REVIEW OF DRUGS AND ITS ANALYTICAL METHODS TO TREAT ALLERGIC RHINITIS IN COMBINATION WITH OTHER DRUGS IN DIFFERENT DOSAGE FORM

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ABSTRACT

Current paper describes various analytical methods available for detection of Antibiotic drugs alone and in combination with other drugs from various pharmaceutical formulations. Hence a literature was undertaken replete with the publications on the development of methods of drug substance and drug products. Antibiotic drugs like Fluoroquinolones and Cephalosporins etc in combination with Mucolytic agents are the first class of choice for cough suppression and also in the management for the relief of symptoms of seasonal allergic rhinitis, perennial (non-seasonal) allergic rhinitis in both adult and child. The various analytical techniques have been discussed, from simple classical methods of intermediate selectivity and sensitivity to highly sophisticated, selective and sensitive chromatographic methods applied in a modern analytical laboratory.

Keywords: Spectroscopy, RP-HPLC, Ambroxol, Levofloxacin, Gemifloxacin, Cefixime, Cefadroxil.

INTRODUCTION

Now a day, various Antibiotics drugs are available in combination with Mucolytic agents in market in different dosage form. Among them Fluoroquinolones (e.g. Levofloxacin Hemihydrate, Gemifloxacin Mesylate) are the choice for treatment of serious bacterial infections, urinary tract infections, pyelonephritis and post exposure treatment for inhalation anthrax. Cephalosporins (e.g. Cefadroxil Monohydrate, Cefixime Trihydrate) are used for the prophylaxis and treatment of infections caused by bacteria while Mucolytic agents (e.g. Ambroxol Hydrochloride) are the first class of choice for cough suppression and also in the management for the relief of symptoms of seasonal allergic rhinitis, perennial (non-seasonal) allergic rhinitis in both adult and child. Few example of Mucolytic agent with Fluoroquinolones and Cephalosporins are as follow (Table 1).

Table 1: Combination of Mucolytic agent with Fluoroquinolones and Cephalosporins

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Drug combination</th>
<th>Marketed formulation</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ambroxol HCl (75mg) + Levofloxacin Hemihydrate (500mg)</td>
<td>AM[1]</td>
<td>Nicholas Piramal India Ltd.</td>
</tr>
<tr>
<td>3</td>
<td>Ambroxol HCl (60mg) + Cefixime trihydrate (200mg)</td>
<td>CEFTAS – AL[3]</td>
<td>Intas Pharmaceuticals Laboratories Pvt Ltd</td>
</tr>
<tr>
<td>4</td>
<td>Ambroxol HCl (30mg) + Cefadroxil monohydrate (250mg)</td>
<td>KEFDIL – AX[4]</td>
<td>Ajanta Pharma</td>
</tr>
</tbody>
</table>

Ambroxol Hydrochloride (AMB) (Fig. 1) is chemically Trans-4-[[2-Amino-3,5-dibromobenzyl (aminomethyl) cyclohexanol][5]. It is used in the treatment of tracheobronchitis, emphysema with bronchitis pneumonia, chronic inflammatory pulmonary conditions, bronchiectasis, bronchitis with bronchospasm asthma[6]. It is official in Indian Pharmacopoeia (IP) and British Pharmacopoeia (BP). IP[5] describes High Performance Liquid Chromatography (HPLC) method and BP[7] describes HPLC, Spectrophotometric and Thin Layer Chromatography (TLC) method.

Levofloxacin Hemihydrate (LEV) (Fig. 2) is chemically 9-fluoro-2,3-dihydro-3-Methyl-10-[4-(4-methylpiperazin-1-yl)7-oxo-7H-pyridin1,2,3-de]-1,4-benzoazine-3-carboxylic acid hemihydrate[8]. It is official in IP and describes High Performance Liquid Chromatography (HPLC) method.

Gemifloxacin Mesylate (GEM) (Fig. 3) is chemically 7-[[42]-3-(aminomethyl)-4-(methoxymino) pyrroloidin-1-yl]-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid mono methane sulphonate[9]. It is not official in any Pharmacopoeia.

Cefadroxil Monohydrate (CEF) (Fig. 4) is chemically 6R,7R)-7-[[2R]-2-amino-2-[4-hydroxyphenyl]acetamido]-3-methyl-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid mono hydrate[10]. It is official in IP, BP and United State Pharmacopoeia (USP).

Cefixime Trihydrate (CEFI) (Fig. 5), chemically 6R,7R)-7-[[2Z]-2-(2-amino-1,3-thiazol-1-yl)-2-[[(carboxymethyl) (aminomethyl)-3-ethenyl-8-oxo-5-thia-1-azabicyclo [4.2.0] oct-2-ene-2-carboxylic acid tri hydrate[11]. It is official in BP and USP.
Various methods are available for the detection of antihistaminic drugs along with antibiotics from their pharmaceutical formulations which helps in the estimation of the active products, impurities and the active pharmaceutical ingredients. However literature survey revealed that there is no stability indicating method available. The methods can be selected for the quantitation of the drug based upon its cost effectiveness, its running time, ease of operating and its suitability. Here from the literature survey various methods have been shown along with their characteristic so form the given data one can produce better methods with short analysis time, and low running cost. Various analytical methods for the estimation of drugs are as follows (Table 2).

<table>
<thead>
<tr>
<th>Table 2: Reported Methods to estimate drug alone and in combination with other drugs</th>
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<tbody>
<tr>
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<tr>
<td>(Bulk drug and formulation)</td>
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<td>-----------------------------</td>
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<tr>
<td>24 Ambroxol HCl + Loratadine</td>
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<tr>
<td>(Bulk drug and formulation)</td>
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<tr>
<td>Mesylate (Bulk drug and</td>
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<tr>
<td>26 Ambroxol HCl + Gemifloxacin</td>
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<td>Mesylate (Bulk drug and</td>
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<td>formulation)</td>
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<td>27 Ambroxol HCl + Cetirizine</td>
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<td>Propylparaben (Liquid</td>
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<td>formulation)</td>
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<tr>
<td>28 Levofloxacin Hemihydrate</td>
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<td>+ Cefpodoxime Proxetil</td>
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<td>Q absorbance Ratio method</td>
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<td>29 Levofloxacin Hemihydrate</td>
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<td>+ Ornidazole</td>
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<td>Simultaneous Equation Method</td>
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<td>+ Gelfine Trihydrate</td>
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<td>Simultaneous Equation Method</td>
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<td>31 Levofloxacin Hemihydrate</td>
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<td>Spectro-photometric Method</td>
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<td>32 Levofloxacin Hemihydrate</td>
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<td>34 Levofloxacin Hemihydrate</td>
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<td>35 Levofloxacin Hemihydrate</td>
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<tr>
<td>37 Levofloxacin Hemihydrate</td>
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<tr>
<td>HPLC</td>
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<tr>
<td>38 Levofloxacin Hemihydrate</td>
</tr>
<tr>
<td>+ Ornidazole</td>
</tr>
<tr>
<td>39 Levofloxacin HCl + Lomefloxacin HCl + Gitofloxin + Sparfloxacin</td>
</tr>
</tbody>
</table>
42 Cefadroxil Monohydrate

Difference Spectroscopy method

Diluent- 0.1 M NaOH and 0.1 M HCl

λ: 278nm and 320nm

Concentration range -0.5-30 μg/ml [62]

43 Gemifloxacin Mesylate + Ambroxol HCl

Simultaneous Equation Method

Diluent- water

λ: 271.0 nm and 245.5 nm

Concentration range - 10-60 μg/ml for Gemifloxacin Mesylate and 2-12 μg/ml for Ambroxol HCl [63]

44 Gemifloxacin Mesylate

Spectroscopy method

Diluent- Double Distilled Water

λ: 269nm

Concentration range - 2 -10 μg/ml [64]

45 Gemifloxacin Mesylate

Spectroscopy method

Diluent- 0.05 N H₂SO₄

λ: 267nm

Concentration range - 10 -70 μg/ml [65]

46 Gemifloxacin Mesylate

Direct and Derivative Spectroscopy method

The method is based on chelate formation between GFX and Palladium (Pd II) in aqueous media. The complex showed an absorption maximum at 430 nm, 1st derivative at 480nm and Second derivative at 500nm respectively with apparent molar absorptivities of 1.365 x 10³ L.mol⁻¹.cm⁻¹, 9.37x10⁴ L.mol⁻¹.cm⁻¹ for first order derivative, 1.59 x 10³ L.mol⁻¹.cm⁻¹ for 2nd order derivative respectively. The solution of the complex obeyed beer’s law in the concentration range of 20-14 μg/ml for zero order, 1 to 10 μg/ml for 1st order and 1 to 15 μg/ml for 2nd order respectively. [66]

47 Gemifloxacin Mesylate

HPLC

Column: - Cyano column (250 x 4.6 mm, 5μm particle size)

Mobile phase-1% v/v formic acid: Acetonitrile: Methanol 75:20.5: v/v/v

λ: 292 nm, Flow Rate: 1 ml/min [67]

48 Gemifloxacin Mesylate

HPLC

Column: - phenomenex C₁₈ pre-packed column

Mobile phase- phosphate Buffer: Acetonitrile: methanol(50:25:25 v/v/v) with triethylamine 0.2% adjusted to pH 6.0 with ortho phosphoric acid

λ: 246 nm, Flow Rate: 1 ml/min [68]

49 Gemifloxacin Mesylate + Hydrochlorothiazide + furosemide

RP-HPLC

Column: - Purospher Start C₁₈ (250 mm x 4.6 mm, 5 μm) column

Mobile phase- methanol: water: Acetonitrile (70:25:5 v/v/v) adjusted to pH 3.0 via phosphoric acid 85%

λ: 265 nm, Flow Rate: 1 ml/min [69]

50 Gemifloxacin Mesylate

RP-HPLC

Column: -cyberlabaccepcelpak,ODS C₁₈ (250 × 4.6 mm i.d, 5 μm particle size) column

Mobile phase-Buffer (KH₂PO₄ with pH 6.8): acetonitrile in the ratio of 80:20 (v/v)

λ: 232 nm, Flow Rate: 0.8 ml/min [70]

51 Gemifloxacin Mesylate

RP-HPLC

Column- C₁₈ column (250mm x 4.6mm i.d, 5 mm)

Mobile phase- methanol: 7% formic acid (80:20v/v)pH was adjusted to 2.1

λ: 260 nm, Flow Rate: 1 ml/min [71]

52 Gemifloxacin Mesylate and H₂-receptor antagonists i.e. Gmetidine, Famotidine

RP-HPLC

Separation was achieved on the RP-Mediterranea column [C₁₈ (250 x 4.6 mm, 5 μm)] at ambient temperature using mobile phase consisting of Acetonitrile: methanol: water (20:28:52 v/v/pH 2.8 adjusted by phosphoric acid). Flow rate was 1.0 ml/min with an average operating pressure of 180 kg/cm². Gatifloxacn was used as an internal standard (IS).

λ: 232 nm, Flow Rate: 1 ml/min [72]

53 Gemifloxacin Mesylate

RP-HPLC

Column:- Hypersil BDS C₁₈ column

Mobile phase- citratebuffer (adjusted to 2.5 pH by citric acid)Acetonitrile (70:30v/v)

λ: 232 nm, Flow Rate: 1 ml/min [73]

54 Gemifloxacin Mesylate (Human Plasma)

RP-HPLC

The plasma sample was extracted using Chloroform: Acetic acid (5:4:0.1, v/v). A concentration range from 30 to 600ng/ml was used for calibration curve. The % recovery of Gemifloxacin Mesylate was found to be 80.06±8.48. The mobile phase used consist of Methanol: sodium acetate (1%): ortho phosphoric acid (65:35:0.5, v/v/v) with pH 2.1 and flow rate 0.8 ml/min in isocratic mode. The separation was carried out by UV-detector at wavelength 263 nm.

λ: 267 nm, Flow Rate: 1.1 ml/min [74]

55 Cefadroxil Monohydrate

Visible Spectroscopy method

Cefadroxil with Ninhydrine reagent in methanol gives blue colour chromogen, maximum absorbance at 578 nm

λ: 264 nm [75]

56 Cefadroxil Monohydrate

UV method

Diluent- Methanol: water (50:50 v/v)

λ: 264 nm

Concentration range - 10 - 50 μg/ml [76]

57 Cefadroxil Monohydrate

UV method

Diluent- Methanol

λ: 257 nm

Concentration range -10 - 100 μg/ml [77]

58 Cefadroxil Monohydrate + Ceftriaxone

Colorimetric method

Derivatization with 1, 2-naphthoquinone-4- sulfonic acid sodium in alkaline

A: 475 nm for Cefadroxil and 480 nm for Ceftriaxone

Concentration range - 10 - 100 μg/ml Cefadroxil and 25 - 175 for Ceftriaxone [78]

59 Cefadroxil Monohydrate

Bromination Method

Cefadroxil was brominated with bromate – bromide mixture under strong acidic conditions. After bromination, the excess mixture was treated with methylene blue result in formation of green complex. The absorbance was [79]
Cefixime + Ambroxol HCl
HPLC
measured at 670 nm.
Concentration Range: - 100 – 800 μg/ml
Column: - Purospher BDS C18 column (25 cm x 4.6mm, 5 μm)
Mobile phase: 0.5M Ammonium acetate buffer- Acetonitrile (50:50v/v), pH adjusted to 7 using ortho phosphoric acid
λ: - 247 nm, Flow Rate: -1 ml/min

Cefixime Monohydrate
HPLC
Column: -Supelco RP C18 column (250 mm × 4.6 mm) with 5 μm particle size.
Mobile phase- methanol and 0.05M disodium hydrogen orthophosphate buffer (60: 40 v/v) and with pH 3.0 adjusted with ortho phosphoric acid
λ: - 264 nm, Flow Rate: -0.75 ml/min

Cefixime Monohydrate
RP-HPLC
Column: -X Terra RP18 column(250 × 4.0 mm, 5 μm)
Mobile phase- mixture of phosphate buffer (pH 5) and acetonitrile (96:4%v/v)
λ: - 254 nm, Flow Rate: -1 ml/min

Cefixime Monohydrate
RP-HPLC
Column: - Phenomenex-Luna RP C18 (250 x 4.6 mm, 5μm) column
Mobile phase- Acetonitrile: 0.05M phosphate buffer (45: 55 v/v) of pH 5.0 ±0.2
λ: -257 nm, Flow Rate: -1 ml/min

Cefixime Monohydrate
RP-HPLC
Column: - C18 column (250mm × 4.6mm id, 5 μm)
Mobile phase- methanol: Double Distilled Water (60: 40 v/v)
λ: -264 nm, Flow Rate: -1 ml/min

Gefixime + Ofloxacin
Q absorbance
Ratio method
Diluent: Ethanol and iso absorptive point at 282 nm, 297.4 nm λ max of ofloxacin
Concentration Range: 5 - 25 μg/ml for Cefixime and 2 -10 μg/ml ofloxacin.
Simultaneous Equation Method
Diluent: Ethanol
λ: - 290.4 nm and 297.4 nm
Concentration range - 5 - 25 μg/ml for Cefixime and 2 -10 μg/ml ofloxacin.

Cefixime Trihydrate + Linezolid
Q absorbance
Ratio method
Isosborsptive point at 278.72 nm, 256.70 nm λ max of Linezolid
Concentration range - 2 - 10 μg/ml for Cefixime and 5 - 25 μg/ml Linezolid
Simultaneous Equation Method
Diluent: Methanol
λ: - 288.72 nm and 256.70 nm
Concentration range - 2 - 10 μg/ml for Cefixime and 5 - 25 μg/ml ofloxacin.

Cefixime + Ofloxacin
Q absorbance
Ratio method
Isosborsptive point at 275 nm, 296 nm λ max of ofloxacin
Concentration range - 4 - 20 μg/ml for Cefixime and 2 -10 μg/ml ofloxacin.
Simultaneous Equation Method
Diluent: Methanol
λ: - 234 nm and 296 nm
Concentration range - 4 - 20 μg/ml for Cefixime and 2 -10 μg/ml ofloxacin.

Cefixime Trihydrate + Azithromycin Dihydrate
First Derivative Spectroscopy
λ: -zero crossing point for Azithromycin dihydrate and Cefixime trihydrate was 326.4 nm and 226.8 nm, respectively
Concentration range -10 - 40 μg/ml Cefixime trihydrate and 25 - 100 Azithromycin Dihydrate

Cefixime + Moxifloxacin
Q absorbance
Ratio method
isosborsptive point at 279 nm, 295 nm λ max of Moxifloxacin
Concentration range - 2 - 18 μg/ml for Cefixime and 2 -12 μg/ml Moxifloxacin.
Simultaneous Equation Method
Diluent: 0.1 N HCl
λ: - 286 nm and 295 nm
Concentration range - 2 - 18 μg/ml for Cefixime and 2 -12 μg/ml Moxifloxacin.

Cefixime + Moxifloxacin
First Derivative Spectroscopy
Diluent: Methanol
λ: -zero crossing point for Cefixime 316.4 nm and for Moxifloxacin 289 nm
Concentration range -4 - 14 μg/ml for both Cefixime and Moxifloxacin

Cefixime Trihydrate + Azithromycin Dihydrate
Simultaneous Equation Method
Diluent: Water
λ: -235 nm and 288 nm
Concentration range -2 - 10 μg/ml for Cefixime and 10 - 50 μg/ml Azithromycin

Cefixime Trihydrate + Ornidazole
RP-HPLC
Column: -PhenomenexC18 column(25 cm x 4.6 mm i.d.)
Mobile phase- Acetonitrile: 40mM KH2PO4, in proportion of 4:65(v/v) with pH adjusted to 6±0.5 by using Triethylamine
λ: - 310 nm, Flow Rate: -1 ml/min

Moxifloxacin
RP-HPLC
Column: -Phenomix C18(250 mm x 4.6 mm, 5 μm) column
Mobile phase- Acetonitrile: 0.08 M potassium Dihydrogen ortho phosphate (adjusted to pH 8 with NaOH) (40: 60 v/v)
λ: -290 nm, Flow Rate: -1 ml/min

Cefixime + Ambroxol HCl
HPLC - PDA
Column: - Phenomenex-Gemini, RP 18 column (250 x 4.6 mm, 5 μm size)
Mobile phase- Acetonitrile: Methanol: 0.5% ammonium acetate buffer (pH 5.54) (44: 16: 40 v/v/v)
λ: - 220 nm, Flow Rate: -1 ml/min

| 76 | Cefixime Trihydrate | RP-HPLC | methanol in a ratio of 3:1 v/v | λ: 254 nm, Flow Rate: 1 ml/min | [96] |
| 77 | Cefixime + Cloxacin | RP-HPLC | Column: SS aokisil II C18, 250 x 4.6 mm, 5 μm column | Mobile phase: Acetonitrile: Methanol: 0.5% ammonium acetate (44:16:40 v/v/v) (pH 5.4) | λ: 295 nm, Flow Rate: 0.8 ml/min |
| 78 | Cefixime Trihydrate + Ambroxol HCl | RP-HPLC | Column: c-column C8 | Mobile phase: Acetonitrile: Methanol: Triethylamine (50: 50: 0.1 v/v/v), pH 3 | λ: 225 nm, Flow Rate: 1 ml/min |
| 79 | Cefixime + Ornidazole | RP-HPLC | Column: Hypersil ODS C18 (150 mm × 4.6 mm) | Mobile phase: Triethylamine buffer (pH 5.5): Acetonitrile (75:25) v/v | λ: 295 nm, Flow Rate: 1 ml/min |
| 80 | Cefixime Trihydrate | RP-HPLC | Column: C18 HyperSil ODS | Mobile phase: Tetra Butyl ammonium hydroxide solution: Acetonitrile (760:240 v/v) | λ: 254 nm, Flow Rate: 2 ml/min |
| 81 | Cefixime + Ofloxacin | RP-HPLC | Column: HypSil C18 Neosphere column (150 × 4.6 mm i.d.) | Mobile phase: Methanol: 0.02 mM potassium dihydrogen phosphate buffer (70:300 v/v) | λ: 290 nm, Flow Rate: 1 ml/min |
| 82 | Cefixime Trihydrate + Glavulanate | HPLC | Column: L1 column (Hypersil Gold) 250mm x 4.6 mm, 5 μm | Mobile phase: 0.0075 M Tetra Butyl Ammonium hydroxide of pH 6.8: Methanol (80:20 v/v) | λ: 230 nm, Flow Rate: 1 ml/min |
| 83 | Cefixime + Cloxacin | RP-HPLC | Column: C18 column (5 μm, 25 cm x 4.6 mm, i.d.) | Mobile phase: Phosphate buffer (pH 5.0): Acetonitrile (80:17:3 v/v/v) | λ: 225 nm, Flow Rate: 2 ml/min |
| 84 | Cefixime + Ornidazole | RP-HPLC | Column: C18 HyperSil ODS,4.6x250mm, 5 μm | Mobile phase: Acetonitrile: Water (30:70 v/v) and pH 3.4 with Orthophosphoric acid | λ: 237 nm, Flow Rate: 1.5 ml/min |
| 85 | Cefixime Trihydrate + Erdosteine | RP-HPLC | Column: HypSil C18 column (2.5 cm x 4.6 mm, 5 μm) | Mobile phase: Tetra Butyl Ammonium hydroxide pH adjusted to 6.5 with Orthophosphoric acid (10% aqueous): Acetonitrile (2:1 v/v) | λ: 254 nm, Flow Rate: 1 ml/min |
| 86 | Cefixime + Dicloxacin | RP-HPLC | Column: C18 - inertisol | Mobile phase: Potassium hydroxyde bufferAcetonitrile (60:40 v/v) | λ: 220 nm, Flow Rate: 1 ml/min |
| 87 | Cefixime + Moxifloxacin | RP-HPLC | Column: Purospher BDS C18 | Mobile phase: Acetonitrile: 0.1M KH2PO4 (40:60 v/v) | λ: 276 nm, Flow Rate: 1 ml/min |
| 88 | Cefixime Trihydrate + Ofloxacin | RP-HPLC | Column: Phenomenex C18, 5 μ, 250 mm x 4.6 mm | Mobile phase: Methanol: Water: Phosphate buffer, pH 4.9 (60: 20: 20 v/v/v) | λ: 290 nm, Flow Rate: 1 ml/min |

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S. A Validated RP


