ANNEXURES

ANNEXURE I: PUBLICATIONS & POSTER PRESENTATION

POSTER PRESENTATION


Khurana LK, Kaur IP, Singh M, Singh R, Sharma M; Selectivity and choice of in-vitro technique as a surrogate to animal study for bacterial keratitis animal model: A case study using in-situ ocular nano-suspension of Moxifloxacin HCl; National conference on alternatives to animal experiments (NCAAE-2018); 27 Nov 2018.


PUBLICATIONS

Research Publication


Book Chapter

Singh H, Khurana LK, Singh R; Chapter 3 - Pharmaceutical Development; In Vohora D, & Gursharan S eds; Pharmaceutical Medicine and Translational Clinical Research, pp. 33-46, Academic Press
ANNEXURE II: APPROVALS RELATED TO ANIMAL STUDIES
Project title “Development and evaluation of sustained release moxifloxacin ocular formulations for bacterial conjunctivitis and bacterial keratitis” Submitted by Dr. Manju Sharma, Department of Pharmacology, School of Pharmaceutical Education and Research; Jamia Hamdard was presented in IAEC (Institutional Animal Ethics Committee) of Jamia Hamdard for information.
APPROVAL CERTIFICATE

This is certify that the project title “Development and Evaluation of Sustained Release Mexifloxacin Ocular Formulations for Bacterial Conjunctivitis and Bacterial Keratitis” has been approved (Approval No: PU/45/99/PCSEA/IAEC/2018/183 by the IAEC, Panjab University, Chandigarh-160014).

No. of animals approved: 25 Rabbitts

(Chairman IAEC)

Member Secretary, IAEC

(CPCSEA Nominee)

Panjab University, Chandigarh

(Chairman IAEC)

Member Secretary, IAEC

(CPCSEA Nominee)

(NOTE: Make sure that minutes of the meeting duly signed by all the IAEC members are maintained by the Office.)

Convenor
Institutional Animals Ethics Committee
Panjab University
Chandigarh
BIOSAFETY APPROVAL

IBSC NUMBER: IBSC-PANUNI-049-2018

Name of PI: Prof. Praveen Rishi (Department of Microbiology, Panjab University, Chandigarh)

Name of Co-P.I:
- Dr. Manju Sharma (Associate Professor) Department of Pharmacology, School of Pharmaceutical Education and Research, Jamia Hamdard, New Delhi-110062.
- Dr. Indu Pal Kaur (Professor) University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh.

Affiliation: Department of Microbiology, Panjab University, Chandigarh

Title of Proposal: Development and Evaluation of Sustained Release Moxifloxacin Ocular Formulation for Bacterial Conjunctivitis and Bacterial Keratitis.

Names of people involved in the experiments: Mr. Lalit Kumar Khurana, (Department of Pharmacology, School of Pharmaceutical Education and Research Jamia Hamdard New Delhi-110062).

IBSC approval: To carry out research with: Staphylococcus aureus (Subsp. aureus) MTCC96.

Biosafety level: BSL-II

Special Information: The PI has taken permission from C1C, Sector 25 campus, PU, Chd for carrying out the work.


Please submit six monthly progress reports to Member Secretary: biosafe@pu.ac.in IBSC, PU.

Dr. Archana Bhatnagar
Member Secretary
Professor & Head
Department of Biochemistry

(Dr. Rakesh Tuli)
Chairperson, IBSC
Professor
UIET PU, CHD

Note: It is the responsibility of the PI to provide SOPs and experimental training to the students/staff whose name is approved to conduct the experiments and handle the organism requested for biosafety approval. The IBSC member would periodically inspect the SOPs and facility.
ANNEXURE III: CERTIFICATE OF ANALYSIS: MOXIFLOXACIN HCl
MSN Pharmachem Private Limited
Plot No.212/A,B,C,D,Phase-II,IDA Pashamylaram, Pashamylaram (Village), Patancheru (Mandal) Medak District, Telangana, Pin Code: 502 307, India.
Tel:+91-8455 305700, Fax:+91-8455 305750, Alternate Fax:+91-40-30438799.

CERTIFICATE OF ANALYSIS

<table>
<thead>
<tr>
<th>Product</th>
<th>Customer name</th>
<th>Mfg. Date</th>
<th>Date of Expiry</th>
<th>Date of Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOXIFLOXACIN HYDROCHLORIDE USP (ANHYDROUS)</td>
<td>N/A</td>
<td>November 2016</td>
<td>October 2021</td>
<td>05.12.2016</td>
</tr>
</tbody>
</table>

Storage: Material is hygroscopic, store at controlled room temperature between 20°C and 25°C (excursions allowed between 15°C and 30°C) in a tightly closed container under nitrogen atmosphere protect from light and moisture.

<table>
<thead>
<tr>
<th>S.No.</th>
<th>TEST</th>
<th>RESULT</th>
<th>SPECIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>Description</td>
<td>Yellow powder</td>
<td>Slightly yellow to yellow powder or crystals</td>
</tr>
<tr>
<td>2.0</td>
<td>Solubility</td>
<td>Complies</td>
<td>Soluble in 0.1 N sodium hydroxide; sparingly soluble in water and in methanol; slightly soluble in 0.1 N hydrochloric acid, in dimethylformamide, and in alcohol; practically insoluble in methylene chloride, in acetone, in ethyl acetate, and in toluene; insoluble in tert-butyl methyl ether and n-heptane.</td>
</tr>
<tr>
<td>3.0</td>
<td>Identification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1</td>
<td>Specific optical rotation</td>
<td>Complies</td>
<td>Shall comply</td>
</tr>
<tr>
<td>3.2</td>
<td>By IR</td>
<td>Complies</td>
<td>To match with standard specrum</td>
</tr>
<tr>
<td>3.2</td>
<td>By HPLC</td>
<td>Complies</td>
<td>The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the assay.</td>
</tr>
<tr>
<td>3.3</td>
<td>Reaction for chlorides</td>
<td>Positive</td>
<td>To respond to the test for chlorides</td>
</tr>
<tr>
<td>4.0</td>
<td>Sulfate</td>
<td>Less than 0.04%</td>
<td>Sample portion shows no more sulfate than corresponds to 0.25 mL of 0.020 N sulphuric acid (0.04%)</td>
</tr>
<tr>
<td>5.0</td>
<td>Water content by KFR</td>
<td>0.20% w/w</td>
<td>Not more than 1.0% w/w</td>
</tr>
<tr>
<td>6.0</td>
<td>Residue on ignition</td>
<td>0.06% w/w</td>
<td>Not more than 0.10% w/w</td>
</tr>
<tr>
<td>7.0</td>
<td>Heavy Metals</td>
<td>Less than 10 ppm</td>
<td>Not more than 10 ppm</td>
</tr>
<tr>
<td>8.0</td>
<td>Appearance of the solution</td>
<td>Complies</td>
<td>The solution is clear and not more intensely coloured than reference solution GY2</td>
</tr>
<tr>
<td>9.0</td>
<td>pH (0.2% Solution in water)</td>
<td>4.46</td>
<td>Between 3.9 and 4.6</td>
</tr>
<tr>
<td>10.0</td>
<td>Specific optical rotation (On anhydrous basis)</td>
<td>-129.7°</td>
<td>Between -125° and -138° at 20°C</td>
</tr>
</tbody>
</table>

The product CONFORMS to above specifications.

Compiled by: [Signature]
V. Annapurna, Executive/QC
Date: 23/12/2016

Checked by: [Signature]
K. Sadeer Kumar, Asst.Manager/QC
Date: 23/12/2016

Head, Quality Control:
D. Srinivasa Rao, DGM/QC
Date: 23/12/2016

Page 1 of 2
MSN Pharmachem Private Limited
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Tel:+91-8455 305700, Fax:+91-8455 305750, Alternate Fax:+91-40-30438799.

CERTIFICATE OF ANALYSIS

<table>
<thead>
<tr>
<th>Product</th>
<th>MOXIFLOXACIN HYDROCHLORIDE USP (ANHYDROUS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Batch No.</td>
<td>MA0041116</td>
</tr>
<tr>
<td>Batch Quantity</td>
<td>104.30 Kgs</td>
</tr>
<tr>
<td>A R No.</td>
<td>FP160983</td>
</tr>
<tr>
<td>Specification No.</td>
<td>QC-FPMA-USP/00</td>
</tr>
</tbody>
</table>

Storage: Material is hygroscopic, store at controlled room temperature between 20°C and 25°C (excursions allowed between 15°C and 30°C) in a tightly closed container under nitrogen atmosphere protect from light and moisture.

<table>
<thead>
<tr>
<th>S.No.</th>
<th>TEST</th>
<th>RESULT</th>
<th>SPECIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.0</td>
<td>Organic impurities by HPLC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11.1</td>
<td>Moxifloxacin Related compound A</td>
<td>Below detection limit (0.007%)</td>
<td>Not more than 0.10%</td>
</tr>
<tr>
<td>11.2</td>
<td>6,8-Dimethoxy</td>
<td>Below detection limit (0.006%)</td>
<td>Not more than 0.10%</td>
</tr>
<tr>
<td>11.3</td>
<td>8-Ethoxy</td>
<td>Below detection limit (0.012%)</td>
<td>Not more than 0.10%</td>
</tr>
<tr>
<td>11.4</td>
<td>6-Methoxy-8-fluoro</td>
<td>Below detection limit (0.011%)</td>
<td>Not more than 0.10%</td>
</tr>
<tr>
<td>11.5</td>
<td>8-Hydroxy</td>
<td>Below detection limit (0.014%)</td>
<td>Not more than 0.10%</td>
</tr>
<tr>
<td>11.6</td>
<td>Other individual impurity</td>
<td>0.02%</td>
<td>Not more than 0.10%</td>
</tr>
<tr>
<td>11.7</td>
<td>Other total impurities</td>
<td>0.02%</td>
<td>Not more than 0.20%</td>
</tr>
<tr>
<td>11.8</td>
<td>Total impurities</td>
<td>0.04%</td>
<td>Not more than 0.30%</td>
</tr>
<tr>
<td>12.0</td>
<td>Assay by HPLC (On anhydrous basis)</td>
<td>100.0% w/w</td>
<td>Not less than 98.0% and Not more than 102.0% w/w</td>
</tr>
<tr>
<td>13.0</td>
<td>Residual solvents by GC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13.1</td>
<td>Methanol</td>
<td>Below detection limit (18 ppm)</td>
<td>Not more than 3000ppm</td>
</tr>
<tr>
<td>13.2</td>
<td>Isopropyl alcohol</td>
<td>Below quantitation limit (85 ppm)</td>
<td>Not more than 5000ppm</td>
</tr>
<tr>
<td>13.3</td>
<td>Acetonitrile</td>
<td>Below detection limit (30 ppm)</td>
<td>Not more than 410ppm</td>
</tr>
<tr>
<td>13.4</td>
<td>Toluene</td>
<td>371 ppm</td>
<td>Not more than 890ppm</td>
</tr>
<tr>
<td>14.0</td>
<td>Chiral purity by HPLC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14.1</td>
<td>R,R Isomer</td>
<td>0.05%</td>
<td>Not more than 0.15%</td>
</tr>
</tbody>
</table>

The product CONFORMS to above specifications.

Compiled by: V.Annapurna, Executive/QC
Checked by: K.Sudheer Kumar, Asst.Manager/QC
Head, Quality Control: D.Srinivasa Rao, DGM/QC
Date: 23.12.16

F-QC-056/03-01.10.2014
Test solution. Use the filtrate, diluted if necessary, with the dissolution medium.

Reference solution.

For 2.5 mg tablets—

Weigh 26.5 mg of moxapride citrate dihydrate RS and dissolve in 25 ml of the mobile phase. Dilute 5 ml of this solution to 1000 ml with the medium.

For other than 2.5 mg tablets—

Weigh 26.5 mg of moxapride citrate dihydrate RS and dissolve in 25 ml of the mobile phase. Dilute 5 ml of this solution to 500 ml with the medium.

Use the chromatographic system described under Assay.

Inject the reference solution. The test is not valid unless the column efficiency is not less than 4000 theoretical plates and the tailing factor is not more than 2.0.

Inject the reference solution and the test solution.

Calculate the content of C₂₅H₂₅ClF₂N₂O₅, C₆H₄ClO₂.

D. Not less than 70 per cent of the stated amount of C₂₅H₂₅ClF₂N₂O₅, C₆H₄ClO₂.

Uniformity of content. Complies with the test stated under tablets.

Determine by liquid chromatography (2.4.14) as described in the Assay using the following solutions.

Test solution. Dissolve 1 tablet in 100 ml of the mobile phase. Centrifuge for 15 minutes. Dilute the clear supernatant liquid if necessary, with the mobile phase to produce a solution containing 0.02 mg of moxapride citrate per ml.

Reference solution. Weigh 26.5 mg of moxapride citrate dihydrate RS and dissolve in 100 ml of the mobile phase. Dilute with the mobile phase to produce a solution containing 0.02 mg of moxapride citrate per ml.

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Weigh and powder 2 tablets. Weigh a quantity of the powder containing about 10 mg of moxapride citrate and dissolve in 50 ml of the mobile phase. Centrifuge for 15 minutes. Dilute 5 ml of the clear supernatant liquid to 50 ml with the mobile phase.

Reference solution. Weigh 21.2 mg of moxapride citrate dihydrate RS and dissolve in 100 ml of the mobile phase. Dilute 5 ml of this solution to 50 ml with the mobile phase.

Chromatographic system:

- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 μm);
- mobile phase: 60 volumes of a buffer solution, prepared by dissolving 1.4 ml of orthophosphoric acid (1M) in 1000 ml of water and adjusting the pH to 3.0 with triethylamine, and 40 volumes of acetonitrile,
  - flow rate: 1 ml per minute.
  - spectrophotometer set at 276 nm,
  - injection volume: 20 μl.

Inject the reference solution. The test is not valid unless the column efficiency is not less than 4000 theoretical plates, the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject the test solution and reference solution.

Calculate the content of C₂₅H₂₅ClF₂N₂O₅, C₆H₄ClO₂ in the tablets.

Labelling. The label states the strength in terms of the equivalent amount of anhydrous moxapride citrate.

Moxifloxacin Hydrochloride

\[
\text{C}_{25}\text{H}_{25}\text{ClF}_2\text{N}_2\text{O}_5, \quad \text{HCl}
\]

Moxifloxacin Hydrochloride is 1-Cyclopropyl-6-fluoro-8-
metoxy-7-[(4aS,7aS)-octahydro-6H-pyrrolo[3,4-b] pyridin-6-
yl]-4-oxo-1,4-dihydroquinoline-3-carboxylic acid hydrochloride.

Moxifloxacin Hydrochloride contains 98.0 per cent to 102.0 per cent of C₂₅H₂₅ClF₂N₂O₅, calculated on the anhydrous basis.

Category. Antibacterial.

Dose. Orally. 400 mg or intravenous infusion every 24 hours.

Description. A light yellow or yellow powder or crystals, slightly hygroscopic.

Identification

A. Determined by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with moxifloxacin hydrochloride RS or with the reference spectrum of moxifloxacin hydrochloride.

B. Dissolve 50 mg in 5 ml of water, add 1 ml of dilute nitric acid, mix, allow to stand for 5 minutes and filter. The filtrate gives reactions of chlorides (2.3.1).

Tests

Appearance of solution. A 5.0 per cent w/v solution in dilute sodium hydroxide solution is not more opalescent than
Moxifloxacin Hydrochloride

standard OS2 and not more intensely coloured than reference solution GYS2 (2.4.1). If intended for use in the manufacture of parental preparations, the solution is clear and not more intensely coloured than reference solution GYS2 (2.4.1).

pH (2.4.24). 3.9 to 4.6, determined in 0.2 per cent w/v solution in carbon dioxide-free water.

Specific optical rotation (2.4.22). -125.0° to -138.0° determined on 1.0 per cent w/v solution in equal mixture of acetoniitrile and water.

Related substances. Determined by liquid chromatography (2.4.14).

Solvent mixture. Dissolve 0.5 g of tetrabutylammonium hydrogen sulphate and 1.0 g of potassium dihydrogen phosphate in 500 ml of water. Add 2 ml of orthophosphoric acid and 0.05 g of anhydrous sodium sulphite, dilute to 1000 ml with water.

Test solution (a). Dissolve 50 mg of the substances under examination in the solvent mixture and dilute to 50.0 ml with the solvent mixture.

Test solution (b). Dilute 2.0 ml of test solution (a) to 20.0 ml with the solvent mixture.

Reference solution (a). A 0.01 per cent w/v solution of moxifloxacin hydrochloride RS in the solvent mixture.

Reference solution (b). Dilute 1.0 ml of test solution (a) to 100.0 ml with the solvent mixture. Dilute 10.0 ml of this solution to 10.0 ml with the solvent mixture.

Chromatographic system
- a stainless steel column 25 cm x 4.6 mm, packed with phenylsilane bonded to porous silica (5 μm),
- column temperature: 45°C,
- mobile phase: a mixture of 28 volumes of methanol and 72 volumes of a solution containing 0.05 per cent w/v of tetrabutylammonium hydrogen sulphate and 0.1 per cent w/v of potassium dihydrogen phosphate and 0.34 per cent w/v of orthophosphoric acid,
- flow rate: 1.3 ml per minute,
- spectrophotometer set at 293 nm,
- injection volume: 10 μl.

<table>
<thead>
<tr>
<th>Name</th>
<th>Relative retention time</th>
<th>Correction factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moxifloxacin (Retention time: about 14 minutes)</td>
<td>1.0</td>
<td>--</td>
</tr>
<tr>
<td>Moxifloxacin impurity A</td>
<td>1.1</td>
<td>--</td>
</tr>
<tr>
<td>Moxifloxacin impurity B2</td>
<td>1.3</td>
<td>1.4</td>
</tr>
<tr>
<td>Moxifloxacin impurity C3</td>
<td>1.4</td>
<td>--</td>
</tr>
<tr>
<td>Moxifloxacin impurity D4</td>
<td>1.6</td>
<td>--</td>
</tr>
<tr>
<td>Moxifloxacin impurity E5</td>
<td>1.7</td>
<td>3.5</td>
</tr>
</tbody>
</table>

1-cyclopropyl-6,8-di(p-fluoro-7-[(4aS,7aR)-octahydro-6H-pyrrolo[3,4-b]pyridin-6-yl]-4-oxo-1,4-dihydroquinoline-3-carboxylic acid.

Inject reference solution (a). The test is not valid unless the column efficiency is not less than 2000 theoretical plates and the tailing factor is not more than 2.0.

Inject reference solution (b) and test solution (a). Run the chromatogram 2.5 times the retention time of the principal peak. In the chromatogram obtained with test solution (a), the area of any secondary peak is not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.1 per cent). The sum of areas of all the secondary peaks is not more than 3 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.3 per cent). Ignore any peak with an area less than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.05 per cent).

Sulphated ash (2.3.18). Not more than 0.1 per cent.

Water (2.3.43). Not more than 4.5 per cent, determined on 0.2 g.

Assay. Determine by liquid chromatography (2.4.14), as described in the Related substances.

Test solution. Dissolve 50 mg of the substance under examination in the solvent mixture and dilute to 50.0 ml with the solvent mixture. Dilute 2.0 ml of this solution to 20.0 ml with the solvent mixture.

Reference solution. A 0.01 per cent w/v solution of moxifloxacin hydrochloride RS in the solvent mixture.

Inject the reference solution and the test solution. Calculate the content of C₂₀H₂₅CIFN₄O₆.

Storage. Store protected from light and moisture.

Moxifloxacin Eye Drops

Moxifloxacin Eye Drops are a sterile solution of Moxifloxacin Hydrochloride in purified water.

Moxifloxacin Eye Drops Contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of moxifloxacin, C₂₀H₂₅CIFN₄O₆.

Usual strength. 0.5 per cent w/v.
Identification

In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

Tests

pH (2.4.24). 6.3 to 7.3.

Related substances. A. Determine by liquid chromatography (2.4.14) as described in the Assay using following modifications.

Inject the test solution. The area of any secondary peak is not more than 0.5 per cent and the sum of areas of all the secondary peaks is not more than 1.5 per cent, calculated by area normalization.

Other tests. Comply with the tests stated under Eye Drops.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Dilute a suitable volume of the eye drops containing 3 mg of moxifloxacin to 50.0 ml with mobile phase A.

Reference solution (a). A 0.01 per cent w/v solution of moxifloxacin hydrochloride RS in mobile phase A.

Reference solution (b). A 0.001 per cent w/v solution of moxifloxacin impurity A RS (1-cyclopropyl-6,8-difluoro-1,4-dihydro-7-[(4aS,7aS)-octahydro-6H -pyrrolo[3,4-b]pyridin-6-yl]-7H-oxo-3-quinolinoylcarbonyl acid RS) in reference solution (a).

Chromatographic system

- a stainless steel column 25 cm x 4.0 mm, packed with phenyl groups chemically bonded to porous silica (5 μm),
- column temperature: 45°C,
- mobile phase: A: dissolve 0.5 g of tetrabutylammonium hydrogen sulphate and 1.0 g of monobasic potassium phosphate in 1000 ml of water, add 2 ml of orthophosphoric acid, filter,
- B: methanol,
- a gradient programme using the conditions given below,
- spectrophotometer set at 295 nm,
- injection volume: 25 μl.

<table>
<thead>
<tr>
<th>Time (min)</th>
<th>Mobile phase A (per cent w/v)</th>
<th>Mobile phase B (per cent v/v)</th>
<th>Flow rate (ml per minute)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>69</td>
<td>31</td>
<td>0.5</td>
</tr>
<tr>
<td>30</td>
<td>69</td>
<td>31</td>
<td>0.5</td>
</tr>
<tr>
<td>31</td>
<td>60</td>
<td>40</td>
<td>0.9</td>
</tr>
<tr>
<td>36</td>
<td>60</td>
<td>40</td>
<td>0.9</td>
</tr>
<tr>
<td>37</td>
<td>69</td>
<td>31</td>
<td>0.5</td>
</tr>
<tr>
<td>42</td>
<td>69</td>
<td>31</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Inject reference solutions (a) and (b). The test is not valid unless the resolution between the peaks due to moxifloxacin and moxifloxacin impurity A is not less than 2.0 in the chromatogram obtained with reference solution (b). The column efficiency is not less than 4000 theoretical plates, the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent in the chromatogram obtained with reference solution (a).

Inject reference solution (a) and the test solution.

Calculate the content of C_{18}H_{28}FN_{2}O_{6} in the eye drops.

Multiple Electrolytes and Dextrose Injection Type I

Multiple Electrolytes and Dextrose Injection Type I is a sterile solution of Dextrose and suitable salts in: Water for Injection to provide sodium, potassium, magnesium, acetate, phosphate and chloride ions. It may contain Hydrochloric Acid or Sodium Hydroxide used for adjusting the pH.

Usual strength.

- Sodium acetate: 0.32 g
- Potassium chloride: 0.13 g
- Dipotassium hydrogen phosphate: 0.026 g
- Magnesium chloride: 0.031 g
- Dextrose: 5.0 g
- Water for Injections to: 100 ml
- Concentration of electrolytes in mmol / l
  - Sodium: 23.0
  - Potassium: 20.0
  - Magnesium: 1.5
  - Acetate: 23.0
  - Chloride: 20.0
  - Phosphate: 1.5

Multiple Electrolytes and Dextrose Injection Type I contains not less than 90.0 per cent and not more than 110.0 per cent of the stated amounts of sodium, Na, Potassium, K, magnesium, Mg, acetate, C_{3}H_{6}O_{2}, and phosphate, P_{4}O_{6}. It also contains not less than 90.0 per cent and not more than 120.0 per cent of the stated amount of chloride, Cl and not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of dextrose, C_{6}H_{12}O_{6}. It contains no antimicrobial agent.

Description: A clear, colourless or faintly straw-coloured solution.