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A review on chromatographic and spectrophotometric method for estimation of Sumatriptan and Promethazine in bulk and in different dosage forms

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Abstract

Sumatriptan is use for the migraine with and without aura and for cluster headaches. It is a 5-Hydroxy tryptamine (5-HT) receptor agonist type (5-HT_{IB} and 5-HT_{ID}). Promethazine is an antiemetic drug belonging to the class of Phenothiazine. Sumatriptan plus Promethazine was proved to be effective at a dose of 50mg and 25mg in management of migraine compare to the Sumatriptan monotherapy. Addition of Promethazine to Sumatriptan was proved effective in relief of nausea and vomiting, rate of pain recurrence reduced with significant improvement in the headache free rate. A triptan plus antiemetic showed the effective results in relief of the migraine associated Headache, Nausea, Vomiting, Photophobia and Phonophobia.

Keywords: sumatriptan succinate, promethazine hydrochloride, UV- spectroscopy, HPLC (high performance liquid chromatography), HPTLC (high performance thin layer chromatography), LC (liquid chromatography)

Introduction

Sumatriptan is a drug use for the migraine with and without aura and for cluster headaches. It is a 5-Hydroxy tryptamine (5-HT) receptor agonist type (5-HT_{1B} and 5-HT_{1D}). At the 5-HT1B/1D receptors on sensory nerves and intracranial blood vessels of the trigeminal system, it exerts agonist effect which result in inhibition of pro-inflammatory neuropeptide release and cranial vessel constriction. It works by 3 mechanisms of action, vasoconstriction of the dilated vessels, Inhibiting the nociceptive transmission in the trigeminal nerves system preventing the central sensitization development.

Promethazine is an antiemetic drug use in nausea, vomiting, in treatment of migraines, as a sedative for better sleep, pain reliever. It works as a strong H_1 receptor antagonist and a moderate mAch receptor antagonist (anticholinergic). It competes with free histamine for binding at the H_1 receptor

sites present in large blood vessels, GIT, uterus. The relief of nausea appears to be related to central anticholinergic actions. Combination of a triptan and an anti-emetic found to be effective in the migraine by reducing the reoccurrence of headache, reducing rate of pain recurrence. Combination of the Sumatriptan and Promethazine showed effective result in relief of nausea and vomiting along with greater significant relief in photophobia and phonophobia.

Reported methods are categorized depending on the following considerations

- 1. Single component analyzed by UV-spectroscopy methods and chromatographic method.
- 2. Analysis of Sumatriptan and Promethazine in combination with other drugs by UV-spectroscopy methods and chromatographic method.

 Table 1: Reported Analytical Method of Sumatriptan [3-24]

| S. No. | Drug | Method | Description |
|--------|---|---|---|
| 1 | Sumatriptan Succinate in Formulation. | Stability indicating Miceller electro kinetic chromatography Capillary electrophoresis. | Wavelength: 226nm Linearity range: 100-2000µg/ml Electrolyte: 25mM sodium dihydrogen phosphate pH 2 Solvent: water Stationary phase: fused silica capillary 50µm×40cm. |
| 2 | Sumatriptan Succinate In Pharmaceutical Dosage Forms. | RP-HPLC-UV | Wavelength: 227nm Linearity range: 25-600 ng/ml Co-relation Coefficient: 0.9998 Mobile phase: 25mM sodium dihydrogen phosphate pH 4 and acetonitrile (65:35, v/v) Stationary phase: thermoshypersil C_4 column (250mm \times 4.5mm, 5 μ m) Retention time: 4.51 min Flow rate: 1 ml/min |
| 3 | Sumatriptan Succinate and Naproxen Sodium in Bulk and | RP-HPLC | Wavelength: 229 Linearity range: 1-5µg/ml Co-relation Coefficient: Sumatriptan: 0.994 Naproxen: 0.999 |

| | Pharmaceutical Dosage Form. | | Mobile phase: Acetonitrile: Methanol: phosphate buffer (50:10:40) pH 6 Stationary phase: C18 column (250x 4.6 mm, 5μm) Retention time: Sumatriptan: 2.81 min Naproxen: 4.037 min. |
|----|---|----------------------------------|--|
| 4 | Sumatriptan and Zolmitriptan in Presence of Their Degradation Products | HPTLC | Wavelength: -Sumatriptan: 228 -Zolmitriptan: 222 Linearity range: -Sumatriptan: 0.5–4 μg/spot -Zolmitriptan: 0.5–3 μg/spot Mobile phase: -Sumatriptan: chloroform–ethyl acetate–methanol–ammonia (4:3: 3:0.1, v/v) -Zolmitriptan: chloroform–ethyl acetate–methanol– ammonia (3:3:3:1, v/v) Stationary phase: TLC silica gel 60 F254 plates Rf value: -Sumatriptan: 0.16 -Zolmitriptan: 0.85 |
| 5 | Sumatriptan Succinate and Naproxen Sodium in Pharmaceutical Dosage Form. | Stability indicating RP- HPLC | Wavelength: 280nm Linearity range: -Sumatriptan: 0.4-6.4 mg/ml -Naproxen: 0.076-1.2 mg/ml Co-relation Coefficient: -Sumatriptan: 0.999 -Naproxen: 0.999 Mobile phase: A- 0.05mm 1-hexane sulphonate sodium salt 3 ml of tri ethyl amine for 1000 ml of HPLC water, pH 6.7), acetonitrile: methanol (65:30:5 v/v/v) B- Water-Acetonitrile (10:90 v/v) Stationary phase: Phenomenex Luna C8 column (250 mm x 4.6 mm, 5μm) Retention time: -Sumatriptan: 3.55min -Naproxen: 4.44min |
| 6 | Sumatriptan Succinate and Naproxen Sodium in Combine Tablet. | Stability indicating UPLC | Wavelength: 225nm Linearity range: -Sumatriptan: 850-2565 μg/ml -Naproxen: 5000-15000 μg/ml Co-relation Coefficient: 0.999 Mobile phase: 0.2% Ortho Phosphoric Acid: Acetonitrile (90:10; v/v) Stationary phase: C18,50×4.8mm,1.8-μm) Retention time: -Sumatriptan: 1.7min -Naproxen: 2.7min Flow rate: 1ml/min |
| 7 | Sumatriptan Succinate Tablets Using Folin Reagent | visible spectrophotometric | Wavelength: 455 nm Linearity range: 16-48 μg/ml Correlation coefficient: 0.9989 %RSD: 0.55 |
| 8 | Sumatriptan Succinate from Pharmaceutical Formulation. | visible spectrophotometric | Wavelength:552 nm Linearity range: 5-20µg/ml. Co-relation Coefficient:0.9996 %RSD: 0.88 |
| 9 | Sumatriptan In Tablet Dosage Form. | HPTLC | Wavelength: 230 nm Linearity range: 200-800ng/spot Co-relation Coefficient: 0.9978 Mobile phase: Methanol: Water: Glacial Acetic Acid (4.0:8.0:0.1, v/v/v) Stationary phase: Precoated silica gel 60F254 LOD: 63.87ng/spot LOQ: 193.54ng/spot |
| 10 | Sumatriptan and Naproxen Tablets. | Stability indicating HPLC | Wavelength: 225 nm Co-relation Coefficient: 0.999 Stationary phase: WatersSpherisob ODS (250 x 4.6 mm, 5µm) Mobile phase: A- 0.05M potassium dihydrogen phosphate bufferpH 3 B-Water: Methanol: Acetonitrile (200:150:650 v/v) Flow rate: 1ml/min |
| 11 | Sumatriptan | RP-HPLC | Wavelength: 277 nm |

| | Succinate and Naproxen Sodium in Pharmaceutical Dosage Form. | | Co-relation Coefficient: 0.999 of both drugs. Linearity range: 5-80 µg/ml Stationary phase: Purospher (250x 4.6 mm, 5µm) Mobile phase: ACN: Water (60:40) Retention time: -Sumatriptan: 2.26 min -Naproxen: 5.79 min Flow rate: 1ml/min |
|----|---|-----------------------|--|
| 12 | Sumatriptan Succinate in Bulk and Dosage Form. | RP-HPLC | Wavelength: 228 nm Co-relation Coefficient: 1 Linearity range: 5-30μg/ml Stationary phase: Hypersil BDS C18 (150×4.6 mm, 5μm) Mobile phase: phosphate buffer pH 6.8: ACN (70:30) Flow rate: 1ml/min |
| 13 | Sumatriptan Succinate in Pharmaceutical Dosage Form. | RP-HPLC | Wavelength: 232 nm Co-relation Coefficient: 0.997 Linearity range: 10-50μg/ml Stationary phase: Purospher® 5μm, 250mm X 4.6mm Mobile phase: ACN: Water (18:82) 0.05% v/v trifluoro acetic acid Retention time: 5.2 min Flow rate: 1ml/min |
| 14 | Sumatriptan succinate and naproxen sodium in bulk and pharmaceutical dosage form. | RP-HPLC | Wavelength: 284nm Linearity range: -Sumatriptan: 30-70 μg/ml -Naproxen: 20-60 μg/ml Co-relation Coefficient: -Sumatriptan: 0.999 -Naproxen: 0.999 Mobile phase: Buffer and Acetonitrile (25:75 v/v) Stationary phase: XTerra C18 (150mm x 4.6mm i.d., 3.5μm Retention time: -Sumatriptan: 2.622 min -Naproxen: 4.07 min Flow rate: 0.8 ml/min |
| 15 | Sumatriptan Succinate in Bulk and Pharmaceutical Dosage Form. | UV spectrophotometric | Wavelength: 282 nm Linearity range: 10-70 µg/ml Correlation coefficient: 0.999 Solvent: Methanol LOD: 0.33 µg/ml LOQ: 1.01 µg/ml %RSD: 0.40 |
| 16 | Sumatriptan Succinate, Metoclopramide Hydrochloride and Paracetamol | RP-HPLC | Wavelength: 230 nm for 6.8 min, 248 nm from 6.81 to 8.5 min and 213 nm for rest of the time. Linearity range: 0.5-32 μg/mL Co-relation Coefficient: -Sumatriptan: 1 -Metoclopramide: 0.999 -Paracetamol: 0.999 Mobile phase: KH ₂ PO ₄ buffer: MeOH (60:40 v/v), pH 5 Stationary phase: XTerra C18 (150mm x 4.6mm i.d., 3.5μm Retention time: -Sumatriptan: 6.1 min -Metoclopramide: 7.4 min -Paracetamol: 10.8 min |
| 17 | Sumatriptan Succinate, Naproxen and Domperidone | RP-HPLC | Wavelength: 280 and 262 nm. Linearity range: 0.9 to 30 μg/ml Co-relation Coefficient: -Sumatriptan: 0.999 -Naproxen: 1 -Domperidone: 1 Mobile phase: Phosphate Buffer: Acetonitrile: Methanol (40: 10: 50) pH adjusted to 3.5 with dilute orthophosphoric acid |

| | | | Stationary phase: |
|----|--|----------------------------|--|
| | | | LichroCART, C-18 column (250mm×4.6mm, 5μm) |
| | | | Retention time: |
| | | | -Sumatriptan: 2.21 min |
| | | | -Naproxen: 7.91 min |
| | | | -Domperidone: 3.71 min |
| | | | Wavelength: 230 nm |
| | Cumatrintan | | Co-relation Coefficient: 0.999 |
| | Sumatriptan | | Linearityrange:50–1050 ng/ml |
| 10 | Succinate in | LIDI C | Stationary phase: Ascentis® Si HPLC Column (25cm×2.1mm, 5µm) |
| 18 | Bulk Drug and | HPLC | Mobile phase: Ammonium phosphate – acetonitrile (80:20, v/v, pH 3.5 adjusted with ortho- |
| | Tablet Dosage Form | | phosphoric acid |
| | FOIIII | | Retention time: 6.8 min |
| | | | Flow rate: 1ml/min |
| | Sumatriptan | | Wavelength: A- 548 nm, B- 660 nm |
| | Succinate Based | | Linearity range: A- 5-25µg/ml |
| | on Charge | | B- 20 - 60 μg/ml |
| 19 | Transfer | Visible spectrophotometric | Correlation coefficient: 0.9989 |
| | Complex | | Solvent: chloroform |
| | Formation | | %RSD: A- 0.5675, B- 0.839 |
| | | | Wavelength: 545nm |
| | Sumatriptan | Visible | Linearity range: 0.8-16.0 µg/ml |
| | Succinate in | Spectrophotometric | Correlation coefficient: 0.999 |
| 20 | Pure Drug and | Spectrophotometric | Solvent: water |
| | Pharmaceutical | | |
| | Formulation | | LOD:0.41 µg/ml |
| | | | LOQ:1.23 µg/ml |
| | | | Wavelength: 225 nm |
| | | | Co-relation Coefficient: 0.999 |
| | Sumatriptan | Cr. 1. 11. | Linearity range:50-800 ng/ml |
| | And Kinetic | Stability | Stationary phase: Grace C18 (2.1 x 250 mm, 5 µm |
| 21 | Study of The | indicating | Mobile phase: water (contains 0.1% triethylamine, pH 6.5 by phosphoric acid): acetonitrile (6: |
| | Degradation | liquid chromatography | 4, v/v) |
| | | | Retention time: 4.1 min |
| | | | Flow rate: 0.2 ml/min |
| | | | LOD: 16.6 ng/ml |
| | | | LOQ: 50 ng/ml |
| | | | Wavelength: 280 nm. |
| | | | Linearity range: |
| | | | -Sumatriptan: 3.125-37.5 μg/ml |
| | | | -Naproxen: 31.25-375 μg/ml |
| | | | -Domperidone: and 1.25-15 μg/ml |
| | | | Co-relation Coefficient: |
| | Sumatriptan, Naproxen and Domperidone. | | -Sumatriptan: 0.999 |
| | | | -Naproxen: 0.999 |
| 22 | | RP-HPLC | -Domperidone: 0.999 |
| | | | Mobile phase: |
| | | | Acetonitrile: Methanol: 20mM Phosphate Buffer pH 4 (10:50:40) |
| | | | Stationary phase: |
| | | | Grace C18 5µm (4.6 x 150 mm) |
| | | | Retention time: Sumatriptan: 1.64 min |
| | | | -Naproxen 7.53 min |
| | | | -Domperidone: 3.83 min |
| | | | Flow rate: 1ml/min |
| | | | HPLC |
| | | HPLC LC/MS-MS | Wavelength: 282nm |
| | Sumatriptan impurity | | Stationary phase: C18 (2.1 x 250 mm, 5 µm) |
| | | | Mobile phase: |
| | | | A: Buffer pH 7.5 (by ammonium solution): Acetonitrile (90:10, v/v) |
| | | | B: Buffer pH 7.5 (by ammonium solution): Acctonitric (70.16, v/v) |
| 23 | | | Retention time: 20.49 min |
| 23 | | | Flow rate: 0.9 ml/min |
| | | | LC/MS-MS |
| | | | |
| | | | Wavelength: 282nm Stationary phase: C18 (2.1 x 250 mm. 5 um) |
| | | | Stationary phase: C18 (2.1 x 250 mm, 5 µm) |
| | | | Mobile phase: |
| | | | A: Buffer (1ml trifluoracetic acid in 1000ml water adjusted pH 7.5 by ammonium solution): |

| | | | |
|----|---|-------------------|--|
| | | | Acetonitrile. B: acetonitrile in gradient Flow rate: 0.75ml/min m/z: 587.25 |
| 24 | Sumatriptan and Naproxen in bulk and tablet dosage form | RP-HPLC | Wavelength: 277nm Linearity range: 20-80 µg/ml Co-relation Coefficient: 1 Mobile phase: Water: methanol (45:55 v/v) Stationary phase: ODS C18 (250mm x 4.6mm i.d., 5µm) Retention time: Sumatriptan: 2.79 min -Naproxen: 3.4 min Flow rate: 1 ml/min |
| 25 | Sumatriptan in bulk and pharmaceutical dosage form | RP-HPLC | Wavelength: 221 nm Co-relation Coefficient: 0.999 Linearity range: 5-150 μg/ml Stationary phase: C18 ODS Inertsil (250×4.6mm, 5μm) Mobile phase: buffer: acetonitrile: methanol (80:10:10 v/v/v), pH was adjusted to 2.5 with orthophosphoric acid (OPA) Retention time: 4.4 min LOD: 1.967 μg/ml LOQ: 5.961 μg/ml |
| 26 | Sumatriptan and naproxen in spiked human plasma | RP-HPLC | Wavelength: 229nm Linearity range: 1-3 µg/ml Co-relation Coefficient: Sumatriptan: 0.995, Naproxen: 0.987 Mobile phase: Acetonitrile: Methanol: phosphate buffer pH 6 (50:10:40 v/v) Stationary phase: ODS C18 (250mm x 4.6mm i.d., 5µm) Flow rate: 1 ml/min |
| 27 | Sumatriptan and naproxen in bulk and pharmaceutical dosage form | RP-HPLC | Wavelength: 285nm Linearity range: 60-100 µg/ml Co-relation Coefficient: 0.999 Mobile phase:Buffer: acetonitrile (50:50) Stationary phase: C8(4.6x150mm.3.5µm) Retention time: Sumatriptan: 5.87min -Naproxen: 2.24min LOD: 3.36µg/ml LOQ: 3.206µg/mL Flow rate: 0.7 ml/min |
| 28 | Sumatriptan in rat plasma and brian | UV-HPLC | Wavelength: 228 nm Co-relation Coefficient: Plasma:0.9998 Brain: 0.9994 Linearity range: Plasma: 3–2000 ng/ml and Brain: 3-1000 ng/ml Stationary phase: C18 Mobile phase: 22% acetonitrile and 78% ammonium phosphate buffer (0.04 M, adjusted pH 3.7) |
| 29 | Sumatriptan in pure and dosage form | Spectrophotometry | Wavelength: A: 508 nm B: 610 nm Reagent: Bromate-Bromide Dyes: A: Methyl Orange B: Indigo Carmine Linearity range: A:0.2-1.6 µg/ml B: 2.0-12.0 µg/ml Correlation coefficient: A:0.999 B:0.998 |
| 30 | Sumatriptan and naproxen in pharmaceutical dosage form | HPTLC | Wavelength: 277nm Linearity range: -Sumatriptan:250-1500 ng/spot -Naproxen: 1000-6000 ng/spot Co-relation Coefficient: -Sumatriptan: 0.997 -Naproxen: 0.996 Rf: Sumatriptan: 0.49, Naproxen: 0.28 LOD: Sumatriptan:39.85ng/spot Naproxen: 80.35 ng/spot LOQ: Sumatriptan: 120.77 ng/spot -Naproxen: 243.5 ng/spot |

| 31 | Sumatriptan and naproxen in pharmaceutical dosage form | UV spectrophotometry (first order derivative) | Wavelength: 226.50 nm and 230 Linearity range: Suma: 0.5-2.5μg/ml, Naproxen: 2-10 μg/ml Correlation coefficient: Suma: 0.998, Naproxen: 0.997 Solvent: Water LOD: 0.09 μg/ml, 0.97 μg/ml LOQ: 0.28 μg/ml, 1.98 μg/ml |
|----|---|--|--|
| 32 | Sumatriptan and naproxen in pharmaceutical dosage form | UV spectrophotometry A: Q absorption ratio B: first order derivative | Wavelength: A: 272 nm NAP and 284 nm B: Nap 298 nm, Suma335 nm Linearity range: A: 10-90 μg/ml B: 20-190 μg/ml Solvent: Methanol Correlation coefficient: Sumatriptan: 0.9991 at 272 nm 0.9994 at 284 nm Naproxen:0.9967 272nm 0.9994 at 284 nm |
| 33 | Sumatriptan in human plasma | HPLC/MS-MS | Wavelength: 296nm Co-relation Coefficient: 0.999 Linearity:0.3–100 ng/mL Stationary phase: C18 column (150 × 2.1 mm, 5 μm) Mobile phase: 40% acetonitrile in water with 0.1% formic acid Flow rate: 0.2ml/min m/z 296: 58 |
| 34 | Sumatriptan in bulk and dosage form | A: Titrimetric B: Spectrophotometry C: Spectrophotometry | Brominating Agent: N-Bromosuccinimide Method A: Titrated with thiosulphate. Method B: Wavelength: 370nm Linearity: 0.0–15.0 µg/ml Co-relation Coefficient: 0.999 Method C: Wavelength: 570nm Linearity: 0.0–4.0 µg/ml Co-relation Coefficient: 0.999 |
| 35 | Sumatriptan, Rizatriptan, Zolmitriptan in bulk | RP-HPLC | Wavelength: 280nm Co-relation Coefficient: 0.999 Linearity range: 1-10 µg/ml Solvent: Methanol Stationary phase: ODS C18 Mobile phase: Acetonitrile: Sodium Phosphate buffer Retention time: Rizatriptan:7.215 Sumatriptan:8.432 Zolmitriptan:9.185 |

 Table 2: Reported Method of Promethazine [24-41]

| S. No | Drug | Method | Description |
|-------|--|---|---|
| 1 | Paracetamol and Promethazine in Tablet Dosage Forms | U.V spectrophotometric Absorbtion ratio method | Wavelength: PMZ: 254 and 248 PCM: 244 and 248 Linearity range: PMZ: 5-25 μg/ml PCM: 5-25 μg/ml Correlation coefficient: PMZ: 254:0.9967, 248: 0.9982 PCM: 244:0.9982, 248: 0.999 Solvent: distill water. LOD: PMZ:0.1251 μg/ml, 0.0233 μg/ml PCM: 0.0346 μg/ml, 0.0117 μg/ml LOQ: PMZ:0.417 μg/ml, 0.0776 μg/ml PCM:0.1153 μg/ml, 0.039 μg/ml |
| 2 | Promethazine HCl In Phosphate Buffer Saline pH 7.4 | U.V spectrophotometric | Wavelength:251 nm Linearity range: 2-10 µg/ml Correlation coefficient: 0.9986 Solvent: phosphate buffer saline pH 7.4 |
| 3 | Promethazine Hydrochloride by | UV spectrophotometric | Wavelength: 304 nm Linearity range: 2-20ug/m1 |

| | in (111) | | Correlation coefficient: 0.997 |
|----|--|---|---|
| 4 | Promethazine Hydrochloride in Dosage Form. | HPLC | Solvent: water. Wavelength: 249 nm Stationary phase:150 mm x 4.6 mm 3µ, C8 Mobile phase: acetonitrile-25mM phosphate buffer (pH 7.0) 50:50 (v/v) Flow rate: 1ml/min |
| 5 | Promethazine Enantiomers in Pharmaceutical Formulations | HPLC | Wavelength: 254 nm Co-relation Coefficient: 0.999 Linearity range: 0.8–6 µg/ml Stationary phase: Vancomycin Chirobiotic V column 250 ´ 4.6 mm Mobile phase: methanol: acetic acid: triethylamine (100:0.1:0.1% V) Retention time: 4.1 min Flow rate: 1 ml/min LOD: 0.04 mg/mL LOQ: 0.07 mg/Ml |
| 6 | Promethazine Hydrochloride Determination Using Bromcresol Green | U.V visible spectrophotometric | Wavelength: 415 nm Complexing agent: bromcresol green Linearity range: 1.2-8.5 μg/ml Solvent: chloroform |
| 7 | Promethazine Hydrochloride | A-Flame Atomic Emission B- Molecular Absorption Spectrophotometry | A Method: Wavelength:766 nm Linearity range:1-18 µg/mL Co-relation Coefficient: 0.9914 B Method: Wavelength:440 nm Linearity range:1-18 µg/ml Co-relation Coefficient: 0.9984 |
| 8 | Promethazine Hydrochloride in Pharmaceutical Formulation | Visible spectrophotometric | Wavelength:516 nm Linearity range:2-15 µg/ml Co-relation Coefficient: 0.9993 %RSD: 0.86 |
| 9 | Thiazinamium, Promazine And Promethazine in Pharmaceutical Dosage Form | Capillary zone electrophoresis | Wavelength: 254 nm Voltage: 30kV Separation: silica fused capillary 58.5×50μm LOD: TMS: 2.8 μg/ml PMS and PTH: 3.3 μg/ml %RSD: 5.3% Buffer: 100 mM tris(hydroxymethyl) aminomethane (tris) pH 8 |
| 10 | Determination of Sumatriptan and Promethazine in rat plasma | LC-MS/MS | Probe: -Sumatriptan: APCI probe -Promethazine: ESI probe Source: Duospray ion source Mobile phase: Methanol-water-formic acid (15:85:0.1) Stationary phase: ACE Excel 2 C18 PFP Column(2µm;2.1×100mm) Retention time: -Sumatriptan: 1.58min -Promethazine: 2.73min Flow rate: 0.7mL/min |
| 11 | Promethazine and Pholcodine in Marketed Formulation. | UV spectrophotometry | Wavelength: Promethazine: 248 nm Pholcodine: 284 nm % Recovery: Promethazine: 98.73% Pholcodine: 102.16% |
| 12 | Promethazine and Its Metabolites in Plasma | HPLC | Wavelength: 236 nm Mobile phase: methanol–0.15M ammonium acetate (pH 5.0)–water (38:50:12) Stationary phase: 5-µm CN column (250- ×4.6-mm i.d.) LOD: 1.0 ng/mL Flow rate: 0.9 mL/min |
| 13 | Promethazine Hydrochloride. | Chiral HPLC | Wavelength: 250 nm Mobile phase: 20mM PBS (pH 4.13) Stationary phase: chiral column AGC Flow rate: 0.8 mL/min |
| 14 | Promethazine Hydrochloride | ¹ H NMR spectroscopy | Wavelength: 254 nm Mobile phase: |

| 15 | Dextromethorpha n and Promethazine in Pharmaceutical Syrups | RP-HPLC | A- n-hexane/EtOH (95:5, v/v) B- n-hexane/tert-BuOH/ Et3N (96.5:3:0.5, v/v/v) Stationary phase:n Chiralcel OJ chiral. Flow rate: 0.5 mL/min Wavelength: 280 nm Linearity range: 0.02-0.06 μg/mL Co-relation Coefficient: -Dextromethorphan: 0.9997 -Promethazine: 0.998 Mobile phase: Sodium lauryl sulphate: water: CAN (3g:400ml:600ml) Stationary phase: C8,250- ×4.6-mm, 5μm Retention time: -Dextromethorphan: 8.5min -Promethazine: 9.9min Flow rate: 1 mL/min |
|----|---|----------------------------|---|
| 16 | Promethazine Hydrochloride and Glycyrrhizic Acid | RP-HPLC | Wavelength: 250 nm Linearity range: Promethazine: 0. 0794-0. 3176 mg/ml glycyrrhizic acid: 0.060 3-0.241 mg/ml Co-relation Coefficient: -Promethazine: 0.999 - glycyrrhizic acid: 0.999 Mobile phase: methanol-glacial acetic acid-0. 2 mol·L-1 ammonium acetate solution (58: 1: 41) Stationary phase: Thermo BDS C18 column (250 mm × 4. 6 mm,5µm) Flow rate: 1 mL/min |
| 17 | Promethazine Hydrochloride in Its Bulk Powder and Its Dosage Form | Visible spectrophotometric | Wavelength: 412 nm Oxidizing agent: acidic potassium permanganate Linearity range: 10-80 µg/ml Solvent: water. |

Conclusion

This review depicts the reported Spectroscopic and Chromatographic methods developed and validated for estimation of Sumatriptan and Promethazine. According to this review it was concluded that for Sumatriptan and Promethazine Different Spectroscopic and Chromatographic methods are available for single and combination. The mobile phase containing Acetonitrile, Water, Methanol, Phosphate buffer were common for most of chromatographic method to provide more resolution. For chromatographic method flow rate is observed in the range 0.7.0-1 ml/min to get good resolution time. For most of the Spectroscopic methods common solvent is Methanol and water. Hence this all methods found to be simple, accurate, economic, precise and reproducible in nature. Most of Methods were of RP-HPLC and UV absorbance detection because these methods provided with best available reliability, repeatability, analysis time and sensitivity.

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References

- 1. Tepper SJ, Rapoport AM, Sheftell FD. mechanism of action of the 5-HT1D/1B receptor agonist. Arch Neurol. 2002; 59(7):1084-8.
 - https://www.ncbi.nlm.nih.gov/pubmed/12117355
- Shadi Asadollahi MD, Kamran Heidari MD, Reza Vafaee MD, Mohammad Mahdi Forouzanfar MD, Afshin Amini

- MD, Ali Shahrami MD. Promethazine Plus Sumatriptan in the Treatment of Migraine: A Randomized Clinical Trial. Wiley Periodicals, Inc. ISSN 0017-8748 doi: 10.1111/head.12259.
- 3. Khaldun M, Al Azzam, Bharuddin Saad, Chai Yuan Tat, Ishak Mat, Hassan Y Aboul-Enein. Stability Indicating Micellar Electrokinetic Chromatography Method For Analysis Of Sumatriptan Succinate In Pharmaceutical Formulation. Journal of Pharmaceutical and Biochemical Analysis. 2011; (56):937-943.
- 4. Ravi S, Darwis Y, Khan N. Development and Validation of an RP-HPLC– UV Method for Analysis of Sumatriptan Succinate in Pharmaceutical Dosage Forms. Acta Chromatographica. 2009; 21(3):421-432.
- Gondolia Riddhi, Dr. Abhay Dharamsi. Simultaneous Estimation of Sumatriptan Succinate and Naproxen Sodium in Bulk Drug and Pharmaceutical Dosage Form By RP-HPLC. Journal of Drug Delivery and Therapeutics. 2013; 3(2):93-97.
- Hayam Lofty M, Mamdouh Rezk R, Adel Micheal M, Mostofa Shehata A. Determination of Sumatriptan And Zolmitriptan In Presence of Their Corresponding Degradation Products by HPTLC Methods." Chromatographia. 2013; 76:187-194.
- 7. Vivekananda Reddy D, Sreelatha P, Rama Devi B. A rapid novel RP- HPLC stability indicating assay method development and validation of simultaneous determination of Sumatriptan Succinate and Naproxen Sodium. ACAIJ. 2015; 15(5):151-159.
- Yarram Ramakoti Reddy, Kakumani Kishore Kumar, MRP Reddy, Mukkanti K. Rapid Simultaneous

- Determination of Sumatriptan Succinate and Naproxen Sodium In Combined Tablets By Validated Ultra-Performance Liquid Chromatographic Method. Anal Bioanal Techniques. 2011, 2-3.
- Buridi Kalyana Ramu, Raghubabu K. Visible spectrophotometric determination of Sumatriptan succinate in tablet dosage forms using folin reagent. Int J Pharm Biomed Sci. 2010; 1(3):49-52 ISSN No: 0976-5263
- 10. Kalyanaramu B, Raghubabu K. A simple visible spectrophotometric determination of Sumatriptan Succinate from pharmaceutical formulations. Der Pharma Chemica. 2011; 3(1):223-228
- 11. Shah CR, Suhagia BN, Shah NJ, Shah RR. Development and Validation of a HPTLC Method for the Estimation of Sumatriptan in Tablet Dosage Forms. Indian J Pharm Sci. 2008; 70(6):831-834.
- 12. Palavai Sripal Reddy B, Shakil Saita, Gururaj Vasudevmurthya, Mathivanan Natarajan, Vure Prasada, Jayapal Reddya S. Impurities Profiling Method and Degradation Studies for Sumatriptan Succinate in Sumatriptan Succinate and Naproxen Sodium Tablets. Journal of Chemical and Pharmaceutical Research. 2012; 4(6):3263-3274.
- 13. Sagar Solanki D.1, Dr. Paresh Patel U. Development and Validation of Reversed-Phase High Performance Liquid Chromatographic Method for Simultanious Estimation of Sumatriptan Succinate and Naproxen Sodium in Pharmaceutical Dosage Form. International Journal of Pharmacy and Pharmaceutical Sciences. 2012; 4(1). ISSN-0975-1491.
- 14. Jampala Balaji, Aruna K, Naidu NVS. A Simple Validated RP-HPLC Method for Quantification of Sumatriptan Succinate in Bulk and Pharmaceutical Dosage Form. Int. J of Pharmacy and Analytical Research. 2015; 4(1):83-87.
- 15. Solanki Sagar D, Dr. Patel Paresh U, Dr. Suhagiya Bhanubhai N. Development And Validation Of Reversed-Phase High Performance Liquid Chromatographic Method For Estimation Of Sumatriptan Succinate In Pharmaceutical Dosage Form. Int. J Drug Dev. & Res. 2011; 3(3):266-269.
- Kamepalli Sujana, Gowri Sankar D, Konda Abbulu. Simultaneous Estimation of Sumatriptan Succinate and Naproxen Sodium by Reverse Phase HPLC in Bulk and Pharmaceutical Dosage Form. IJPSR. 2012; 3(9):3433-3437.
- 17. Rajesh Kumar Nayak, Sunil Kumar Swain, Susanta Kumar Panda, Kanhu Charana Sahu, Debananda Mishra, Sanjay Kumar. Method Development and Validation of Sumatriptan In Bulk and Pharmaceutical Dosage Forms by UV Spectrophotometric Method. International Journal of Pharmaceutical & Biological Archives. 2011; 2(4):1100-1105.
- 18. Aaditya Singh, Shiv Bhadra Singh. Simultaneous Estimation of Sumatriptan Succinate, Metoclopramide Hydrochloride and Paracetamol by RP-HPLC Method. J Pharm. Sci. & Res. 2012; 4(6):1848-1851.
- 19. Minakshi Pandey, Pooja Chawla, Shubhini A. Saraf, "Simultaneous Estimation of Sumatriptan Succinate,

- Naproxen and Domperidone by Reverse Phase High Performance Liquid Chromatography. Asian J Pharm Clin Res. 2012; 5(3):176-178.
- 20. Singh L, Nanda S, Chomwal R. A validated sensitive liquid chromatographic method for the estimation of Sumatriptan succinate in bulk drug and tablet dosage form." Chron Young Sci. 2011; 2:37-41
- 21. Buridi Kalyanaramu, Rupakumari G, Ramarao K, Raghubabu K. Development Of New Visible Spectrophotometric Methods For Quantitative Determination Of Sumatriptan Succinate Based On Charge-Transfer Complex Formation. International Journal of Pharmacy and Pharmaceutical Science Research. 2011; 1(2):47-51.
- 22. Prashanth KN, Basavaiah K, Raghu MS. Permaganometric determination of Sumatriptan succinate in pure drug and pharmaceutical formulation. Thai J. Pharm. Sci. 2013; 37:95-106.
- 23. Hayum Lofty M, Mamdouh Rezk R, Adel Michael M, Ayman El-Kadi OS, Mostofa Shehata A. A Validated Stability Indicating Method For Determination of Sumatriptan and Kinetic Study of The Degradation. ACAIJ. 2013; 12(4):127-132.
- 24. Siddhi Hemant Shirodkar, Teja Walke. RP-HPLC Method for Simultaneous Estimation of Sumatriptan Succinate, Naproxen Sodium and Domperidone. World Journal of Pharmaceutical Research. 4(8):1543-1551.
- Ramesh L. Sawant *, Raihan Ahmed, Ramdin S. Supriya and Darade. R. Sheetal, "Spectrophotometric estimation of paracetamol and Promethazine in tablet dosage forms." Der Pharma Chemica, 2012, 4 (2):714-719
- 26. Dwi Nurahmanto. Development and validation of UV spectrophotometric method for quantitative estimation of Promethazine HCl in phosphate buffer saline pH 7.4. International Current Pharmaceutical Journal. 2013; 2(8): 141-142.
- 27. Alham Ngamesh Mezal. Spectrophotometric Determination of Promethazine Hydrochloride by In (111).
- 28. Thumma S, Zhang SQ, Repka MA, "Development and validation of a HPLC method for the analysis of Promethazine hydrochloride in hot-melt extruded dosage forms." Pharmazie. 2008; 63(8):562-7.
- 29. Ola A. Saleh, Aida A. El-Azzouny, and Hassan Y. Aboul-Enein, A Validated HPLC Method for Separation and Determination of Promethazine Enantiomers in Pharmaceutical Formulations. Drug Development and Industrial Pharmacy 2009, 35:19-25.
- 30. Emami Khoi AA, "Spectrophotometric Promethazine hydrochloride determination using bromcresol green. J Pharm Sci. 1983; 72(6):704-5
- 31. Abbas S. Hasan Al-kahdimy, "Flame Emission and Molecular Absorption Spectrophotometric Determination of Promethazine Hydrochloride via Potassium Dichromate as Oxidant Reagent." World J Pharm Sci 2016; 4(3): 323-329
- 32. Ramesh KC, Gowda BG, Keshavayya J. Spectrophotometric Determination of Promethazine Hydrochloride in Pharmaceutical Formulations. Indian Journal of Pharmaceutical Science. 2003, 432.

- 33. Francisco Lara J, Ana Gracia-Campana M, Fermin Ales-Barrero, Juan Bosque-Sendra M. Determination of Thiazinamium, Promazine and Promethazine in Pharmaceutical Formulations Using A CZE Method. Analytical Chimica Acta. 2005; 535:101-108.
- 34. Jeffry Plomley, Mohammed Makhloufi, Monica Vilan Ceasar, And Anahita Keyhani. Combining Mixed Mode LC, Polymer-Based Supported Liquid Extraction, and A Duospray Ion Source for Determination of Sumatriptan And Promethazine By LC-MS/MS. WRIB, 2015.
- 35. Ajay Sharma, Navneet Upadhyay, Sameer Sapra, K. L. Dhar and Megha Sharma. Method, development and validation for simultaneous estimation of Promethazine hydrochloride and pholocodine in bulk and marketed formulation (Linctus) by UV spectrophotometry. J Develop Drugs. 2013; 2:4.
- 36. Sreenivasa Vanapalli R, Sivarama Kambhampati P, Lakshmi Putcha, David Bourne WA. A Liquid Chromatographic Method for the Simultaneous Determination of Promethazine and Three of Its Metabolites in Plasma Using Electrochemical and UV Detectors. Journal of Chromatographic Science. 2001; 39:70-72.
- 37. Sanchez FG, Navas Diaz A, Sanchez Torreno E, Aguilar A, Medina Lama I, Algarra M. Determination of Enantiomeric Excess by Chiral Liquid Chromatography Without Enantiomerically Pure Starting Standard." Biomed. Chromatogr, 2012.
- 38. Pawel Boroweicki. Enantiodifferentiation of Promethazine Using (S)-(-)-BINOL as the NMR Chiral Solvating Agent: Determination of The Enantiometric Purity and Performance Comparison with Traditional Chiral HPLC. Tetrahedron: Asymmetry. 2015; 26:16-23.
- Saleh Trefi. Simultaneous Determination of Dextromethorphan and Promethazine in Pharmaceutical Syrups by Rapid HPLC Method. Int J Pharm Sci Nanotech. 2015; 18:2.
- 40. Shemin Guo. Determination of Promethazine Hydrochloride and Glycyrrhizic Acid in Compound Promethazine and Gly-Cyrrhizae Oral Solution by HPLC. China Pharmacist. 2015; 18(10):1807-1809.
- 41. Devani MB, Suhagia BN, Shah SA. Spectrophotometric Determination of Promethazine Hydrochloride in Bulk Powder and in Its Dosage Forms. Indian J Pharm. Sci. 1999; 61(2):110-112.