauline, L. M.; Brian, D. A.; Roger, S. W.; Bruce, B. D.; Terry, C. D.; Jean-Claude, E. *J. Pharm. Biomed. Anal.* 1998, *18*, 383-402.

(16) Fan, G. R.; Linn, M.; Zhang, Z. X.; An, D. K. *Yaowu. Fenxi. Zazhi.* 2000, *20*, 231-234.

(17) Halker, U. P.; Bhandari, N. P.; Rane, S. H. *Indian Drugs* 1988, *35*, 168.

(18) Indravadan, C. B.; Bhanu, R.; Sundaresan, M.; Ashok, M. B. *J. Pharm. Biomed. Anal* 1998, *17*, 539-546.

(19) Sankar, S. R.; Nanjan, M. J.; Vasudevan, M.; Shaat, N.; Suresh, B. *Indian J. Pharm. Sci* 1997, *59*, 171-173.

(20) Dhorda, V. J.; Shetkar, N. B. *Indian Drugs* 1999, *36*, 638-641.

(21) Yagnesh, P. P.; Suvarna, P.; Indravadan, C. B.; Sundaresan., M. *J. Chromatogr. A* 1998, *828*, 283-286.

(22) Raghu, N. K.; Udhav, N. K.; Murlidhar, S. S. *J. Pharm. Biomed. Anal* 2005, *39*, 147-155.

(23) Agrekar, A. P.; Powar, S. G. *J. Pharm. Biomed. Anal* 2000, *21*, 1137-1142.

(24) Mohamed, Y. E.; Naglaa, M. E. K.; Bahia, A. M.; Nasshwa, G. M. *Bull Fac Pharm* 1998, *36*, 1-9.

(25) Singhvi, I.; Chaturvedi, S. C. *Indian J. Pharm. Sci* 1998, *60*, 309-310.

(26) Singhvi, I.; Chaturvedi, S. C. *Indian J. Pharm. Sci* 1999, *61*, 190-191.

(27) Prasad, C. V. N.; Parihar, C.; Chowdhary, T. R.; Purohit, S.; Parimoo, P. *Pharm Pharmacol Commun* 1998, *4*, 325-330.

(28) Prasad, C. V. N.; Saha, R. N.; Parimoo, P. *Pharm. Pharmacol. Commun* 1999, *5*, 383-388.

(29) Ravi, J.; Jain, C. L. *Indian J. Pharm. Sc.* 1992, *54*, 250-252.

(30) Mashru, C. R.; Parikh, P. P. *East Pharm* 2000, *43*, 111-114.

(31) Basavaiah, K.; Chandrashekar, U.; Prameela, H. C. *IL Farmaco* 2003, *58*, 141-148.

(32) Barry, L. H.; Mark, W.; Anna, I.; Tarik, V.; Ernest, P. *J. Pharm. Biomed. Anal.* 2000, *23*, 637-651.

(33) Belal, F.; Al-Zaagi, I. A.; Gadkariem, E. A.; Abounassif, M. A. *J. Pharm. Biomed. Anal.* 2001, *24*, 335-342.

(34) Bhushan, R.; Deepak, G.; Shravan, K. S. *Biomed. Chromatogr.* 2005, *20*, 217 - 224.

(35) Bonazzi, D.; Gotti, R.; Andrisano, V.; Cavrini, V. *J. Pharm. Biomed. Anal.* 1997, *16*, 431-438.

(36) Veeran, G. K.; Uttam, M.; Senthamil, S. P.; Sam, S. W. D.; Animesh, G.; Amlan, K. S.; Sangita, A.; Nageswar, R. T.; Tapan, K. P. *J. Chromatogr. B* 2007, *858*, 13-21.

(37) Xiao-yang, L.; Jian-zhong, S.; Jian, L. *J. Pharm. Biomed. Anal.* 2006, *40*, 478-483.

(38) Zhimeng, Z.; Andre, V.; Len, N. *J. Chromatogr. B* 2002, *779*, 297-306.

(39) Bengt-Arne, P.; Christina, F.; Magnar, E.; Martin, A. *J. Pharm. Biomed. Anal.* 2006, *40*, 794-798.

(40) Al-Majed, A. A.; Al-Zehouri, J. *Il Farmaco* 2001, *56*, 291-296.

(41) Rahman, N.; Ahmad, Y.; Azmi, S. N. *AAPS PharmSciTech.* 2005, *6*, EE543-EE551.

(42) Rontogianni, M. A.; Markopoulou, C. K.; Koundourellis, J. E. *J. Liq. Chromatogr. Relat. Technol.* 2006, *29*, 2701-2719.

(43) Hisham, E. A. *Spectrochimica Acta Part A: Mol. Biomol. Spectroscopy* 2007, *66*, 701-706.

(44) Al-Majed, A. A.; Belal, F.; A., A.; Al-Obaid, A. M. *Il Farmaco* 2000, *55*, 233-238.

(45) Prieto, J. A.; Jimenez, R. M.; Alonso, R. M. *Il Farmaco* 2003, *58*, 343-350.

(46) Gotti, R.; Andrisanoa, V.; Cavrinia, V.; Bertuccib, C.; Furlanettoc, S. *J. Pharm. Biomed. Anal.* 2000, *22*, 423-431.

(47) Hillaert, S.; De Grauwe, K.; Van den, B. W. *J. Chromatogr. A* 2001, *924*, 439-449.

(48) Hisham, E. A.; Magda, M. A.; Elham, A. T. *J. Pharm. Biomed. Anal.* 1999, *18*, 1021-1027.

(49) Magda, M. A.; Abdalla, A. S.; Hisham, E. A.; Mervat, M. H. *J. Pharm. Biomed. Anal.* 2002, *28*, 311-321.

(50) Singh, S.; Singh, B.; Bahuguna, R.; Wadhwa, L.; Saxena, R. *J. Pharm. Biomed. Anal.* 2006, *41*, 1037-1040.

(51) Sistla, R.; Tata, V. S. S. K.; Kashyap, Y. V.; Chandrasekar, D. P. V.; Diwan *J.Pharm. Biomed. Anal.* 2005, *39*, 517-522.

(52) Rajkondawar, V. V. *Asian Journal of Chemistry* 2006, *18*, 3230-3232.

(53) Imran, M.; Singh, R. S. P.; Chandran, S. *PHARMAZIE* 2006, *61*, 766-769.

(54) Gowri Sankar, D.; Kumar, D. V. S. P.; Krishna, M. V.; Latha, P. V. M. *Asian Journal of Chemistry* 2005, *17*, 2812-2814.

(55) Ramakrishna, N. V. S.; Vishwottam, K. N.; Koteshwara, M.; Manoj, S.; Santosh, M.; Varma, D. P. *J. Pharm. Biomed.Anal.* 2005, *39*, 1006-1013.

(56) Patel, L. J.; Suhagia, B. N.; Shah, P. B. *Indian J. Pharm. Sc.* 2007, *69*, 594-596.

(57) Kamila, M. M.; Mondal, N.; Ghosh, L. K.; Gupta, B. K. *Pharmazie* 2007, *62*, 486-487.

(58) Mario, T.; Georg, O.; Wilhelm, S. *Biomed. Chromatogr.* 2001, *15*, 393 - 402.

(59) Selvan, P. S.; Gowda, K. V.; Mandal, U.; Solomon, W. D.; Pal, T. K. *J Chromatogr B Analyt Technol Biomed Life Sci.* 2007, *858*, 143-150.

(60) Hans, H. M.; Oliver, T.; Carsten, K.; Armin, A. W.; Frank, T. P. *J. Chromatogr. A* 2004, *1058*, 169-181.

(61) Dragica, Z.; Traje, S.; Petar, M. *Biomed. Chromatogr.* 2004, *18*, 71-76.

(62) Richter, K.; Oertel, R.; Kirch, W. *J. Chromatogr. A* 1996, *729*, 293-296.

(63) Aleksandra, C.; Lucyna, K.; Alina, P.; Henryk, L. *J. Chromatogr. B* 2006, *839*, 102-111.

(64) Ramakrishna, N. V. S.; Vishwottam, K. N.; Manoj, S.; Koteshwara, M.; Wishu, S.; Varma, D. P. *Biomed. Chromatogr.* 2005, *19*, 751 - 760.

(65) Hadi, V.; Parvin, Z.; Ziba, I.; Hosniyeh, T. *J. AOAC INTERNATIONAL* 2006, *89*, 88-93.

(66) Okan, A.; Ugur, T.; Dilek, A. *Anal. Letters* 2001, *34*, 1153 - 1161.

(67) Lin, L.; Jin, S.; Ping, Y.; Zhonggui, H. *Anal. Letters* 2006, *39*, 2797 - 2807.

(68) Nevin, E. *J. Liq. Chrom. & Related Tech.* 2003, *26*, 2581 - 2591.

(69) Shetkar, P. B.; Shinde, V. M. *Anal. Letters* 1997, *30*, 1143 - 1152.

(70) Bebawy, L. I.; El Kousy, N. *Anal. Letters* 1997, *30*, 1379-1397.

(71) Shailesh, A. S.; Ishwarsinh, S. R.; Bhanubhai, N. S.; Shrinivas, S. S.; Jignesh, B. P. *J. AOAC INTERNATIONAL* 2001, *84*, 1715-1723.

(72) Dorota, K.; Hanna, H. *J. AOAC INTERNATIONAL* 2004, *87*, 847-851.

(73) Ustundag, O.; Dinc, E. *Pharmazie* 2003, *58*, 623-628.

(74) Nevin, E. *Pharmazie* 2003, *58* 543-548.

(75) Claudio, V.; Almagrazia, G. *Anal. Letters* 2003, *36*, 1051-1064.

(76) Nevin, E.; Feyyaz, O. *Anal. Letters* 1996, *29*, 1963 - 1974.

(77) Joseph-Charles, J.; Brault, S.; Boyer, C.; Langlois, M. H.; Cabrero, L.; Dubost, J. P. *Anal. Letters* 2003, *36*, 2485 - 2495.

(78) Erdal, D.; Bengi, U.; Sibel, A. O. *Anal. Letters* 2005, *37*, 679-693.

(79) Nevin, E.; Feyyaz, O. *Anal. Letters* 1997, *30*, 1503 - 1515.

(80) Lories, I. B.; Samah, S. A.; Laila, A. F.; Heba, H. R. *IL Farmaco* 2005, *60*, 859-867.

(81) Abbaspour, A.; Mirzajani, R. *J. Pharm. Biomed. Anal.* 2005, *38*, 420-427.

(82) Erdal, D.; Dumitru, B. *J. Pharm. Biomed. Anal.* 2002, *30*, 715-723.

(83) Murat, P.; Erdal, D.; Feyyaz, O. *J. Pharm. Biomed. Anal.* 2004, *34*, 473-483.

(84) Erdal, D.; Bengi, U.; Ozkan, S. A. *Anal Lett* 2004, *37*, 679-693.

(85) Garcia, G. M. D.; Frenich, G. A.; Vidal, M. J. L.; Galera, M. M.; Munoz, P.; Salinas, F. *Anal. Chimca Acta* 1997, *348*, 177-185.

(86) Garrido, F. A.; Martinez, G. M.; Martínez, V. J. L.; Gil García, M. D. *J Chromatogr, A* 1996, *727*, 27-38.

(87) Herrero, A.; Ortiz, M. C. *Anal Chim Acta* 1997, *348*, 51-59.

(88) Rosangela, B. C.; Luiz, M. H.; Ronei, P. J. *J Pharm Biomed Anal* 2005, *38*, 94-99.

(89) Adams, M. J. *Chemometrics in Analytical Spectroscopy*; The Roy. Soc. of Chem: Thomas, Graham House, Science Park, Cambridge, 1995.

(90) Beebe, K. R.; Kowalski, B. R. *Anal. Chem.* 1987, *59*, 1007A-1018A.

(91) Brereton, R. G. *Analyst* 2000, *125*, 2125-2154.

(92) Frans, S. D.; Harris, J. M. *Anal. Chem.* 1985, *57*, 2880-2684.

(93) Haaland, D. M.; Thomas, E. V. *Anal. Chem.* 1988, *60*, 1193-1202.

(94) Kramer, R. *Chemometric Techniques in Quantitative Analysis*; Marcel Dekker Inc.: New York, 1998.

(95) Superko, R. H.; Madan, S.; Tonnemacher, D.; Chronos, N.; Garrett, B.; Sheehan, D.; Raul, E.; Frohwein, S.; McGrath, K. *J. Am. College. Cardiol.* 2003,, *41*, 316.