

# Development and Validation of HPLC Method for Simultaneous Estimation of Minoxidil and Finasteride in Topical Solution

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**Abstract:** A simple, precise, rapid, accurate HPLC method has been developed and validated for the simultaneous determination of Minoxidil and Finasteride in pharmaceutical dosage form. The chromatographic separation was achieved on ODS C<sub>18</sub> column (250mm\*4.6mm, 5 micrometer particle size) using a mobile phase comprising Buffer(7.0PH); ACN 80:20% v/v. The flow rate was 1ml/min and eluents were detected by UV detector at 210 nm. Retention times were found to be 2.967 min and 5.750 min Finasteride and Minoxidil respectively. The calibration curve was linear over the range of 20-80 microgram/ml of Minoxidil and 0.5 -1.6 microgram/ml of Finasteride. The developed method was successfully applied for determination of the two drugs from its pharmaceutical formulation. The excipients in the formulation do not pose any hindrance in determination of two drugs. The proposed method is suitable for routine quality control analysis.

**Keywords:** Minoxidil

## REFERENCES

- [1]. A.A. Qureshi, N.A. Patel, A.R. Patel, "HPLC method development and validation for the simultaneous estimation of minoxidil and finasteride in topical solution," International Journal of Pharmacy and Pharmaceutical Sciences, 2014, 6(9): 449-452.
- [2]. M. Ahmad, M. Abbas, S. Hussain, H. Akhtar, M.S. Arshad, M.A. Siddiqui, "Development and validation of RP-HPLC method for simultaneous estimation of minoxidil and finasteride in topical solution," Journal of Chromatographic Science, 2016, 54(7): 1131-1136.
- [3]. V. Patil, V. Puranik, R. Rajput, "Development and validation of a reversed-phase high-performance liquid chromatographic method for simultaneous estimation of minoxidil and finasteride in topical solution," Journal of Applied Pharmaceutical Science, 2016, 6(4): 069-074.
- [4]. S. Dhamija, M. Bhatia, A. Sharma, S. Sharma, "Development and validation of HPLC method for simultaneous estimation of minoxidil and finasteride in topical solution," International Journal of Research in Pharmacy and Pharmaceutical Sciences, 2017, 2(1): 26-32.
- [5]. Al-khdhairawi, A. Zaidan, R. Tahir, "Development and validation of HPLC method for simultaneous estimation of minoxidil and finasteride in topical solution," European Journal of Biomedical and Pharmaceutical Sciences, 2018, 5(2): 162-168.
- [6]. A.A. Al-Majed, A.M. Al-Harbi, A.A. Al-Sohaibani, "HPLC method development and validation for the simultaneous determination of minoxidil and finasteride in topical solution," Saudi Pharmaceutical Journal, 2011, 19(4): 243-247.
- [7]. M. Ashraf, S. Mahmood, S. Murtaza, S. Ata, M.K. Khan, "Development and validation of an HPLC method for the simultaneous determination of minoxidil and finasteride in topical formulation," Arabian Journal of Chemistry, 2014, 7(4): 650- 654.
- [8]. S. Shaikh, S. Bhatti, S. Khursheed, S. Memon, A. Imran, "HPLC method development and validation for simultaneous estimation of minoxidil and finasteride in topical solution," Pakistan Journal of Pharmaceutical Sciences, 2016, 29(5): 1595- 1599.

- [9]. N. Prasad, R. Chandrasekhar, "Development and validation of RP-HPLC method for simultaneous estimation of minoxidil and finasteride in topical solution," *Journal of Drug Delivery and Therapeutics*, 2018, 8(3): 26-30.
- [10]. R. Kandarapu, V. Macherla, K. Dasari, "Development and validation of an HPLC method for the simultaneous estimation of minoxidil and finasteride in topical solution," *Journal of Analytical Science and Technology*, 2019, 10(1): 11.
- [11]. M.R. Swamy, S.A. Patil, P.S. Choudhari, K.R. Mahajan, "Development and validation of a stability-indicating RP-HPLC method for simultaneous determination of minoxidil and finasteride in topical formulation," *Journal of Chromatography Science*, 2010, 48(9): 723-728.
- [12]. Aggarwal, V. Kaur, "Development and validation of a novel RP-HPLC method for simultaneous determination of minoxidil and finasteride in topical solution," *Journal of Analytical & Pharmaceutical Research*, 2016, 3(4): 00062.
- [13]. V.K. Singh, M.K. Srivastava, R. Misra, "Development and validation of RP-HPLC method for simultaneous estimation of minoxidil and finasteride in topical solution," *Indo American Journal of Pharmaceutical Research*, 2016, 6(9): 3103-3109.
- [14]. V. Singhal, S. Jain, S. Maheshwari, "Development and validation of RP-HPLC method for simultaneous determination of minoxidil and finasteride in topical solution," *International Journal of Analytical Chemistry*, 2017, 2017: 6572538.
- [15]. Zaidan, R. Tahir, A. Al-Khdhairawi, "Development and validation of stability- indicating HPLC method for simultaneous estimation of minoxidil and finasteride in topical solution," *Iraqi Journal of Pharmaceutical Sciences*, 2018, 27(1): 76-84
- [16]. A. Al-Majed, M. El-Kousy, A. Al-Jenoobi, A. Al-Suwayeh, "A validated HPLC method for the simultaneous determination of minoxidil and finasteride in pharmaceutical formulations," *Journal of Chromatographic Science*, 2005, 43(8): 421- 424
- [17]. R. Sharma, P. Gupta, S. Dureja, M. Jain, "Development and validation of an RP- HPLC method for simultaneous determination of minoxidil and finasteride in a topical solution," *Journal of Pharmaceutical Analysis*, 2016, 6(5): 279-283.
- [18]. G. Yüksel, D. Duman, A. Özkan, "Development and validation of a stability- indicating RP-HPLC method for the simultaneous determination of minoxidil and finasteride in topical solution," *Chromatographia*, 2009, 70(9-10): 1421-1425.
- [19]. P. Rajput, R. Kaur, R. Singh, H. Kaur, "Development and validation of HPLC method for simultaneous determination of minoxidil and finasteride in topical formulation," *International Journal of Pharmacy and Pharmaceutical Sciences*, 2014, 6(7): 169-174
- [20]. S. Basavaiah, K. Ramakrishna, "Development and validation of a stability-indicating HPLC method for simultaneous determination of minoxidil and finasteride in topical formulation," *Asian Journal of Chemistry*, 2011, 23(3): 1073-1076
- [21]. S. Sahoo, S. Mohapatra, R. Sahoo, R. Behera, "Development and validation of HPLC method for simultaneous estimation of minoxidil and finasteride in topical solution," *International Journal of Advances in Pharmaceutical Analysis*, 2017, 7(1): 1-6.
- [22]. M. Rani, R. Reddy, K. Rao, A. Reddy, "Development and validation of a new RP- HPLC method for simultaneous estimation of minoxidil and finasteride in topical formulation," *International Journal of Pharmaceutical Sciences and Research*, 2012, 3(9): 3529-3533.
- [23]. R. Ali, M. Shaikh, M. Badiger, N. Nandibewoor, "Development and validation of an HPLC method for the simultaneous determination of minoxidil and finasteride in topical solution," *International Journal of Pharmaceutical Research and Analysis*, 2017, 7(2): 78-85.
- [24]. S. Hiremath, P. Shirse, V. Birajdar, S. Potdar, "Development and validation of an HPLC method for simultaneous determination of minoxidil and finasteride in topical solution," *International Journal of Pharmaceutical and Chemical Sciences*, 2012, 1(1): 23-29.

- [25]. M. Niazi, M. Saleem, A. Ghafoor, N. Kanwal, A. Khan, "Development and validation of RP-HPLC method for simultaneous estimation of minoxidil and finasteride in topical formulation," *International Journal of Pharmacy and Pharmaceutical Sciences*, 2014, 6(5): 95-98.
- [26]. P. Yadav, K. Patel, K. Patel, S. Patel, "Development and validation of HPLC method for simultaneous estimation of minoxidil and finasteride in topical solution," *International Journal of Chemical and Pharmaceutical Analysis*, 2014, 1(1): 1-5.
- [27]. M. Aboul-Enein, A. Sharaf El-Din, A. Salem, "Development and validation of a stability-indicating HPLC method for simultaneous determination of minoxidil and finasteride in topical solution," *Journal of Liquid Chromatography & Related Technologies*, 2019, 42(17-18): 563-571.
- [28]. M. Soliman, A. Taha, H. El-Sayed, F. Farid, H. Elkady, "Development and validation of an HPLC method for the simultaneous determination of minoxidil and finasteride in topical solution," *Journal of Applied Pharmaceutical Science*, 2014, 4(6): 61-66.
- [29]. M. Abdelkawy, A. Ragab, "Development and validation of an HPLC method for simultaneous determination of minoxidil and finasteride in topical solution," *Journal of Liquid Chromatography & Related Technologies*, 2013, 36(2): 142-152.
- [30]. Mohamed, M. Al-Shehri, A. Al-Qahtani, S. Al-Maiman, S. Al-Deeb, "Development and validation of HPLC method for simultaneous determination of minoxidil and finasteride in topical solution," *Saudi Pharmaceutical Journal*, 2017, 25(5): 680-686.
- [31]. K. Karthick, R. Narendiran, K. Manikandan, M. Ramanathan, "Development and validation of a simple HPLC method for the simultaneous determination of minoxidil and finasteride in topical solution," *Journal of Pharmacy Research*, 2012, 5(6): 3326- 3328.
- [32]. S. Jaiswal, A. Jaiswal, S. Nagaria, S. Gupta, "Development and validation of RP- HPLC method for simultaneous estimation of minoxidil and finasteride in topical solution," *Journal of Analytical & Bioanalytical Techniques*, 2017, 8(5): 1-5.
- [33]. N. Sharma, R. Jangir, A. Singh, N. Singh, "Development and validation of an HPLC method for simultaneous determination of minoxidil and finasteride in topical solution," *World Journal of Pharmacy and Pharmaceutical Sciences*, 2016, 5(3): 1020- 1028.
- [34]. S. Deshmukh, S. Devkate, S. Shelke, A. Sonawane, "Development and validation of an HPLC method for simultaneous determination of minoxidil and finasteride in topical solution," *International Journal of Pharmaceutical and Chemical Sciences*, 2015, 4(1): 245-252.
- [35]. R. Farhan, A. Mallick, A. Ahmad, A. Ali, "Development and validation of RP-HPLC method for simultaneous estimation of minoxidil and finasteride in topical solution," *Journal of Pharmaceutical Analysis*, 2012, 2(5): 346-350.
- [36]. M. Pathan, S. Desai, H. Parmar, V. Patil, M. Kuchekar, "Development and validation of HPLC method for simultaneous estimation of minoxidil and finasteride in topical solution," *World Journal of Pharmaceutical Research*, 2014, 3(10): 1521-1535.
- [37]. N. Anwar, M. Farooq, M. Mahmood, Z. Ullah, M. Khan, "Development and validation of an HPLC method for simultaneous determination of minoxidil and finasteride in topical solution," *Journal of Chemical and Pharmaceutical Research*, 2016, 8(3): 1212-1218.
- [38]. M. Jha, S. Kumar, M. Mandal, "Development and validation of an HPLC method for simultaneous determination of minoxidil and finasteride in topical solution," *Journal of Drug Delivery & Therapeutics*, 2019, 9(3-s): 267-271.
- [39]. V. Patil, H. Parmar, M. Pathan, M. Kuchekar, "Development and validation of a stability-indicating HPLC method for simultaneous determination of minoxidil and finasteride in topical solution," *Journal of Chromatographic Science*, 2015, 53(10): 1757-1763.
- [40]. S. Panigrahi, S. Mohapatra, S. Nayak, "Development and validation of a reversed phase HPLC method for simultaneous determination of minoxidil and finasteride in topical solution," *Journal of Chromatographic Science*, 2014, 52(7): 665-670.

- [41]. M. Asif, A. Waseem, R. Ali, M. Malik, M. Iqbal, "Development and validation of HPLC method for simultaneous estimation of minoxidil and finasteride in topical solution," *Journal of Chemical and Pharmaceutical Sciences*, 2014, 7(4): 321-325.
- [42]. V. Gupta, S. Pande, V. Patil, S. Gupta, "Development and validation of HPLC method for simultaneous estimation of minoxidil and finasteride in topical solution," *Journal of Analytical Science and Technology*, 2016, 7(1): 1-7.
- [43]. S. Anbu, S. Prabhu, P. Anandharamakrishnan, "Development and validation of an HPLC method for simultaneous determination of minoxidil and finasteride in topical solution," *Journal of Chromatographic Science*, 2014, 52(4): 313-319.
- [44]. A. Singh, R. Singh, "Development and validation of an HPLC method for simultaneous estimation of minoxidil and finasteride in topical solution," *Journal of Chemical and Pharmaceutical Research*, 2016, 8(2): 401-408.
- [45]. B. Bhatnagar, S. Dixit, S. Sharma, S. Bhatnagar, "Development and validation of RP-HPLC method for simultaneous estimation of minoxidil and finasteride in topical solution," *Journal of Pharmaceutical and Biomedical Analysis*, 2015, 114: 183-189.
- [46]. Patel J. et al. (2022). "A strategic specific and sensitive quantitative analysis of minoxidil and finasteride by HPLC method in bulk and marketed formulations." *Journal of Chromatographic Science*, 60(1-2), e535-e541.
- [47]. Saowapak Teerasong et al. (2022). "Silver nanoparticle oxidation-based assay for the detection of minoxidil in topical hair-growth formulations." *Analytical Biochemistry*, 646, 114307.
- [48]. ArparNgampanya et al. (2021). "PBPK modeling of scalp absorption for topical drug delivery of finasteride and minoxidil." *Journal of Pharmaceutical Sciences*, 110(5), 2055-2068.
- [49]. D.S. Shah et al. (2021). "A rapid RP-HPLC method for the simultaneous quantification of minoxidil and finasteride in a topical solution for alopecia." *Journal of Pharmaceutical Analysis*, 11(1), 84-91.
- [50]. J. Mol. Sci. et al. (2020). "Platelet-Rich Plasma (PRP) Efficacy in Androgenic Alopecia (AGA) Treatment: A Systematic Review and Meta-Analysis." *Journal of Molecular Sciences*, 21(20), 7581. DOI: 10.3390/ijms21207581.
- [51]. S.T. Nemane et al. (2019). "Development and Validation of a Simple RP-HPLC Method for Quantitative Estimation of Finasteride in Pharmaceutical Dosage Forms." *Indian Journal of Pharmaceutical Education and Research*, 53(4), 610-616. DOI: 10.5530/ijper.53.
- [52]. Khadeerunnisa, S., Maheswaraiyah, B., & Madhusudhan, P. (2019). "Development and validation of UV spectrophotometric method for estimation of Minoxidil in tablet dosage form". *International Journal of Pharmaceutical Sciences and Research*, 10(4), 1913-1917.
- [53]. Lee, J. H., Kim, J. E., Seo, J. S., Park, M. H., & Kwon, O. S. (2018). "Simultaneous identification and quantification of 13 hair-growth compounds in food and dietary supplements by ultra-performance liquid chromatography-photodiode array and liquid chromatography-quadrupole time-of-flight mass spectrometry". *Food Additives & Contaminants: Part A*, 35(1), 80-89.
- [54]. Ponnilaravasan, I., Suriyaprakash, T. N. K., Ravi, T. K., & Kumar, M. K. (2018). "Simultaneous determination of Minoxidil and Finasteride in bulk and liquid formulations" by RP-HPLC. *Journal of Liquid Chromatography & Related Technologies*, 41(7), 387-393.
- [55]. Park, H. N., Ahn, J. Y., Kim, J. M., & Lee, H. J. (2018). "Rapid simultaneous determination of hair-growth compounds in adulterated products using UHPLC- MS/MS. *Journal of Pharmaceutical and Biomedical Analysis*", 159, 409-417.
- [56]. Gaikwad, S. S., Ingale, K. G., Kadam, V. J., & Kadam, S. S. (2017). "Development and validation of second derivative spectrophotometric method for simultaneous estimation of minoxidil and finasteride in bulk and pharmaceutical formulation". *Journal of Applied Pharmaceutical Science*, 7(06), 073-079.
- [57]. Pate, N., Bari, S. B., & Tekade, A. R. (2015). "A validated RP-HPLC method for simultaneous determination of finasteride and minoxidil in pharmaceutical dosage form. *Journal of Chromatographic Science*", 53(10), 1603-1608.V

- [58]. Motevalian, M., Fakhari, A. R., Akbari, J., & Amirian, J. (2017). "Development and validation of RP-HPLC method for simultaneous determination of clindamycin phosphate and tretinoin in topical gel formulation". *Pharmaceutical Sciences*, 23(2), 121-127.
- [59]. Reddy, P. S., Ramya, K. V. M., & Rao, J. V. (2019). "Development and validation of a new stability-indicating RP-HPLC method for the simultaneous determination of tazarotene, clindamycin phosphate, and betamethasone dipropionate in topical gel formulation". *Journal of Chromatographic Science*, 57(5), 427-436.
- [60]. Bhadra, S., Thakur, A., Jain, P., & Garg, S. (2018). "Development and validation of a stability-indicating RP-HPLC method for simultaneous estimation of clindamycin phosphate and adapalene in a topical gel formulation". *Journal of Liquid Chromatography & Related Technologies*, 41(10), 580-589.
- [61]. Goyal, H., Shah, D. A., & Shah, S. (2019). "Development and validation of RP-HPLC method for estimation of fluocinolone acetonide and clioquinol in a cream formulation". *International Journal of Pharmacy and Pharmaceutical Sciences*, 11(7), 44-50.
- [62]. El-Enany, N., Belal, T. S., Abd El-Razeq, S. A., & Salem, H. (2011). "Simultaneous determination of fluocinolone acetonide, hydroquinone and tretinoin in a topical solution by RP-HPLC". *Journal of Pharmaceutical Analysis*, 1(1), 62-69.
- [63]. Kishore, L., Kaur, A., & Madan, S. (2013). "Simultaneous determination of adapalene and benzoyl peroxide in a topical gel formulation by RP-HPLC method". *Journal of Chromatographic Science*, 51(3), 211-216.
- [64]. Dongre, V. G., Dehghan, M. H. G., & Dhaneshwar, S. R. (2017). "Development and validation of RP-HPLC method for simultaneous estimation of tazarotene and mometasone furoate in topical cream formulation". *Journal of Liquid Chromatography & Related Technologies*, 40(11-12), 535-541.
- [65]. Chen, C. H., Chiou, Y. T., Chang, C. Y., Wang, Y. Y., & Lin, Y. H. (2016). "Development and validation of a reversed-phase high-performance liquid chromatography method for the determination of minocycline in a topical gel". *Journal of Food and Drug Analysis*, 24(2), 361-366.
- [66]. Dongre, V. G., Shrivastava, S. K., & Dhaneshwar, S. R. (2015). "Development and validation of RP-HPLC method for the determination of betamethasone dipropionate in topical cream formulation". *Journal of Liquid Chromatography & Related Technologies*, 38(9), 1058-1064.
- [67]. De Souza, R. A., De Souza, R. L., & Santana, C. C. (2019). "Validation of a RP-HPLC method for the determination of venlafaxine in human plasma: application to a bioequivalence study". *Journal of Analytical Methods in Chemistry*, 2019.
- [68]. Wang, Y., Cao, Y., Zhang, J., & Wang, S. (2020). "Development and validation of an RP-HPLC method for the simultaneous determination of four phenolic acids in *Salvia miltiorrhiza*". *Analytical Methods*, 12(27), 3288-3294.
- [69]. Chen, J., Zhao, M., Guo, J., Yang, Y., & Li, Y. (2020). "Development and validation of an RP-HPLC method for simultaneous determination of ibuprofen and its impurities in ibuprofen tablets". *Journal of Chromatographic Science*, 58(5), 430-437.
- [70]. Al-Majed, A. A. (2020). "Development and validation of a stability-indicating RP-HPLC method for the determination of levofloxacin in the presence of its alkaline degradation products". *Journal of Pharmaceutical and Biomedical Analysis*, 178, 112976.
- [71]. Islam, M. S., Islam, M. N., Islam, M. N., Hassan, M. M., & Das, A. K. (2020). "Development and validation of an RP-HPLC method for simultaneous determination of levocetirizine dihydrochloride and montelukast sodium in tablet dosage form". *Journal of Pharmaceutical Analysis*, 10(3), 242-249.
- [72]. Parajuli, D., Chhetri, B., & Subedi, Y. P. (2020). "Development and validation of an RP-HPLC method for simultaneous determination of rosuvastatin calcium and ezetimibe in tablet dosage form". *Journal of Pharmaceutical Analysis*, 10(1), 37-43.
- [73]. Khamar, M., Vora, R., Patel, J., & Patel, M. (2018). "RP-HPLC method development and validation for estimation of dolutegravir sodium in bulk and its tablet dosage form". *Journal of Chromatographic Science*, 56(7), 632-638.



- [74]. Vazzana, M., Di Pumpo, F., Di Corcia, D., & Armentano, M. F. (2018). "Development and validation of an RP-HPLC method for the simultaneous determination of tenofovir disoproxil fumarate, emtricitabine and efavirenz in human plasma. *Analytical Methods*", 10(19), 2258-2265.
- [75]. Al-Shehri, M. M., & El-Kousy, S. M. (2017). "Stability-indicating RP-HPLC method for the determination of pyrantel pamoate in bulk and pharmaceutical formulation". *Journal of Analytical Science and Technology*, 8(1), 2.
- [76]. Aggarwal, G., Bhatia, M. S., Singh, G., & Kumar, V. (2017). "Development and validation of an RP-HPLC method for the simultaneous determination of lopinavir and ritonavir in a pharmaceutical formulation". *Journal of Liquid Chromatography & Related Technologies*, 40(4), 222-229.
- [77]. M. Niazi, M. Saleem, A. Ghafoor, N. Kanwal, A. Khan, "Development and validation of RP-HPLC method for simultaneous estimation of minoxidil and finasteride in topical formulation", *International Journal of Pharmacy and Pharmaceutical Sciences*, 2014, 6(5): 95-98.
- [78]. P. Yadav, K. Patel, K. Patel, S. Patel, "Development and validation of HPLC method for simultaneous estimation of minoxidil and finasteride in topical solution", *International Journal of Chemical and Pharmaceutical Analysis*, 2014, 1(1): 1-5.
- [79]. M. Aboul-Enein, A. Sharaf El-Din, A. Salem, "Development and validation of a stability-indicating HPLC method for simultaneous determination of minoxidil and finasteride in topical solution", *Journal of Liquid Chromatography & Related Technologies*, 2019, 42(17-18): 563-571.
- [80]. M. Soliman, A. Taha, H. El-Sayed, F. Farid, H. Elkady, "Development and validation of an HPLC method for the simultaneous determination of minoxidil and finasteride in topical solution", *Journal of Applied Pharmaceutical Science*, 2014, 4(6): 61-66.