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# A Review on IPQC Tests done for Parenterals as per I.P., B.P., and U.S.P.

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**ABSTRACT:** Allowing In-Process Quality Control (IPQC) Approaches can be helpful for pharmaceutical manufacturing companies to achieve their goal by producing high-quality products. The value of IPQC in carrying out comprehensive testing for products before, after, and during the manufacturing process, or in monitoring and improving the entire applied procedure at every single step of manufacturing of the finished pharmaceutical goods as per the Standard Operating Procedures (SOPs). Currently, efforts are being made all over the world to assure the practice of quality along with the accessibility of cost-effective, medicines of finest quality. Parenteral products are aseptic as they are administered intravenously directly into systemic circulation, bypassing the digestive system. These treatments have a faster onset of effect than others, but one of the most concerning issues is their stability, which emerges from microbial contamination of the products. As a result, laws governing quality control through pharmacopeial requirements are critical in ensuring their sterility and stability. Following good manufacturing practices and developing standard operating procedures, pharmacopoeias give a viable guideline for overcoming those challenges. In-process quality control tests are performed with the goal of eliminating errors at every stage of manufacturing and ensuring that the final product meets the compendial requirements outlined in pharmacopoeias. Finished product quality controls tests assess the qualitative and quantitative aspects of pharmaceutical products. According to the research done for the report of "UK Injectable Market Outlook to 2017", in the years 2011 and 2017, the growth rate of the pharmaceutical market was found to be near 4.0 percent. The sale of pharmaceuticals is primarily driven by the growing demand for injectables for conditions such as diabetes, infectious disorders, and arthritis. Injectables are undergoing extensive research and development, so that their therapeutic results can be improved. Numerous regulatory demands of the various countries require items with specific range of limits. The comparability research will be helpful to understand the standards of different pharmacopoeia, as well as the regulatory requirements of that particular country.

**KEYWORDS:** Quality control, Injectable, Implants, British Pharmacopoeia (B.P), Indian Pharmacopoeia (I.P), United States Pharmacopoeia (USP).

## I. INTRODUCTION

Parenteral medicinal products are aseptic treatments, which are mainly administered through injection, but they can be given as an infusion, or can also be planted as an implantation. Another name used for parenteral is injectable preparation.

An injection is a type of infusion in which a liquid preparation is injected inside the body using a hollow needle attached to the syringe. To administer the drug into the body, the skin tissue is punctured using the needle. The puncture should be deep enough to allow the liquid drug to reach to the desired location. An injection is administered by a route other than the digestive tract, which is known as a parenteral mode of administration. Intradermal, subcutaneous, intramuscular, intravenous, intraosseous, and intraperitoneal injections and infusions are all utilised in humans. In addition, intra cerebral and intracerebroventricular injections are frequently given to research rodents. Depot injections are long-acting subcutaneous/intramuscular injections that are accessible for a variety of medications. Injections are one of the most common types of medical treatment, minimum 16 billion used each year in developing countries.

Out of all the purposes, 95% of injections are used for injections, 3% for vaccination, and the left 2% is used for purposes like blood transfusions. Around 40% of total injectable preparations are delivered using unsafe needles or syringes, which are reused without any sterilization, worldwide, with up

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to 70% in some countries, exposing millions of people because of their fragility in an aqueous environment, ready-to-use injectables are not recommended [1,2]. In terms of formulation and process development, parentals injectables are rather basic. Their performance and stability, on the other hand, are a concern.

Although quality is undoubtedly essential for all items, it has a bigger impact in some areas, such as pharmaceuticals (i.e., medications). Because medicines are the most significant aspect of mammalian lives, as the safety and the efficacy is signified by the quality of a medicine. Therefore, the quality is considered as one of the major worldwide concerns [3]. As a result, just for humanity's well-being, requirements linked to pharmaceutical quality control must be thoroughly examined. International regulatory authorities are making efforts to upgrade standards of pharmaceutical production and manufacturing, so that high quality drug with safety and efficacy can be provided to to patients [4].

The European Medicines Agency (EMA), the Food and Drug Administration (FDA) and the Medicines and Healthcare Products Regulatory Agency (MHRA), are responsible of this in Europe, the United Kingdom (UK), and the United States, respectively [5,6]. The FDA has issued current good manufacturing practise (cGMP) and good laboratory practise (GLP) regulatory guidelines, in order to create a structure which could provide effective outline, observation, and control of manufacturing methods and facilities. The performance of two important processes called in-process quality control (IPQC) and final product quality control (FPQC) testing determines the quality of pharmaceuticals. IPQC's function includes observing and, if required, the manufacturing procedures are compiled as per pharmacopoeias [7]. IPQC tests are performed at regular interlude until the manufacturing process is completed, depending on the nature of each test and/or the official rules [8]. By correcting any faults in the production process, in-process testing makes it easier to identify and correct problems [9].

Products fail IPQC tests in two types of cases, one if standard operating procedures is not followed properly and the second case is when required conditions were not kept in control [10]. FPQC, on the other hand, are conducted after the manufacturing process has been completed to ensure that the products' qualitative and quantitative features are in accordance with specifications [11].

Pharmacopoeia is a legally obligatory collection of guidelines and quality stipulations for medications that helps to preserve these criteria. Finished product controls (FPC) are checks performed as analytical tests to check the quality and quantity, after the manufacturing process is completed, as well as test protocols and the finished product should exhibit the features within the acceptance limits, and they should persist as it is during its valid shelf life [12].

The quality features of the production process should be considered when determining the standards of the finished product. It is necessary to design a suitable standard for every single area of quality, which is examined at the time of development stage and throughout the validation process of the manufacturing course. Core elements should be the subject of specifications that are routinely validated. The trade mark respondent establishes the finished product specification limits at the time of batch release so in order to guarantee the projected specifications at the termination of shelf life. To establish these limits, firstly the batches are examined, followed by the collection data, and then this data is critically reviewed in detail [13,14].

As a result, the motive of the current research is to provide an overview of the quality control tests performed on in-process and finished product of parenteral preparation that are acceptable with standards of pharmacopoeia [18].

## II. PARENTERAL DOSAGE

### Introduction of parenteral dosage form

The parenteral dose is considered to be different from rest of the medicinal dosage forms, as they are administered by injecting straight inside the body via the principal protective mechanisms of the living body such as skin tissue along with the mucous membranes. These preparations should be extremely pure and devoid from all kinds of chemical, biological, and physical impurities [25].

These conditions place a huge responsibility on the shoulders of pharmaceutical manufacturing companies to follow cCGMPs i.e., current good manufacturing practises, while producing parenteral dosage forms. Along with it, all health-care professionals including pharmacists and doctors, are bound to obey GAPs i.e., good aseptic practises during the dispensing and administration of parenteral dose to a patient. Several pharmacological compounds cannot be administered orally as they get disabled after entering into the gastrointestinal tract. So, compounds like peptides, proteins and several chemotherapeutic drugs, which are unsuitable for oral route, can be administered through parenteral route. Parenterally delivered medicines found to be inherently unstable and often extremely potent which

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needs the regulation of responsibility towards the patient. The use of parenteral medicines has been increased worldwide due to the evolution of biotechnology [26].

**Characteristics of parenteral products**

Parenteral preparations are considered to be different as compared to other pharmacological dosage forms, and following are some of the major reasons to do so:

- Sterility is required for all items
- Pyrogenic (endotoxin) contamination must be avoided in all goods
- There must be no visible particle debris in injectable solutions. This includes sterile powders that have been reconstituted
- Isotonicity of the products should be maintained, albeit the degree of isotonicity depends upon the route of administration and varies accordingly.
- Isotonic preparations must be used in the cerebrospinal fluid
- Ophthalmic products must be isotonic, even if they are not parenteral. Products that will be given as a bolus injection via a method excluding intravenous route (IV) have to be isotonic, or very close to it.
- Products must be consistent with IV diluents, system of administration, and additional co-administered medicinal preparations, if applicable [27].

| Route | Injection Site |
|---|---|
| Intravenous (IV) | IV is injected into veins. |
| Intramuscular (IM) | IM is injected into Muscle tissue. |
| Intradermal (ID) | ID is injected into Dermis of the skin. |
| Subcutaneous (Subcat; SQ) | This is injected into Subcutaneous Tissue of the skin. |
| Intrathecal (IT) | This is injected into Subarachnoid space of the spinal cord. |
| Epidural | This is injected into Epidural space of the Spinal cord. |
| Intra-arterial | This is injected into Artery. |
| Intra-articular | This is injected into Joint space. |
| Intracardiac | This is injected into Heart. |
| Intraocular | This is injected into Eye. |
| Intraperitoneal | This is injected into Peritoneal cavity |

**TABLE 1 IS MAINLY ABOUT THE ROUTE OF INJECTIONS AND INJECTIONS SITES.**

Note: According to The United States Pharmacopeia (USP), there are five different forms of parenteral preparations:

- **Injection:**
  Solutions of pharmacological compounds or liquid formulations.
- **For injection:**
  When they are combined with appropriate carriers, solutions are formed that fulfil every necessary condition of injection. They exist as dry solid.
- **Injectable emulsions:**
  Liquid preparations of pharmacological compounds that have been dissolved or dispersed in an emulsion media that is appropriate for injection.
- **Injectable suspensions:**

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Solids and liquid preparations get dispersed in a appropriate liquid phase.

- **For injectable suspension:**
  They are similar to for injection and they also exist as dry solids. When combined with appropriate vehicles, provide preparations that meet all injectable suspension standards [29,30,31].

**Advantages of parenteral Dosage**

Many medications are only available by parenteral administration, it is frequently chosen as the preferable method of administration in particular situations. On the basis of this it has some advantages:

- In emergency situations and for customised dosing regimens, multiple drugs must be provided at the same time
- Parenteral delivery of certain drugs allows for convenient continuous infusions and unique titrations
- Patients with a malfunctioning gastrointestinal tract, restricted oral intake, and nausea or vomiting, parenteral preparations is useful form of medication delivered for these patients
- Eliminating the gastrointestinal tract may allow a rapid physiological reaction as well as complete systemic circulation of a drug, resulting in higher drug serum concentrations
- Patients with rheumatoid arthritis are administered corticosteroids through an intra-articular route of administration, it is an example of localised drug delivery
- While selecting medicinal formulations, the potentiality for a longer duration of impact is an important factor to consider and parenteral dosage plays an important role in this [32,33].

**Disadvantages of parenteral Dosage**

- Although there are numerous advantages to administering medications via parenteral routes, this method also carries some potentially complications for the patient.
- In this type of dosage, drug reversal is not possible, which can lead to danger of various types of infections and emboli.
- There is a less chance of accuracy and sterility
- Parenteral administration of medicines may raise the risk of hypersensitivity responses
- The parenteral method of drug administration has a main disadvantage that it is only applied for immediate start of action and not for sustained, prolonged, or extended-release of the drug
- While injecting it causes pain and that is why it should be avoided by the child and older patients
- In parenteral treatment, only soluble medications can be formulated [35].

## III. TESTS ACCORDING TO DIFFERENT PHARMACOPOEIAS

**Uniformity of content**

**According to IP**

Ten containers are selected randomly, and the active ingredients of each container are determined using the technique described in the monograph. Other than this any appropriate analytical approach can be used, but it should be accurate and precise.
Following are the conditions for preparation under inspection, to pass the test:

1. For total sample of 10 containers, every single result attained should lie within the range of 85 % to 115% of the average value.
2. For total sample of 30 containers, not more than one sample should lie outside the limit of 85% to 115%, and each sample should be within the limit of 75% to 125% of the average [1,12,13].

Note: The uniformity of content test is not applicable for injection suspensions having trace elements and multivitamins.

**According to BP**

**Test A**

This test is mainly performed for Tablets, parenteral powders, ophthalmic inserts, and injectable suspensions. In order to fulfil the standards, each single sample of the preparation should have value within the limit range of 85-115% of the average value. In two conditions preparation fails the test, firstly if the number of samples which does not lie within the limited range is more than one, or if not, even a single content have value within the range of 75-125% of the average value. If one specific content has result other than the limitations of 85-115%, but has value between 75-125%, then

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additional 20 units of dosage are picked randomly and their content is determined [14,15,16].

**Test B**

This test is for Capsules, non-parenteral powders, granules, suppositories, and pessaries. The products being inspected pass the test, if not more than one sample has value out of the range of 85-115% of average value, and no sample lies out of the range of 75-125% of the average. The preparation will fail the tests, If more than three single contents comes out of the range of 85-115% percent of the average content, or if one or more than that have content out of the range of 75-125% of the average value.

If two to three single contents have values out of the limit of 85-115%, but lies between 75-125%, then additional 20 units of dosage are chosen, randomly and their separate contents are determined.

If not more than 3 separate contents of the 30 samples exhibit value out of the boundaries of 85-115% percent of the average, and all are within the ranges of 75-125% of the average value, the preparation passes the test [14,15,16].

**According to USP**

**Stage 1**

To perform the assay 10 samples are selected in a random manner. The preparation will pass the test if the RSD i.e., Relative Standard Deviation is not more than 6% and all the resulted values comes within the range of 85-115%. And the test will be failed, if one or more samples have value out of the range of 75-125% [15,16].

**Stage 2**

Additional 20 units are added to the mix and the assay was repeated. The test is considered to be passed, if all the 30 samples have the RSD not more than 7.8%, and only single sample has value beyond 85-115%, and all values lie within the range of 75-125 %, otherwise, the batch will fail to pass the test [15,16].

**General Procedure**

Determine the amount of active component in each of ten randomly selected containers. If the individual values obtained are all within the range of 85-115 % of the mean value, then preparation under observation is passed. If greater than one value lies out of the limits of 85 - 115 % of the average value, or even if single value comes out of the limits of 75-125 % of the mean value, the preparation is considered to be failed. If any value does not lie within the limit of 85 -115 % but remains between the range of 75 - 125 % of the mean value. The calculation is performed again with additional 20 vessels, which are selected randomly. If only single value out of 30 containers comes out of the limit of 85-115 %, and all lies within the limits of 75-125 % of the mean value, the preparation under examination [15,16].

**Particulate matter for the injections**

For sub-visible particles, one method involves observing them using a microscope and counting those particles, while in second method the basis of counting is the particles generating light obscuration. These two strategies are used only for a limited sample of people [1,2,17].

**Microscopic particle count**

The is first type of method involving microscopic technique is useful in detection of particles with a 10m or greater longest axis or effective linear dimension [15].

**Procedure**

Invert the prepared container 20 times. Single units should be tested for parenteral with large quantity. For small quantity parenteral with a capacity of maximum 25 mL, the sample of 10 units or more than that are combined in a fresh vessel. When the quantity of solution in a vessel is modest, the test solution is prepared, when the contents of some containers are combined and then diluted to 25 ml using particle free water. Individual testing is possible for small-volume parenteral with a volume of 25 ml or more. Particle-free water should be used to make powders for parenteral usage. Place the membrane filter holder on top of the membrane filter. Filter 200 ml of filtered water at a frequency of 20 - 30 ml per minute under reduced pressure for particle matter testing. Apply vacuum until the membrane's surface is clear of water, then carefully remove the membrane and dry it below fifty degrees Celsius [15,16]. Place the filter under the microscope after it has dried. The microscope is adjusted to acquire the finest sight of particles with a diameter of 150m or more. Make sure the number isn't greater than one [15,16]. For the particle matter test, attach extra membrane filter after that moisten it using pure water. Fill the filter using the sample liquid. For particle matter testing and filtering, dilute viscous solutions appropriately with filtered water [15,16]. When the quantity of liquid solution on the filter gets tiny, 30 ml of water is added into it. Continue the process is continued thrice, each time

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using 30 ml of water. A gentle vacuum is applied to the filter surface of membrane until it is completely dry. Then, it is dried and examined beneath a microscope. The particle number is counted for the ones having sizes:

- equal to 10 m or greater than that
- equal to or more than 25 m
- equal to or greater than 50 m [15,16].

**Light obscuration particle count test**

This the second type of method which utilizes an appropriate instrument which depends on the concept of light blocking to automatically determine size of particle along with particle count per size.

**Procedure**

The container is inverted 20 times. Only one unit needs to be tested for parenteral having larger capacity. For small volume parenteral with a capacity of maximum 25 mL or less, then solution of 10 or more units are combined together in a fresh vessel. When the container has the limited volume of solution, then test liquid can be prepared, after the contents of some containers are combined and then diluted to 25 ml using particle free water [11,15,17]. Individual testing is possible for parenteral with a volume equal to 25 ml or greater than that. Particle-free water should be used to make powders for parenteral usage. Remove 4 sections of minimum of 5 mL each, then the number of particles having size larger than 10 micro meters are counted and divided by 250 micro meters [1,15,17].

| Volume of solution | Particle size ≥10µm | Particle size ≥ 25µm |
|---|---|---|
| Large volume parenteral | 12 per ml | 2 per ml |
| Small volume parenteral | 3000 per container | 300 per container |

**TABLE 2. LIMITS FOR MICROSCOPIC PARTICLE COUNT TEST AS PER IP, USP, AND BP**

Table 2 is about the standards of various pharmacopoeias for microscopic particle count test and Table 3 is about standards of lights obscuration particle count test [1,15,17].

| Volume of solution | Particle size ≥10µm | Particle size ≥ 25µm |
|---|---|---|
| Large volume parenteral | 25 per ml | 3 per ml |
| Small volume parenteral | 6000 per container | 600 per container |

**TABLE 3. LIMITS FOR LIGHT OBSCURATION PARTICLE COUNT TEST AS PER IP, BP, USP**

**Extractable uniformity**

Before removing the contents of a suspension, it should be shaken. Oil based injections can be heated, but they must be brought to the temperature of 25 ° c prior to testing [1,14,17].

**Unit dose containers as per Indian pharmacopoeia**

**First method**

When the minimal quantity is less than 5ml. Six vessels are needed: five for the tests and one for washing the needle. The syringe is rinsed and content is extracted out of a test container into a graduated cylinder, without evacuating the needle. The volume of that cylinder should be such that the combined volume which is to be calculated occupies minimum 40 % of the minimal volume of cylinder [11,12,13]. Repeat the method until all of the contents of the five containers have been shifted, then take a volume measurement. The average content of the 5 vessels is between the nominal volume and 115 percent of the nominal capacity. The volume of contents can also be estimated by mass of the content divided by the density [11,12,13].

**Second method**

The content is transferred from minimum three vessels into graded cylinders, and the volume should occupy at least 40% of the minimal capacity of the cylinder. Then, this volume is measured. Each container should have content greater than the

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minimal capacity along with that should not be greater than 110% of the minimal capacity [1,14,17].

**Multi dose containers**
Equal to single dose containers
Table 4 is about the extractable volume as per BP and USP [14,15,16,17,18].

**Table 4. Extractable volume as per BP, USP**

| Volume of the solution | Number of containers used in the test |
|---|---|
| Equal to or greater than 10ml | 1 |
| Within the range of 3 to 10 ml | 3 |
| Lesser than 3 ml | 5 |

**Test for pyrogen**

In this test, rabbits are administered with a sterile parenteral preparation which is under study, through intravenous injection. Then, the changes in the body temperature of the animals are observed. For this test animals can be used only single time in every 48 hours. In the pyrogen test, if the body temperature of the animal shows rise of 0.6 °C or greater than that, or in case the substance under study is proved as pyrogenic, the animals should give the rest for at least 2 weeks before being used again [11,15,18].

**Test animals**
Healthy rabbits of any sex are used weighing 1.5kg [11,15,18].

**Temperature record**
A clinical thermometer is used as a temperature detecting thermometer. Other than that thermistor or a relevant probe can also be utilized to determine the temperature of 0.10 accuracy. The temperature detecting instrument is inserted a depth of around 5 cm 7.5 cm in the rectum of the test rabbit –USP [11,15,18].

**Preliminary Test**
A pyrogen free saline heated up to the temperature of 38.50 °C, and 10 ml per kg of body weight was injected. At least 90 minutes prior to the injection body temperature of animal is measured, and after injection for 3 hours temperature is observed. If the temperature difference of 0.6 degree Celsius or more is observed, then the animal is put on rest [11,12,16,17].

**Main test**

Use a group of three rabbits to do the experiment [11,15,18].

**Sample Preparation**
Using pyrogen-free saline solution, dissolve the material. Before injecting the liquid under evaluation, heat it to around 38.5°C [11,15,18].

**Procedure**
Each animal's temperature should be taken 90 minutes prior to the administration of solution and every 30 minutes for the next 3 hours. Each rabbit's "starting temperature" should be recorded, as well as the temperature at an interval 30 minutes. While determining starting temperature, if two consecutive observations have temperature difference of 0.2 degree Celsius, then that animal should not be used. If a rabbit has temperature within the range of 38-39.8 degree Celsius, then it should not be used. Slowly inject the solution into each rabbit's marginal vein in the ear for no more than 4 minutes. The injection volume must be between 0.5 and 10 millilitres per kilogramme of body mass.
The distinction among the "starting temperature" and the "maximum temperature," which is the extreme temperature to which an animal has ever been exposed to, is used to determine its response. The outcome is calculated as a zero response when the difference is negative [11,15,18].

**Result Interpretation**
After performing the test on a group of 3 animals, perform it again, if required, on the other rabbit groups listed in the following table based on the results attained. The material fits the criteria if the sum responses of group 1 does not surpass the amount in the column number three of following table. If the response is greater than the amount in the column number three of following Table, but less than the amount in the column number four, repeat the test as directed previously [11,15,18].

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**Table 5: Result of pyrogen test according to I.P., B.P. and U.S.P.**

| Pharmacopoeia | Number of animals in single group | Test is passed if the temperature is less than: | Test is failed if the temperature is greater than: |
|---|---|---|---|
| BP | 3<br>6<br>9<br>12 | 1.15<br>2.80<br>4.45<br>6.60 | 2.65<br>4.30<br>5.95<br>6.6 |
| IP | 3<br>8 | 1.4<br>3.7 | Temp. rise should not be greater than<br>0.60 °C |
| USP | 3<br>8 | ---<br>3.3 | Temp. rise should not be greater than<br>0.60 °C |

**General procedure**

As stated on the label, insert the injection.
1) The solid entirely dissolves, leaving no undissolved materials visible
2) The established injection is no less pure than an equal number of diluents for water for injections enclosed in an identical vessel and inspected in the similar way [1,14,17].

**Bacterial endotoxin test**

The bacterial endotoxins test (BET) detects the number of bacterial endotoxins that could be found in the preparation or in the items under investigation. In this test alysate is used, which can be obtained from amoebocytes or haemolymph cells of horse shoe crab, and limulus polyphemus.
Following formula is used to determine the endotoxin limit for a specific test material:

Endotoxin limit = K/M

Where, K = threshold value for pyrogenic dose of endotoxin per kilogram of body weight
And, M = highest dose provided per kilogramme per hour to an adult (Let 70 Kg) [15,18,11].
Following are the tests which can be used to determine the endotoxic concentration:

**Gel- Clot Limit Test Method**

Water BET is used to make the solutions and dilutions. With sterilized 0.1M sodium hydroxide BET, 0.1M hydrochloric acid BET, or a suitable buffer produced using water BET, adjust the pH of given solution to 6.0 to 8.0 if necessary. At dilution below MVD (Maximum Valid Dilution) or at any dilution above MVD, the sample solution is prepared. Two positive controls are used, first with a concentration of 2λ and the second one with a concentration of 2λ spiked (A positive response indicates that the amount of endotoxin in the sample meets or exceeds the reagents labelled sensitivity, represented by the symbol lambda). Add the required amounts of negative control (NC), standard CSE (Control Standard Endotoxin) solutions, test solution, and positive control to the water BET (PPC-Positive Product Control). Unless a single vial is used, add an equivalent volume of the suitably prepared lysate at regular intervals. Ingredients are set into an incubator after being combined. Incubation needs to be performed at a temperature of 37º±1º for the duration of 60±2 minutes, undisturbed. Separate the receptacles and inspect them well. When a steady gel is generated that preserves its integrity when overturned through 180º in a single smooth movement, it is considered a good response. A negative response occurs when no hard gel forms [11,15,8].

**Calculations**

Estimate the average of the logarithms of the lowermost endotoxin amount in each dilution series [11,15,18].
Geometric mean end point concentration = antilog (e/f) [11,15,18].
Where, e = sum of the log end point concentration of the series of dilutions used; f = number of replicate test- tubes. The value needs to be within the range of 0.5λ and 2.0λ [11,15,18].

**Result Interpretation**

If the test solutions along with negative control are negative, and the positive control comes as positive,

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the product under evaluation passes the test [11,15,18].

**Retests**

If any of the test solution duplicates has a positive control and another one has a negative outcome, the test can be performed again as outlined previously. The retest 's results needs to be viewed in the same way as the initial tests [11,15,18].

**Semi Quantitative Gel Clot Method**

**Test solution preparation**

Test solutions are prepared at the concentrations of MVD, 0.25MVD, 0.5MVD.

**Procedure**
The procedure is similar to the method A mentioned above.

**Calculation and result interpretation**
Calculate the minimum concentration or maximum dilution yielding a positive (+) response for the sequence of test solutions to find the amount endotoxin in the product. This dilution is multiplied by λ to get the product's endotoxin content. For example, if MVD is 8, the positive response was reached at 0.25 MVD, and 1 was equal to 0.125EU/ml, find the endotoxin content of the preparation being investigated using the endotoxin concentration as a starting point. If the endotoxin content of the product under test is within the endotoxin limit mentioned in the specific monograph, it passes the test [11,15,18].

**Kinetic Turbidimetric Method & Kinetic Chromogenic Method**

To make a standard curve, arrange the solutions with at least three endotoxin concentrations using CSE. The method is carried out in duplicates for every single standard endotoxin solution, following the lysate manufacturer's directions.
**Test solution preparation**

**Solution A:**
Initial dilution solution of the product under analysis (test solution) [11,15,18].
**Solution B:**
Test solution spiked with CSE at a concentration in the middle of the standard curve or close to it (PPC) [11,15,18].
**Solution C:**
CSE standard solutions in water BET covers the linear section of the standard curve [11,15,18]
**Solution D:**
Water BET (NC) [11,15,18].

**Method:**
Solution D should be added first, then solutions C, A, and B are added. Then, the lysate is added and the assay is performed for solution according to the lysate manufacturer's directions [11,15,18].

**Calculation**
The endotoxin concentration is calculated in solutions A and B using the equation of regression derived from series C solutions. Subtract the average concentration of endotoxin in solution A from the average concentration of endotoxin in solution B to get a mean percentage recovery of the added endotoxin [11,15,18].

**Result interpretation**
The assay is only applicable if:
1) For the range of CSE concentrations used, linear standard curve is obtained.
2) In the positive product control of the added endotoxin, the average percentage recovery is within the range of 50-150% [11,15,18].

**End Point Chromogenic Method**
Solution D should be added first, then, solutions C, A, and B are added gradually. The lysate and chromogenic substrate are added to the prepared solution. Then, they are kept for incubation according to given duration. The reaction is stopped and the absorbance is measured at the defined wavelength according to the lysate manufacturer's directions [11,15,18].

**Result Interpretation**
The assay is applicable only if:
1) For the range of CSE concentrations used, linear standard curve is obtained.
2) In the positive product control of the added endotoxin, the average percentage recovery is within the range of 50-150% [1,14,17].

**Sterility test**
The culture media used for this test are:

1. Fluid thioglycolate medium
2. Soyabean-casein digest medium
3. Alternative thioglycolate medium

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**Fluid thioglycolate medium**
For bacteria that live in anaerobic environments. Incubate the medium of fluid thioglycolate within the temperature range of 30° - 35°C [11,15,18].

**Soyabean-casein digest medium**
Fungi and aerobic bacteria are two types of bacteria. Incubate the medium of soybean-casein digest within the temperature range of 20° - 25°C, along with it maintain the aerobic environments [11,15,18].

**Alternative thioglycolate medium**
It is suitable to utilize with products having turbid and viscid nature, as well as instruments with small Lumina tubes.

Table 6 depicts that what microbial strains can be used in the test according to the standards of different pharmacopoeia [11,15,18].

| Medium | Test microorganisms | Incubation | | |
|---|---|---|---|---|
| | | Temperature (Degree C) | Duration | Types of microorganism |
| Soya bean casein digest | *Aspergillus viger* | 20-25 | 5 days | Aerobic |
| | *Candida albicans* | 20-25 | 5 days | Aerobic |
| Fluid thioglycolate | *Bacillus subtilis* | 30-35 | 3 days | Aerobic |
| | *Pseudomonas aeruginosa* | 30-35 | 3 days | Aerobic |
| | *Staphylococcus aureus* | 30-35 | 3 days | Aerobic |
| Alternate thioglycolate | *Bacteroides vulgates* | 30-35 | 3 days | Anaerobic |
| | *Clostridium sporogeneses* | 30-35 | 3 days | Anaerobic |

**TABLE 6. STRAINS OF MICROORGANISM USED IN TEST ACCORDING TO BP, IP, AND USP**

**Test Procedure**

When the chemical under investigation is a liquid, Method A (membrane filtration) is preferable:

1. An oil
2. A non-bacteriostatic solid, which cannot be dissolved in the culture medium
3. An ointment, which is soluble in Liquid solution
4. A soluble powder or a liquid that stop the fungal or bacterial growth [11,15,18].

**Membrane Filtration method**
The procedure necessitates the application of negative and positive regulation on a regular basis.

**Apparatus**
Aqueous, oily, and slightly alcoholic solutions should be filtered with cellulose nitrate filters, while strongly alcoholic solutions should be filtered with cellulose acetate filters [11,15,18].

**Dilution of Fluids (BP and IP)**

**Fluid A:**
To make one litre of animal tissue 's peptic digest (for example bacteriological peptone), a solution is prepared by dissolving one gram of peptic digest its equal in water. Then, to clear the solution it is filtered or centrifuged, and then the pH is maintained 7.1 ± 0.2. the solution is dispensed in flasks of 100-ml capacities, and sterilized for 20 minutes at temperature of 1210 degree Celsius [11,15].

**Fluid B:**
If the test solution comprises of oil or lecithin, then, 1 ml polysorbate 80 per litre of fluid A is added. then the pH is maintained 7.1 ± 0.2. the solution is

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dispensed in flasks, and sterilized for 20 minutes at temperature of 1210 degree Celsius [11,15].

## IV. QUANTITIES OF SAMPLE TO BE USED

### 1. For Parenteral preparations

Utilize the entire filling of the vessel whenever possible, but the minimum quantity should be as recommended in Table 7, and if necessary, dilution of up to 100ml is done with acceptable diluents such as fluid A [11,15,18].

### 2. For ophthalmic and other non-Parenteral preparations

To make up the recommended range of quantity as described in table 7, content of more than one vessel can be combined, and then mixed thoroughly. The given quantity is used from the sample mixture for each media [11,15,18].

### Test method

### For aqueous solutions

Fluid A in a little amount is transferred to the membrane aseptically and then filtered. The preparation being investigated is combined and transferred into recommended two media on single membrane aseptically.
If the sample being investigated contains antibacterial capabilities, the membrane(s) is washed with the help of filtration at least thrice with 100-ml portions of sterile fluid A through it (them). Even though it has been established at the time of validation process that this type of cycle could not completely destroy the antibacterial property, the washing cycle should not be more than 5 times or 200 ml.

In the existence of remaining inhibitory substance on the membrane, the amount of liquid utilised should be adequate to permit growth of a tiny inoculum of microbe (about 50 CFU) sentinent towards the antimicrobial ingredient. when filtration is completed, the membrane(s) is removed from the receptacle aseptically, and the entire membrane is transferred, or divide it into two identical half sections aseptically. One half should be placed in each of two acceptable media. Allow at least 14 days for the media to incubate [11,15,18]. Throughout the 14-day incubation phase, keep an eye on the media containers. Further incubation is not required if the test sample shows any positive response earlier than 14 days. Then, the test sample is incubated for minimum 7 days for products terminally sterilised by an approved moist heat procedure [11,15,18].

### For liquids immiscible with, suspensions and aqueous vehicles

The analysis for aqueous solutions is performed as directed below, but enough fluid A is added to the pooled sample to enable fast filtration. To aid in the dissolution of insoluble material, aseptic enzyme-based products such as cellulose or penicillinase can be mixed to fluid A. If the sample being tested contains lecithin, dilute it with fluid B [11,15,18].

### For oil-based preparations

Less viscous oily preparations are filtered with the help of a dry membrane without dilution. The viscous oils are diluted as needed using isopropyl myristate, which is an aseptic diluent. It has been demonstrated to not exhibit any antibacterial characteristics under the analytical circumstances.
Allow the oil to gradually permeate and filtrate the membrane by the application of suction pressure. Minimum three successive volumes of aseptic fluid B are filtered. Other than that, any acceptable aseptic diluting liquid can be used to filter through the membrane, each of approximately 100ml [11,15,18]. when filtration is completed, the membrane(s) is removed from the receptacle aseptically, and the entire membrane is transferred, or divide it into two identical half sections aseptically. One half should be placed in each of two acceptable media. Allow at least 14 days for the media to incubate [11,15,18].
Throughout the 14-day incubation phase, keep an eye on the media containers. Further incubation is not required if the test sample shows any positive response earlier than 14 days. Then, the test sample is incubated for minimum 7 days for products terminally sterilised by an approved moist heat procedure [11,15,18].

### For ointments and creams

Ointments are diluted using fatty base. A fluid having concentration 1% w/v is used for dilution of water in oil type emulsions and then heated up to the temperature of 40 °C. An appropriate aseptic diluting agent like isopropyl myristate is used. Formerly provided aseptic filtration using a 0.221 m membrane filter, which does not exhibit any antimicrobial activities while going through the test circumstances.

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Filtration is done quickly and the analysis of oil-based solutions is finished as stated below. In rare circumstances, it may be essential to increase the heating temperature of the material to up to 44 degrees Celsius and wash the membrane with heated solutions [11,15,18].

**For soluble solids**

The minimum required amount of the material being investigated is taken and dissolved in an appropriate aseptic
solvent, like fluid A. Then, the suitable analytical procedure is followed for aqueous solutions with the help of a membrane which is suitable for the selected solvent [11,15,18].

**For solids for injection other than antibiotics**

Prepare the test samples according to instructions on given label, and conduct the analytical procedure as recommended for oil-based solutions or aqueous solutions, as appropriate.

**Direct inoculation test method**

The amount of the material or preparation being investigated that will be utilised as inoculum for the culture media differs depending on the number of containers. Follow the instructions in the Table 6[11,15,18].

| **Amount in every single vessel of injectable product** | **Minimum amount required for every single culture medium** |
|---|---|
| **For liquids** | |
| <1ml | Total contents of the container |
| Between 1 to 40 ml | Half the contents of the container |
| Between 40 to 100 ml | 20 ml |
| >100ml | 10% of the contents of container but greater than 20 ml |
| Antibiotic liquids | 1 ml |
| Other preparations that can be dissolved in isopropyl myristate or water | The entire contents of each container to provide greater than 200 mg |
| **For solids** | |
| <50 mg | Total contents of the container |
| 50 to 300 mg | Half the contents of the container |
| >300 mg | 100mg |
| For surgical sutures for veterinary use and catgut | 3 segments of the strand |
| For sutures, surgical dressings, gauge, cotton and other singly packed | 100 mg per package |
| For single use materials | The entire device or materials, cut into pieces or dissembled |

**TABLE 7. MINIMUM AMOUNT REQUIRED FOR EACH MEDIUM**

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**Test method**

**For aqueous solutions and suspensions**

The liquid is removed from the test containers with the help of an aseptic syringe, pipette or a needle. Unless otherwise specified, transfer the amount of the product being examined recommended in data given in table 6, directly to the medium of culture, ensuring that the quantity of the product being examined does not exceed 10% of the amount of the medium. When an only container's quantity is inadequate to complete the tests, the filling of required vessels must be combined for the inoculation of media [11,15,18]. If the sample shows antimicrobial activity, conduct the test after neutralising it using an appropriate neutralising chemical or diluting it in a sufficient amount of culture media. When a large volume of the preparation is required, it could be desirable to utilise a culture medium with more concentration that has been organized to account for subsequent dilution. The concentrated medium can be applied straight to the preparation in its vessels if necessary. The injected media is incubated for at least fourteen days after inoculation. Throughout the incubation period, keep an eye on the cultures. Throughout the 14-day incubation phase, observe media containers. If the sample confirms positive before the incubation time of fourteen days, no further incubation is essential. Test sample is incubated for at least seven days products terminally sterilised by an approved moist heat procedure [11,15,18].

**For oils and oily solutions**

A media having a correct emulsifying agent has been added at an amount demonstrated to be apposite in the test validation, such as polysorbate 80 at an amount of 10g/litre, and which has exhibited to have no antimicrobial activities during the test circumstances. For aqueous solutions and suspensions, do the test as stated below [11,15,18]. Shake the cultures gently every day during the incubation phase. To preserve anaerobic conditions, a minimum mixing and shaking is done, while using thioglycolate medium or another comparable medium for the detection of anaerobic microorganisms [11,15,18].

**For ointments and creams**

To prepare it, the selected emulsifying agent is emulsified in an appropriate aseptic diluent like fluid A to dilute to about 1 in 10. The diluted preparation is transferred to a medium that is free of emulsifiers. (Test the emulsifying agent before use to ensure that it has no significant antimicrobial effects at the concentration used during the time interval for all transfers.) To make aqueous solutions and suspensions, and the fluid mixture of 10 ml volume is combined with the medium of 80 ml volume and continue as described below [11,15,18].

**For solids**

The amount of the preparation being investigated is mixed with the amount of the medium as described in Table 6. For aqueous solutions and suspensions, follow the instructions below [11,15,18].

**Observation and Interpretation of Results**

The media is scrutinized for macroscopic indications of development of microbes at intervals throughout the incubation time and at the end. If the medium becomes turbid due to the testing material, so the visual examination of the occurrence of microbial growth is difficult. Transfer separate portions of at least 1ml of medium to fresh vessels with similar medium 14 days subsequently to the start of incubation, and then the original is incubated and the vessels are transferred for at least 4 days.

If the presence of microbial growth is not indicated, the product under evaluation passes the sterility test. But, If any mark of microbial development is observed, the solution being analysed fails the sterility test. Repeat the test only if it can be demonstrated that it was invalid due to factors unrelated to the preparation under consideration.

Only one or more of the following conditions must be met for the test to be judged invalid:

a) Negative controls show microbial development
b) The sterility testing facility's microbiological monitoring data shows a problem
c) An examination of the test procedure employed for testing purpose indicates a flaw

After recognizing the microbes extracted from the vessels indicating microbial development, flaws with respect to the constituents along with method involved in performing the test operation can be assigned without any doubt. If the test is considered invalid, run it again using the equal number of components like before. If the repeat test does not reveal any indication of growth of any microorganism, the preparation being observed passes the sterility test. In this repeat test, if any kind of growth of microbe is detected and the microscopic confirmation is done, then preparation being investigated fails the sterility test [1,14,17]. Table 8 is about the Minimum of items to be tested and Table

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8 is about Specifications for Irrigations According to BP [15,16,17].

**Table 8. Minimum of items to be tested**

| Count of samples in the batch | Recommended least count of samples to be tested |
|---|---|
| Parenteral preparations<100 containers | 10% or 4 containers |
| Between 100 to 500 | 10 containers |
| >500 | 2% or 20 containers |
| For large volume parenteral | 2% or 20 containers |

**Leakage test**

The package integrity is tested using the leakage test. The ability of a package to retain the goods within while keeping potential contamination out is measured by its integrity. Because a discontinuity in a package's wall allows gas to seep through due to pressure and if there is presence of concentration gradient between the wall of package, then leakage can occur. A dye bath test can be used to detect leakage [1,14,17].

**Dye-Bath Test**

A dye bath is used to immerse the test container. For a period of time, vacuum and pressure are applied. The dye bath is withdrawn from the container, and it is rinsed. The container is then visually or through UV spectroscopy inspected, to check if the dye is present or not. The colour of the dye utilized could be blue, green, or yellowish-green. To accelerate capillary migration through the pores, either a less viscous fluid or a surfactant can be added to the dye solution to improve the dye test. In industry, the dye test is broadly acknowledged, and it is permitted for drug use. This dye bath test does not require any specific dye detecting equipment, which makes it affordable. The test, on the other hand, is qualitative, damaging, and time-consuming. Ampoules and vials are subjected to the test [11,15,18].

**TABLE 9. SPECIFICATIONS FOR IRRIGATIONS ACCORDING TO BP**

| Tests | Reference codes | BP |
|---|---|---|
| Pyrogen | IQC-1 | Total temperature of three rabbits needs to be less than 1.15 °C |
| Particular matter | IQC-2 | Can be more than 25 µm |
| Extractable value | IQC-3 | ---- |
| Deliverable mass or volume | IQC-4 | ---- |
| sterility | IQC-5 | No growth in 14 days |

## V. CONCLUSION

The In-Process Quality Check is meant to give initial warnings related to the quality while production. The first step in ensuring quality in pharmaceutical manufacturing is to monitor operations of production of a finished product, such as the Synthesis of API i.e., Active Pharmaceutical Ingredients. The presence of dependable and repeatable approaches will allow the manufacturing plant to assure the uniformity of medicines in each batch. These in-process regulations are important for ensuring the production of high-quality medicines. It may also make the characterisation of such processes and their chemical profiles easier. The purpose of this study was to evaluate quality control tests performed on in-process and completed goods for sterile and non-sterile dosage forms. This allows us to reduce the amount of material, time, cost, and process repetition. According to the preceding analysis, different pharmacopoeias contained the majority of the in-process along with final product quality control testing for several regular dosage forms. However, some differences have been found. Few tests found to be limited to certain pharmacopoeias only. The variances between the tests and specific limits stated in different pharmacopoeias, require efficient synchronisation, in such a way that if the test lies within the standard limit as per harmonised one, it fulfils the requirements of all pharmacopeial standards and then the regulatory standards of that particular nation. It is considered to be critical for items that are sold over the world.

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