International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 2 Mar – Apr 2025, pp: 804-815 www.ijprajournal.com ISSN: 2456-4494

Stability studies of injectable drugs (Dextrose and Normal Saline) manufactured by different pharmaceutical companies in Bangladesh.

Hasna Hena, Most. Shamima Parvin
Senior Officer, Research and Development Department, Libra Infusions Limited,I/7 Mirpur Industrial Estate, Rupnagar,Section-2, Dhaka-1216,Bangladesh.
Deputy Manager, Quality Control Department, Libra Infusions Limited,I/7 Mirpur Industrial Estate, Rupnagar, Section-2, Dhaka-1216,Bangladesh.

Date of Submission: 20-03-2025 Date of Acceptance: 30-03-2025

ABSTRACT: The ability of a pharmaceutical product to retain its chemical, physical, microbiological, and biopharmaceutical properties within specified limits throughout its shelf-life is called stability. Stability is important in pharmaceutical science because it helps ensure that the quality of a drug is maintained throughout its shelf life and that it's safe and effective for patients. Shelf life is when a drug product, if stored correctly, is expected to comply with the specification as determined by stability studies on many batches. The shelf life is used to establish the expiry date of each batch.

Keywords: Sterility, Stability, Gel Clot Method, Shelf life

I. INTRODUCTION:

A stability test is a series of tests designed to obtain information on the stability of a pharmaceutical product, defining its shelf life and utilization period under specified packaging and storage conditions.

Main objectives of stability testing:

Objective	Type of Study	Use
Toselect adequate formulation and container closure systems	Accelerated	Development of the product
To determine shelf-life and storage conditions	Accelerated and real-time	Development of the product and the registration dossier
To substantiate the claimed Shelf-life	Real-time	Registration dossier
To verify that no changes have been introduced in the formulationormanufacturing process that can adversely affect the stability of the product	Accelerated and real-time	Quality assurance in general, including quality control

Testing frequency of stability studies:

For long-term studies, the testing frequency should be sufficient to establish the stability profile of the drug substance. For drug substances with a proposed re-test period of at least 12 months, the frequency of testing at the long-term storage condition should normally be every 3 months over the first year, every 6 months over the second year, and annually thereafter through the proposed re-test period. At the accelerated storage condition, a minimum of three-time points, including the initial and final time points (0,3,6 months), from a 6-month study is recommended. When testing at the intermediate storage condition is called for due to a significant change at the accelerated storage condition, a minimum of four time points, including the initial and final time points (0,6,9,12 months), from a 12-month study is recommended.

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 2 Mar – Apr 2025, pp: 804-815 www.ijprajournal.com ISSN: 2456-4494

Storage condition for the general case:

Study	Storage condition	The minimumtime covered by data at submissions
Long term	**25°C ± 2°C/ 60%RH ± 5% RH or 30°C ± 2°C/ 65%RH ± 5% RH**	12 months
*Intermediate	**30°C ± 2°C/ 65%RH ± 5% RH**	6 months
Accelerated	**40°C ± 2°C/ 75%RH ± 5% RH**	6 months

*If 30**°C ± 2°C/ 65%RH ± 5% RH is the long-term condition, there is no intermediate condition.**

II. MATERIALS AND METHODS:

Drug sampling: Three samples of Dextrose and Normal Saline injection manufactured by three pharmaceutical companies in Bangladesh were taken to the Quality Control laboratory of Libra Infusion Ltd. in Dhaka, Bangladesh. Finally, samples were kept in a stability testing chamber.

Test parameters:

1) Identification test
2) PH determination
3) Particulate matter
4) Average volume
5) Assay determination
6) Pyrogen/Bacterial Endotoxin test
7) Sterility test
8) Leakage determination

1) Identification Tests

Dextrose Infusion: 50 ml of the sample was taken into a conical flask, 0.2ml of 5M ammonia solution added, and left for 30 minutes. The optical rotation was performed and the reading was positive for Dextrose.

Normal Saline Infusion:

Sodium: Take 1.0 ml of sample in a 100 ml volumetric flask, dilute with water to volume, mix, and then test with a flame photometer. Sodium compounds impart an intense yellow color to a nonluminous flame.

Chloride: Take a 5.0 ml sample in a clean test tube and add 1.0 ml of silver nitrate test solution. This will produce a white precipitate that is insoluble in nitric acid and soluble in a slight excess of 6N ammonium hydroxide.

PH determination: The PH electrode of the meter PH inoLab-7110, made inGermany, was calibrated using PH buffers 4,7, and 10. The PH electrode was dipped in each of the samples contained in a beaker, and the PH of each sample was read.

Dextrose Infusion Assay determination:

Procedure:50 ml of the sample was taken into a 100 mlvolumetric flask and 0.2 mlof 6N ammonium hydroxide was added and sonicated for 5 minutes and it was made up to the mark with the sample and sonicatedfor 5 minutes. The solution was allowed to stand for 30 minutes. The temperature of the polarimeter was adjusted to 25°C and the optical rotation of the sample was taken with the polarimeter. The blank determination was carried out and the reading was repeated three times.

Assay Calculations:

Calculation for 5.5% Dextrose Monohydrate

Dextrose monohydrate /100 ml = 198.17⁄180.16 × [α×100⁄l × {α}]

= B

% of Label claim = B × 100⁄5.5

= ____ %

Here, 198.17= Molecular weights for dextrose monohydrate

180.16 = Molecular weights for anhydrous dextrose

α = Observed rotation, in degrees

l = Length of the polarimeter tube in the decimeter

[α] = Specific optical rotation taken from raw material

100 = Percentage

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 2 Mar – Apr 2025, pp: 804-815 www.ijprajournal.com ISSN: 2456-4494

Normal Saline Infusion Assay (0.9% Sodium Chloride) determination:

Procedure: 10 ml of the sample was taken into a 50 ml conical flask and 3 drops of 5% potassium chromate indicator were added to it and it was titrated with 0.1M silver nitrate solution until a brick red colorendpoint was observed. The reading was recorded and the test was repeated three times. The average reading was taken.

Assay calculation:

NaCl content /100 mL

= Mean titration reading × 0.005844 × 10 × F= A

Here, F = Factor of 0.1M silver nitrate

% Label Claim = (A × 100) ÷ 0.9

= _____ %

Sterility Determination:

Sterility Testing:

Approximate contents of the sample vials were aseptically transferred into the sterility testing funnel of the testing unit. The pooled samples were then drawn through a membrane with the help of a vacuum pump and washed with an appropriate number of rinses of diluents. The membrane filters were aseptically cut off into two equal parts, one part was placed into 100 ml sterile fluid Thioglycolate Medium and the other part into 100 ml sterile Soya Bean Casein Digest Medium. Two tubes, each from the different fluid media were used for negative control by handling as in sterility testing tubes but without the addition of membrane. Fluid Thioglycolate media tubes were incubated at 32.5° C for a minimum of 14 days. Soya Bean Casein digest media tubes were incubated at 22.5°C for a minimum of 14 days.

Interpretation of sterility test results:

All incubated tubes were examined daily during and after the incubation period for macroscopic evidence of microbial growth, such as turbidity and surface growth. If no evidence of microbial growth was observed, the samples tested conformed to the test for sterility. If evidence of microbial growth was found, the sample examined did not conform to the test for sterility.

Bacteria Endotoxin Determination:

Gel Clot Method:

In duplicates, 100 µl of the samples analyzed were pipetted into a hydrogenated test tube. The negative control was prepared by adding 100 µl of LAL Reagent water to a hydrogenated test tube. The positive control was prepared by adding 50µl of the sample being analyzed and 50 µl of the control standard Endotoxin to a hydrogenated test tube. 100 µl of LAL reagent was added to each test tube.All tubes were incubated at 37°C for 60 minutes. After incubation, all tubes were visually inspected for the presence of a firm gel clot by inverting the tubes.

Note; LAL = Limulus Amoebocytes Lysate

Determination of sub-visible particulate matter contamination;

Test for sub-visible particulate matter contamination;

The samples were placed at the sampling point of the liquid particle counter and the syringe of the sampler was lowered each time for sampling and analysis. After analysis, the syringe was lowered to unload it. The counter uses laser light for light obstruction count (this works on the principles of light scattering techniques). These procedures were repeated three times on each sample bottle. The average cumulative count of the three samples was taken, the results were printed, and the particulate matter was calculated for each sample.

Determination of leakages:

3 bags of each of the samples were taken and kept in a basin and 4000ml of 0.1% methylene blue solution was poured into the basin and placed in a vacuum oven.The vacuum oven door was closed to dip the bags and a vacuum of 700nm was applied and maintained for 10 minutes. The vacuum was released and the bags were cleaned and checked for any blue color percolation into the bags. The observation was recorded.

Real-time stability data for ACME's DNS sample (30°C± 2°C/65% RH±5%RH)

Test Parameters	Specification	Results				
		Initial	After 3Month	After 6Month	After 9Month	After 12Month
Appearance	Clear, colourless and odourless,fre	Compiles	Compiles	Compiles	Compiles	Compiles

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 2 Mar – Apr 2025, pp: 804-815 www.ijprajournal.com ISSN: 2456-4494

	ely flowing transparent liquid					
Identification	**Positive**	**Compiles**	**Compiles**	**Compiles**	**Compiles**	**Compiles**
PH	**3.2-6.5**	**5.44**	**5.40**	**5.38**	**5.34**	**5.30**
Particulate Matter	**10.0µm counts<= 25 per 1.0ml 25.0µm counts<= 3 per 1.0ml**	**Compiles**	**Compiles**	**Compiles**	**Compiles**	**Compiles**
Average Volume	**(500-520) ml**	**509**	**508**	**506**	**504**	**502**
Assay	**Dextrose Monohydrate (95-105)**	**99.09**	**98.92**	**98.86**	**98.81**	**98.73**
	Sodium Chloride (95-105)	**98.59**	**98.51**	**98.43**	**98.31**	**98.20**
Pyrogen/Bacterial Endotoxin	**Must be pyrogen-free/ Not More Than 0.25 EU/ml**	**Complies**	**Not Applicable**	**Not Applicable**	**Not Applicable**	**Complies**
Sterility	**Must be sterile**	**Complies**	**Not Applicable**	**Not Applicable**	**Not Applicable**	**Complies**
Leakage Determination	**Must be leakage-free**	**Complies**	**Complies**	**Complies**	**Complies**	**Complies**

Assay Calculation;

Assay of the Initial test for ACME'S DNS sample for (30°C± 2°C/65% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.24,5.25,5.24
Mean=5.242
B=100/52.9 × 198.17/180.16 × 100/200× 5.242=5.450
%=(B×100) ÷ 5.5
= (5.450× 100) ÷ 5.5
= 99.09%

Sodium Chloride content in 100 ml
Titration reading = 14.90, 14.90.14.90
Mean=14.90
=14.90 × 0.005844× 1.019 × 10
=0.887300
%=(0.887300 × 100) ÷0.9
= 98.59%
Here, is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019
Assay Calculation:

Assay of the 3 Month test for ACME'S DNS sample for (30°C± 2°C/65% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.24,5.23,5.23
Mean=5.233
B=100/52.9 × 198.17/180.16 × 100/200× 5.233
=5.441
%=(B×100) ÷ 5.5
= (5.441× 100) ÷ 5.5
= 98.92%
Sodium Chloride content in 100 ml
Titration reading = 14.90, 14.95.14.90
Mean=14.92
=14.92 × 0.005844× 1.017 × 10
=0.886549
%=(0.886549 × 100) ÷0.9
= 98.51%
Here, is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.017

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 2 Mar – Apr 2025, pp: 804-815 www.ijprajournal.com ISSN: 2456-4494

Assay Calculation;
Assay of the 6 Month test for ACME'S DNS sample for (30°C± 2°C/65% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.23,5.22,5.23
Mean=5.227
B=100/52.9 × 198.17/180.16 × 100/200× 5.227
=5.434
%=(B×100) ÷ 5.5
= (5.434× 100) ÷ 5.5
= 98.80%
Sodium Chloride content in 100 ml
Titration reading = 14.92, 14.92.14.92
Mean=14.92
=14.92 × 0.005844× 1.019 × 10
=0.8884913712
%=(0.8884913712 × 100) ÷0.9
= 98.72%
Here, is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

Assay Calculation:
Assay of the 9 Month test for ACME'S DNS sample for (30°C± 2°C/65% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.21,5.21,5.22
Mean=5.213
B=100/52.9 × 198.17/180.16 × 100/200× 5.213
=5.420
%=(B×100) ÷ 5.5
= (5.420× 100) ÷ 5.5
= 98.55%
Sodium Chloride content in 100 ml
Titration reading = 14.90, 14.90.14.90
Mean=14.90
=14.90 × 0.005844× 1.019 × 10
=0.887300364
%=(0.887300364 × 100) ÷0.9
= 98.59%
Here, is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

Assay Calculation:
Assay of the 12 Month test for ACME'S DNS sample for (30°C± 2°C/65% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.20,5.20,5.21
Mean=5.203
B=100/52.9 × 198.17/180.16 × 100/200× 5.203
=5.409
%=(B×100) ÷ 5.5
= (5.409× 100) ÷ 5.5
= 98.35%
Sodium Chloride content in 100 ml
Titration reading = 14.89, 14.89.14.89
Mean=14.89
=14.89 × 0.005844× 1.019 × 10
=0.8867048604
%=(0.8867048604× 100) ÷0.9
= 98.52%
Here, is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

Real-time stability data for Glucosal sample (30°C± 2°C/65% RH±5%RH)

Test Parameters	Specification	Results				
		Initial	After 3Month	After 6Month	After 9Month	After 12Month
Appearance	Clear, colorless, and odorless freely flowing transparent liquid	Compiles	Compiles	Compiles	Compiles	Compiles
Identification	Positive	Compiles	Compiles	Compiles	Compiles	Compiles
PH	3.2-6.5	5.28	5.24	5.22	5.16	5.10
Particulate Matter	10.0µm counts<= 25 per 1.0ml 25.0µm counts<= 3 per 1.0ml	Compiles	Compiles	Compiles	Compiles	Compiles
Average Volume	(500-520) ml	510	507	505	504	501

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 2 Mar – Apr 2025, pp: 804-815 www.ijprajournal.com ISSN: 2456-4494

Assay	**Dextrose Monohydrate (95-105)**	**99.95**	**99.67**	**99.56**	**99.11**	**98.93**
	Sodium Chloride (95-105)	**98.92**	**98.72**	**98.66**	**98.59**	**98.52**
Pyrogen/Bacterial Endotoxin	**Must be pyrogen-free/ Not More Than 0.25 EU/ml**	**Complies**	**Not Applicable**	**Not Applicable**	**Not Applicable**	**Complies**
Sterility	**Must be sterile**	**Complies**	**Not Applicable**	**Not Applicable**	**Not Applicable**	**Complies**
Leakage Determination	**Must be leakage-free**	**Complies**	**Complies**	**Complies**	**Complies**	**Complies**

Assay Calculation:
Assay of the Initial test for Glucosal sample for (30°C± 2°C/65% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.29,5.29,5.28
Mean=5.287
B=100/52.9 × 198.17/180.16 × 100/200× 5.287
=5.497
%=(B×100) ÷ 5.5
= (5.497× 100) ÷ 5.5 = 99.95%
Sodium Chloride content in 100 ml
Titration reading = 14.95, 14.95.14.95
Mean=14.95
=14.95 × 0.005844× 1.019 × 10
=0.890277882
%=(0.890277882× 100) ÷0.9
= 98.92%
Here, is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

Assay Calculation:
Assay of the 3 Month test for Glucosal sample for (30°C± 2°C/65% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.27,5.27,5.28
Mean=5.273
B=100/52.9 × 198.17/180.16 × 100/200× 5.273
=5.482
%=(B×100) ÷ 5.5
= (5.482× 100) ÷ 5.5
= 99.67%
Sodium Chloride content in 100 ml
Titration reading = 14.92, 14.92.14.92
Mean=14.92
=14.92 × 0.005844× 1.019 × 10
=0.8884913712
%=(0.8884913712× 100) ÷0.9
= 98.72%
Here, is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

Assay Calculation:
Assay of the 6 Month test for Glucosal sample for (30°C± 2°C/65% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.26,5.27,5.27
Mean=5.267
B=100/52.9 × 198.17/180.16 × 100/200× 5.267
=5.476
%=(B×100) ÷ 5.5
= (5.476× 100) ÷ 5.5 = 99.56%
Sodium chloride content in 100 ml
Titration reading = 14.92, 14.92.14.92
Mean=14.92
=14.92 × 0.005844× 1.019 × 10
=0.890277882
%=(0.890277882× 100) ÷0.9
= 98.92%
Here, is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

Assay Calculation:
Assay of the 9 Month test for Glucosal sample for (30°C± 2°C/65% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.24,5.24,5.25
Mean=5.243
B=100/52.9 × 198.17/180.16 × 100/200× 5.243
=5.451
%=(B×100) ÷ 5.5
= (5.451× 100) ÷ 5.5
= 99.11%

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 2 Mar – Apr 2025, pp: 804-815 www.ijprajournal.com ISSN: 2456-4494

Sodium Chloride content in 100 ml
Titration reading = 14.90, 14.90.14.90
Mean=14.90
=14.90 × 0.005844× 1.019 × 10
=0.887300364
%=(0.887300364× 100) ÷0.9
= 98.59%
Here, is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

Assay Calculation:
Assay of the 12 Month test for Glucosal sample for (30°C± 2°C/65% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.23,5.23,5.24
Mean=5.233
B=100/52.9 × 198.17/180.16 × 100/200× 5.233=5.441
%=(B×100) ÷ 5.5
= (5.441× 100) ÷ 5.5= 98.93%
Sodium Chloride content in 100 ml
Titration reading = 14.89, 14.89,14.89
Mean=14.89
=14.89 × 0.005844× 1.019 × 10
=0.8867048604
%= (0.8867048604 × 100) ÷0.9 = 98.52%
Here is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

Real-time stability data for Dextrosal sample (30°C± 2°C/65% RH±5%RH)

Test Parameters	Specification	Results				
		Initial	After 3Month	After 6Month	After 9Month	After 12Month
Appearance	Clear, colourless, and odorless freely flowing transparent liquid	Compiles	Compiles	Compiles	Compiles	Compiles
Identification	Positive	Compiles	Compiles	Compiles	Compiles	Compiles
PH	3.2-6.5	5.38	5.30	5.25	5.20	5.15
Particulate Matter	10.0µm counts<= 25 per 1.0ml 25.0µm counts<= 3 per 1.0ml	Compiles	Compiles	Compiles	Compiles	Compiles
Average Volume	(500-520) ml	515	510	508	505	503
Assay	Dextrose Monohydrate (95-105)	99.49	99.29	98.80	98.55	98.35
	Sodium Chloride (95-105)	98.92	98.72	98.59	98.59	98.52
Pyrogen/Bacterial Endotoxin	Must be pyrogen-free/ Not More Than 0.25 EU/ml	Complies	Not Applicable	Not Applicable	Not Applicable	Complies
Sterility	Must be sterile	Complies	Not Applicable	Not Applicable	Not Applicable	Complies

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 2 Mar – Apr 2025, pp: 804-815 www.ijprajournal.com ISSN: 2456-4494

Leakage Determination	**Must be leakage-free**	**Complies**	**Complies**	**Complies**	**Complies**	**Complies**

Assay Calculation:
Assay of the Initial test for Dextrosal sample for (30°C± 2°C/65% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.27,5.26,5.26
Mean=5.263
B=100/52.9 × 198.17/180.16 × 100/200× 5.263
=5.472
%=(B×100) ÷ 5.5
= (5.472× 100) ÷ 5.5
= 99.49%
Sodium Chloride content in 100 ml
Titration reading = 14.95, 14.95.14.95
Mean=14.95
=14.95 × 0.005844× 1.019 × 10
=0.890277882
%=(0.890277882× 100) ÷0.9
= 98.92%
Here is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

Assay Calculation:
Assay of the 3 Month test for Dextrosal sample for (30°C± 2°C/65% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.26,5.25,5.25
Mean=5.253
B=100/52.9 × 198.17/180.16 × 100/200× 5.253
=5.461
%=(B×100) ÷ 5.5
= (5.461× 100) ÷ 5.5
= 99.29%
Sodium Chloride content in 100 ml
Titration reading = 14.92, 14.92.14.92
Mean=14.92
=14.92 × 0.005844× 1.019 × 10
=0.8884913712
%=(0.8884913712× 100) ÷0.9
= 98.72%
Here is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

Assay Calculation:
Assay of the 6 Month test for Dextrosal sample for (30°C± 2°C/65% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.23,5.22,5.23
Mean=5.227
B=100/52.9 × 198.17/180.16 × 100/200× 5.227
=5.434
%=(B×100) ÷ 5.5
= (5.434× 100) ÷ 5.5
= 98.80%
Sodium Chloride content in 100 ml
Titration reading = 14.90, 14.90.14.90
Mean=14.90
=14.90 × 0.005844× 1.019 × 10
=0.887300364
%=(0.887300364× 100) ÷0.9
= 98.59%
Here is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

Assay Calculation:
Assay of the 9 Month test for Dextrosal sample for (30°C± 2°C/65% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.21,5.21,5.22
Mean=5.213
B=100/52.9 × 198.17/180.16 × 100/200× 5.213
=5.420
%=(B×100) ÷ 5.5
= (5.420× 100) ÷ 5.5
= 98.55%
Sodium Chloride content in 100 ml
Titration reading = 14.90, 14.90.14.90
Mean=14.90
=14.90 × 0.005844× 1.019 × 10
=0.887300364
%=(0.887300364× 100) ÷0.9
= 98.59%
Here is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

Assay Calculation:
Assay of the 12 Month test for Dextrosal sample for (30°C± 2°C/65% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.20,5.20,5.21
Mean=5.203
B=100/52.9 × 198.17/180.16 × 100/200× 5.203
=5.409
%=(B×100) ÷ 5.5
= (5.409× 100) ÷ 5.5= 98.35%
Sodium Chloride content in 100 ml
Titration reading = 14.89, 14.89.14.89
Mean=14.89
=14.89 × 0.005844× 1.019 × 10
=0.8867048604
%=(0.8867048604× 100) ÷0.9

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 2 Mar – Apr 2025, pp: 804-815 www.ijprajournal.com ISSN: 2456-4494

= 98.52%

Here is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

Accelerated stability data for ACME's DNS sample (40°C± 2°C/75% RH±5%RH)

Test Parameters	Specification	Results		
		Initial	After 3Month	After 6Month
Appearance	Clear, colorless and odourless freely flowing, transparent liquid	Compiles	Compiles	Compiles
Identification	Positive	Compiles	Compiles	Compiles
PH	3.2-6.5	4.90	4.85	4.82
Particulate Matter	10.0µm counts<= 25 per 1.0ml 25.0µm counts<= 3 per 1.0ml	Compiles	Compiles	Compiles
Average Volume	(500-520) ml	503	501	500
Assay	Dextrose Monohydrate (95-105)	98.55	98.36	98.24
	Sodium Chloride (95-105)	98.72	98.59	98.40
Pyrogen/Bacterial Endotoxin	Must be pyrogen-free/ Not More Than 0.25 EU/ml	Complies	Not Applicable	Not Applicable
Sterility	Must be sterile	Complies	Not Applicable	Not Applicable
Leakage Determination	Must be leakage-free	Complies	Complies	Complies

Assay Calculation;
Assay of the Initial test for ACME'S DNS sample for (40°C± 2°C/75% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.22,5.21,5.21
Mean=5.213
B=100/52.9 × 198.17/180.16 × 100/200× 5.213=5.420
%=(B×100) ÷ 5.5
= (5.420× 100) ÷ 5.5 = 98.55%
Sodium Chloride content in 100 ml
Titration reading = 14.92, 14.92.14.92
Mean=14.92
=14.92 × 0.005844× 1.019 × 10 =0.8884913712
%=(0.8884913712× 100) ÷0.9
= 98.72%
Here is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

Assay Calculation:
Assay of the 3 Month test for ACME'S DNS sample for (40°C± 2°C/75% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.20,5.20,5.21
Mean=5.203
B=100/52.9 × 198.17/180.16 × 100/200× 5.203 =5.410
%=(B×100) ÷ 5.5
= (5.410× 100) ÷ 5.5
= 98.36%
Sodium Chloride content in 100 ml
Titration reading = 14.90, 14.90.14.90
Mean=14.92
=14.90 × 0.005844× 1.019 × 10
=0.887300364
%=(0.887300364× 100) ÷0.9
= 98.59%

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 2 Mar – Apr 2025, pp: 804-815 www.ijprajournal.com ISSN: 2456-4494

Here is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

Assay Calculation:

Assay of the 6 Month test for ACME'S DNS sample for (40°C± 2°C/75% RH±5%RH)

Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.20,5.20,5.19
Mean=5.197
B=100/52.9 × 198.17/180.16 × 100/200× 5.197 =5.403
%=(B×100) ÷ 5.5
= (5.403× 100) ÷ 5.5
= 98.24%
Sodium Chloride content in 100 mlTitration reading = 14.87, 14.87.14.87
Mean=14.87
=14.87 × 0.005844× 1.019 × 10=0.8855138532
%=(0.8855138532× 100) ÷0.9
= 98.40%
Here is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

Accelerated stability data for Glucosal sample (40°C± 2°C/75% RH±5%RH)

Test Parameters	Specification	Results		
		Initial	After 3Month	After 6Month
Appearance	Clear, colourless and odourless freely flowing, transparent liquid	Compiles	Compiles	Compiles
Identification	Positive	Compiles	Compiles	Compiles
PH	3.2-6.5	5.05	5.02	4.95
Particulate Matter	10.0µm counts<= 25 per 1.0ml 25.0µm counts<= 3 per 1.0ml	Compiles	Compiles	Compiles
Average Volume	(500-520) ml	508	504	501
Assay	Dextrose Monohydrate (95-105)	99.24	98.36	98.24
	Sodium Chloride (95-105)	98.79	98.59	98.40
Pyrogen/Bacterial Endotoxin	Must be pyrogen-free/ Not More Than 0.25 EU/ml	Complies	Not Applicable	Not Applicable
Sterility	Must be sterile	Complies	Not Applicable	Not Applicable
Leakage Determination	Must be leakage-free	Complies	Complies	Complies

Assay Calculation:

Assay of the Initial test for Glucosal sample for (40°C± 2°C/75% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.25,5.25,5.25
Mean=5.25
B=100/52.9 × 198.17/180.16 × 100/200× 5.25 =5.458
%=(B×100) ÷ 5.5
= (5.458× 100) ÷ 5.5 = 99.24%
Sodium Chloride content in 100 ml
Titration reading = 14.93, 14.93.14.93
Mean=14.93
=14.93 × 0.005844× 1.019 × 10
=0.8890868748
%=(0.8890868748× 100) ÷0.9

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 2 Mar – Apr 2025, pp: 804-815 www.ijprajournal.com ISSN: 2456-4494

= 98.79%
Here is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

Assay Calculation:
Assay of the 3 Month test for Glucosal sample for (40°C± 2°C/75% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.20,5.20,5.23
Mean=5.21
B=100/52.9 × 198.17/180.16 × 100/200× 5.21
=5.417
%=(B×100) ÷ 5.5
= (5.417× 100) ÷ 5.5
= 99.49%
Sodium Chloride content in 100 ml
Titration reading = 14.90, 14.90.14.90
Mean=14.90
=14.90 × 0.005844× 1.019 × 10
=0.887300364
%=(0.887300364× 100) ÷0.9
= 98.59%
Here is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

Assay Calculation;
Assay of the 6 Month test for Glucosal sample for (40°C± 2°C/75% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.20,5.18,5.18
Mean=5.187
B=100/52.9 × 198.17/180.16 × 100/200× 5.187
=5.393
%=(B×100) ÷ 5.5
= (5.393× 100) ÷ 5.5
= 98.05%
Sodium Chloride content in 100 ml
Titration reading = 14.88, 14.88.14.88
Mean=14.44
=14.88 × 0.005844× 1.019 × 10
=0.8861093568
%=(0.8861093568 × 100) ÷0.9
= 98.46%
Here is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

Accelerated stability data for Dextroosal sample (40°C± 2°C/75% RH±5%RH)

Test Parameters	Specification	Results		
		Initial	After 3Month	After 6Month
Appearance	Clear, colourless and odourless freely flowing, transparent liquid	Compiles	Compiles	Compiles
Identification	Positive	Compiles	Compiles	Compiles
PH	3.2-6.5	4.95	4.88	4.83
Particulate Matter	10.0µm counts<= 25 per 1.0ml 25.0µm counts<= 3 per 1.0ml	Compiles	Compiles	Compiles
Average Volume	(500-520) ml	507	504	502
Assay	Dextrose Monohydrate (95-105)	99.24	98.36	98.24
	Sodium Chloride (95-105)	98.79	98.59	98.40
Pyrogen/Bacterial Endotoxin	Must be pyrogen-free/ Not More Than 0.25 EU/ml	Complies	Not Applicable	Not Applicable
Sterility	Must be sterile	Complies	Not Applicable	Not Applicable
Leakage Determination	Must be leakage-free	Complies	Complies	Complies

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 2 Mar – Apr 2025, pp: 804-815 www.ijprajournal.com ISSN: 2456-4494

Assay Calculation:
Assay of the Initial test for Dextroosal sample for (40°C± 2°C/75% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.25,5.25,5.24
Mean=5.247
B=100/52.9 × 198.17/180.16 × 100/200× 5.247
=5.455
%=(B×100) ÷ 5.5
= (5.455× 100) ÷ 5.5
= 99.18%
Sodium Chloride content in 100 ml
Titration reading = 14.95, 14.95.14.95
Mean=14.95
=14.95 × 0.005844× 1.019 × 10
=0.890277882
%=(0.890277882× 100) ÷0.9
= 98.92%
Here is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

Assay Calculation;
Assay of the 3 Month test for Dextroosal sample for (40°C± 2°C/75% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.23,5.23,5.23
Mean=5.23
B=100/52.9 × 198.17/180.16 × 100/200× 5.23
=5.437
%=(B×100) ÷ 5.5
= (5.437× 100) ÷ 5.5
= 98.85%
Sodium Chloride content in 100 ml
Titration reading = 14.93, 14.93.14.93
Mean=14.93
=14.93 × 0.005844× 1.019 × 10
=0.8890868748
%= (0.8890868748× 100) ÷0.9
= 98.79%
Here is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

Assay Calculation;
Assay of the 6 Month test for Dextroosal sample for (40°C± 2°C/75% RH±5%RH)
Dextrose Monohydrate content in 100 ml
Reading of angular rotation=5.18,5.18,5.20
Mean=5.187
B=100/52.9 × 198.17/180.16 × 100/200× 5.187
=5.393
%=(B×100) ÷ 5.5
= (5.393× 100) ÷ 5.5
= 98.05%
Sodium Chloride content in 100 ml
Titration reading = 14.88, 14.88.14.88
Mean=14.88
=14.88 × 0.005844× 1.019 × 10
=0.8861093568
%= (0.8861093568 × 100) ÷0.9 = 98.46%
Here is the volumetric solution information: 0.1N Silver Nitrate Factor= 1.019

III. CONCLUSION:

The quality of the intravenous infusion (Dextrose and Normal Saline infusions) manufactured by three Bangladeshi Pharmaceutical companies, as analysed, shows relatively high quality in the parameters tested. All the samples passed very well within the British Pharmacopeia limit. Stability studies can ensure that the injectable drug qualities are good for administration to patients who may need them in hospitals.

REFERENCES:

[1]. https: //database.ich.org
[2]. https: // www. Pharmacopiea.com
[3]. I.V. Therapy made Incredibly Easy! 2010. (4th Ed). Wolters Kluwer/ Lippincott Willians &Wilkins. Philadelphia
[4]. Lakshmi Prasanna K (2017) Sterility Assurance of Parenteral Products- Major Deficiency for Recall. J Pharmacovigilant 5: e168 Doi: 10.4172/2329-6887.1000e168
[5]. Lawrence A.T., (2009) Handbook on Injectable Drugs 15th Edition, American Society of Health-System Pharmacists.
[6]. Mick Dawson (2017) ENDOTOXIN LIMITS For Parenteral Drug Products; BET White Paper Vol.1 no