SEMI SOLIDS IN NDDS

RECENT ADVANCES IN SEMISOLIDS: -

A recent advance in semisolid dosage form allows modified release as well as flexibility in route of administration.

INTRODUCTION: -

- Novel semisolids are non greasy since they are made up of water washable bases. Hence they cause less irritation to skin and are superior to conventional semisolid dosage form.
- Novel creams now a days are provided with nanoparticles and microspheres, which has an excellent emollient effect, with better spreadability, and less staining than oleaginous ointments. However both medicated and non-medicated creams provide very good emollient effects, oleaginous ointments are preferred for dry, chapped skin in an environment of low humidity because of its occlusive properties.
- Number of innovation has been taken place in gels in term of modification of release pattern and also some thermoreversible gels are also introduced. Complex gels for Ora / Insulin delivery, chitosan based bioadhesive gels and TIMERx technology for controlled release, amphiphilic and non-aqueous gels are also the latest innovations in gel formulations.
- Number of new bases for Gels, Ointment and Creams are developed which facilitates the delivery of above novel semisolids by various route like Nasal, Parenteral or Ophthalmic route.
- Care should also be used in applying any drug to inflamed skin. The integrity of inflamed skin is generally compromised, resulting in increased percutaneous migration and systemic absorption of most drugs.

IDEAL PROPERTIES OF NOVEL SEMISOLIDS: -

Ideal properties of semisolids are,

a) Novel ointment bases:
   - Should absorb more water and enhance permeation.
   - When applied over skin, an oleaginous ointment film should formed which prevents moisture evaporation from the skin.
   - Should not irritate skin. Substances (e.g., hydrocarbon bases) can form an occlusive barrier on the skin that prevents.

b) Novel semisolids are safe even when applied to inflamed skin.

c) They should be odorless, easy to handle, stable and compatible with large range of drugs and should be safe.

d) Use of Novel semisolids in pediatric, geriatrics and pregnant women should be safe without causing any allergic reaction.
e) Novel semisolids should be able to extend the release pattern in a controlled manner.
f) Novel semisolids should allow its use in different routes of administration with safe, odorless, easy to handle and compatible with biological membrane.

NOVEL ADVANCES IN SEMISOLID DOSAGE FORMS: -

OINTMENTS: -
Rectal Ointment: it is used for the symptomatic relief against anal and peri-anal pruritus, pain and inflammation associated with hemorrhoids, anal fissure, fistulas and proctitis.
Rectal ointment should be applied several times in a day according to the severity of the condition. For intrarectal use, apply the ointment with the help of special applicator.

CREAMS: -

a) Creams containing microspheres: -
  ⇦ Albumin microsphere containing vitamin A can be administered by using creams topically. 222 ± 25 μm size of microsphere of vitamin A were produced by emulsion method.
  ⇦ The in vitro and in vivo drug release of a microencapsulated and nonmicroencapsulated vitamin A cream was studied. The in vivo study in six volunteers revealed that these microspheres were able to remain on the skin for a long period of time, and as a consequence they were able to prolong the release of vitamin A.

b) Lamellar faced creams: -
  ⇦ They are liquid paraffin in water emulsion prepared from cetrimide / fatty alcohol like mixed emulsifiers and ternary system formed by dispersing the mixed emulsifier in require quantity of water.
  ⇦ The cationic emulsifying wax showed phenomenal swelling in water and this swelling was due to electrostatic repulsion which can be suppressed by addition of salt and can be reduced by changing surfactant counter ion.

c) Cream containing lipid Nanoparticles: -
  ⇦ Occlusion of cream is important criteria since it increases the penetration of topical drugs. This can be achieved by using oils and fats like liquid and semisolid paraffin in large quantities. However, such formulations have the limitations of poor cosmetic properties since they have greasy feel and glossy appearance.
  ⇦ The development of a water-in-oil cream containing small particles of solid paraffin was studied. A high degree of occlusivity was obtained with smooth, flexible films prepared by drying aqueous dispersions of solid paraffin particles with a mean size of 200 nm (nanoparticle dispersion).
  ⇦ However, this nanodispersion revealed a rough texture when applied. The development of a water-in-oil cream wherein the aqueous phase was divided into small droplets solved this problem. Nanoparticles were incorporated in the aqueous
phase. Hence, the oil phase in which the water droplets were dispersed served as a lubricant for nanoparticles, thereby preventing a rough feel during application.

GELS:

a) Controlled release gels:

- Drug delivery to nasal or ocular mucosa for either local or systemic action suffers from many obstacles. Gel formulations with suitable rheological and mucoadhesive properties increase the contact time at the site of absorption. However, drug release from the gel must be sustained if benefits are to be gained from the prolonged contact time.
- Gelrite gels were formed in simulated tear fluid at concentrations of polymer as low as 0.1%, and it was shown that sodium was the most important gel-promoting ion in vivo. Rheology, although it may be a questionable technique for evaluating mucoadhesive properties of polymers, showed that interactions between mucin and polymers were most likely to be seen with weak gels.
- It was possible to control the release of uncharged drug substances by including surfactants that form micelles in the gel. The release depends on lipophilic interactions between the drug and the polymer and/or the micelles.
- Controlled-release formulations of charged drugs could be designed by mixing the drugs with oppositely charged surfactants in certain fixed ratios. In this way, vesicles in which the drug and surfactant constituted the bilayer formed spontaneously. The vesicle formation was affected by the presence of polymer, and very small vesicles that gave a slow release rate were formed when a lipophilically modified polymer was used.
- The gels were also evaluated in the chamber using porcine nasal mucosa and from the results it was found that the rate of transport of drugs through the mucosa could be controlled by the rate of release from the formulation. Furthermore, the chamber can be used to evaluate the potential toxicity of formulations.

b) Organogels:

- Sorbitan monostearate, a hydrophobic nonionic surfactant, gels a number of organic solvents such as hexadecane, isopropyl myristate, and a range of vegetable oils.
- Gelation is achieved by dissolving/dispersing the organogelator in hot solvent to produce an organic solution/dispersion, which, on cooling sets to the gel state.
- Cooling the solution/dispersion causes a decrease in the solvent-gelator affinities, such that at the gelation temperature, the surfactant molecules self-assemble into toroidal inverse vesicles.
- Further cooling results in the conversion of the toroids into rod-shaped tubules. Once formed, the tubules associate with others, and a three-dimensional network is formed which immobilizes the solvent. An organogel is thus formed.
- Sorbitan monostearate gels are opaque, thermoreversible semisolids, and they are
stable at room temperature for weeks. Such organogels are affected by the presence of additives such as the hydrophilic surfactant, polysorbate 20, which improves gel stability and alters the gel microstructure from a network of individual tubules to star-shaped "clusters" of tubules in the liquid continuous phase.

- Another solid monoester in the sorbitan ester family, sorbitan monopalmitate, also gels organic solvents to give opaque, thermoreversible semisolids. Like sorbitan monostearate gels, the microstructure of the palmitate gels comprises an interconnected network of rod-like tubules.

- Unlike the stearate gels, however, the addition of small amounts of a polysorbate monoester causes a large increase in tubular length instead of the "clustering effect seen in stearate gels. The sorbitan stearate and palmitate organogels may have potential applications as delivery vehicles for drugs and antigens.

c) Extended release gels: -

- TIMERx is a controlled release technology consists of an agglomerated, hydrophilic complex that, when compressed, forms a controlled-release matrix.

- The matrix, consisting of xanthan and locust bean gums (two polysaccharides) combined with dextrose, surrounds a drug core. In the presence of water, interactions between the matrix components form a tight gel while the inner core remains unwetted.

- The drug is encapsulated in the pores of the gel, and as the matrix travels through the patient’s digestive system, the tablet swells and begins to erode. This erosion allows the drug to “back-diffuse” out through the gel-matrix at a controlled rate until the matrix erodes and a majority of the drug is released. The fundamental component controlling the rate of release lies in the properties of the gel matrix. Advantage of this system includes,

  a) Predictable modified release profile like zero order or first order or initial immediate release kinetics

  b) It can be manufacture on standard manufacturing equipment.

  c) Cheap.

d) Amphiphilic gels: -

- Amphiphilic gels can prepared by mixing the solid gelator like sorbitan monostearate or sorbitan monopalmitate and the liquid phase like liquid sorbitan esters or polysorbate and heating them at 60°C to form a clear isotropic sol phase, and cooling the sol phase to form an opaque semisolid at room temperature.

- Amphiphilic gel microstructures consisted mainly of clusters of tubules of gelator molecules that had aggregated upon cooling of the sol phase, forming a 3D network throughout the continuous phase.

- The gels demonstrated thermoreversibility. Gelation temperature and viscosity
increased with increasing gelator concentration, indicating a more robust gel network.

At temperatures near the skin surface temperature, the gels softened considerably; this would allow topical application. This study has demonstrated the formation/preparation of stable, thermoreversible, thixotropic surfactant gels (amphiphilogels) with suitable physical properties for topical use.

e) **Hydrophilic gels:** Hydrophilic gels are bicoherent systems composed of the internal phase made of a polymer producing a coherent three-dimensional net-like structure, which fixes the liquid vehicle as the external phase. Intermolecular forces bind the molecules of the solvent to a polymeric net, thus decreasing the mobility of these molecules and producing a structured system with increased viscosity. The physical and chemical bonds binding the particles of the internal phase provide a relatively stable structure, which can originate by swelling of solid polymers, or by decreasing the solubility of the polymer in a solution. An important group of gels used in pharmacy are hydrophilic gels, or hydrogels, usually made of hydrophilic polymers, which under certain conditions and polymer concentration, jellify. Attention of pharmaceutical research now concentrates primarily on hydrophilic gels, as this dosage form seems to be prospective for the development of modern drugs based on systems with prolonged and controlled release of active ingredients.

f) **Non aqueous gels:** Ethylcellulose was successfully formulated as a nonaqueous gel with propylene glycol dicaprylate/dicaprate. The novel nonaqueous gel exhibited rheological profiles corresponding to a physically cross-linked three dimensional gel network, with suitable mechanical characteristics for use as a vehicle for topical drug delivery. Molecular conformation of the solvent was found to influence the molecular interactions associated with formation of ethylcellulose gel networks.

The gel matrices exhibited prominent viscoelastic behavior, yield stress and thixotropy. Rheological and mechanical properties showed significant upward trends with increased polymeric chain length and polymer concentrations. Good linear correlations were obtained between rheological and mechanical properties. The solvent molecular conformation was found to play a role in affecting the formation of gel networks via intermolecular hydrogen bonding between ethylcellulose polymer chains.

g) **Bioadhesive Gels:** Chitosan bioadhesive gel was formulated for nasal delivery of insulin. A nasal perfusion test was carried out to study the toxicity of four absorption enhancers like saponin, sodium deoxycholate, ethylenediamine tetra-Acetic Acid (EDTA) and lecithin. The gels contained 4000 Iu/dl insulin, 2 or 4% of low and medium molecular weight of chitosan, and lecithin or EDTA. Drug release was studied by a membraneless diffusion method and bioadhesion by a modified tensiometry test. The optimized gel was administered nasally in diabetic rats. The serum insulin levels were analyzed by an insulin enzyme immunoassay kit and serum glucose by glucose oxidase method kits. Formulations containing 2% of low molecular weight of chitosan with EDTA had higher release percentage and dissolution efficiency (DE)2.5%, lower t50% (Time required to release 50% of the drug), mean dissolution
time, and bioadhesion than gels containing 4% of medium molecular weight of chitosan with lecithin. Insulin was released by a zero-order kinetic from the gels. The gel of 2% medium molecular weight of chitosan with EDTA caused increase in insulin absorption and reduction the glucose level by as much as 46% of the intravenous route. Considering in vitro and in vivo studies, the formulated gel could be a useful preparation for controlled delivery of insulin through the nasal route.

h) **Thermosensitive sol-gel reversible hydrogels**: They are theaqueous polymeric solutions which undergo reversible sol to gel transformation under the influence of environmental conditions like temperature and pH which results in insitu hydrogel formation.

Advantages of thermosensitive sol-gel reversible hydrogels over conventional hydrogels are,

a) It is easy to mix pharmaceutical solution rather than semisolids
b) Biocompatibility with biological systems
c) Convenient to administer
d) The pharmaceutical and biomedical uses of the such sol-gel transition include solubilization of low-molecular-weight hydrophobic drugs
e) Release can be in a controlled fashion.
f) Helps to deliver labile biomacromolecules such as proteins and genes.
g) Immobilization of cells
h) And tissue engineering

i) **Complexation gels**: - The goal of oral insulin delivery devices is to protect the sensitive drug from proteolytic degradation in the stomach and upper portion of the small intestine. In this work, the use of pH-responsive, poly (methacrylic-g-ethylene glycol) hydrogels as oral delivery vehicles for insulin were evaluated. Insulin was loaded into polymeric microspheres and administered orally to healthy and diabetic Wistar rats. In the acidic environment of the stomach, the gels were unswollen due to the formation of intermolecular polymer complexes. The insulin remained in the gel and was protected from proteolytic degradation. In the basic and neutral environments of the intestine, the complexes dissociated which resulted in rapid gel swelling and insulin release. Within 2 h of administration of the insulin-containing polymers, strong dose-dependent hypoglycemic effects were observed in both healthy and diabetic rats. These effects lasted for up to 8 h following administration.

**NOVEL ADVANCES IN SEMISOLID APPLICATIONS:**

**NASAL:**

Numerous drug substances can be prepared as nasal solutions or suspensions to be administered either as drops or sprays gels, jellies or ointments. Some drugs are sufficiently volatile they can be carried into the nose through an inhaler.

a) **Introduction**: Drug delivery to nasal mucosa for either local or systemic action faces
obstacles like cilia, mucus. These routes are protected by effective mechanisms. Nasal drug administration has been routinely used for administration of drugs for the upper respiratory tract, like adrenergic agents, and is now also being used as a viable alternative for the delivery of many systemic therapeutic agents. A number of dosage forms are common and include solutions, suspensions and gels.

Nasal gels are semisolid preparations prepared for nasal application and can be for either local or systemic use, in a water soluble or water miscible vehicle where as Nasal ointments are prepared from either water miscible/soluble or oleaginous bases.

b) Advantage, Application and uses: The advantages of nasal delivery include,

(1) Lower doses,
(2) Rapid local therapeutic effect,
(3) Rapid systemic therapeutic blood levels,
(4) rapid onset of pharmacological activity, and
(5) Few side effects.

In addition to the nasal decongestants, saline and other routine locally acting drugs, nasal administration is being investigated for the delivery of insulin, vaccines, number of polypeptides and proteins, progesterone, metoclopramide, propranolol (for migraine headaches), dihydroergotamine, desmopressin, atropine, vitamin B12, antihistamines, anti-obesity agents, narcotic analgesics like Butorphanol tartarate (analgesic), cyanocobalamin (haematopoietic), nafaralin acetate (treat endometriosis), nicotine (adjunct in smoking cessation) and a host of other agents.

An example of drug that shows effectiveness upon administration as a nasal gel, as compared to an oral tablet, is vitamin B12, where clinical studies showed a six fold increase in maximum blood levels, a doubling of speed in entering the bloodstream, and a 2.5 fold increase in measurable vitamin B12 in the blood 48 hours after administration. Similar results have been reported in other studies.

c) Risk associated with nasal semisolids: The risk of patient-to-patient contamination is very high with nasally administered products; patients should be advised that a nasal product is for ONE PATIENT ONLY.

d) Formulation aspect: In addition to the active drugs, nasal preparations contain a number of excipients, including vehicles, buffers, preservatives, tonicity adjusting agents, gelling agents and possibly antioxidants. Important in the formulation process is the use of ingredients that are nonirritating and compatible with the nose as discussed within each category. In general, the same excipients used in ophthalmic formulations can also be used in nasal formulations.

It was possible to control the release of uncharged drug substances by including surfactants that form micelles in the gel. This release depended on lipophilic interactions between the drug and the polymer and/or the micelles. Controlled-release formulations of charged drugs could be designed by mixing the drugs with oppositely charged surfactants in certain ratios. In this way, vesicles in which the drug and surfactant constituted the bilayer formed spontaneously. The vesicle formation was affected by the presence of polymer, and very small vesicles that gave a slow release rate were formed when a lipophilically modified polymer was used.
SKIN: -

Delivery of drugs to the skin is an effective and targeted therapy for local dermatological disorders.

a) Introduction: Topical gel formulations provide a suitable delivery system for drugs because they are less greasy and can be easily removed from the skin.

Topical dermatologic products are intended for localized action on one or more layers of the skin (e.g., sunscreens, keratolytic agents, local anesthetics, antiseptics and anti-inflammatory agents). Although some medication from these topical products may unintentionally reach systemic circulation, it is usually in sub-therapeutic concentrations, and does not produce effects of any major concern except possibly in special situations, such as the pregnant or nursing patient.

b) Advantage, application and uses: This route of drug delivery has gained popularity because,

(1) Provides a largest surface area
(2) It avoids first-pass effects, gastrointestinal irritation,
(3) And metabolic degradation associated with oral administration.

Galentic also manufactures zinc oxide ointment (5% and 25%), anti-hemorrhoid ointment, tiabendazole ointment, hydrocortisone and urea cream, fluocinole ointment, salicylic acid ointment, dexamethasone acetate and clotrimazole cream, griseofulvin ointment, white petroleum jelly (sterile or non-sterile), diclofenac diethylammonium oleum lini methyl salicylate and menthol gel (rubigel), nystatin cream / ointment, salicylic acid and precipitated sulphur ointment, fucidic acid cream, aciclovir cream and diclofenac gel. Viable epidermal or dermal sites (such as local anesthetics or anti-inflammatory agents) may also occasionally include a vasoconstrictor, such as epinephrine, in the formulation to retard systemic uptake of the drugs and, thereby, prolong its local effect.

Rubigel ointment is used to reduce backache, joint pains, sprains and muscle cramp, as well as offering faster penetration of active medication thereby providing faster onset of pain relief; versept cream is used for cleansing and antisepsis of skin and mucous membranes that include wounds, burns, ulcers and abscesses. Avalon NF skin cream is a combination of Neomyci and Fluocinolone acetonide that is used for topical application.

The company also offers anti-hemorrhoid ointment for hemorrhoid patients. Betamethosone valerate ointment is used for anti-inflammatory effect; phenylephrine HCL ointment reduces bleeding and swelling, and relieves itching and discomfort by tightening the blood vessels. Lidocaine HCL local anesthetic ointment provides fast, effective and lasting pain relief.

OPHTHALMIC: -

The present invention relates to novel ophthalmic pharmaceutical compositions comprising an inflammation-treating amount of a 4-aminoquinoline compound, derivative, isomers, or chemical salts, and methods for using these compositions for the treatment of ocular inflammatory conditions by topical administration directly to the eye.
a) **Introduction:** In ocular drug delivery, many physiological constraints prevent a successful drug delivery to the eye due to its protective mechanisms. Drug loss occurs via,

(1) Less capacity of culdary sac (up to 7.5 µl)
(2) Dilution of drug due to lachrymal secretion.
(3) Nasolachrymal drainage

So formulation is administration by increasing the viscosity of dosage form in order to achieve increase in contact time with corneal membrane. This can be achieved by use of ophthalmic semisolids

b) **Ophthalmic administration:** Ophthalmic semisolid compounds are useful for preventing and treating ocular inflammation by application of the compositions to the eye prior to, during and after an inflammatory disorder, especially inflammation of the outer and middle coats of the eye, such as dry eye, conjunctivitis, scleritis, keratitis, and uveitis.

c) **Application and uses:** Galenic supplies a wide range of eye ointments for a variety of ophthalmic infections. The product range includes aciclovir eye ointment, chloramphenicol ophthalmic ointment, gentamicin sulphate ophthalmic ointment, hydrocortisone acetate ophthalmic ointment, tetracycline hydrochloride ophthalmic eye ointment USP 1%, netracycline eye ointment (oxytetracycline eye ointment), oxytetracycline hydrochloride and hydrocortisone ophthalmic eye ointment, triosporin antibiotic eye ointment and sulphacetamide sodium ophthalmic ointment.

Uveitis is an inflammation of the uvea, the middle layer of tissue behind the white of the eye. The cause of uveitis is poorly understood, but a variety of systemic diseases are associated with it. Uveitis has been treated by various classes of compounds including steroids and nonsteroidal anti-inflammatory agents such as dexamethasone, flurometholone, prednisolone, indomethacin, aspirin, flubiprofen and diclofenac.

d) **Risks of ophthalmic semisolids:** Visual disturbances, including blurred vision

e) **Formulation ophthalmic semisolids:** The ophthalmic pharmaceutical composition of the invention includes one or more additional ophthalmic pharmaceutical compositions including buffers, surfactants, stabilizers, preservatives, ophthalmic wetting agents, and ophthalmic diluting agents. Semisolid ophthalmic vehicle contain soft petrolatum.

Absorption and water soluble bases generally are used for preparation of ophthalmic semisolids are

Mineral oil is added to petrolactum to lower its fusion point (but its addition increases chance of separation and to avoid this Ozokerite, Ceresin, Micro crystalline wax in small quantity are added

White petrolatum (white petroleum jelly, white soft paraffin) is a white-colored, translucent, soft, unctuous mass that is inert, odorless and tasteless. It is a mixture of semisolid saturated hydrocarbons obtained from petroleum.

It is practically insoluble in ethanol, glycerin and water but is soluble in chloroform and most fixed and volatile oils. Heating above its melting range (about 70°C) for extended times should be avoided, but it can be sterilized by dry heat

f) **Packaging and labeling:** Package in sterile, collapsible ophthalmic ointment tubes.
For the eye. Keep out of reach of children. Use only as directed. Prevent contaminating the tip of the tube and gel; avoid contact with the eyelids or surrounding areas.

**RECTAL:**

Rectal tissues are much thicker than other gastro intestinal epithelial tissue. Bioavailability of this route depends upon pH of environment, lipid solubility of drug.

**a) Introduction:** rectal preparation includes Ointment, creams; gels are used for application to perianal area. Preanal area is the skin immediately surrounding anus. Substance applied rectally may be absorbs by diffusion into circulation via network of three hemorrhoid arteries (superior inferior and middle hemorrhoid artery)

**b) Rectal administration:** previously this route was use for bowel evacuation. But now a day’s rectal route is widely use for administration of drugs like paracetamol, aspirin, indomethacin, theophyllin, barbiturates, chlorpromazine and several other anticonvulsant agents

**c) Advantage, application and uses:** several advantages of using rectal semisolids are

(1) Large surface area
(2) The ability to bypass first-pass liver metabolism,
(3) Prolongs the residence time
(4) And permeability to large molecular weight drugs, such as peptides and proteins. *(insulin gels administered deep rectally)*

Rectal preparation are used to treat anorectal pruritis, inflammation (hydrocortisone), discomfort with hemorrhoids (hydrocortisone), pain (pramoxine hydrochloride) Astringent (for example ZnO), protectants and lubricants (coca-butter, lanolin)

**d) Risks of Rectal semisolids:** less frequent risk with rectal administration of drug include skin rash, dizziness, pain, headache, abdominal pain, nervousness, diarrhea, feeling unsteady or clumsy, and wheezing

**e) Formulation of Rectal semisolids:** Bases for preparation of anorectal ointment and creams are polyethylene glycol 300-3350, emulsion cream bases containing cetyl alcohol, cetyl ester wax, white petrolatum and mineral oil

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**PATENTED TECHNOLOGIES IN SEMISOLIDS:**

**DELIVERY OF MONOCLONAL ANTIBODY USING SEMISOLID DOSAGE FORM:**

Lysostaphin was formulated into a hydrophilic cream that forms an emulsion with the secretions of the nasal mucosa, and aqueous formulations were made containing the mucoadhesive polymers polystyrene sulfonate and chitosan. Intranasal pharmacokinetics of
the drugs was measured in mice and cotton rats. Lysostaphin formulated in the cream increased nasal retention of the drug as compared to lysostaphin in saline drops. Furthermore, the levels of lysostaphin in the nose after instillation of cream are still above the minimum bactericidal concentration for most bacterial strains. The liquid polymer formulations also resulted in prolonged retention of antibody in the nose, with higher levels as compared to antibody in saline drops.

The results demonstrate that cream and polymer delivery systems significantly decrease the clearance rate of lysostaphin from the nose, thereby enhancing their therapeutic potential for eradicating S. aureus nasal colonization.

**Advances in the formulation of semisolid dosage forms**

The formulation of a suitable semisolid dosage form involves the selection of an appropriate drug carrier system, with a special emphasis on the drug’s physicochemical properties and required therapeutic application. Drug delivery by means of semisolid dosage forms has seen new challenges in the past few years in terms of altered drug-release profiles as well as the enhanced stability of active pharmaceutical ingredients (APIs).