Estimation of Nadifloxacin and Clobetasol Propionate by Various Analytical Method: Review Article

Neetu Rajeshbhai Dharu¹ & Bhumi R. Patel²
¹,²Ph.D., pursuing, M.Pharm
¹,²Department of Pharmaceutical Quality Assurance, Sharda School of Pharmacy, Pethapur, Gandhinagar, Gujarat, India

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ABSTRACT: Analytical method development and its validation is an important aspect in drug discovery process. Development of analytical method producing accurate and precise data is necessary to ensure the quality and safety of the drugs. At present, the most common analytical method employed for estimation of drugs is Reverse Phase High Pressure Liquid Chromatography (RP-HPLC) because of its high sensitivity, accuracy and speed. Different types of analytical methods are available for estimation of Nadifloxacin and Clobetasol Propionate including RP-HPLC. This review article briefly discusses analytical methods available for the estimation of Nadifloxacin and Clobetasol Propionate individually, in combination with other drugs as well as in combine dosage form.

Key Words: Analytical methods, RP-HPLC Method, UV-Spectrometry, Nadifloxacin and Clobetasol Propionate.

Introduction¹-⁴

ACNE VULGARIS DISEASE:
Skin has tiny holes called pores which can become blocked by oil, bacteria, dead skin cells, and dirt. When this occurs, you may develop a pimple Nadifloxacin is [RS]-9-Fluoro-8-(4-hydroxy-piperdin-1-yl)-5-methyl-1-oxo-6,7-dihydro-1H,5H-pyrido[3,2,1-ij]quinoline-2-carboxylic acid inhibits the enzyme DNA gyrase that is involved in bacterial DNA synthesis and replication, thus inhibiting the bacterial multiplication. It is a potent and broad-spectrum antibacterial activity against aerobic Gram-positive, Gram-negative and anaerobic bacteria, including Propionibacterium acnes and Staphylococcus epidermidis. Nadifloxacin showed potent antibacterial activity against methicillin-resistant Staphylococcus aureus (MRSA), which was similar to potency against methicillin-sensitive Staphylococcus aureus (MSSA). The drug was also active against new quinolone-resistant MRSA.

Clobetasol Propionate is [17-(2'-Chloroacetyl)-9-fluoro-11-hydroxy-10,13,16-trimethyl-3-oxo-6,7,8,11,12,14,15,16-octahydrocyclopenta[a]phenanthren-17-yl]propanoate thought to act by the induction of phospholipase A inhibitory proteins, collectively called lipocortins.
Table 1: REPORTED METHOD FOR NADIFLOXACIN

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Drugs</th>
<th>Method</th>
<th>Brief Introduction</th>
<th>Ref. No.</th>
</tr>
</thead>
</table>
| 1       | Nadifloxacin                               | HPLC           | Mobile phase: 0.05 %v/v Trifluoro acetic acid : Acetonitrile (65:35)  
Column: Hypersil C18, (150 mm × 4.6 mm, 5µ,)  
Flow rate: 1.2 ml/min  
Wavelength: 237 nm.                                                                 | 28       |
| 2       | Nadifloxacin                               | HPLC           | Mobile phase: 0.05 %v/v Trifluoro acetic acid : Acetonitrile (70:30)  
Column: Zorbax C18, (150 mm × 4.6 mm, 5µ,)  
Flow rate: 1.0 ml/min  
Wavelength: 237 nm.                                                                 | 29       |
| 3       | Nadifloxacin                               | Stability indicating HPTLC | Mobile phase: Chloroform: Methanol: Ammonia (4.3: 4.3: 1.4 v/v/v)  
Plate: Silicagel 60F 254  
Wavelength: 296 nm.                                                                                                                                 | 30       |
| 4       | Nadifloxacin                               | UV Spectroscopy | Wavelength: 296.5 nm in Absorbance maxima method, and in the first order derivative spectra, showed sharp peak at 278.0 nm. in area under curve (AUC) in the wavelength range of 291-301 nm.  
Concentration range: 5-25 µg/ml  
Solvent: Methanol                                                                 | 31       |
| 5       | Nadifloxacin and Adapalene                 | HPLC           | Mobile phase: Acetonitrile: Methanol: Water (35:45:20, pH 2.8)  
Column: Sheisedo C18, (250 mm × 4.6 mm, 5µ,)  
Flow rate: 1.0 ml/min  
Wavelength: 271 nm.                                                                 | 32       |
| 6       | Nadifloxacin, Terbinafine Hydrochloride, Mometasone Furoate, Methyl Paraben, and Propyl Paraben | Stability indicating UPLC | Column: Waters C18, (50 mm × 2.1 mm, 1.7µ,)  
Flow rate: 0.4 ml/min  
Wavelength: 255 nm.                                                                 | 33       |
| 7       | Nadifloxacin and Mometasone furoate        | HPTLC          | Mobile phase: Dichloroethane: Diethyl ether: Ammonia: Methanol: Ethylacetate (6: 3: 0.2: 1.75: 3.5 v/v)  
Plate: Silicagel 60F 254  
Wavelength: 34       |
8 Nadifloxacin, Mometasone furoate and Miconazole Nitrate
HPTLC
Mobile phase:
Methanol: Ethyl acetate: Toluene: Acetonitrile:3M Ammonium formate in water (1:2.5:6.0:0.3:0.2, % v/v)
Plate:
Silicagel 60F254
Wavelength:
224 nm.

9 Nadifloxacin and Ibuprofen
UV Spectroscopy
Multi wavelength method:
Wavelength: 224 nm, 280 nm and at 294 nm for Ibuprofen and Nadifloxacin.
Concentration range:
2-20 μg/ml for Nadifloxacin and for Ibuprofen
Solvent:
Methanol: Water (20:80)

CLOBETASOL PROPIONATE
Table 2:- OFFICIAL METHOD OF CLOBETASOL PROPIONATE10-11

<table>
<thead>
<tr>
<th>Sr. No</th>
<th>Official in</th>
<th>Method</th>
<th>Description</th>
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</tr>
</thead>
</table>
| 1      | BP-2009     | RP-HPLC  | **Mobile phase:** Phosphate Buffer, pH 5.5: Methanol: Acetonitrile (42.5:10:47.5)
**Column:** C18 (15 cm X 4.6 mm), 5 μm
**Flow Rate:** 1.0 ml/min
**Wavelength:** 240 nm | 13       |
| 2      | USP30-NF25  | RP-HPLC  | **Mobile phase:** Phosphate Buffer, pH 2.5: Methanol: Acetonitrile (85:20:95)
**Column:** Packing L1 (15 cm X 4.6 mm)
**Flow Rate:** 1.0 ml/min
**Wavelength:** 240 nm | 14       |

Table 3:- REPORTED METHOD FOR CLOBETASOL PROPIONATE 12-24

<table>
<thead>
<tr>
<th>Sr no.</th>
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<th>brief introduction</th>
<th>Ref. No</th>
</tr>
</thead>
</table>
| 1      | Clobetasol Propionate | RP-HPLC  | **Mobile phase:** Methanol: Water (80:20)
**Column:** Gemini C18 (25 cm X 4.6 mm), 5 μm
**Flow Rate:** 1.0 ml/min
**Wavelength:** 241 nm | 15       |
<table>
<thead>
<tr>
<th>2</th>
<th>Clobetasol Propionate</th>
<th>RP-HPLC</th>
<th>Mobile phase: Acetonitrile: Phosphate Buffer, pH 7.0 (65:35)</th>
<th>Column: Varian C18 (25 cm X 4.6 mm), 5 μm</th>
<th>Flow Rate: 1.0 ml/min</th>
<th>Wavelength: 240 nm</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Clobetasol Propionate</td>
<td>RP-HPLC</td>
<td>Mobile phase: Acetonitrile: Water (60:40)</td>
<td>Column: Lichrocart C18 (25 cm X 4.6 mm), 5 μm</td>
<td>Flow Rate: 1.0 ml/min</td>
<td>Wavelength: 237 nm</td>
</tr>
<tr>
<td>4</td>
<td>Clobetasol Propionate</td>
<td>RP-HPLC</td>
<td>Mobile phase: Methanol: Acetonitrile: Water (50:15:35)</td>
<td>Column: RP C18 (15 cm X 4.6 mm), 5 μm</td>
<td>Flow Rate: 1.2 ml/min</td>
<td>Wavelength: 240 nm</td>
</tr>
<tr>
<td>5</td>
<td>Clobetasol Propionate</td>
<td>UV spectrophotometry</td>
<td>The method is based on the formation of colored adduct Triphenyl formazan between the Clobetasol propionate and Chromogenic reagent</td>
<td>Wavelength: 523 nm</td>
<td>Concentration range: 5-25 μg/ml</td>
<td>Solvent: Ethanol</td>
</tr>
<tr>
<td>6</td>
<td>Clobetasol Propionate</td>
<td>Stability indicating HPTLC</td>
<td>Mobile phase: Ethyl acetate: Hexane: Ammonia (5:5:0.2)</td>
<td>Stationary phase: silica gel 60 F254</td>
<td>Wavelength: 240 nm</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Clobetasol Propionate</td>
<td>Stability indicating HPTLC</td>
<td>Mobile phase: Toluene: Methanol (8:2)</td>
<td>Stationary phase: silica gel 60 F254</td>
<td>Wavelength: 239 nm</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Clobetasol Propionate and Fusidic acid</td>
<td>RP-HPLC</td>
<td>Mobile phase: Acetonitrile: Water, pH 5.0 (80:20)</td>
<td>Column: Phenomenex Luna C18 (25 cm X 4.6 mm), 5 μm</td>
<td>Flow Rate: 1.0 ml/min</td>
<td>Wavelength: 240 nm</td>
</tr>
</tbody>
</table>
### Stability indicating RP-HPLC

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</table>
| 9       | Ofloxacin, Ofloxacin, Ornidazole, Clobetasol Propionate, Terbinafine Hydrochloride, Methyl Paraben, Propyl Paraben | Stability indicating RP-HPLC | **Mobile phase:** Acetonitrile: Phosphate Buffer, pH 2.5 (82:18)  
**Column:** Zodiac C18 (25 cm X 4.6 mm), 5 μm  
**Flow Rate:** 1.0 ml/min  
**Wavelength:** 255 nm |
| 10      | Clobetasol Propionate and Calcipotriol      | RP-HPLC      | **Mobile phase:** Methanol: Water (74:26)  
**Column:** Novapack C18 (25 cm X 4.6 mm), 5 μm  
**Flow Rate:** 1.0 ml/min |
| 11      | Clobetasol and Chlorocresol                 | Stability indicating RP-HPLC | **Mobile phase:** Solvent-A: Phosphate Buffer, pH 4.5: Methanol (80:20)  
Solvent-B: Acetonitrile  
**Solvent (min)** | **Sol-A** | **Sol-B** |
|         |                                             |              | 0   | 80  | 20  |
|         |                                             |              | 10  | 40  | 60  |
|         |                                             |              | 18  | 40  | 60  |
|         |                                             |              | 20  | 80  | 20  |
|         |                                             |              | 22  | 80  | 20  |
|         |                                             |              | **Stationary phase:** Luna Column (250 mm X 4.60 mm, 5μm)  
**Flow rate:** 1.5 ml/min  
**Wavelength:** 240 nm |
| 12      | Terbinafine HCl, Clobetasol Propionate, Ornidazole and Ofloxacin | RP-HPLC     | **Mobile phase:** Acetate Buffer, pH 4.0: Acetonitrile (10:90)  
**Stationary phase:** C18 (250 mm X 4.60 mm, 5 μm)  
**Flow rate:** 1 ml/min  
**Wavelength:** 239 nm |
| 13      | Clobetasol Propionate and Salicylic Acid    | RP-HPLC      | **Mobile phase:** Solvent-A: Phosphate Buffer, pH 4.7  
Solvent-B: Methanol  
Solvent-C: Methanol: Acetonitrile (50:50)  
**Stationary phase:** Eclipse XDBC18 (250 mm X 4.60 mm, 5μm)  
**Flow rate:** 1 ml/min  
**Wavelength:** 240 nm |

### Table 4: REPORTED METHOD FOR NADIFLOXACIN AND CLOBETASOL PROPIONATE IN COMBINATION

<table>
<thead>
<tr>
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</tr>
</thead>
</table>
| 1       | Nadifloxacin and Clobetasol Propionate      | HPLC   | **Mobile phase:** Water: Acetonitrile (50:50)  
**Column:** Shimpack C18, (250 mm × 4.6 mm, 5 μm)  
**Flow Rate:** 1.0 ml/min  
**Wavelength:** 242 nm. |
CONCLUSION
Presented review includes various analytical methods for the determination of Nadifloxacin and Clobetasol Propionate in various pharmaceutical formulations alone or in combination with other drugs with help of RP-HPLC. For quantitative estimation of Nadifloxacin and Clobetasol, RP-HPLC method is the most common among others. All the reported methods are sensitive, precise and accurate; consisting mainly LC-20 AT C18 column as stationary phase and variety of polar solvents (like methanol, water, acetonitrile, buffers) in different ratios as mobile phase. For development of analytical methods, for newly developed or for upcoming research work, this can be taken for consideration.

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