COMMONWEALTH OF AUSTRALIA

Therapeutic Goods Act 1989

THERAPEUTIC GOODS ORDER NO. 49

General Standard for Sutures

I, DERRICK ROY BEECH, delegate of the Minister for Family Services for the purposes of the exercise of the Minister's powers under Section 10 of the *Therapeutic Goods Act 1989*, acting under that section:

(a) revoke, on and from 25 July 1995, Therapeutic Goods Order No. 15, "Standard for Stainless Steel Sutures" made on the twenty-fourth of July 1984;

(b) revoke, on and from 25 July 1995, Therapeutic Goods Order No.16, "Standard for Absorbable Sutures" made on the twenty-fourth day of July 1984; and

(c) revoke, on and from 25 July 1995, Therapeutic Goods Order No. 17, "Standard for Non-absorbable Sutures" made on the twenty-fourth day of July 1984.

(d) **determine** that with respect to quality, the standard for sutures shall be the standard (including Appendices A, B, C, D, E, F, G, and Schedules 1, 2, 3, 4, 5, 6, 7, 8 and 9) specified in this Order.

1 Application

This Order applies to all absorbable and non-absorbable monofilament and multifilament sutures, including those made from stainless steel, which are intended for therapeutic use in humans and animals.

2 Interpretation

In this Order -

'absorbable suture' means a uniform strand, consisting of the intestinal membranes of mammals or synthetic material which is absorbable by the body tissues, that may consist of a single filament or fibre, or of a thread prepared by spinning, twisting or braiding single filaments or fibres, that may be intended to be sterile or non-sterile and that may be coated;

'acetone-' means acetone that is specified in the British Pharmacopoeia;

'alcohol' means ethanol or isopropyl alcohol that is specified in the British Pharmacopoeia;

'antimicrobial agent' means a substance, other than alcohol, which has been added to the storage solution to prevent the growth of micro-organisms;

'batch number or serial number', in relation to a suture means characteristic markings:

(a) given by a manufacturer to a particular device or to all devices in a batch for the purposes of uniquely identifying that device or batch and which enables that device or batch to be traced through any or all critical stages of its manufacture and supply; and

(b) which may be immediately preceded by the words "Batch", "Batch Number", "Lot", "Lot Number", "Lot No." or "Lot Code", "Serial Number", Serial No." or by having a similar meaning, or by the symbol "B", "(B)", or "0", "SN", "S/N", or "FABR".

The date of manufacture may be used as the "batch number" or "serial number" if clearly identifiable as a date;

'calcium chloride' means calcium chloride reagent that is specified in the British Pharmacopoeia;

'chromic catgut sutures' consist of strands prepared from collagen derived from healthy mammals which are processed by physical or chemical means so as to provide greater resistance to resorption in living mammalian tissues;

'Class I sutures' consist of sutures composed of silk or synthetic fibres of monofilament, twisted or braided construction;

'Class II sutures' consist of sutures composed of cotton, linen fibres or coated natural or synthetic fibres where the coating forms a casing of significant thickness which does not contribute appreciably to the strength of the suture, other than braided sutures which have been treated for capillarity;

'diphenylcarbazide' means an almost white powder containing 1,5-diphenylcarbazide $C_{13}H_{l2}N_4O$ analytical grade reagent meeting the following specification -

Insoluble matter	< 0.01 per cent
Sulphated ash	< 0.05 per cent

'formic acid' means formic acid reagent that is specified in the British Pharmacopoeia;

'5M hydrochloric acid' means 5M hydrochloric acid reagent that is specified in the British Pharmacopoeia;

'iodinated zinc chloride solution' means zinc chloride solution iodinated reagent that is specified in the British Pharmacopoeia;

'methyl orange' means methyl orange reagent that is specified in the British Pharmacopoeia;

'phosphoric acid' means phosphoric acid that is specified in the British Pharmacopoeia;

'potassium dichromate' means potassium dichromate reagent that is specified in the British Pharmacopoeia;

'potassium permanganate' means potassium permanganate reagent that is specified in the British Pharmacopoeia;

'simple knot' means a knot formed by passing the end of a suture held in the one hand over that held in the other hand then drawing the free end through the loop and pulling it taut;

'sodium azide' means a white powder containing not less than 99 per cent sodium azide, NaN3, when assayed iodimetrically, and meeting the following specification -

Water insoluble matter	< 0.05 per cent
Loss on drying	< 0.1 per cent
Lead	< 0.001 per cent
Free alkali (NaOH)	< 0.2 per cent;

'stainless steel' means fully-softened stainless steel, the composition of which conforms with British Standard 4106-1967;

'stainless steel suture' means a uniform suture of stainless steel wire, which is circular in cross section, that consists of a single monofilament wire, or of a thread prepared by twisting or braiding monofilament wires and may be intended to be sterile or non-sterile;

'sterile surgical catgut' consists of sterile strands prepared from collagen derived from healthy mammals;

'strong ammonia solution' means strong ammonia solution that is specified in the British Pharmacopoeia;

'sulphuric acid' means sulphuric acid reagent that is specified in the British Pharmacopoeia;

'surgeon's knot' means a square knot in which the free end is first passed twice through the loop, and pulled taut, then passed once through a second loop and the ends drawn taut so that a single knot is superimposed on a compound knot, the initial loop for the knot being formed by one turn of the suture around flexible rubber tubing of 6.5 mm inside diameter and 1.6 mm wall thickness;

'suture' means a uniform strand of natural or synthetic material which resists absorption by the body tissues, that may consist of a single filament or fibre, or of a thread prepared by spinning, twisting or braiding single filaments or fibres, that may be intended to be sterile or non-sterile and may be coated;

'synthetic absorbable sutures' consist of sutures composed of coated or uncoated synthetic fibres which are absorbable by body tissues;

'xylene' means xylene reagent that is specified in the British Pharmacopoeia.

3 Length

When measured in accordance with the test for length of suture specified in Appendix A, the sutures shall comply with the standard for length:

(a) where the suture is not intended to be sterile, if the length of the suture is greater than 90% of the length stated; or

(b) where the suture is intended to be sterile, if the total length of any individual suture in each container does not exceed 350 cm, and the length of each suture is greater than:

(i) Non-absorbable sutures : 95% of the length stated; and

(ii) Absorbable sutures : 90% of the length stated; or

(c) where the suture is solely intended to be used for veterinary use the length of the suture is greater than 90% of the length stated.

4 Diameter

When determined in accordance with the test for diameter of suture, specified in Appendix B.2, the sutures shall comply with the standard for diameter, if:

(a) the mean of the diameters of the sutures in the sample is within the limits specified in Schedule 1;

(b) none of the individual diameters is less than the minimum value specified in Schedule 1;

(c) none of the individual diameters is greater than the maximum value specified in Schedule 1; and

(d) not less than two-thirds of the diameters recorded on each suture are within the limits for mean diameter specified in Schedule 1.

5 Knot Pull Breaking Force

(This clause applies to absorbable and non-absorbable sutures excluding those made of monofilament and multifilament stainless steel wire.)

5.1 When determined in accordance with the test for knot pull breaking force specified in Appendix C.2, the sutures shall comply with the standard for knot pull breaking force:

(a) where the suture is non-absorbable and is intended to be sterile, if the mean value for knot pull breaking force is not less than the mean value given in Schedule 2; except that if the knot pull breaking force of not more than one suture is found to be less than 70% of the mean value specified in Schedule 2, then the sutures shall comply with the standard if the knot pull breaking force of each of an additional 20 sutures is not less than 70% of the specified mean value; or

(b) where the suture is non-absorbable and not intended to be sterile, if the mean value for knot pull breaking force shall be not less than 125% of the mean value given in Schedule 2; except that if the knot pull breaking force of not more than one suture is found to be less than 87.5% of the mean value specified in Schedule 2, then the sutures shall comply with the standard if the knot pull breaking force of each of an additional 20 sutures is not less than 87.5% of the specified mean value; or

(c) where the suture is made of catgut, if the mean value for the knot pull breaking force is not less than the value given in Schedule 3; except that if the knot pull breaking force of not more than one suture is less than 50% of the mean value specified in Schedule 3, then the sutures shall comply with the standard if the knot pull breaking force of each of an additional 20 sutures is not less than 50% of the specified value; or

(d) where the suture is a synthetic absorbable suture, if the value for the knot pull breaking force is not less than the mean value given in Schedule 4; except that if the knot pull breaking force of not more than one suture is less than 70% of the mean value specified in Schedule 4, then the sutures shall comply with the standard if the knot pull breaking force of each of an additional 20 sutures is not less than 70% of the specified value.

6 Straight Pull Breaking Force

This clause applies only to monofilament and multifilament stainless steel sutures.

6.1 When determined in accordance with the test for straight pull breaking force and elongation specified in Appendix D.2, the sutures shall comply with the standard for straight pull breaking force if the mean value for straight pull breaking force is not less than the mean value given in Schedule 5, and no value for an individual suture is less than 80% of the mean value given in Schedule 5.

7 Elongation

This clause applies only to monofilament and multifilament stainless steel sutures.

7.1 For both monofilament and multifilament stainless steel sutures, the sutures shall comply with the standard for elongation if the elongation of each suture is not less than 25% when measured in accordance with the test for straight pull breaking

force and elongation specified in Appendix D.2.

8 Strength of Needle Attachment

8.1 When determined in accordance with the test for strength of needle attachment specified in Appendix E, the suture shall comply with the standard for strength of needle attachment:

(a) where the sutures are made of non-absorbable material including monofilament or mulitfilament stainless steel, the sutures shall comply with the standard for strength of needle attachment if neither the average value nor any of the individual values of the force required to break the needle attachment is less than the value given in Schedule 6 except that if not more than one of the individual forces is less than the specified value, then the sutures shall comply with the standard if none of the values from

i) an additional four sutures in the case of monofilament or multifilament stainless steel wire, or

ii) an additional 10 sutures in the case of other non-absorbable material,

is less than the specified value; or

(b) where the suture is made of catgut, if neither the mean value nor any of the individual values of the force required to break the needle attachment are less than the values given in Schedule 7 except that if not more than one of the individual forces is less than the specified value, the sutures shall comply with the standard if none of the values from an additional 10 sutures is less than the specified value; or

(c) where the suture is a synthetic absorbable suture, if neither the mean value nor any of the individual values of the force required to break the needle attachment is less than the values given in Schedule 8 except that if not more than one of the individual forces is less than the specified value, the sutures shall comply with the standard if none of the values from an additional 10 sutures is less than the specified value.

9 Identity

This requirement does not apply to monofilament or braided multifilament stainless steel sutures.

9.1 When the relevant test for identification of composition of sutures, as specified in Appendices F 1-6, is carried out, the sutures shall pass the test.

10 Colouring Agents

This requirement does not apply to monofilament and braided multifilament stainless steel sutures.

10.1 The sutures may be pigmented or dyed with a suitable non-toxic, non-irritant colouring agent to give a uniform colour which is fast in alcohol, in the fluid in which the suture is packed and in boiling water. The colouring agent shall be a chemical approved by the Therapeutic Goods Administration for this purpose.

11 Content of Soluble Chromium

11.1 When the suture is fabricated from chromicised catgut and is tested in accordance with the test for content of soluble chromium specified in Appendices G 1 - 3, the suture shall comply with the standard for content of soluble chromium if the content of chromium does not exceed a concentration of 100 micrograms per gram of the suture.

12 Sterility

12.1 If the sutures are intended to be supplied in a sterile condition, then when tested for sterility in accordance with Therapeutic Goods Order Number 11 "Standard for Sterile Therapeutic Goods", the sutures shall comply with the criteria in that document.

Note: Good manufacturing practice will generally ensure that sutures are manufactured sterile. Manufacturers should ensure that their quality control procedures are such that their sutures are capable of complying with the requirements of TGO No. 11. However, where a dispute may arise, TGO 11 will be the reference method of test.

13 Labelling

13.1 Sutures are required to comply with the labelling requirements of the Order made under the Therapeutic Goods Act 1989, which specifies the minimum labelling requirements for therapeutic devices.

Dated this 25th day of January 1995

Derrick Roy Beech
Delegate of the Minister for Family Services

Appendix A: Test for length of suture

The test shall be carried out by -

(a) removing the suture from its container and laying it flat on a smooth surface;

(b) subjecting the suture to just sufficient tension to keep it straight during the measurement;

(c) measuring the length of the suture to the nearest cm; and

(d) repeating the procedure specified in paragraphs (a), (b) and (c) using a further four sutures.

Appendix B

B.1 - Test for diameter of suture - Apparatus

B 1.1 The gauge required for the determination of the diameter of sutures is a dead weight type instrument which is equipped with a direct reading dial graduated to at least 0.002mm.

B 1.2 The anvil of the gauge is approximately 50 mm in diameter and the presser foot is circular with a diameter of 12.7+/- 0.02 mm.

B.1.3 The presser foot and anvil surfaces are planed to be parallel to each other to within 0.005 mm.

B.1.4 The presser foot and the moving parts connected to it are weighted so as to apply a total load of 205+/- 5 g to the sutures under test.

B.1.5 The apparatus is fitted with two clamps capable of securing the sutures.

B.1.6 The clamps can be rotated through 90^{o}.

B.1.7 When the apparatus is used to measure the diameter of sutures of metric size 0.5 or less, the weighting on the presser foot is such that the load on the sutures is not more than 60g and not less than 50g.

B.2 - Test for diameter of suture – Procedure

B.2.1 Where the sutures are monofilament or catgut sutures the test shall be carried out by -

(a) removing the suture from its container and immediately clamping it at one end, without carrying out any prior drying or conditioning of the suture;

(b) laying the suture across the centre of the anvil, drawing the suture sufficiently taut and clamping the other end;

(c) positioning the presser foot at the point one-quarter along the length of the suture and gently lowering the presser foot until its entire weight rests upon the suture;

(d) measuring the diameter of the suture;

(e) repeating the measurement of diameter at the points half and three-quarters along the length of the suture;

(f) recording the average diameter of the suture;

(g) repeating the procedure described in paragraphs (a), (b), (c), (d), (e) and (f) using a further four sutures; and

(h) calculating the overall mean diameter of the sutures.

B 2.2 Where the sutures are multifilament sutures the test shall be carried out by -

(a) removing the suture from its container, taking care to ensure that no alteration to the twist of the suture occurs;

(b) laying the suture across the centre of the anvil, clamping one end and attaching a suitable length of thread to the other end;

(c) passing the thread and suture through the unclosed clamp, positioning the clamp so that it is not in contact with the suture;

(d) attaching to the free end of the thread a weight of sufficient magnitude to achieve a tension on the suture of 50 per cent of the corresponding mean straight pull breaking load shown in Schedule 2;

(e) securing the suture with the unclosed clamp;

(f) positioning the presser foot at the point one-quarter along the length of the suture and gently lowering the presser foot until its entire weight rests upon the suture;

(g) measuring the diameter of the suture and if the suture is larger than metric size 2, rotating the suture through 900 by rotating the clamps, measuring the diameter again and recording the average of the two values;

(h) repeating the measurement of diameter at the points half and three quarters along the length of the suture;

(j) recording the average diameter of the suture;

(k) repeating the procedure described in paragraphs (a), (b), (c), (d), (e), (f), (g), (h) and (j) using a further four sutures; and

(l) calculating the overall mean diameter of the sutures.

Appendix C

C.1 - Test for knot pull breaking force - Apparatus

Note: This requirement does not apply to stainless steel sutures

C.1.1. The apparatus to be used in the test shall be a power-driven tensile strength testing machine which uses the principle of constant rate of extension and possesses suitable clamps for holding the specimen.

C.1.2 The instrument shall have an electronic load cell as the force measuring device. the breaking force of the suture should not be less than 10 per cent of the range of the load cell selected.

C.1.3 The instrument shall be capable of indicating the maximum force applied in breaking the specimen and this force shall be indicated clearly and continuously on a dial or chart or other output device (e.g computer).

C.1.4 The machine shall be capable of extending the specimen under test at a constant rate of 200 +/- 25 mm per min.

C.1.5 The weighting mechanism shall allow negligible movement in the direction of the applied force.

C.1.6 The jaws of the machine shall be constricted so that the specimen under test is not damaged. Suitable packing pieces or embedding techniques may be used whenever necessary to prevent slipping of the specimen in the jaws.

C.1.7 The machine shall comply with the requirements specified in Australian Standard AS 2193-1978, Methods for Calibration of Force-measuring Systems of Testing Machines.

C.2 Test for knot pull breaking force - Procedure

Note: This requirement does not apply to stainless steel sutures

C.2.1 If the suture is made of catgut carry out the test by

(a) setting the machine to give a constant rate of extension of 200+/- 25 mm per min;

(b) removing the suture from its container and, without carrying out any prior drying or conditioning of the suture, tying a surgeon's knot in the suture;

(c) placing the suture in the testing device with the knot approximately midway between the clamps and so that the distance between the clamps is not less then 120 mm and not more than 130 mm;

(d) attaching one end of the suture in the clamp at the load end of the machine and passing the other end of the suture through the opposite clamp;

(e) applying a tension of not more than 2.5 per cent of the corresponding knot pull breaking force, as specified in Schedule 2, to the suture and clamping the free end;

(f) setting the mechanism of the machine in motion and breaking the suture;

(g) recording the maximum force required to break the suture;

(h) discarding the result if the suture slips in the clamp or breaks within 10 mm of the point of attachment on the jaw face;

(i) repeating the test if the suture is 45 cm or longer and obtaining the average value of both measurements;

(j) repeating the procedure described in paragraphs (a), (b), (c), (d), (e), (f), (g), (h) and (i) using a further nine sutures; and

(k) calculating the mean result.

C.2.2 If the suture is a synthetic absorbable suture carry out the test by -

(a) setting the machine to give a constant rate of extension of 200+/- 25 mm per min;

(b) removing the suture from its container and, without carrying out any prior drying or conditioning of the suture tying a simple knot in the suture;

(c) carrying out the procedures described in paragraphs (1)(c) to (1)(l) inclusive.

Appendix D

Appendix D.1 Test for straight pull breaking force and elongation - Apparatus

Note: this test applies only to single filament and multifilament stainless steel sutures

D.1.1 The apparatus to be used in the test shall be a power-driven tensile strength machine which uses the principle of constant rate of extension and possesses suitable clamps for holding the specimen.

D.1.2 The instrument shall have an electronic load cell as the force measuring device and the breaking force of the suture should be not less than 10 per cent of the range of the load cell selected.

D.1.3 The instrument shall be capable of indicating the maximum force and maximum delongation applied in breaking the specimen and the force. The elongation shall be indicated clearly and continuously on a dial, chart or other output device (e.g. computer).

D.1.4 The machine shall be capable of extending the specimen under test at a constant rate of 100+/- 10 mm per min.

D.1.5 The weighting mechanism shall allow negligible movement in the direction of the applied force.

D.1.6 The jaws of the machine shall be constructed so that the specimen under test is not damaged. Suitable packing pieces or embedding techniques may be used whenever necessary to prevent slipping of the specimen in the jaws.

D.1.7 The machine shall comply with the requirements specified in Australian Standard AS2193 - 1978 - Methods for Calibration and Grading of Force Measuring Systems of Testing Machines.

Appendix D.2 Test for straight pull breaking force and elongation - Procedure

The test shall be carried out by -

D.2.1 setting the machine to give a constant rate of extension of 100+/- 10 mm per minute and setting the speed of the recorder to l00+/- 10 mm per min;

D.2.2 removing the suture from its container and placing it in the testing device so that the distance between the clamps is not less than 125 mm and not more than 130 mm;

D.2.3 attaching one end of the suture in the clamps at the load end of the machine and passing the other end of the suture through the opposite clamp;

D.2.4 applying sufficient tension to straighten the suture and clamping its free end;

D.2.5 setting the mechanism of the machine and the chart in motion and breaking the specimen;

D.2.6 recording the maximum force required to break the suture and the maximum elongation obtained when the suture breaks;

D.2.7 discarding the result if a specimen slips in the clamp or breaks within 10 mm of the point of attachment on the jaw face;

D.2.8 repeating the test if the suture is 45 cm or longer and obtaining the average value of both measurements;

D.2.9 repeating the procedure described in paragraphs (a), (b), (c), (d), (e), (f), (g) and (h) on a further four sutures; and

D.2.10 calculating the mean values from the results obtained for maximum load and elongation.

Appendix E

Test for strength of needle attachment

The test shall be carried out by -

E.1 using a tensile strength testing machine of the same type as described in Appendices C1 and D1;

E.2 using a constant rate of extension of 200+/- 25 mm per min;

E.3 fixing the suture in the mobile clamp of the machine and the needle in the fixed clamp so that the whole of the swaged end of the needle is free of the clamp and in line with the direction of pull on the suture;

E.4 determining the maximum force required to break the suture or to detach it from the needle;

E.5 repeating the procedures described in paragraphs (a), (b), (c) and (d) using another four sutures; and

E.6 calculating the mean value for strength of needle attachment.

Appendix F

Tests for identification of composition of sutures

Appendix F.1 linen sutures

Carry out the test by -

(a) isolating a few individual fibres and examining them under a microscope;

(b) verifying that the fibres are 25 to 50 mm in length and 12 to 31 micrometres in width, and have long finely pointed ends and a narrow lumen along the greater part of their length;

(c) verifying that the fibres have thick walls occasionally marked with fine longitudinal striations and observing unilateral swellings with transversal lines; and

(d) impregnating the fibres with iodinated zinc chloride solution which colours them violet blue.

Appendix F.2 nylon sutures

Carry out the test by -

(a) adding 40 ml of 5M hydrochloric acid to approximately 0.02g of suture cut into pieces of 5 mm length so that the suture disintegrates and dissolves completely within 15 minutes;

(b) adding 40 ml of 90 per cent formic acid to approximately 0.02 g of suture cut into pieces of 5 mm length so that the pieces of suture dissolve at room temperature;

(c) adding 40 ml of cold phosphoric acid to approximately 0.02 g of suture cut into pieces of 5 mm length in a boiling tube, gently bringing the solution to the boil and boiling for 2 min. so that the pieces of suture dissolve completely; and

(d) comparing the results obtained in paragraphs (a), (b) and (c) with the corresponding solubility for nylon sutures in Schedule 9.

Appendix F.3 polyester sutures

Carry out the test by -

(a) adding 40 ml of 5M hydrochloric acid to approximately 0.02 g of suture cut into pieces of 5 mm length so that the suture remains intact even after prolonged immersion;

(b) adding 40 ml of sulphuric acid to approximately 0.02 g of suture cut into pieces of 5mm length so that the suture disintegrates and dissolves completely within 10 min;

(c) adding 40 ml of cold phosphoric acid to approximately 0.02g of sample cut into

pieces of 5 mm length in a boiling tube, bringing the solution quickly to the boil and boiling for 2 min so that the suture remains intact; and

(d) comparing the results obtained in paragraphs (a), (b) and (c) with the corresponding solubility for polyester sutures in Schedule 9.

Appendix F.4 polypropylene sutures

Carry out the test by -

(a) adding 40 ml of sulphuric acid to approximately 0.02 g of suture cut into pieces of 5 mm length so that the suture remains intact after 10 min;

(b) adding 40 ml of cold phosphoric acid to approximately 0.02 g of suture cut into pieces of 5 mm length so that the suture fuses together but remains intact;

(c) adding 40 ml of xylene to approximately 0.02 g of suture cut into pieces of 5 mm length and bringing to the boil so that the suture dissolves within 5 min; and

(d) comparing the results obtained in paragraphs (a), (b) and (c) with the corresponding solubility for polypropylene sutures in Schedule 9.

Appendix F.5 silk sutures

Carry out the test by -

(a) isolating a few individual fibres and examining them under a microscope;

(b) verifying that the fibres are approximately triangular to semicircular in cross section with rounded edges, without a lumen and sometimes marked with very fine longitudinal striations parallel to the axis of the fibre;

(c) adding 40 ml of 5M hydrochloric acid to approximately 0.02 g of suture cut into pieces of 5 mm length so that the suture remains intact;

(d) adding 40 ml of a mixture of one part of calcium chloride and ten parts of 90 per cent formic acid to approximately 0.02g of suture cut into pieces of 5 mm length at room temperature with a gentle swirling action so that the suture dissolves within 15 min; and

(e) comparing the results obtained in paragraphs (c) and (d) with the corresponding solubility for silk sutures in Schedule 9.

Appendix F.6 synthetic absorbable sutures

Carry out the test by -

(a) weighing approximately 25 mg of a sample of the suture and placing it in a vial which can be closed with a stopper;

(b) adding 1 ml of spectroscopic grade hexafluoroisopropanol and closing the vial with a stopper;

(c) shaking the solution until the entire sample is dissolved and placing several drops onto a potassium bromide plate or a KRS-5 plate;

(d) allowing the solvent to evaporate;

(e) annealing the film by heating the plate at 65 C for one hour;

(f) allowing the plate to cool and recording the infra-red spectrum of the polymer in accordance with the procedure described in 'Guidelines for the Determination of Infra-red Spectra' in Appendix D to the Code of Good Manufacturing Practice; and

(g) confirming the identity of the polymer by comparing the spectrum obtained with the spectrum for a reference substance which has been similarly treated.

Appendix G.1 - Test for content of soluble chromium - Preparation of solutions

Prepare the solutions for use in the test by carrying out the following procedures.

(1) stock chromium solution

Dissolve 0.1414 g of potassium dichromate in distilled water and dilute to 1 litre (1 ml = 50.0 micrograms Cr).

(2) standard chromium solution

Dilute 10.00 ml of stock chromium solution to 100 ml (l ml = 5.00 micrograms Cr).

(3) 50 per cent sulphuric acid solution

Dilute 100 ml of sulphuric acid to 200 ml with distilled water.

(4) methyl orange indicator solution

Prepare a 0.04 per cent w/v solution of methyl orange in 20 per cent alcohol.

(5) potassium permanganate solution

Dissolve 4.0 g of potassium permanganate in 100 ml of distilled water.

(6) sodium azide solution

Dissolve 0.5 g of sodium azide in 100 ml of distilled water.

(7) diphenylcarbazide solution

Dissolve 0.25 g diphenylcarbazide in 50 ml of acetone, store in a brown bottle and discard when the solution becomes discoloured.

Appendix G.2 - Test for content of soluble chromium - Preparation of calibration curve

Carry out the procedure for the preparation of a calibration curve by -

(a) pipetting measured volumes of standard chromium solution into a series of 125 ml erlenmeyer flasks to give a series of standards of from 5 to 50 micrograms of chromium;

(b) adding strong ammonia solution to each flask until the solution in the flask is just basic to methyl orange indicator solution;

(c) adding 50 per cent sulphuric acid solution dropwise until the solution is acidic;

(d) adding an additional 20 drops of 50 per cent sulphuric acid solution and adjusting the volume of the solution to approximately 40 ml;

(e) heating the solution to boiling and adding 20 drops of potassium permanganate solution;

(f) if fading occurs, adding potassium permanganate solution dropwise to maintain an excess of about 2 drops and boiling the solution for a further two minutes;

(g) adding 1 ml of sodium azide solution and continuing to boil the solution gently;

(h) if the red colour does not fade completely after 30 seconds, adding another 1 ml of sodium azide solution;

(j) continuing to boil the solution for one minute after the colour has faded completely and then cooling the solution;

(k) adding 0.25 ml of phosphoric acid, transferring to a 50 ml volumetric flask, diluting to volume and mixing the solution;

(l) adding 2.0 ml of diphenylcarbazide solution, mixing and allowing the solution to stand for 10 minutes;

(m) transferring a suitable portion of each coloured solution to a 1 cm absorption cell;

(n) measuring the absorbance at 540 nm against distilled water and, using a reagent blank, correcting the absorbance readings by subtracting the blank value; and

(o) preparing a calibration curve by plotting the corrected absorbance values against micrograms of chromium.

Carry out the test by -

(a) accurately weighing approximately 0.250 g of suture into a 125 ml erlenmeyer flask and adding 25 ml of distilled water;

(b) soaking the suture for 24 hours at 37 C;

(c) allowing the solution to cool, decanting the solution into another 125 ml flask and rinsing the original flask with distilled water;

(d) developing the colour according to the procedure described in paragraphs G.2 (b) to G.2 (k) inclusive;

(e) measuring the absorbance of the solution at 540 nm and correcting the reading by subtracting the reading for the solution blank; and

(f) determining the concentration of chromium present in the solution from the calibration curve.

SCHEDULE 1

DIAMETER OF ABSORBABLE AND NON-ABSORBABLE SUTURES

METRIC SIZE (GAUGE NO.)	DIAMETER (mm)				
	RANGE FOR THE MEAN			INDIVIDUAL MINIMUM	INDIVIDUAL MAXIMUM
0.01	0.001	-	0.009	-	0.015
0.1	0.010	-	0.019	0.005	0.025
0.2	0.020	-	0.029	0.015	0.035
0.3	0.030	-	0.039	0.025	0.045
0.4	0.040	-	0.049	0.035	0.060
0.5	0.050	-	0.069	0.045	0.085
0.7	0.070	-	0.099	0.060	0.125
1	0.10	-	0.149	0.085	0.175
1.5	0.15	-	0.199	0.125	0.225
2	0.20	-	0.249	0.175	0.275
2.5	0.25	-	0.299	0.225	0.325
3	0.30	-	0.349	0.275	0.375
3.5	0.35	-	0.399	0.320	0.450
4	0.40	-	0.499	0.375	0.550
5	0.05	-	0.599	0.450	0.650
6	0.60	-	0.699	0.550	0.750
7	0.70	-	0.799	0.650	0.850
8	0.80	-	0.899	0.750	0.950

SCHEDULE 1 (continue)

DIAMETER OF STAINLESS STEEL SUTURES

METRIC SIZE (GAUGE NO.)	DIAMETER (mm)				
	RANGE FOR THE MEAN			INDIVIDUAL MINIMUM	INDIVIDUAL MAXIMUM
0.5	0.050	-	0.069	0.045	0.085
0.7	0.070	-	0.099	0.060	0.125
1	0.10	-	0.149	0.085	0.175
1.2	0.12	-	0.149	0.110	0.175
1.5	0.15	-	0.199	0.125	0.225
2	0.20	-	0.249	0.175	0.275
2.5	0.25	-	0.299	0.225	0.325
3	0.30	-	0.349	0.275	0.375
3.5	0.35	-	0.399	0.320	0.450
4	0.40	-	0.449	0.375	0.550
4.5	0.45	-	0.499	0.425	0.550
5	0.50	-	0.599	0.450	0.650
6	0.60	-	0.699	0.550	0.750
7	0.70	-	0.799	0.650	0.850
8	0.80	-	0.899	0.750	

SCHEDULE 2

BREAKING FORCE OF NON-ABSORBABLE SUTURES

METRIC SIZE (GAUGE NO.)	MEAN BREAKING FORCE USING SIMPLE KNOT			
	CLASS I		CLASS II	
	NEWTONS	(kgf)	NEWTONS	(kgf)
0.01	0.010	(0.001)		-
0.1	0.039	(0.004	0.029	(0.003)
0.2	0.137	(0.014)	0.098	(0.010)
0.3	0.294	(0.030)	0.216	(0.022)
0.4	0.49	(0.05)	0.294	(0.03)
0.5	0.98	(0.10)	0.490	(0.05)
0.7	1.86	(0.19)	0.98	(0.10)
1	3.72	(0.38)	2.16	(0.22)
1.5	5.68	(0.58)	4.31	(0.44)
2	8.43	(0.86)	6.27	(0.64)
2.5	10.29	(1.05)	8.04	(0.82)
3	12.15	(1.24)	9.02	(0.92)
3.5	19.21	(1.96)	12.25	(1.25)
4	24.70	(2.52)	15.78	(1.61)
5	32.54	(3.32)	22.93	(2.34)
6	45.08	(4.6)	34.10	(3.48)
7	54.19	(5.53)	39.59	(4.04)
8	68.60	(7.00)	47.24	(4.82)

SCHEDULE 3

BREAKING FORCE OF CATGUT SUTURES

METRIC SIZE (GAUGE NO.)	MEAN BREAKING FORCE USING SURGEONS KNOT NEWTONS	(KGF)
0.3	0.225	(0.023)
0.4	0.333	(0.034)
0.5	0.441	(0.045)
0.7	0.588	(0.06)
1	1.67	(0.17)
1.5	3.43	(0.35)
2	7.35	(0.75)
2.5	8.82	(0.90)
3	11.27	(1.15)
3.5	17.64	(1.80)
4	25.19	(2.57)
5	35.28	(3.60)
6	41.45	(4.23)
7	55.08	(5.62)
8	65.86	(6.72)

SCHEDULE 4

BREAKING FORCE OF SYNTHETIC ABSORBABLE SUTURES

METRIC SIZE (GAUGE NO.)	MEAN BREAKING FORCE USING SIMPLE KNOT NEWTONS	(kgf)
0.3	0.441	(0.045)
0.4	0.588	(0.06)
0.5	1.27	(0.13)
0.7	2.25	(0.23)
1	6.47	(0.66)
1.5	8.33	(0.85)
2	15.39	(1.57)
3	24.30	(2.48)
3.5	36.26	(3.70)
4	47.04	(4.80)
5	59.49	(6.07)

SCHEDULE 5

STRAIGHT PULL FORCE OF STAINLESS STEEL SUTURES

METRIC SIZE (GAUGE NO.)	MEAN BREAKING FORCE ON STRAIGHT PULL NEWTONS	(kgf)
0.5	1.57	0.16
0.7	2.65	0.27
1.0	5.29	0.54
1.2	6.66	0.68
1.5	8.04	0.82
2	13.30	1.36
2.5	15.5	1.58
3	17.6	1.80
3.5	33.3	3.40
4	46.7	4.76
4.5	52.2	5.33
5	57.8	5.90
6	89.3	9.11

SCHEDULE 6

STRENGTH OF NEEDLE ATTACHMENT FOR NON-ABSORBABLE SUTURES INCLUDING THOSE COMPOSED OF STAINLESS STEEL

METRIC SIZE (GAUGE NO.)	MINIMUM BREAKING FORCE			
	MEAN		INDIVIDUAL	
	NEWTONS	(kgf)	NEWTONS	(kgf)
0.4	0.392	(0.04)	0.196	(0.020)
0.5	0.686	(0.070)	0.294	(0.030)
0.7	1.57	(0.16)	0.686	(0.070)
1 & 1.2	2.16	(0.22)	0.98	(0.10)
1.5	4.21	(0.43)	2.17	(0.22)
2	6.47	(0.66)	3.14	(0.32)
2.5	8.13	(0.83)	3.72	(0.38)
3	9.80	(1.00)	4.21	(0.43)
3.5	11.76	(1.20)	4.21	(0.43)
4 & 4.5	15.68	(1.60)	5.68	(0.58)
5+	15.68	(1.60)	6.66	(0.68)

SCHEDULE 7

STRENGTH OF NEEDLE ATTACHMENT FOR CATGUT SUTURES

METRIC SIZE (GAUGE NO.)	MINIMUM BREAKING FORCE			
	MEAN		INDIVIDUAL	
	NEWTONS	(kgf)	NEWTONS	(kgf)
0.4	0.392	(0.040)	0.196	0.020
0.5	0.392	(0.040)	0.196	0.020
0.7	0.686	(0.070)	0.294	0.030
1	1.57	(0.16)	0.686	0.07
1.5	2.16	(0.22)	0.98	0.10
2	4.21	(0.43)	2.17	0.22
2.5	5.39	(0.55)	2.65	0.27
3	6.47	(0.66)	3.14	0.32
3.5	9.80	(1.00)	4.21	0.43
4	11.76	(1.20)	4.21	0.43
5+	15.68	(1.60)	5.88	0.60

SCHEDULE 8

STRENGTH OF NEEDLE ATTACHMENT FOR SYNTHETIC ABSORBABLE SUTURES OTHER THAN FOR THOSE MANUFACTURED USING CATGUT

METRIC SIZE (GAUGE NO.)	MINIMUM BREAKING FORCE			
	MEAN		INDIVIDUAL	
	NEWTONS	(kgf)	NEWTONS	(kgf)
0.4	0.392	(0.040)	0.196	(0.020)
0.5	0.686	(0.070)	0.294	(0.030)
0.7	1.57	(0.16)	0.686	(0.070)
1	2.16	(0.22)	0.98	(0.10)
1.5	4.21	(0.43)	2.17	(0.22)
2	6.47	(0.66)	3.14	(0.32)
2.5	8.13	(0.83)	3.72	(0.38)
3	9.80	(1.00)	4.21	(0.43)
3.5	11.76	(1.20)	4.21	(0.43)
4	15.68	(1.60)	5.68	(0.58)
5+	15.68	(1.60)	6.66	(0.68)

SCHEDULE 9

SOLUBILITY OF SUTURE MATERIALS

Suture	Formic Acid	H_3PO_4	5M HC1	H_2SO_4	Xylene	Formic Acid/$CaC1_2$
Polyester	insoluble	insoluble	insoluble	soluble	insoluble	insoluble
Polypropylene	insoluble	insoluble	insoluble	insoluble	soluble	insoluble
Linen	insoluble	soluble	insoluble	soluble	insoluble	insoluble
Nylon	soluble	soluble	soluble	soluble	insoluble	soluble
Silk	insoluble	soluble	insoluble	soluble	insoluble	soluble