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RESEARCH ARTICLE

STABILITY STUDY OF GENTAMICIN SULPHATE INJECTION USING HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY

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Abstract

Stability is the main quality characteristic of any drug product, it involves changes in physical, chemical and biopharmaceutical properties. The current work studied the stability of gentamicin (Gen) sulfate injection using HPLC, four samples of Gen were selected. Inj-I, Inj-II, Inj-III, and Inj-IV. The selected injections were stored at room temperature and analyzed at zero time then after three and six months. The analysis was achieved using reverse-phase chromatography with isocratic elution at a flow rate of 1.1 ml/min. Chromatography analysis was performed on the ODS (C8) column, 15× 0.45 cm, 5µm particle size, the column temperature was 30 ºC, and a manual injector with a 20 µl loop was used for the injection of the sample solution and mobile phase. The mobile phase was a mixture of methanol/water / glacial acetic acid/sodium 1-heptane sulfonate. The eluent was monitored with a UV-Detector at a wavelength of 330 nm with a flow rate of 1.1 ml/min. The results of the analysis showed that the pH values of all samples decreased slightly however, it was still within the acceptance range of USP. The influence of storage temperature on the degradation of the drug was evidenced whereas the Inj-I sample was the least degraded, while Inj-IV was the highest degraded sample. The accuracy was evaluated by the percent of recovery at three different concentrations in the range (99.38-100%), the precision of the method was satisfactory, and the values of relative standard deviation were less than 2%.

Keywords: Gentamicin, HPLC, Stability, USP.

1. Introduction

Stability is the main quality characteristic of any drug product. Like any chemicals, the drug molecules can be degraded over time. However, the stability of drug products not only involves chemical degradation but also involves a change in the physical, chemical, and biopharmaceutical properties. In general, pharmaceutical instability includes, but is not limited to: a decrease in active ingredient efficacy, rise in impurity levels changes in bioavailability, consistency of content (especially suspension), appearance (such as color or shape), mechanical strength (such as tablet hardening or softening), dissolution/release rate, or other pharmaceutical elegances [1].

In the pharmaceutical manufacturing process, it is crucial to perform an analysis of the raw materials used and the medicinal product during, after, and throughout its use period to confirm that it remains within the constitutionally acceptable limits, either regarding the magnitudes of impurities formed throughout its manufacture or far along. Due to the safety of drug users, some limits should be carefully controlled. The expiration date of drugs is the last day that the manufacturer assures the complete efficacy and safety of a pharmaceutical (i.e drug cannot be used after the expiration date since the percentage of a drug is reduced and become lower than the therapeutic concentration). Additionally, some drug breakdown byproducts are poisonous and dangerous to humans. Following good manufacturing practices, stability testing is used to estimate a drug's expiration date to assess a drug's quality, shelf life, and ideal storage circumstances [2].

Gen is a water-soluble, broad-spectrum antibiotic produced by fermenting micromonospora purpura used to treat various bacterial infections. It belongs to the class of aminoglycosides (AGs). It can be administered topically, intravenously, or via injection into a muscle. Topical preparations can be applied to burns or external eye infections. It is frequently only used for two days till bacterial cultures detected the exact antibiotics the infection is sensitive to. It consists of a mixture of the major components Gens C_1, C_{1a}, C_2, C_{2a}, and minor one C_{2b}, also the related substances such as (Sisomicin, Garamine, Gen A, Gen B and 2 – deoxystreptamine, etc) are formed in small amounts during fermentation [3, 4]. Gen injection is stable at room temperature and doesn't need to be stored in a refrigerator but it should be kept below 25ºC [5].

The literature review revealed that there was no study carried out in Yemen related to the stability of Gen injection, however, there was a study carried out in Indonesia to examine the stability of Gen injection in ringer's dextrose infusion and ringer's lactate infusion at room temperature (27ºC) and cold temperature (40C) for 24 hours. The result revealed that the Gen stability was influenced by the infusion type. Gen stable in the ringer's dextrose infusion (102.10%) than in the ringer's lactate infusion (96.00%) [6].

Aden is a coastal city with a hot and humid climate and suffers from a continuous electric shortage, there was no previous study that mimic the storage condition in pharmacies, so there was a need for a study to evaluate the stability of Gen injection which was the aim of the current study.

2. Materials and Methods

2.1. Samples collection and distribution

Four samples of Gen injection were selected from the market, and stability testing for these samples was performed by HPLC in higher Pharmaceutical Authority-Aden.

Table 1: Samples information about the Gen sulfate injection.

Name of company	Strength samples	Manuf. date	Expired date
Inj-I (China)	80/2mg/ml	03/2019	03/2022
Inj-II (Yemen)	80/2mg/ml	01/2019	01/2022
Inj-III (Slovonia)	80/2mg/ml	07/2019	07/2022
Inj-IV(Korea)	80/2mg/ml	03/2019	03/2022

2.2. Storage conditions

Using a digital hygro-thermometer, the temperature and humidity were recorded daily to evaluate the temperature of various storage circumstances during the study period. The range of temperatures and humidity was between 27.41 and 29.82 ºC / 51.5 and 68.04 RH.

2.3. Study parameters

At each sampling point throughout the stability testing, the appropriate physical and chemical aspects of the product that could change during usage were observed:

- ✓ Physically: pH.
- ✓ Chemically: Active substance assay and degradation product.

2.3.1. Physical stability study

- ✓ PH test

The sample was poured into a beaker and the electrode of the pH meter was immersed in the sample and the result was recorded at zero time. The pH test was repeated during the interval time of stability evaluation with intervals (0, 3, and 6 months).

2.3.2. Chemical stability study

Chromatography conditions

Analysis of gen is not so easy due to its polar basic nature and the absence of a UV-absorbing chromophore. The applied HPLC method used derivatization. Chromatography separation was attained using reverse-phase chromatography with isocratic elution at a flow rate of 1.1 ml/min. Chromatography analysis was performed on the ODS (C_8) column, 15× 0.45 cm, 5µm particle size, and the column temperature were 30 ºC and a manual injector with a 20 µl loop was used for the injection of the sample solution and mobile phase. The mobile phase was a mixture of methanol/water / glacial acetic acid/sodium 1-heptane sulfonate. The eluent was monitored with a UV-Detector at a wavelength of 330 nm with a flow rate of 1.1 ml/min.

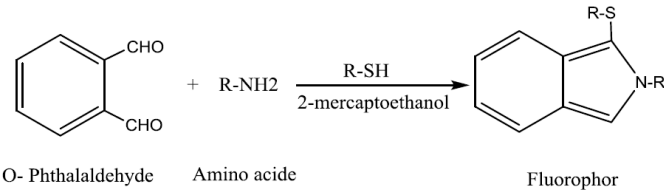
Preparation of Mobile phase

The mobile phase was prepared by mixing methanol, water, and glacial acetic acid (70: 25: 5). Sodium 1-heptane sulfonate was next added in 0.5% w/v concentration. The mobile phase was filtered through a 0.45 µm Millipore filter before use and degassed in sonicate for 15 min [7].

Preparation of standard solution for Gen

Exactly weigh 5 g of Gen standard and was dissolved in 100 ml of water to make the stock solution of 50 mg/ml. Then (1, 1.5, 2, 2.5, and 3 mg/ml) of the standard stock solution were transferred to a 25 ml volumetric flask to get (2, 3, 4, 5, and 6 mg/ml) respectively. Transfer 10 ml of each solution to a 25 ml volumetric flask and five ml

of methanol alcohol and 4 ml of OPA solution were then added and mixed. For pre-column derivatization, the OPA solution was prepared by dissolving 1.0 g of OPA in 5 ml methanol and adding 95 ml of 0.4 M boric acid which had been adjusted with potassium hydroxide (8N) to pH 10.4. After that two ml of thioglycolic acid was added, and the resulting solution was adjusted again with potassium hydroxide (8N) to pH 10.4. The flask was then filled with methanol alcohol to a mark of 25 ml to give the final concentration (0.8, 1.2, 1.6, 2, and 2.4 µg/ml). Flasks were heated in a 60°C water bath for 15 min and cooled to room temperature [7].



O- Phthalaldehyde Amino acide Fluorophor

Preparation of the samples

To prepare the sample, 2 ml of Gen sulfate (80 mg) was transferred to a 100 ml volumetric flask filled with water, and 2.5 ml of this solution was diluted to 100 ml in water. Transfer 10 ml of each solution to a 25 ml volumetric flask. Five ml of methanol alcohol and 4 ml of OPA solution were then added and mixed. The flask was then filled with methanol alcohol to a mark of 25 ml. the concentration of Gen sulfate was obtained from the linear equation of the calibration curve of Gen sulfate. The % of Gen sulfate was calculated as the following:

$$\% \text{ Gen} = \frac{\mathbf{X}}{\mathbf{2\mu g/ml}} \times 100\% \quad (1)$$

Where x is the concentration of Gen (µg/ ml) from the linear equation and 2 µg/ml is the final concentration of Gen solution for the HPLC method.

2.4 Validation of the HPLC method

The HPLC method for determination of Gen content was validated according to ICH Guidelines for validation of analytical procedures by using the following parameters:

2.4.1. Linearity

The linearity of the HPLC method was assessed by analysis of the Gen standard solutions of five different concentrations (0.8-2.4 µg/ml) in triplicates. The straight-line equation was used to calculate the calibration equation and correlation coefficients.

2.4.2. Limit of detection and limit of quantification

The limit of detection (LOD) of a compound is defined as the lowest concentration of analyte that can be detected. The limit of quantitation (LOQ) is the lowest concentration of a compound that can be quantified with acceptable precision and accuracy. The LOD and LOQ for Gen were calculated from the linearity data using the standard deviation of the response and slope of the calibration curve:

$$\text{LOD} = \frac{3.3\sigma}{s} \quad (2)$$

$$\text{LOQ} = \frac{10\sigma}{s} \quad (3)$$

Where s is the slope of the calibration curve and σ is the standard deviation of response.

2.4.3. Accuracy

The accuracy of the method was confirmed by a recovery study at three different concentration levels (80-120%) of the target concentration (2µg/ml) by spiking a known quantity of standard into a previously analyzed sample (2µg/ml) in triplicate. The percentages of recovery were calculated using the equation [7].

$$\%\text{Recovery} = \frac{\textbf{Amount Found}}{\textbf{Amount Added}} \times 100 \quad (4)$$

2.4.4. Precision

The precision of the method was tested by repeatability and intermediate precision studies. The repeatability (intra-day) precision of the method was evaluated by performing six replicated samples, using solutions of Gen standard at 50 mg/ml over one day under the same condition. The intermediate precision (inter-day) was carried out by analyzing standard solutions of Gen at three different concentrations 0.8, 1.6, and 2.4 µg/ ml three times a day for three consecutive days. Results for each type of precision were expressed by the relative standard deviation (% RSD).

2.5 Statistical data

All line graphs and bar charts were drawn with Microsoft Excel 2010. The data were analyzed using Statistical Package for Social Sciences (SPSS, version 23). One-way repeated-measures analysis of variance (ANOVA) was used to determine the significance of differences related to storage conditions (time, temperature, and humidity). *P*- values > 0.05 mean that no significant difference is statistical among the result's samples.

3. Results and Discussion

3.1. Storage conditions

The results of temperature and humidity measurement through simulation of pharmaceutical storage conditions, the injections were kept within the outer carton. The results were shown in Table 2 below. The measured temperature and humidity during the period of study (May-October) were 27.41-29.82 ºC/ 51.5-68.04 RH as shown in Table 2.

Table 2: Temperature and Humidity record of storage conditions.

Month	Temperatures/Humidity (mean)
May	27.41˚C /68.04RH
June	27.88 ˚C /54.57RH
July	29.82 ˚C/ 51.56RH
August	29.66 ˚C/ 53.77RH
September	28.65 ˚C / 56.1RH
October	28.45 ˚C / 61RH
Range	27.41-29.82 ˚C 51.5-68.04 RH

The recorded temperature at storage conditions was above the stated by USP [8] also, the humidity was higher. This may result from the fact that Aden has a hot desert climate which is regarded as BWh in the KÖppen-Geiger climate classification system [9]. Moreover, Aden suffers from a serious problem of power outages which results in fluctuating the temperature of the room between 27.41-29.82˚C exceeding the USP definition of room temperature (20-25˚C)

3.2 Physical stability study

pH test

The results of the pH test for Gen samples stored under temperature and humidity storage conditions are shown in Table 3, the pH variations were observed in all samples during the period of study. The pH values at the zero time were between (4.81-4.83), which were within the USP acceptance criteria (3.5-5.5) [8]. After that, there was a slight reduction in pH values during the six months duration of the study. The results showed that samples stored for three months have a *p*-value > 0.05, which indicated no difference between samples, and this change was the least in comparison to samples stored for six months.

The pH of all samples at zero time was 4.81, 4.83, 4.82, and 4.82 respectively which were within the USP acceptance criteria. After three months, pH values showed a minor reduction with the range of 0.17, 0.16,0.14, and 0.17 for Inj-I, Inj-II, Inj-III, and Inj-IV respectively. After six months, pH values showed a minor reduction for all samples 0.01, 0.05, 0.01, and 0.04 from the pH after three months. There was a slight reduction in pH values during the six months duration of the study period were 0.18, 0.21, 0.15, and 0.21 for injections respectively. However, these change still within the USP criteria. The pH reduction may be due to chemical degradation of the preparation or byproducts of microbial contamination (e.g., lactic acid which makes vinegar fermentation) that cause a change in the pH of liquid drug preparations [10]. Also, the presence of impurities in drug substances may lead to a change (reduction) in pH values [11].

Table 3: The pH results of Gen samples stored under temperature storage conditions during 6 months of storage.

Time	The pH value (Mean ± SD) n=3			
	Inj-I	Inj-II	Inj-III	Inj-IV
0	4. 81±0.01	4.83±0.04	4.82±0.01	4.82±0.01
3	4.64 ± 0.04	4.67 ± 0.01	4.68 ± 0.02	4.65 ± 0.04
6	4.63±0.04	4.62±0.03	4.67 ± 0.01	4.61 ± 0.02

Mean of three measurements, SD= Standard Deviation, n= number of measurements.

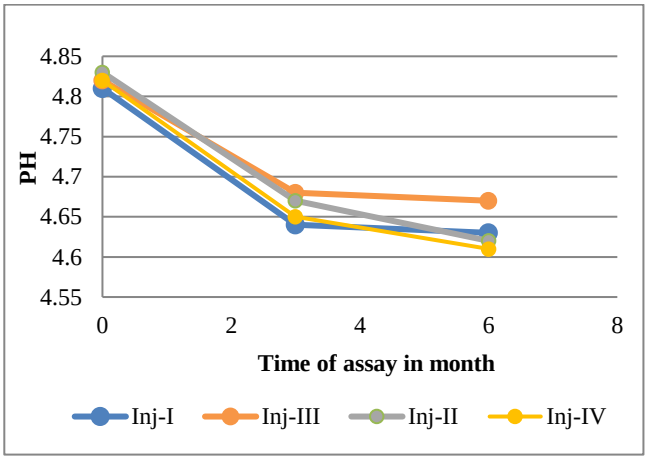


Fig. 1: The pH change in Gen samples stored at various temperatures during six months of storage.

3.3. Chemical stability study

3.3.1 Validation of the method

The calibration curve of Gen was established from five standard calibration solutions over the 0.8-2.4 µg/ml concentration range by plotting the peak area vs. concentration of Gen, Table 4. The calibration curve was performed in triplicate. The result is linear in the concentration range of 0.8 to 2.4 µg/ml and the correlation coefficient (R^2= 0.9989) is illustrated in Figure 2. The parameters of the calibration curve are summarized in Table 5.

Table 4: Illustrates the peak area vs. the concentration of Gen.

Con. (µg/ml)	Mean Peak area± SD(n=3)	RSD%
0.8µg	1014973 ± 16698.33	1.6
1.2µg	2034886± 11835.55	0.6
1.6µg	2992797 ± 49751.33	1.6
2µg	3946364 ± 67489.81	1.7
2.4µg	4913902 ± 113398	2.3

Table 5: Parameters of calibration curve of Gen.

Parameters	Gen standard
Linear	Y= 2423941 x - 799377
Slope	2423941
Intercept	799377-
Correlation coefficient	0.9989
Standard deviation	58763.87
LOD	0.08
LOQ	0.24

The LOD and LOQ for Gen were calculated from the linearity data using the standard deviation of the response and slope of the calibration curve. LOD was found to be 0.08 and LOQ was found to be 0.24 :

$LOD=3.3\sigma/s = 3.3\times58763.87/2423941 = 0.08$ µg/ml

$LOQ=10\sigma/s = 10\times58763.87/2423941 = 0.24$ µg/ml

The values of LOD and LOQ were observed to be low and it indicated good sensitivity of the HPLC method.

The accuracy of the current method was determined by Gen recovery. The recovered was in the range of 99.38 to 100.00 % for various concentrations as shown in Table 6. The recovery study indicates that the method is accurate for the quantitative estimation of Gen injection during interval periods since the statistical results were within the acceptance range (100±2%).

Table 6: Results of Accuracy Studies (n=3).

Assay level%	Amount of Sample (µg/ml)	Amount added of standard (µg/ml)	Total drug recovered (µg/ml)	Amount found of standard (µg/ml)	Recovery%	Criteria
80	2	1.6	3.59	1.59	99.38	%100±2
100	2	2	4.00	2.00	100.00	
120	2	2.4	4.39	2.39	99.58	

The precision of the method was confirmed by repeatability (intra- day precision), and intermediate (inter-day precision). The results were evaluated by a common statistical value, including the calculation of SD, and RSD. Results of precision are given in Tables 7 and 8 which indicated that the method was precise.

Table 7: Results of repeatability precision studies.

No. of the sample set	Intraday assay%
1	99.35
2	102.38
3	102.56
4	103.09
5	100.99
6	102.38
Mean	101.79
SD	1.384
R.S.D%	1.4
Acceptance criteria	**RSD% < 2.0**

Table 8: Results of intermediate precision in three consecutive days.

Mean% (n=3)			
Day	**0.8 µg/ml**	**1.6 µg/ml**	**2.4 µg/ml**
1	40.95	79.94	121.15
2	41.02	80.19	120.46
3	41.23	79.85	120.05
Mean%	41.07	79.99	120.55
SD	0.15	0.18	0.56
RSD%	0.36	0.22	0.46
Acceptance Criteria		**RSD% (< 2.0)**	

However, it is impossible to have exact control of every variable from run to run, so a small difference in retention is normal. Variations in the ±0.02-0.05 min range are normal and for some methods, perhaps +0.1 min [12]. Gen preparation usually is analyzed in the presence of a large excess of dyes, preservatives, and other excipients due to the lack of a suitable chromophore, so different RT may occur due to dyes in the preparation [7].

3.3.2. Estimation of the content of Gen samples

The results of the assay test as mean percentage concentration versus concentration of sampling of four samples (Inj-I, Inj-II, Inj-III, and Inj-IV) of Gen injection over six months are illustrated in Table 9. The results showed that the four samples of Gen at day zero were 104.86 ± 0.13, 101.35 ± 0.56, 104.84 ± 0.16, and 100.57 ± 0.09 for Inj-I, Inj-III, Inj-II, and Inj-IV respectively. The USP monograph states that the content% of Gen injection (80 mg/2 ml) limits are (90%-125%). Accordingly, all samples passed the assay content test at the zero time of the study. After that, all samples showed a reduction in their percentage concentrations throughout the study.

Table 9: Assay results for samples Gen.

Time(mon)	Gen samples			
	Concentration Mean (µg/ml%) (n=3) ± SD			
	Inj-I	Inj-II	Inj-III	Inj-IV
0	104.86 ± 0.13	104.84 ± 0.16	101.35 ± 0.56	100.57 ± 0.09
3	104.67 ± 0.73	100.23 ± 0.63	97.17 ± 0.07	93.15 ± 0.42
6	102.07 ± 0.05	98.72 ± 0.28	96.26 ± 0.60	88.83 ±0. 19

Chromatograms of Gen standards solution and four samples were shown in Figures 4, and 5. The RT variate randomly from one run to the next run. There are numerous possible reasons. Some problems can be the result of physical failure of system apparatuses such as pump seals or check valves, errors in mobile-phase composition, either from instrument malfunction or manual mixing, unwise selection of pH, and column temperature fluctuations.

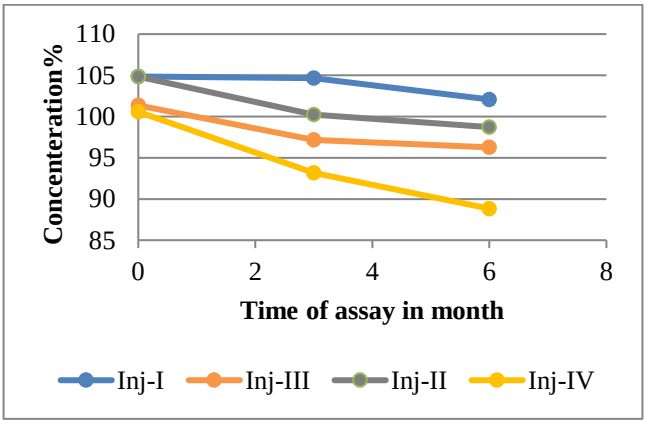


Fig. 2: Rate degradation of Gen samples under temperature storage conditions.

Rates of degradation of Gen samples are represented in Figure 2 illustrating that sample Inj-I was the most stable. The sample Inj-IV was the least stable. The percentage degradation of Gen samples under temperature storage condition studies is shown in Figure 3. The Figure shows that sample Inj-I had less degradation (2.79%) and sample Inj-III (5.09%) and sample Inj-II (6.12%), whereas sample Inj-IV had the highest degradation (11.74%).

The changes were small between samples throughout the study. One-way repeated measures ANOVA was used to determine the significance of the effect of temperature on the rates of degradation of Gen samples. Differences were considered insignificant at *p*-values because the value was 0.285 > 0.05.

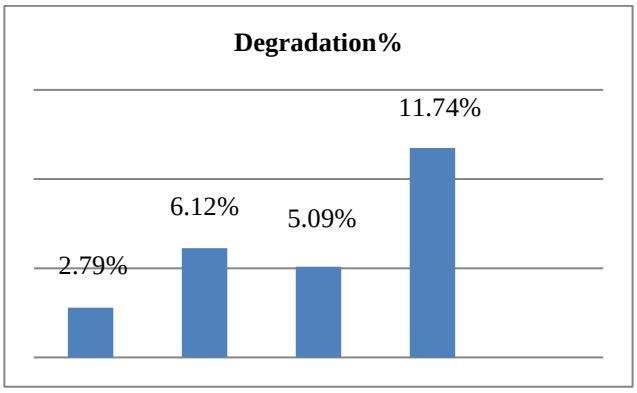


Fig. 3: Percentage degradation of Gen samples under temperature storage conditions over the period study.

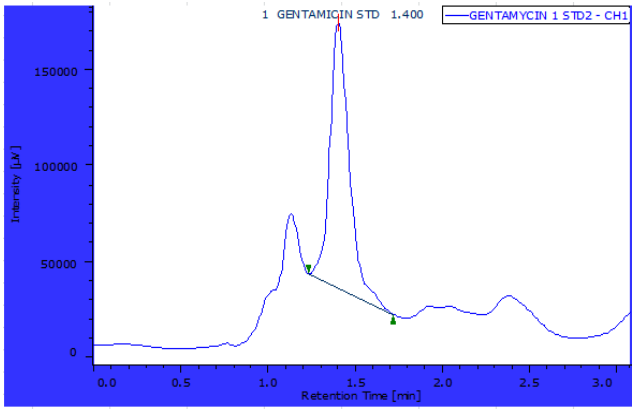


Fig. 4: Chromatogram of Gen standard.

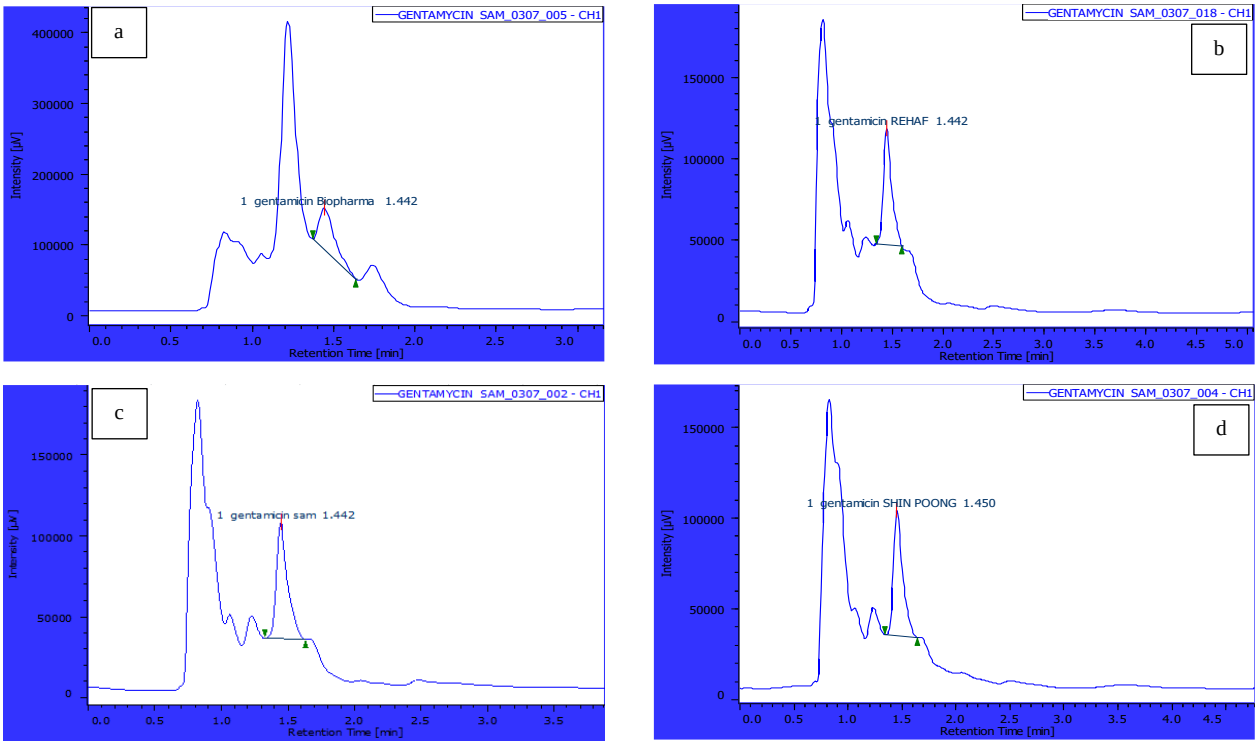


Fig. 5: Chromatograms of four samples of Gen. (a) Inj-I (b) Inj-II (c) Inj-I (d) Inj-IV.

4. Conclusions

The objective of the study was stability testing of Gen injection by HPLC method since Aden city has a hot and humid climate that exceeds the USP definition of a cool place and controlled room temperature (20-25ºC) as well as suffering from continuous electric shortages. From the obtained results, it can be concluded that:

- ✓ The stability of Gen injection (80mg/ 2ml) decreases with time but still recommended a range of USP is.
- ✓ The content percent of Gen injection decrease according to the storage conditions (temperature, humidity).
- ✓ It was observed that sample Inj-I was more stable, while sample Inj-IV was the least stable.

The pharmacies and storage places should have continuous electric power to avoid the degradation of the medicines.

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مقالة بحثية

دراسة استقرارية كبريتات الجنتاميسين الحقني باستخدام جهاز كروماتوجرافيا السائل عالية الاداء

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المُلخّص

الهدف من هذه الدراسة هي دراسة استقرارية كبريتات الجنتاميسين الحقني باستخدام جهاز HPLC لأربع عينات من الجنتاميسين وقد تم اجراء التحاليل الكيميائية في الهيئة العليا للأدوية – عدن . نتائج التحليل اظهرت بأن قيم PH في كل العينات تتناقص ومع ذلك لاتزال ضمن المعايير المقبولة وفقاً لدستور الادوية الامريكي. تم اثبات تأثير درجة حرارة الخزن على تحلل الدواء حيث كانت عينة Inj-I اقل تحللاً بينما عينة Inj-IV اعلى تحللاً. ومن ناحية اخرى كان تركيز الجنتاميسين في عينة Inj-I اعلى استقرارً بينما عينة Inj-IV اقل استقرارً. تم فحص الدقة وتراوحت نسبة الاسترجاع المئوية للجنتاميسين والتي تم فحصها في ثلاثة مستويات مختلفة 99.38-100% وتم اثبات قابلية الطريقة للتكرار حيث لم يتجاوز الانحراف المعياري النسبي 2%.

الكلمات المفتاحية: الجنتاميسين، كروماتوجرافيا السائل عالية الأداء، الثباتية، دستور الأدوية الامريكي.

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