Chapter III

MATERIALS
3. MATERIALS

3.1. List of General Chemicals Used

i. Hydrochloric acid (AR Grade) : E. Merck India Ltd., Mumbai.


iii. Hydroxy Propyl Methyl Cellulose : E. Merck India Ltd., Mumbai.


vi. Calcium chloride dihydrate : E. Merck India Ltd., Mumbai.

vii. Glacial acetic acid : SD Fine Chem Ltd., India.

viii. Agar : Difco Laboratories, Detroit, MI.

ix. Horse Serum : Invitrogen, NY.

x. Iso Vitalex : Becton Dickinson, MD.

xi. Brain Heart Infusion : Difco Laboratories, Detroit, MI.

3.2. List of Instruments Used

i. UV Spectrophotometer : UV- 1700, Shimadzu, Japan.


iii. Hot Air Oven : Neutron Scientific Corporation, Kolkata.


v. Electric Stirrer : RQ-121/D, Remi, India

vi. Dial Calipers : AEROSCAPE (150 x 0.2 mm).

vii. Syringe & Needle (18 G) : Dispovan, India.

viii. Triangular Microscope : Magnus; Model MLX.

ix. Whatman Filter Paper : Ashless, Circular 110 mm, Dye and Satin, India
3.3. Drug Profile

3.3.1. Drug Name: Amoxicillin trihydrate

3.3.2. Physicochemical Properties [1, 2]:

3.3.2.1. Chemical Formula: C\textsubscript{16}H\textsubscript{19}N\textsubscript{3}O\textsubscript{5}S\cdot3H\textsubscript{2}O

3.3.2.2. Chemical Name: 2S,5R,6R)-6-[[2R]-2-amino-2-(4-hydroxyphenyl)acetyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid trihydrate.

3.3.2.3. Molecular Weight: 419.45

3.3.2.4. Chemical Structure:

3.3.2.5. Description: White or almost white, crystalline powder. A broad-spectrum semisynthetic antibiotic similar to ampicillin except that its resistance to gastric acid permits higher serum levels with oral administration.

3.3.2.6. Solubility: Slightly soluble in water, in ethanol (95%) and in methanol; practically insoluble in chloroform, in ether and in fixed oils. It is soluble in dilute solutions of acids and of alkali hydroxides. (water solubility: 3430 mg/L)
3.3.2.7. **Storage Condition:** Store in tightly-closed containers in a cool place. Amoxicillin should be kept in the container it came in, tightly closed, and out of reach of children. Amoxicillin in capsules and tablets are crystalline in structure, so they should be stored at room temperature and away from excess heat and moisture (not in the bathroom). The liquid medication preferably should be kept in the refrigerator, but it may be stored at room temperature.

3.3.2.8. **Melting Range:** 194 °C.

3.3.2.9. **Category:** Antibiotic.

3.3.2.10. **Heavy Metals:** Not more than 20 ppm.

3.3.2.11. **Category:** Antibacterial.

3.3.3. **Pharmacokinetics** [3, 4, 5]:

3.3.3.1. **Absorption:** Rapidly absorbed after oral administration.

3.3.3.2. **Distribution:** Amoxicillin plasma protein binding is approximately 20%. The substance remains extracellular. The tissue concentrations depend on the circulation in those tissues and on the quantity of extracellular fluid. Amoxicillin diffuses adequately into the sputum, mucosa, bone tissue and aqueous humor of the eye to produce therapeutically active levels.

The concentrations in the bile are two to four times higher, or even higher than those in the blood. In the amniotic fluid and umbilical cord blood 25-30% of the mother's blood levels are attained. Amoxicillin diffuses poorly into the cerebrospinal fluid of patients with normal meninges. In inflamed meninges the concentrations are approximately 20% of those found in the blood.

3.3.3.3. **Metabolism:** Hepatic metabolism accounts for less than 30% of the biotransformation of most penicillins.
3.3.3.4. **Elimination:** Most of the amoxicillin is excreted unchanged in the urine; its excretion can be delayed by concurrent administration of probenecid. Amoxicillin is primarily eliminated via the kidneys, largely (ca. 80%) via tubular excretion, for the remainder (ca. 20%) via glomerular filtration. Approximately 60% of an orally administered dose of amoxicillin is excreted in the urine within 6 to 8 h. Detectable serum levels are observed up to 8 h after an orally administered dose of amoxicillin.

3.3.3.5. **Volume of Distribution:** 0.3 L/kg.

3.3.3.6. **Half life:** 61.3 min.

3.3.3.7. **pH:** 3.5-5.5

3.3.3.8. **pKa:** 9.48

3.3.3.9. **Plasma Protein Binding:** In blood serum, amoxicillin is approximately 20% protein-bound.

3.3.3.10. **Dose:** The equivalent of 750 mg to 4.5 g of amoxicillin daily, in divided doses.

3.3.4. **Pharmacodynamics [3-5]:**

Amoxicillin is a moderate-spectrum antibiotic active against a wide range of gram-positive, and a limited range of gram-negative organisms. It is usually the drug of choice within the class because it is better absorbed, following oral administration, than other beta-lactam antibiotics.

Amoxicillin is stable in presence of gastric juices and it also produces less gastric disturbance and has the same antibacterial activity as ampicillin. It is a drug of choice in treatment of typhoid, meningitis, endocarditis, septicaemia, peritonitis and gonorrhoea. Another advantage of amoxicillin is that it penetrates equally well in to the purulent and mucoid sputum in distinction to ampicillin which does not cross the bronchial mucosa.
Amoxicillin is in the free acid form is a white crystalline powder sparingly soluble in water; it is stable in acid solution and thus can be given by mouth. It is well absorbed and produces high serum levels.

Peak serum concentrations are obtained within 60 to 90 minutes after drug administration. Animal studies demonstrated that amoxicillin is distributed evenly throughout the body tissues and is concentrated in the liver and kidneys. Small quantities enter the non-infected cerebrospinal fluid. Administration of high doses results in proportionate increase in serum levels in patients with normal renal function. The drug is excreted in an active form in urine.

3.3.5. Pharmacology [3-5]:

3.3.5.1. Mechanism of Action: Amoxicillin binds to penicillin-binding protein 1A (PBP-1A) located inside the bacterial cell wall. Penicillins acylate the penicillin-sensitive transpeptidase C-terminal domain by opening the lactam ring. This inactivation of the enzyme prevents the formation of a cross-link of two linear peptidoglycan strands, inhibiting the third and last stage of bacterial cell wall synthesis. Cell lysis is then mediated by bacterial cell wall autolytic enzymes such as autolysins; it is possible that amoxicillin interferes with an autolysin inhibitor.

Bactericidal; inhibit bacterial cell wall synthesis. Action is dependent on the ability of penicillins to reach and bind penicillin-binding proteins (PBPs) located on the inner membrane of the bacterial cell wall.

The more rapid bactericidal activity is linked with a different effect on the growing cells. Thus while ampicillin and some other antibiotics such as cephalexin interfere primary with septation, resulting initially in elongated filamentous forms of gram negative bacteria, amoxicillin causes rapid interference with the cell wall leading to the formation of spheroplasts and lysis.
The cell wall of bacteria is essential for the normal growth and development. Peptidoglycan is a heteropolymeric component of the cell wall that provides rigid mechanical stability by virtue of its highly cross linked lattice work structure. In gram positive organism the cell wall is 50 to 100 molecules thick, while in gram negative micro organisms it is only 1 or 2 molecules thick. The biosynthesis of peptidoglycan involves about thirty bacterial enzymes and may be considered in three stages, which are as follows:

- The first stage involves the precursor formation which takes place in cytoplasm. The product, uridinediphosphate (UDP) accumulates in the synthesis of this compound is the addition of a dipeptide, D-alanyl-D alanine.
- During reactions of the second stage, UDP acetylmuramylpentapeptide and UDP acetylglucoseamine is linked to form a long polymer. To form this species, the sugar pentapeptide is first attached by a pyrophosphate bridge to a phospholipid in the cell membrane. The second sugar is then added, followed by the addition of five glycine residue as a branch of the heteropentapeptide. The molecule is then assumed to flip across the cell membrane such that the peptidoglycan precursor faces the periplasm. The completed unit is then cleaved from the membrane bound phospholipid.
- The final stage involves the completion of the cross link. This is accomplished by a transpeptidation reaction that occurs outside the cell membrane. The transpeptidase itself is membrane bound. The terminal glycine residue of the pentaglycine bridge is linked with the fourth residue of the pentapeptide (D-alanine) releasing the fifth residue (also D-alanine). It is this last step in peptidoglycan synthesis that is inhibited by the beta lactam antibiotics.

The lysis of bacteria that usually follows their exposure to beta lactam antibiotics ultimately depend on the cell wall autolytic enzymes i.e. autolysins. The relationship between inhibition of penicillin binding proteins (PBP) activity and activation of autolysins is unclear. Some
evidence suggests that exposure of bacteria to beta lactam antibiotics results in the loss of an inhibitor of the autolysins.

Beta lactam antibiotics can interfere with cell wall synthesis only in growing cells, but presumably this antibiotic can bind to the transpeptidase and related enzymes even in resting cells thus inhibiting the terminal stages of cell wall synthesis if growth is subsequently resumed.

3.3.5.2. Indication[6]: For the treatment of infections of the ear, nose, and throat, the genitourinary tract, the skin and skin structure, and the lower respiratory tract due to susceptible (only β-lactamase-negative) strains of Streptococcus spp. (α- and β-hemolytic strains only), S. pneumoniae, Staphylococcus spp., H. influenzae, E. coli, P. mirabilis, or E. faecalis. Also used for the treatment of acute uncomplicated gonorrhea (ano-genital and urethral infections) due to N. gonorrhoeae (males and females).

i. Infections of the ear, nose, and throat: Due to Streptococcus species. (α- and β-hemolytic isolates only), Streptococcus pneumoniae, Staphylococcus spp., or Haemophilus influenzae.

ii. Infections of the genitourinary tract: Due to Escherichia coli, Proteus mirabilis, or Enterococcus faecalis.

iii. Infections of the skin and skin structure: Due to Streptococcus spp. (α- and β-hemolytic isolates only), Staphylococcus spp., or E.coli.

iv. Infections of the lower respiratory tract: Due to Streptococcus spp. (α- and β-hemolytic isolates only), S. pneumoniae, Staphylococcus spp., or H. influenzae.

v. Gonorrhea, acute uncomplicated (ano-genital and urethral infections in males and females) due to Neisseria gonorrhoeae.

vi. H. Pylori eradication to reduce risk of doudenal ulcer.

vii. Triple therapy for H. pylori with clarithromycin and lansoprazole.
viii. Dual therapy for *H. pylori* with lansoprazole

3.3.5.3. **Contraindications** [6]: Contraindicated in patients with known serious hypersensitivity to amoxicillin or to other drugs in the same class or patients who have demonstrated anaphylactic reactions to beta-lactams.

3.3.5.4. **Drug Interactions** [6]:

i. **Probenecid**: Probenecid decreases the renal tubular secretion of amoxicillin. Probenecid may result in increased and prolonged blood levels of amoxicillin. The clinical relevance of this finding has not been evaluated.

ii. **Other Antibiotics**: Chloramphenicol, macrolides, sulfonamides, and tetracyclines may interfere with the bactericidal effects of amoxicillin. This has been demonstrated in in-vitro; however, the clinical significance of this interaction is not well documented.

iii. **Oral Contraceptives**: As with other antibiotics, amoxicillin may affect the gut flora, leading to lower estrogen reabsorption and potentially resulting in reduced efficacy of combined oral estrogen/progesterone contraceptives.

3.3.5.5. **Overdose** [6]: In case of overdose, discontinue of medication, symptomatic treatment and supportive measurements are required. If the overdose is very recent and there is no contraindication, an attempt for emesis or other means of removal of drug from the stomach may be performed. A prospective study of 51 pediatric patients at a poison-control center suggested that overdosages of less than 250 mg/kg of amoxicillin are not associated with significant clinical symptoms and do not require gastric emptying.

Interstitial nephritis resulting in oliguric renal failure has been reported in a small number of patients after overdosage with amoxicillin.
Crystalluria, in some cases leading to renal failure, has also been reported after amoxicillin overdosage in adult and pediatric patients. In case of overdosage, adequate fluid intake and diuresis should be maintained to reduce the risk of amoxicillin crystalluria.

Renal impairment appears to be reversible with cessation of drug administration. High blood levels may occur more readily in patients with impaired renal function because of decreased renal clearance of amoxicillin. Amoxicillin may be removed from circulation by hemodialysis.

3.4. Excipients Profile

3.4.1. Sodium Alginate [7]

3.4.1.1. Structure:

3.4.1.2. Description: A linear chain polymer extracted from seaweed composed of mannuronic acid and guluronic acid linked in the 1 to 4 positions and neutralized to form sodium salt.

3.4.1.3. Solubility: Soluble in water forming a viscous colloidal solution.

3.4.1.4. Appearance: Ivory colour, practically odorless powder.

3.4.1.5. CAS Number: 9005-38-3

3.4.1.6. Chemical Formula: (C₆H₇NaO₆)ₙ

3.4.1.7. Formula Weight: Structural unit 198.11 (theoretical), 222 (actual average).

Macromolecule: 10,000 – 60,000 (typical average).
3.4.1.8. **Generic Nomenclature:** Algin, Sodium polymannuronate, Alginic acid and its sodium salt.

3.4.1.9. **Pharmacopeal Listing:** NF, FCC (Ammonium alginate, calcium alginate, Potassium Alginate, Sodium Alginate), Codex Alimentarius.

3.4.1.10. **Assay:** Yeilds on the dried basis 18.00 % and not more than 21.00 % of carbon-di-oxide equivalent to not less than 90.80 % and not more than 106.00 % of sodium alginate.

3.4.1.11. **Identification:**

i. 0.2 gm dissolved in 20 ml of water and to 5 ml of resulting solution 1 ml of CaCl$_2$ Solution is added, a voluminous gelatinous precipitate is produced.

ii. To 10 ml of the solution obtained in test A 1 ml of 1M H$_2$SO$_4$ is added, a gelatinous mass is produced.

iii. 5 ml of water is added to 5 mg of sodium alginate. 1 ml of freshly prepared 1 % w/v solution of napthalene-1, 3-diol in ethanol (95 %) and 5 ml of HCl are added to it. Boiled for 3 minutes, cooled, and add 5 ml of water and shake with 15 ml of di-isopropyl ether. The upper layer exhibits a deeper bluish red color than the upper layer obtained by repeating the procedure without the substance being examined.

3.4.1.12. **Purity:**

i. Heavy metals: Not more than 40 ppm.

ii. Chlorides: Not more than 1.0 %.

iii. Microbial Counts: 1.0 gm must be free from *E. coli*; 10.0 gm free from salmonellae

Yeast and Moulds: Not more than 500 colonies per gram.

iv. Sulphated Ash: 30.0% - 36.0%.

v. Loss on drying: Not more than 15 % (105°, 4 h).

vi. Water insoluble materials: Not more than 2 % on the dried basis.

3.4.1.13. **Uses:** Thickener, suspension stabilizer.
3.4.2. Hydroxy Propyl Methyl Cellulose [8]:

3.4.2.1. Nonproprietary Names: BP/USP: Hypromellose, PhEur: Hypromellosum

3.4.2.2. Synonyms: Methyl hydroxypropyl cellulose, propylene glycol ether of methyl cellulose, methyl cellulose propylene glycol ether, methocel, HPMC.

3.4.2.3. Chemical Names: Cellulose, 2-hydroxy propyl methyl ether.

3.4.2.4. Structural Formula:

\[
R = \overset{-}{H}, \quad \overset{-}{CH}_3, \text{ or } \overset{-}{CH}_2CH(OH)CH_3
\]

3.4.2.5. Functional Category: Suspending and/or viscosity increasing agent, tablet binder, coating agent, Viscosity increasing agent, adhesive anhydrous ointment ingredient, film former, emulsion stabilizer, rate-controlling polymer for sustain release.

3.4.2.6. Method of Manufacture: A purified form of cellulose fibers obtained from cotton linters or wood pulp, are treated with caustic (sodium hydroxide) solution. The alkali cellulose thus obtained is in turn treated with methyl chloride and propylene oxide to provide methylhydroxypropyl ethers of cellulose. The fibrous reaction product is then purified and ground to a fine, uniform powder or granules.

3.4.2.7. Description: An odorless, tasteless, white or creamy-white fibrous or granular powder.

3.4.2.8. Applications in Pharmaceutical Formulation or Technology [9, 10]: Hypromellose is widely used in oral and topical pharmaceutical formulations. In oral products, primarily used as a tablet binder, film coating material and extended release tablet
matrix. Concentrations between 2 % and 5 % w/w may be used as a binder in either wet or dry granulation. Depending upon the viscosity grade, concentrations of 2-20 % w/w are used for film-forming solutions to film-coat tablets. Hypromellose is also used as a suspending and thickening agent in topical formulations, particularly ophthalmic preparations. Concentrations between 0.45-0.1 % w/w may be added as a thinking agent to vehicles for eye drops and artificial tear solutions. It is also used as an emulsifier, suspending agent, and stabilizing agent in topical gels and ointments. It is used as an adhesive in plastic bandages and wetting agent for hard contact lenses.

3.4.2.9. Typical Properties:

Acidity/alkalinity: pH = 5.5-8.0 for a 1 % w/w aqueous solution.

Autoignition temperature: 360\(^{0}\)C

Density (bulk): 0.341 g/cm\(^{3}\).

Density (tapped): 0.557 g/cm\(^{3}\).

Density (true): 1.326 g/cm\(^{3}\).

Melting point: Browns at 190-200\(^{0}\)C, chars at 225-230\(^{0}\)C, glass transition temperature is 170-180\(^{0}\)C.

Moisture content: Hypromellose absorb moisture from the atmosphere, the water absorbed depending upon the initial moisture content and temperature and relative humidity of the surrounding air.

Specific gravity: Approximately 1.3

3.4.2.10. Solubility: Soluble in cold water, forming a viscous colloidal solution; insoluble in alcohol, ether and chloroform, but soluble in mixtures of methyl alcohol and methylene chloride. Certain grades are soluble in aqueous acetone, mixtures of methylene chloride and isopropyl alcohol and other organic solvents.
3.4.2.11. **Stability and Storage Conditions:** Very stable in dry condition. Solutions are stable at pH 3-11. Aqueous solution is liable to be affected by microorganisms when used as a viscosity-increasing agent in ophthalmic solutions and anti-microbial agent. Hypromellose powder should be store in a well-closed container, cool and dry place.

3.4.2.12 **Incompatibilities:** Hypromellose is incompatible with some oxidizing agents. Since it is nonionic, hypromellose will not complex with metallic salts or ionic organics to form insoluble precipitates.

3.4.3. **Chitosan**

3.4.3.1. **Description:** Chitosan is a polysaccharide extracted from the shells of crustaceans, such as shrimp, crab and other sea crustaceans, including *Pandalus borealis* and cell walls of fungi.

3.4.3.2. **Structure:** Chitosan is also known as soluble chitin. Chitin consists mainly of unbranched chains of beta-(1→4)-2-acetamido-2-deoxy-D-glucose(=N-acetyl-d-glucosamine). It is similar to cellulose, in which the C-2 hydroxyl groups are replaced by acetamido residue. Chitin is practically insoluble in water, dilute acids, and alcohol, with variation depending on product origin.
Chitosan, the partially deacetylated polymer of N-acetyl-D-glucosamine, is water-soluble. Structure of the chitin molecule, showing two of the N-Acetylglucosamine units that repeat to form long chains in beta-1, 4 linkages. Structure of the chitosan, composed of randomly distributed β-(1-4)-linked D-glucosamine (deacetylated unit) and N-acetyl-Dglucosamine (acetylated unit).

3.4.3.3. Chemical Name: 2-amino-2-deoxy-β-D-glucopyranose.

3.4.3.4. Chemical Formula: \((\text{C}_6\text{H}_{11}\text{O}_4\text{N})_n\)

3.4.3.5. Preparation of Chitosan from Raw Materials: Chitosan is not a single chemical entity, but varies in composition depending on the source and method of preparation and also on physiological conditions. Chitosan could be defined as sufficiently deacetylation of chitin to form a soluble amine salts. The degree of deacetylation must be 80 to 85% or higher or the acetyl content must be less than 4-4.5% to form the soluble product. Chitosan is manufactured commercially by a chemical method. Firstly the sources such as crab or shrimp shells are washed and grinded in to powdered form and then it is deproteinized by treatment with an aqueous 3-5% solution of sodium hydroxide. After that it is neutralized and demineralized at a room temperature by treating it with aqueous 3-5% of hydrochloric solution to form a white or slightly pink precipitate of chitin. Then chitin is deacetylated by treatment with an aqueous 40-45% of sodium hydroxide solution and the precipitate is then washed with water. The insoluble part is removed by dissolving in an aqueous 2% acetic acids solution. The supernatant solution is then neutralized with an aqueous sodium hydroxide solution to obtain a purified chitosan [12].

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Description</th>
<th>Instrument</th>
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<tbody>
<tr>
<td>Appearance (powder or flake)</td>
<td>White or yellow</td>
<td>External shape estimation</td>
</tr>
<tr>
<td>Particle size</td>
<td>Less than 30 μm</td>
<td>Optical microscopy</td>
</tr>
<tr>
<td>Viscosity (1% solution/1% acid)</td>
<td>Less than 5 cps</td>
<td>Intrinsic viscosity (Capillary test)</td>
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<tr>
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<td>Moisture content</td>
<td>More than 10 %</td>
<td>Gravimetric analysis</td>
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<tr>
<td>Ash value</td>
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<td>Gravimetric analysis</td>
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<td>Degree of deacetylation</td>
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<tr>
<td>Heavy metal (Pb)</td>
<td>Less than 10 ppm</td>
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<tr>
<td>Heavy metal (As)</td>
<td>Less than 10 ppm</td>
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</tr>
<tr>
<td>Protein content</td>
<td>Less than 0.3 %</td>
<td>Kjeldal method</td>
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<tr>
<td>Loss on drying</td>
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<tr>
<td>Glass transition temperature</td>
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</table>

3.4.3.7. Pharmaceutical Applications: Chitosan has received considerable attention as a possible pharmaceutical excipient in recent decades, due to its good biocompatibility and low toxicity properties in both conventional excipient applications as well as in novel application.

Some of the general applications of chitosan in pharmaceutical fields are:

- Diluents in direct compression of tablets,
- Binder in wet granulation,
- Slow-release of drugs from tablets and granules,
- Drug carrier in micro particle systems,
- Films controlling drug release,
- Preparation of hydrogels, agent for increasing viscosity in solutions,
- Wetting agent, and improvement of dissolution of poorly soluble drug substances,
- Disintegrant,
- Bioadhesive polymer,
- Site-specific drug delivery (e.g. to the stomach or colon),
- Absorption enhancer (e.g. for nasal or oral drug delivery),
- Biodegradable polymer (implants, microparticles),
- Carrier in relation to vaccine delivery or gene therapy.

3.4.4. Sunflower Oil

3.4.4.1. Non-proprietary Name: Sunflower oil

3.4.4.2. Functional Category: Solvent and oleaginous vehicle

3.4.4.3. Origin of the Compound: Sunflower oil is the non-volatile oil compressed from sunflower (*Helianthus annuus*) seeds.

3.4.4.4. Description: Pale yellow color or yellow oily liquid, odorless.

3.4.4.5. Typical Properties:

(a) **Density**: 0.91gm/ml

(b) **Viscosity**: 0.046 Pa-S at 30.3°C

(c) **Iodine value**: 140.30

(d) **Free fatty acid content (% as oleic)**: 0.2

(e) **Peroxide value**: 0.07

3.4.4.6. Structural Formula: Sunflower oil is mainly triglycerides (fats), typically derived from the fatty acids linoleic acid (with is doubly unsaturated) and oleic acid.
The British Pharmacopoeia lists the following profile: [13]

Palmitic acid (saturated): 5%
Stearic acid (saturated): 6%
Oleic acid (monounsaturated omega-9): 30%
Linoleic acid (polyunsaturated omega-6): 59%

3.4.4.7. Storage: Should be stored in an airtight, light resistant container protected from light and excessive heat.

3.4.4.8. Application in Pharmaceutical Formulation: Used as oily vehicle, as floating aid.

3.5. References


