

# AN UPDATED REVIEW ON IPQC TEST OF SURGICAL

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**Abstract:** IPQC is the activity, performed between Quality control and Quality assurance. It controls the procedure involved in manufacturing, the maintenance of quality product. In process material should be tested to identify, strength, quality and purity. This is updated fully brief information of IPQC test for surgical. The test which has been performed for certain surgical by own simultaneous study. In this review involves the Identification test, parameter of IPQC as per standards. Some test had carried out by its own study parameter. It also includes the individual test of each surgical by its moisture contents, texture, stickiness of bandages, gloves, scissors etc. Extra test have been included in this for steel gloves bandages etc. This will improve the defects while operation. The use of this surgical are mostly used for surgery operations etc. This will help to reduce the defects while doing operation. Gloves are most sensitive thing for used it should be safe clean. These IPQC test helps to ensure how quality good of surgical. These have shown that corrective and have been a prospective strategy for improving surgical test. The specific test for surgical are being additional added for its Safe clinical purpose. The sutures are most important for its terminologies for repair the cuts. They are commonly used to close incision. Such product should not show the chemical action with the body or physiology of the patients.

**Keywords:** Surgical, IPQC Test, Quality Control, Gloves, Bandages, Sutures

## INTRODUCTION

The present study deals with brief of over comparative study of IPQC test for surgical as per IP, BP and USP. It is mostly performed within the production. It is concerned with providing precise, specific and correct introduction of the another activity to be employed, from the raw material to release of finished Dosage form. It is controlling the procedures involved in manufacturing of dosage form. It is activity between the quality assurance and quality control. Surgical products they are not to be contaminated while using. But their test has to be carried out to use safely. Surgical products are those which are used by surgeons, Nurses, pharmacist, veterinary doctor etc. It is relating to or used in surgery. The products which are safe for use their test had to be studied. It are used in or connection with surgery or surgical gauze. The main reason to perform IPQC of surgical is no defects should come within operation.

### 1. IPQC TEST FOR COTTON

Cotton is a natural fiber harvested from the cotton plant. It is one of the oldest fibers under human cultivation, Cotton is also one of the most used natural fibers in existence today, with consumers from all classes and nations wearing and using cotton in a variety of applications. Foreign fibers or other contaminants can enter into the cotton during harvesting, field storage and ginning. Module covers and tie downs have been major source of fiber contamination. Once this material gets into the gin or the mill, it is distributed throughout the fibers and is difficult to remove. It is very difficult to detect until the fabric has been dyed. Fire neps, trash particles and seed coat fragments are visible foreign matters in cotton fiber. These foreign matters in raw cotton influence yarn quality the running characteristics of spinning machine, disability and also the quality of woven or knitted fabric. According to BP following tests are to be done for surgical Cotton.



**Fig :1.1 Cotton**

### 1.1 Identification test –

- A) It is examined under the microscope, each fiber is seen to consist of single cell, up to about 4 cm long and up to 40 μm wide, in the form of flattened tube with thick and rounded walls and often twisted.
- B) When treated with iodinated zinc chloride solution R, the fibers become violet.
- C) Take 0.1g add 10 ml of zinc chloride formic acid and solution R, heat to 40 °C and allow to stand for 2 hr. 30 min so the cotton it will not dissolve in solution

### 1.2. Acidity or Alkalinity –

To 25 ml of solution S add 0.1 ml of phenolphthalein solution R and to another 25 ml add 0.05 ml of methyl orange solution R. Then solution becomes pink.

### 1.3. Foreign fibers Test

It is examined under the microscope, it is seen to consist exclusively of typical cotton fibers, except that occasionally a few isolated foreign fibers may be present.

### 1.4. Fluorescence Test

An imaging apparatus containing blue and UV LED excitation sources was integrated to examine the feasibility of using fluorescence imaging to detect cotton foreign matter. The results showed that fluorescent imaging is a promising tool to detect cotton foreign matter on the surface of cotton lint.

Examine a layer under UV light at 365 nm. It displays only slight light brownish violet fluorescence & few yellow particles

## 2. IPQC TESTS FOR SUTURES:

Sutures material is an artificial fiber used to keep wound together until they hold themselves by natural which is synthesized and oven into a stronger scar. Sutures is a stitch or series of stitches made to secure apposition of edges of a surgical or traumatic wound.

### 2.1 According to BP and USP:

Physical performance characteristics diameter, breaking load, needle attachment, packaging, sterility. Information supplied by the manufacturer.



**Fig: 2.1 Sutures**

**2.2 Sutures test –**

Testing the tensile strength of sutures is a critical measure of performance to determine how likely a stitch is to break. Precise, consistent and reliable measures of strength are essential for product development and quality control.

The U.S. Pharmacopeia (USP) defines the test requirements for surgical sutures made from synthetic or natural materials which may be absorbable or non-absorbable. DDL performs all of the mechanical tests required to demonstrate compliance with the suture Monographs.

2.3 USP mechanical suture testing standards are:

- Suture Length
- USP 861 Suture Diameter
- USP 871 Needle Attachment
- USP

881

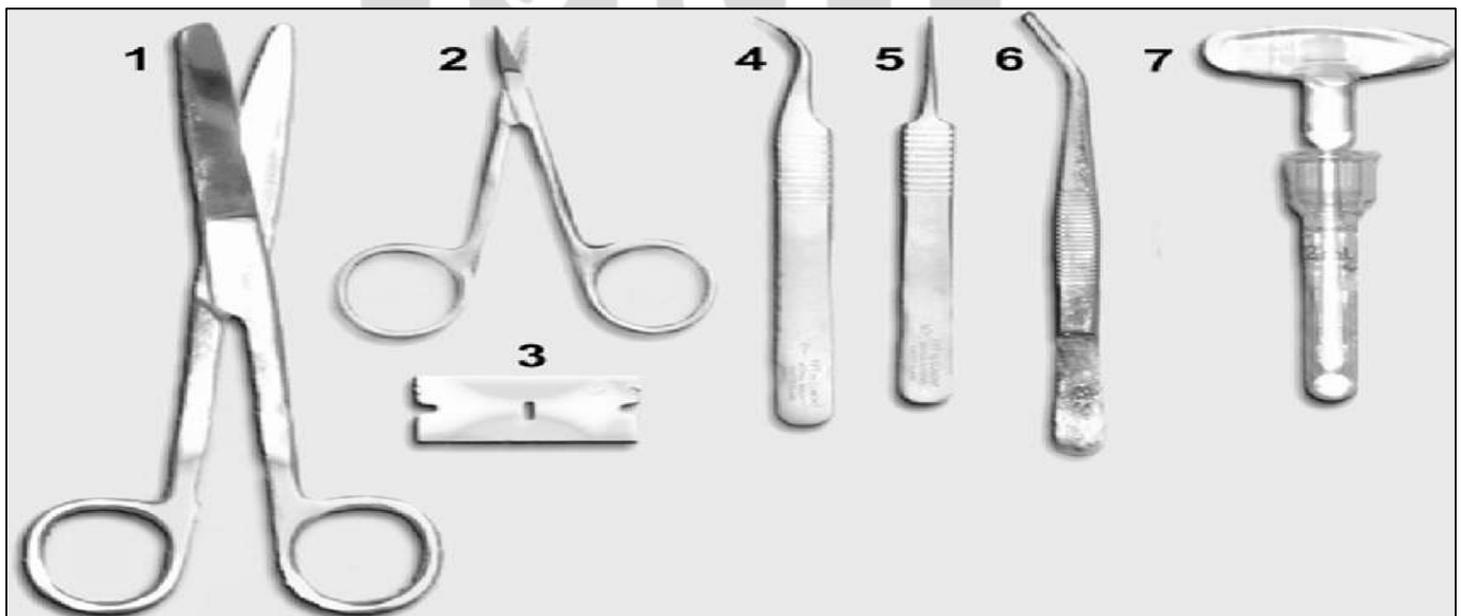
Tensile

Strength

**3. Scissors –**

Surgical scissors are required for cutting skin, undermining the sub cutis and deeper facial layers, cutting sutures, and removing wound dressings . Scissors may have long or short handles, and the blades are straight or curved and serrated or smooth. The tips may be sharp or blunt. Scissors used in cutaneous surgery can be either completely stainless steel (most popular, least expensive) or have tungsten carbide inserts to strengthen the blades.

Gradle scissors are small, delicate, sharp-tipped, and tapered to a very fine point with a gentle curve. Due to their sharpness and precision, Supercuts® Gradle scissors are ideal for removing thin stages during Mohs micrographic surgery and for removing skin tags. Gradle scissors must be used with care, and they should never be used to cut sutures. With improper use, they are quickly dulled, the cutting surfaces are nicked, and the tips are easily malpositioned.



**Fig: 3.1 Scissors**

Tissue scissors have relatively short handles and sharp tips. They are available in straight or curved models, with or without the serrations that prevent tissue motion during cutting. Of the various models available, the authors prefer curved Supercut® iris scissors to cut tissue and for sharp dissection. Of the standard tissue scissors available, Supercut® iris scissors have the sharpest edge and they are easily recognized by their black handles. These scissors have a fine bevel angle at the cutting edge, and they are available with smooth edges or one serrated edge. The 'razor-like' edge of these scissors enables the surgeon to cut tissue in a smooth, easy motion.

Westcott and Castroviejo scissors are delicate, spring-loaded tissue scissors with very sharp tips. The configuration of their handle and spring-loaded action make them ideal for manipulation in small delicate sites. For this reason, they are popular with oculoplastic surgeons. They should only be used for cutting thin tissue, such as that encountered in eyelid surgery, or they will dull quickly.

### 3.1 Identification Test of stainless steel;

Remove the oxide layer on the steel, put a drop of water, rub it with copper sulfate, and if it does not change color after rubbing, it is usually stainless steel. If it turns purple, the non-magnetic steel is high manganese steel, and the magnetic steel is generally ordinary steel or low alloy steel

## 4 .Adhesive bandages

### 4.1 As per BP adhesive bandages-

Adhesive bandages consist of compress of four layers of type I absorbent gauze, or other suitable material, a fixed to a firm or fabric coated with a pressure sensitive adhesive substances , It is sterile .the compress may contain a suitable colors. The adhesive surface is protected by a suitable removable covering.

An adhesive bandage, also called a sticking plaster, medical plaster, or simply plaster in British English, is a small medical dressing used for injuries not serious enough to require a full-size bandage. They are also known by the generalized trademarks of Band-Aid (as "Band-Aid" or "band aid" in Australia, Canada, India and the US) or Elastoplast (in the UK).

### 4.2 Function of Bandages

The adhesive bandage protects the wound and scab from friction, bacteria, damage, and dirt. Thus, the healing process of the body is less disturbed. Some of the dressings have sterile properties. An additional function is to hold the two cut ends of the skin together to make the healing process faster.<sup>[1]</sup>

### 4.3 Materials of Bandages

The backing and bag are often made of coated paper, but may be made of plastic.

The adhesive sheet is usually a woven fabric, plastic (PVC, polyethylene or polyurethane), or latex strip. It may or may not be waterproof; if it is airtight, the bandage is an occlusive dressing. The adhesive is commonly an acrylate, including methacrylates and epoxy diacrylates (which are also known as vinyl resins).<sup>[2]</sup>

The absorbent pad is often made of cotton, and there is sometimes a thin, porous-polymer coating over the pad, to keep it from sticking to the wound. The pad may also be medicated with an antiseptic solution. In some bandages, the pad is made of a water-absorbing hydrogel. This is especially common in dressings used on blisters, as the gel acts as a cushion.<sup>[medical citation needed]</sup>

Many people have allergies to some of these materials, particularly latex and some adhesives.<sup>[3]</sup>

### 4.4 Stickiness test of Bandages –

The adhesive is commonly an acrylate, including methacrylates and epoxy diacrylates (which are also known as vinyl resins). The absorbent pad is often made of cotton, and there is sometimes a thin, porous-polymer coating over the pad, to keep it from sticking to the wound.

A ZwickRoell zwickiLine or ProLine (Z005) testing machine is typically used for these tests.

## 5. Gloves –

Medical gloves are disposable gloves used during medical examinations and procedures to help prevent cross-contamination between caregivers and patients.<sup>[1]</sup> Medical gloves are made of different polymers including latex, nitrile rubber, polyvinyl chloride and neoprene; they come unpowered, or powdered with corn starch to lubricate the gloves, making them easier to put on the hands.<sup>[2]</sup>

Corn starch replaced tissue-irritating lycopodium powder and talc, but even corn starch can impede healing if it gets into tissues (as during surgery). As such, unpowered gloves are used more often during surgery and other sensitive procedures. Special manufacturing processes are used to compensate for the lack of powder.

There are two main types of medical gloves: examination and surgical. Surgical gloves have more precise sizing with a better precision and sensitivity and are made to a higher standard. Examination gloves are available as either sterile or non-sterile, while surgical gloves are generally sterile.<sup>[3]</sup>

**5.1** Medical gloves are defined as disposable gloves used during medical procedures; they include:

1. Examination gloves (non sterile or sterile)
2. Surgical gloves that have specific characteristics of thickness, elasticity and strength and are sterile
3. Chemotherapy gloves – these gloves are not addressed within this document

**5.2 Rationale for using medical gloves:-** Medical gloves are recommended to be worn for two main reasons:

1. To reduce the risk of contamination of health-care workers hands with blood and other body fluids.
2. To reduce the risk of germ dissemination to the environment and of transmission from the health-care worker to the patient and vice versa, as well as from one patient to another.



**Fig: 5.1** Gloves

### 5.3 Gloves Testing

Glove tests are used to evaluate dimensions, tensile strength and elongation, puncture, residual powder, leakage, simulated use, heat aging degradation, and viral barriers. These tests are appropriate for rubber, nitrile, and vinyl materials. Nelson Labs performs tests in compliance with ASTM D3578 (rubber exam), ASTM D3577 (rubber surgical), ASTM D6319 (nitrile), ASTM D5250 (vinyl), and ASTM F1342 puncture test standards. Samples are heat aged in an oven. Glove tests are used to evaluate dimensions, tensile strength and elongation, puncture, residual powder, leakage, simulated use, heat aging degradation, and viral barriers.

In Test Method A, a die cut “dumbbell” shaped piece of glove material is stretched from either end by a machine at a constant speed until it breaks. The computer on the machine collects the data as the piece is stretched. Once the piece breaks, the sample's elongation is measured and recorded.

### Conclusion –

IPQC test for surgical plays an important role in general health care for doctors in surgery purpose. Some test are included in this like scissors and they are sterilized before use. The surgicals directly comes in contact with patient in surgery so is should be well sterilized and performed the test .Hence the main purpose is to focus in surgical and its test for its safety purposes.

### References -

1. British pharmacopoeia 2016, volume IV
2. British pharmacopoeia 2016 volume V
3. British pharmacopoeia 2016 veterinary
4. Krishnakanth. B, In process Quality control test for Tablets R.S Bhat (2010), 2-9.
5. Leon Lachman, Herbert A. Liberman, Joseph L. Kanig: The Theory and practice of industrial pharmacy, Varghese publishing house, 3rd ed. 296-392
6. Loyd V. Alle Jr. Nicholas G. Popovich, Howard C. Ansel, Ansel's Pharmaceutical dosage forms and drug delivery system, Lippincott Williams and Wilkins, 8th ed.; 218,219,234,235, 236.237,238,388,392,463,464.
7. NikunjVora, Vikas, In Process Quality Control A review, International Journal of Industrial Pharmacy and Technology 1(4), 2012, 2000-2019.
8. Indian Pharmacopeia, Volume II; 659-660.

9. Manohar A. Potdar, Pharmaceutical Quality Assurance, 2006, Nirali Prakashan , 6.7-6.8 .
10. British Pharmacopeia, Volume I; A 90,141.143.
11. United States of Pharmacopeia Volume I; 311,312,313,369.

