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Rp-Hplc Method Development and Validation for the Analysis of Pharmaceutical Drugs- 60 % Sodium Lactate

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Abstract: ***A simple, selective, linear, precise and accurate RP-HPLC method was developed and validated for rapid assay of 60% SODIUM LACTATE NaC3H5O3. Isocratic elution at a flow rate of 1.2ml /min was employed on a symmetry phenomenex hypersil L17 (300mm x 7.80 mm, 8 µm- rezex RHM – monosaccharide H+) column at ambient temperature. The mobile phase consisted of 0.1M Sulphuric acid. The UV detection wavelength was at 210 nm. Linearity was observed in concentration range of 0.001 – 0.005gm/ml. The retention time for 60% Sodium Lactate was 4.0 min. The method was validated as per the ICH guidelines. The proposed method can be successfully applied for the estimation of 60% Sodium Lactate.***

Keywords: Sodium Lactate, HPLC Method, Development, 210nm

1. Introduction

DRUG: Sodium Lactate
Sodium lactate is the sodium salt of lactic acid that has a mild saline taste. It is produced by fermentation of a sugar source, such as corn or beets, and then, by neutralizing the resulting lactic acid[3] to create a compound having the formula NaC3H5O3.

Structure:

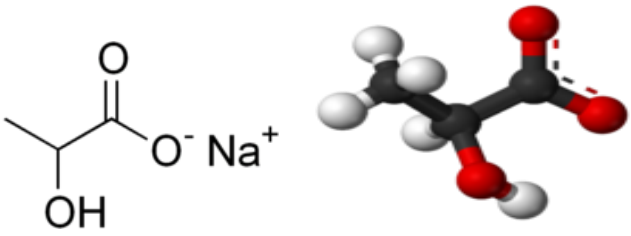

Figure 1: Molecular structure of Sodium Lactate

Table 1: Sodium Lactate

IUPAC NAME	Sodium 2-hydroxypropanoate
Formula	C3H5NaO3
Molacular Weight	112.06 g mol−1
Solubility	> 1.5 g/mL
Density	1.33 g/mL, [1] 1.31 g/ml (60 % syrup) [1]
Melting Point	161–162 °C 17 °C (60 % syrup) [2]
Boiling Point	113 °C (60 % syrup) [2]

Pharmacology
Sodium lactate is an alkalizing agent. Lactate is slowly metabolized to bicarbonate and water. This reaction depends on the cellular oxidative activity. Under normal physiological conditions conversion of sodium lactate to bicarbonate requires about one to two hours. The bicarbonate metabolite then has similar actions to those of sodium bicarbonate preparations. That is, bicarbonate metabolites react with acid to produce carbon dioxide and water.

Pharmacokinetics
Sodium Lactate is used as Compound Sodium Lactate (Hartmann's) is directly administered to the systemic circulation, the bioavailability (absorption) of the active components is complete (100%). Excess of calcium is predominantly excreted by the renal system, as in the case of potassium and sodium excretion.

A. Usage

As a food additive, sodium lactate has the E number E325 and is naturally a liquid product, but also is available in powder form. It acts as a preservative, acidity regulator, and bulking agent.[4]

Sodium lactate is sometimes used in shampoo products and other similar items such as liquid soaps as it is an effective humectant and moisturizer.[5]

Sodium lactate is used to treat arrhythmias caused by overdosing of class I antiarrythmics, as well as pressor sympathomimetics which can cause hypertension.[6]

It also can be given intravenously as a source of bicarbonate for preventing or controlling mild to moderate metabolic acidosis in patients with restricted oral intake (for sodium bicarbonate) whose oxidative processes are not seriously impaired. However, the use in lactic acidosis is contraindicated.[7] It can cause panic attacks in patients with existing panic disorder.[8]

B. Regarding milk

Despite the similarity in name, sodium lactate is not chemically similar to lactose (milk sugar) and therefore need not be restricted by those with a milk allergy.[3][9] In general, lactates such as sodium, calcium, and potassium lactate are salts derived from the neutralization of lactic acid and most commercially used lactic acids are fermented from dairy-free products such as cornstarch, potatoes, or molasses.[10] Sugar or tapioca additionally may be used. However some lactic acid is fermented from dairy products

such as whey[3] and lactose.[10] Whey is made of up 6.5% solids of which 4.8% is solid lactose.[11] Waste whey typically is used to produce lactic acid when the whey itself is produced as waste during the manufacture of certain dairy products.[12] As a result, such dairy-type lactic acid generally goes back into dairy products, such as ice cream and cream cheese,[10] rather than into non-dairy products. Moreover, although the lactic-acid starter culture to ferment corn or beets may contain milk,[3] sodium lactate does not contain milk protein and need not be restricted by someone avoiding milk or those with a milk allergy.[3] [9]

2. Experimental

2.1 Materials

60% Sodium Lactate was provided by Denis chem lab Ltd. as raw material. HPLC grade Sulphuric Acid and Water were obtained from Finar laboratory.

Instrumentation

The chromatographic system used to perform development and validation of this assay method was comprised of a LC-20ATvp binary pump, a SPD-20Avp UV-VIS detector and a rheodyne manual injector model 7725i with 20µl loop (Shimadzu, Kyoto, Japan) connected to a multi-instrument data acquisition and data processing system (Class-VP 6.13 SP2, Shimadzu).

Mobile phase preparation

The mobile phase consisted of 0.1M Sulphuric Acid. To prepare 0.1M Sulphuric Acid solution, 5.4ml Sulphuric Acid were pipette out and dissolve in 1000 ml HPLC grade Water. Mobile phase was filtered through a 0.45 µm nylon membrane (Millipore Pvt. Ltd. Bangalore, India) and degassed in an ultrasonic bath (Spincotech Pvt. Ltd., Mumbai).

Diluents' Preparation

HPLC grade Water was used as diluents.

Standard Preparation

Standard solution containing 60% Sodium Lactate was prepared by dissolving accurately about 0.1 gm in 100 mL volumetric flask by diluents [water] (standard solution).

Chromatographic Conditions

Chromatographic analysis was performed on phenomenex hypersil L17 (300mm x 7.80 mm, 8 µm- rezex RHM – monosaccharide H+) column. The mobile phase was consisted of 0.1M Sulphuric Acid. The flow rate of the mobile phase was adjusted to 1.2 mL/min and the injection volume was 10µl. Detection was performed at 210nm.

Table 2: Chromatographic conditions for 60% Sodium Lactate

S.NO	TEST	RESULT
	H.P.L.C CONDITIONS	
1	Elution	ISOCRATIC
2	A.P.I CONC	0.001gm/ml
3	Mobile Phase	0.1M Sulphuric Acid
4	pH	1.0
5	Column	L17
6	Wavelength	210 nm
7	Flow Rate	1.2ml/min
8	Runtime	8.0 min
9	Retention Time	4.0 min
10	Area	590.752
11	Th.Plates	131103.3
12	Tailing Factor	1.0010
13	Pump Pressure	150 kgf

3. Method Validation procedure

The objective of the method validation is to demonstrate that the method is suitable for its Intended purpose as it is stated in ICH guidelines. The method was validated for linearity, precision, accuracy, specificity, and limit of detection, limit of quantification, robustness and system suitability.

Linearity

Table 3: Linearity of 60% Sodium Lactate

S.NO	CONC.	AREA
1	0.001gm/ml	590.833
2	0.002gm/ml	1181.666
3	0.003gm/ml	1772.500
4	0.004gm/ml	2363.333
5	0.005gm/ml	2954.166

The developed method has been validated as per ICH guidelines. Solutions of 60% Sodium Lactate in the mass concentration range of 0.001 gm/ml to 0.005 gm/ml was injected into the chromatographic system. The chromatograms were developed and the peak area was determined foreach concentration of the drug solution. Calibration curve of 60% Sodium Lactate was obtained by plotting the peak area ratio versus the applied concentrations of 60% Sodium Lactate. The linear correlation coefficient was found to be 0.9999.

Table 4: Linear Regression Data for Calibration curve

Drug	60% Sodium Lactate
Concentration range	0.001-0.005 gm/ml
Slope (m)	590833.5
Intercept (b)	-0.0005
Correlation coefficient	0.9999

Precision

Repeatability of the method was checked by injecting replicate injections of 0.001 gm/ml of the solution for six times on the same day as intraday precision study of 60% Sodium Lactate and the RSD was found to be 0.0812 for intraday and 0.1138 for interday.

Table 5: Precision parameters of 60% Sodium Lactate

Injection	*Concentration*	*Intra Day*	*Inter Day*
1	0.001 gm/ml	590.752	603.105
2	0.001 gm/ml	591.133	604.099
3	0.001 gm/ml	589.990	603.433
4	0.001 gm/ml	590.254	605.072
5	0.001 gm/ml	590.555	604.272
6	0.001 gm/ml	589.872	604.089
	RSD	0.0812	0.1138

Accuracy

The accuracy of the method was determined by calculating recovery of 60% Sodium Lactate by the method of standard addition. Known amount of 60% Sodium Lactate (0.001 gm/ml) was added to a prequantified sample solution and the amount of 60% Sodium Lactate was estimated by measuring the peak arearatios and by fitting these values to the straight line equation of calibration curve. The recovery studies were carried out three times over the specifiedconcentration range and amount of 60% Sodium Lactate was estimated by measuring the peak area ratios by fitting these values to the straight line equation ofcalibration curve.

Specificity

The specificity of the method was determined by comparing test results obtained from analysis ofsample solution containing excipients with that of test results those obtained from standard drug.

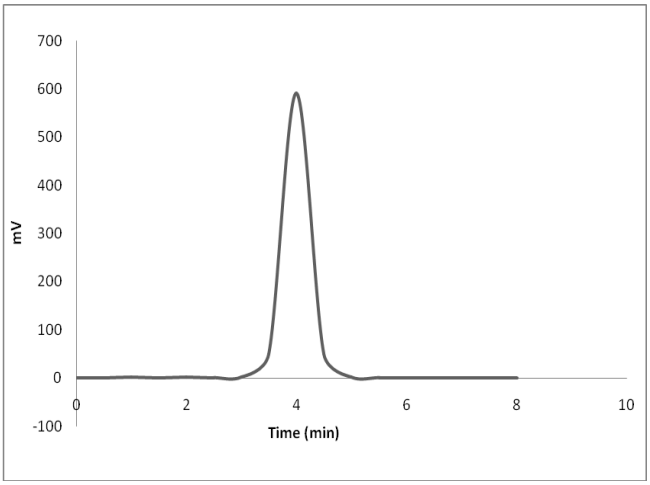

Figure 2: Typical chromatogram of 60% Sodium Lactate (0.001 gm/ml)

LOD and LOQ

Limit of detection (LOD) and limit of quantification (LOQ) were calculated as 0.00001gm/ml and 0.0001gm/ml respectively as per ICH guide-lines. Results are shown in table 6.

Table 6: Results of LOD and LOQ.

Parameter	Measured
LOD	0.00001gm/ml
LOQ	0.0001gm/ml

Robustness

To determine the robustness of the method, two parameters from the optimized chromatographic conditions were varied. First, Instrument and place were changed and second pH was changed, third column was changed. Results of Robustness are shown in table 7.

Table 7: Robustness parameters and result

Robust conditions	% Assay	System suitability parameters	
		Theoretical plates	Asymmetry
Flow 0.9 ml/min	100.9	131103.3	1.0010
Flow 1.5 ml/min	99.17	113949.2	1.0074
0.05M Sulphuric Acid	100.3	116738.9	1.0111
0.2M Sulphuric Acid	99.80	103741.4	0.9965
Column change	100.0	121252.8	1.0002

System Suitability Parameter:

System suitability tests were carried out on freshly prepared standard stock solutions of 60% Sodium Lactate and it was calculated by determining the standard deviation of 60% Sodium Lactate standards by injecting standards in five replicates at 5 minutes interval and the values were recorded in Table 8. Acceptance criteria for system suitability, asymmetry not more than 2.0, Theoretical plate not less than 5000 and % RSD of peak area not more then 2.0, were full fill during all validation parameter.

Table 8: System suitability parameters of 60% Sodium Lactate

Parameters	**Values**
λ max (nm)	210nm
Correlation coefficient	0.999
Retention time	4.0
Theoretical plates	131103.3
Tailing factor	1.00
Limit of detection	0.00001 gm/ml
Limit of quantification	0.0001 gm/ml
RSD	0.0812

4. Result and Discussion

Optimization of the chromatographic conditions

The nature of the sample, its molecular weight and solubility decides the proper selection of the stationary phase. The drug 60% Sodium Lactate is preferably analyzed by reverse phase columns and accordingly L17 column was selected. So the elution of the compound from the column was influenced by polar mobile phase. Different mobile phases were tried but satisfactory separation, well resolved and good symmetrical peaks were obtained with the mobile phase 0.1M Sulphuric Acid .The retention time of 60% Sodium Lactate was found to 4.0 min, which indicates a good base line. The RSD values for accuracy and precision studies obtained were less than 2% which revealed that developed method was accurate and precise.

5. Conclusion

A validated RP-HPLC method has been developed for the determination of 60% Sodium Lactate in bulk form. The proposed method is simple, rapid, accurate, precise and specific. Its chromatographic run time of 4.0 min allows the analysis of a large number of samples in short period of time. Therefore, it is suitable for the routine analysis of 60% Sodium Lactate in pharmaceutical analysis.

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