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Research Article

Formulation And Evaluation Of Antiperspirant/Hyperhidrosis Solution

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ABSTRACT

Antiperspirant Solution has gained significant attention in recent years due to their role in controlling hyperhidrosis and bad odor, enhancing personal hygiene and improving overall well-being. This paper provides a comprehensive study overview of the formulation and evaluation of antiperspirant solution, focusing on key aspect such as API, formulation strategies, and evolution parameter. The formulation of an effective antiperspirant solution involves the selection of appropriate active ingredients, such Aluminum Sulphate Octahydrate, including chemical with hydroxethyl cellulose, polysorbate 20 (tween 20), purified glycerol, propylene glycol, disodium EDTA and phenoxethanol utilized as the exipients. The solution was prepared by homogenous mixing API and exipients. Evaluation of antiperasprant solution encompasses a range of physical, chemical and sensory test to ensure efficacy. Parameter such as clarity test, stability test, volatilization test, spreadibility test and irritation test. In conclusion, the formulation and evaluation of antiperspirant solution represent a multidisciplinary endeavor that combines principles of chemistry, pharmacology, dermatology and sensory science. By continually advancing our understanding of formulation principles and evaluation methodologies, researchers and industry professionals can develop antiperspirant solutions that meet the evolving needs and preferences while promoting health and well-being.

INTRODUCTION

Hyperhidrosis (HH) is a pathologic condition characterized by the secretion of sweat in excess to the normal physiologic needs of the body. Patient seeking medical help often fiend sweating, commonly affecting the axilla, palms of the hand or soles of the feet. Psychosocial difficulties, physical discomfort, and disruption are all problems experienced by people. Damp hand may be misinterpreted as a sign of anxiety, and damp axillae soaking through clothes are a cause of acute personal embarrassment. Peoples may feel discomfort related to sodden shoes and clothing and experience difficulties in performing simple tasks at work, such as handling paper or ink, gripping tools[1]. Sweating is the elaboration of a

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fluid secretion on the general body surface produced by sweat glands within the skin. These glands are developed only in mammals in which the evolved, along with sebaceous glands as fur conditioning organ and for defence at the skin surface against microbial invasion. While most mammals process at least rudimentary sweat gland, surprisingly, it is only in higher primates, horse and some bovidae that the organ plays a true major role in the critical physiological function of the skin. The function of the glands seems to be primarily limited to producing substances required for maintenance of a healthy skin or for lubrication contact surface[2]. Thermoregulatory sweating is clearly of selective advantages since it permits work to be done under condition otherwise adverse since it permits work to be done under conditions otherwise adverse to heat dissipation that is above the thermo culture zone. Mathematically and perhaps more automatically only about 1% of human body weight need be evaporated as sweat to prevent a 10o C rise in body temperature. It is clearly the sweat glands that have given humans the ability to excel in tumid climates. The ability to elaborate secretion carries with it potentially heavy expenses as it is biologically impossible to move water without coupling it to the movement of salts[3]. The principle salts in the body fluids and potassium and sodium chloride. Contrary to the common opinion, NaCl is not an abundant substance biological and in no marine animals it must be sought and conserved. Since salt is the principle osmotic ingredients of bloods and extracellular fluid, proper circulation circularly depends on an adequate salts contains in the body[4].

Classification of hyperhidrosis

Hyperhidrosis is classified as a primary or secondary complaint. With regard to anatomic distribution. Hyperhidrosis can be classified into focal indigenous, symmetric, asymmetric, or generalised[5]. Primary HH is idiopathic focal, bilateral, and symmetrical exaggerated perspiration that typically affects the axillae, palms, soles, and craniofacial regions[6] and is not caused by any underline medical diseases or medication. Primary HH is diagnosed in 93% of all cases with HH. It can appear continuously or in phase and does not generally do at night. Primary HH can be convinced by thermal provocations, emotional triggers, or physical excretion[7]. Secondary HH is less common than primary HH and is most constantly related to an underpinning cause. Secondary HH is most commonly classified as generalised but can also present focally or regionally. Secondary HH occurs when the patient is awake or a sleep. Generalized secondary HH may be caused b physiologic condition such as excessive heat, fever, pregnancy, or menopause. Potential pathologic causes for secondary HH can include malignancy, infection (acute &chronic viral infection), and endocrine metabolic disorder (diabetes mellitus/hypoglycaemia, hypothyroidism, thyrotoxicosis, phenochromocytoma, hyperpituitarism and carcinoid syndrome)[8]. Cardiovascular disease (en- docarditis, congestive heart failure, or cardiovascular shock), respiratory disease (respiratory failure), neurologic disorders (stroke or Parkinson disease), or psychiatric disorders, among others, In addition, many drugs can cause secondary gener- alized HH, including antidepressants (tricyclic anti- depressants, anxiolytics, antipsychotics, or selective serotonin reuptake inhibitors), antibiotics (ciproflox- acin), antivirals (acyclovir), hypoglycemic agents (insulin or glyburide), triptans, antipyretics, nonste- roidal antiinflammatory drugs, antiemetics, adren- ergic or cholinergic agents, alcohol, cocaine, heroin (including withdrawal), and many others[9].

Table 1: Secondary causes of hyperhidrosis

Examples of Secondary Causes of Hyperhydrosis		
Generalised Secondary Hyperhydrosis		
Physiologic		Heat
		Fever
		Pregnancy
		Menopause
Pathologic	Malignancy	Lymphoma
		Myeloproliferative Disorder
	Infection	Acute viral or Bacterial Infection
		Tuberculosis
		Malaria
		Brucellosis
		HIV
	Endocrine/Metabolic	Diabetes Mellitus
		Diabetes Insipidus
		Hyperthyroidism
		Thyrotoxicosis
		Acromegaly
	Cardiovascular	Endocarditis
		Congestive Heart failure
		Cardiovascular shock
	Respiratory	Respiratory Failure
	Neurologic	Stroke
		Parkinson's diseases
		Psychiatric disorder
	Drug	Antibiotics (ciprofloxacin)
		Antiviral (acyclovir)
		Triptants
		Antipyretics
		NASIDS
		Cocaine
		Heroin
		Adrenergic or cholinergic drugs
Symmetric Focal Secondary Hyperhydrosis		
		Compensatory sweating
		Physiologic/pathologic gustatory
Asymmetric Focal Secondary Hyperhydrosis		
		Tumour's
		Eccrine Nervous

Material and Method

List of Chemicals

Table 2: List of chemicals

Sr. No	**Name of Chemicals**	**Manufacture Name/ Supplier Name**

1.	Aluminum Sulphate Octadecahydrate $[Al_2(SO_4)_2.18H_2O]$	Chemdyes Corporation.
2.	Hydroxyethyl Cellulose $[C_2H_6O_2]_n$	Chemdyes Corporation.
3.	Polysorbate 20 $[C_{58}H_{114}O_{26}]$	SD Fine Chemicals
4.	Glycerol, Purified $[C_3H_8O_3]$	HiMedia Laboratories Pvt. Ltd.
5.	Propylene Glycol $[C_3H_8O_2]$	HiMedia Laboratories Pvt. Ltd.
6.	Disodium EDTA $[C_{10}H_{14}N_2O_8 2Na 2H_2O]$	Avantor Performance Material Pvt. Ltd.
7.	Phenoxy Ethanol $[C_8H_{10}O_2]$	Chemdyes Corporation.

List of Glassware

Table 3: List of glassware

Sr. No.	Name of Glassware
1.	Beaker
2.	Funnel
3.	Measuring Cylinder
4.	Glass rod
5.	Pipette
6.	Watch Glass

Drug and excipients profile[10][11]

1. **Aluminum sulphate octadecahydrate**

- It is used as a active ingredients.
- Aluminum Sulphate was utilized to give the antiperspirant effect.
- Upto 10% of API was utilized to give desired therapeutic effect on human skin topically.
- Aluminum (Al), also spelled aluminum, chemical element, a lightweight, silvery-white metal of main Group 13 (IIIa, or boron group) of the periodic table.
- Aluminum Sulphate is found in materials used in the pharmaceutical industry, and in manufactured foodstuffs, cosmetics, and tap water. By overcoming the body barriers, Aluminum Sulphate may infiltrate into the blood and lead to toxic effects in liver, bone and the central nervous system

2. **Glycerine**

- Glycerin is commonly classified as an osmotic laxative but may act additionally or alternatively through its local irritant effects.
- it may also have lubricating and fecal softening actions.
- Glycerin suppositories usually work within 15 to 30 minutes.

3. **Hydroxyethyl cellulose**

- Hydroxyethyl cellulose is a polysaccharide derivative with gel thickening, emulsifying, bubble-forming, water-retaining and stabilizing properties.
- It is used as a key ingredient in many household cleaning products, lubricants and cosmetics due to its non-ionic and water-soluble nature.
- It is often used as an ingredient in ophthalmic pharmaceutical preparations such as artificial tear solutions and adjunct agent in topical drug formulations to facilitate the delivery of drugs with hydrophobic character.

4. **Polysorbate 20**

- It is a nonionic surfactant that's used in many pharmaceutical, household, and commercial products

- It's a wetting agent in food products, a washing agent, stabilizer, and solubilizer in industrial applications and laboratory assays.
- It's also an excipient that stabilizes suspensions and emulsions in pharmaceutical products and a lubricant in ophthalmic solutions.

5. Disodium EDTA

- Disodium Edetate is Ethylene-diamine-tetraacetic acid (EDTA) as the sodium salt.
- It is known by several other names, and used widely across industrial and medical purposes due to its unique functionality as a chelating agent.
- It is supplied as a white crystalline, odorless powder with a slightly acidic taste

6. Phenoxy ethanol

- Phenoxyethanol is a colorless liquid with a pleasant odor. It is glycol ether used as a perfume fixative, insect repellent, antiseptic, solvent, preservative, and also as an anesthetic in fish aquaculture.
- Phenoxyethanol is an ether alcohol with aromatic properties. It is both naturally found and manufactured synthetically.
- Phenoxyethanol (EU), or PE, is the most commonly used globally-approved preservative in personal care formulations.

FORMULA DEVELOPMENT

According to the hidden trial method the formula has been categorized in three group Antiperspirant solution I (APS-I), Antiperspirant solution II (APS-II) and Antiperspirant solution III (APS-III).

Table 4: Development Of Formula

Sr. No.	Ingredients	APS-I	APS-III	APS-III
1.	Aluminum Sulphate Octadecahydrate	10gm	10gm	5gm
2.	Hydroxyethyl Cellulose	4.5gm	1gm	1gm
3.	Polysorbate 20	10ml	10ml	10ml
4.	Glycerol, Purified	3ml	3ml	3ml
5.	Propylene Glycol	3ml	3ml	3ml
6.	Disodium EDTA	0.01 gm	0.01 gm	0.01 gm
7.	Phenoxy Ethanol	0.1ml	0.1ml	0.1ml
8.	Distilled Water	100ml	100ml	100ml

Preformulation studies

Organolaptic properties

a. State-

The formulation was taken in a required container and examined with naked eyes.

b. Color-

The formulation was taken in a container and the color of the preparation was observed with the naked eyes.

c. Odor-

The formulation was taken in a suitable container and the fragrance was observed with the nose.

d. Texture-

The formulation was taken in a required container and rubbed the sample on hand to check the texture.

Solubility-

Solubility is a chemical property that measures how many grams of a substance will dissolve in a given volume of solution. It is the ability of a substance, known as the solute, to form a solution with another substance, the solvent. The solubility test is performed by using various solvents 10ml water, chloroform and methanol and 0.01g drug has been dissolved by continuous staring.

Flow property

6Bulk and Tapped density

Bulk density measurement carried out by using flat- round measuring cylinder with a volume of 100 ml. The measuring cylinder was half filled with the 10gm of the powder and the reading was observed to the nearest milliliter.

Bulk density = w/v0

After 50 and 100 taps the corresponding reading was observed to the nearest milliliters. The tapped volume was recorded when the difference between the two volumes was smaller than 1 ml.

Tapped density: After 50 tapping = w/v1

After 100 tapping = w/v2

Angle of Repose

It was determined by fixed funnel method onto a bottom graph paper. The funnel was fixed on a height, and moved according to the height of the conical heap in order to keep a constant distance between the top of the heap and the funnel. The angle of repose was determined by measuring the height of the cone of powder with the help of the formula.

Tan α = height/base

Hausner's Ratio

Flow property was defined according to the Hausner ratio.

Hausner ratio = (Tapped density)/ (Bulk density)

Flow of powder was measured using a standard funnel. In a dry funnel, whose bottom opening has been blocked, the sample was introduced without compacting. After removing the blockage from the bottom opening of the funnel, the time taken for the entire sample to flow out thought the funnel was measured.

Hausner ratio = (tapped density/ bulk density)

Compressibility Index

Compressibility index was determined according to Carr's index

Carr's Index = (Tapped density) – (Bulk density)
(Tapped density)

Method of antiperspirant solution

- Wash and sterile all the needed glassware.
- Then measure 100ml distilled water using measuring cylinder (100ml) and poured it into 250 ml of beaker.
- Measure the Aluminum Sulphate Octadecahydrate and Hydroxyethyl Cellulose as per the formula mention above and poured into water with continuous staring.
- After mixing then heat the solution up to 60o C to 70oC on burner.
- After heating cool the solution and then pour propylene glycol and glycerin 3ml into solution with continues staring.
- After that add 10ml polysorbate 20 into the solution and 0.01g disodium EDTAE with continuous staring.
- After mixing all the chemicals filter the solution using muslin cloth and add the fragrance in the solution as q.s.

EVALUATION PARAMETER

Organolaptic properties

a. State –

The formulation was taken in a required container and examined with naked eyes.

b. Color-

The formulation was taken in a container and the color of the preparation was observed with the naked eyes.

c. Odour-

The formulation was taken in a suitable container and the fragrance was observed with the nose.

d. Appearance-

The formulation was taken in a container and the appearance of the preparation was observed with the naked eyes

Stability test

- Stability Testing is the process for determining, through storage at defined conditions and testing at specific intervals, how long a drug substance or product remains safe and effective at particular storage conditions.

- The solution was stored in a transparent container and was stored at room temperature. After 1 month the solution was checked for its organoleptic property.

Irritation test

- Skin irritation testing, also known as the Skin Irritation Test (SIT), is a non-animal method that predicts whether a chemical or substance can cause skin irritation. The test involves applying a chemical to a reconstructed human epidermis model for 42 minutes, then incubating the model for 42 hours.
- The formulation which we have made it applied on the skin and kept for 5 minutes and then we observed it. Wash the hand and take 2 minute break and repeat same process.

Spreadability test

- Spreadability is a measure of how easily a product can be spread. It is a desired characteristic of many products, including: Butter, Margarines, Chocolate spreads, Creams, and Waxes.
- Mark a 1 cm diameter circle in the center of the slide.
- Place 1drop of solution dropper on the circle.
- Place another glass slide on top of the gel.
- Note the time it takes for the two slides to separate in seconds.

Volatilization test

Volatilization is a process that converts a chemical substance from a liquid or solid state to a gaseous or vapor state.

In this process we have used 5ml each from formulation and poured into petridish and it into room temperature, hot air oven at 50oC and at cold temperature 2-3oC.

RESULT

The active ingredient tested in this paper exhibit the considerable properties as mentioned below.

Organoleptic Properties:

As per the method given in 6.1 the following result obtain the color was seen white, the odor of the API is odorless, the state of the API was solid amorphous in nature.

Table 5: Organoleptic properties of API

Sr. No.	Organoleptic Properties	Observation
1.	State	Solid fine powder
2.	Color	White
3.	Odor	Odorless
4.	Texture	Amorphous nature

Solubility

As per the method given 6.2 the following result obtain

Table 6: Solubility test

Sr. No.	Solvent	Observation
1.	Water	Soluble
2.	Chloroform	Slightly Soluble
3.	Menthol	Insoluble

Flow Property

- As per the method given 6.3.1 the following result obtain that
- The bulk density of the preparation was 0.76 g/ml.
- Tapped density of preparation after 50 times = 0.344g/ml and after 100 tapping = 0.4 g/ml.

Angle of Repose

- As per the method given 6.3.2 the following result obtains that angle of repose of

aluminum sulphate 38.65 which is fair(aid not needed).

Hausner's Ratio

- As per the method given 6.3.3 the following result obtains that Hausner's ratio of the API was 0.35 g/m3.

Compressibility Index

As per the method given 6.3.4 the following result obtains that Carr's compressibility index of the API was 36%.

Organoleptic Properties:

As per the method given in 8.1 the following result obtain the color of the folrmulation was seen milkish white, the odor of the formulation is lavender flower, the state of the formulation was liquid in nature and appearance of the formulation was opaque nature.

Table 7: Organoleptic properties of formulation

Sr. No.	Organoleptic Properties	APS-I	APS-III	APS-III
1.	State	Liquid	Liquid	Liquid
2.	Color	Milkish white	Milkish white	Milkish white
3.	Odor	Lavender flower aroma	Lavender flower aroma	Lavender flower aroma
4.	Appearance	Opaque	Opaque	Opaque

Stability Test

As per the method given in 8.2 the following result obtain the preparation was found safely stable at room temperature after the inspection of 1 month.

Day 1

Table 8: Stability test day 0

Sr. No.	Formulation	Color	Odor	Appearance
1.	APS-I	Milkish White	Lavender Flower Aroma	Opaque
2.	APS-II	Milkish White	Lavender Flower Aroma	Opaque
3.	APS-III	Milkish White	Lavender Flower Aroma	Opaque

Day 30

Table 9: Stability test day 30

Sr. No	Formulation	Color	Odor	Appearance
1.	APS-I	No Change	No Change	No Change
2.	APS-II	No Change	No Change	No Change
3.	APS-III	No Change	No Change	No Change

Irritancy Test

As per the method given in 8.3 the following result obtain

Table 10: Irritancy test

Sr. No.	Formulation	Result
1.	APS-I	No Irritancy
2.	APS-II	No Irritancy
3.	APS-III	No Irritancy

Spreadability Test

As per the method given in 8.4 the following result obtain

Table 11: Spreadability test

Sr. No.	Formulation	Solution Spread (cm)	Time
1.	APS-I	5cm	31 sec
2.	APS-II	7cm	25 sec
3.	APS-III	7cm	27sec

Volatilization Test

As per the method given in 8.5 the following result obtain

1. at normal room temperature

Table 12: Volatilization test at normal room temperature

Sr. No.	Formulation	Before	After(30minute)
1.	APS-I	5ml	No Change
2.	APS-II	5ml	No Change
3.	APS-III	5ml	No Change

2. at 50oC in hot air oven

Table 13: Volatilization test at 50ºC

Sr. No.	Formulation	Before	After(30minute)
1.	APS-I	5ml	4.9ml
2.	APS-II	5ml	4.8ml
3.	APS-III	5ml	4.8ml

CONCLUSION

As per over overview we have done we conclude that HH in cure, unpleasant, physical and psychological effect streaming from the volume of sweat production. The majority of patient's survey for treatment related mainly to the upper limb and mainly to the upper limb and many has suffered for several years before seeking help. Although many treatment used varies, depending in part on the area of the body affected and servecity of the problems. The ideal treatment of choice should be successfully, safe and inexpecive. Conservative treatment should be taired before progressing to the more permanent and usually irreversible effect of surgery. Botulinum toxin is a relatively new treatment and provides good results in achieving euthidoris over prolonged periods of time. It is particularly useful in the treatment of axillary hyperhidrosis and will probably replace tissue excision of symapathetomy as a treatment for aggressive axillary hyperhidrosis, such as that seen in frey syndrome, are also easily and adequate treated by botulinum toxin. Sympathotomy and sympathectomy are the most invasive procedure for HH, but for these patients whose daily life was disrupted by HH, despite trails of other therapeutics option, sympathetic chain disruption may present an appealing opportunity for treatment. In order to limit the risk of CH and chest pain, parasthesias and scars, experimentation with altering the techniques and levels disrupted during sympathotomy/sympathectomy continues. Preliminary investigations of new technology

(laser, microwave, and ultrasound) for less invasive eccrine glands disruption are promising.

As per our formulation has been developed in which the formulation contain Aluminium Sulphate Octadechydrate as API and various exipients like glycerine, hydroxyethyl cellulose, polysorbate 20, propylene glycol, disodium EDTAE and phenoxethanol are mixed with API and formulation was developed. The organoleptic property of the API before formulation was the color of the API was seen white, the odor of the API is odorless, the state of the API was solid amorphous in nature. In the solubility test of the API was dissolved in 10ml of distilled water, chloroform & menthol after dissolution we observe in water the API was soluble, in chloroform the API was slightly soluble & in menthol API was insoluble. The flow property of API was performed through which the bulk density of the preparation was 0.76 g/ml, tapped density of preparation after 50 times = 0.344g/ml and after 100 tapping = 0.4 g/ml, angle of repose of API is 38.65 which is fair (aid not needed), Hausner's ratio of the API was 0.35 g/m3 & Carr's compressibility index of the API was 36%.The organolaptic property of the prepared formulation was checked which are same for all APS-I, APS-II, APS-III, which are observed color of formulation milkish white, the odor of the formulation is lavender flower aroma, the state of formulation was liquid in nature and appearance of the formulation was opaque nature. The preparation was found safely stable at room temperature after the inspection of 1 month the result was obtained which are observed color of formulation milkish white, the odor of the formulation is lavender flower aroma, the state of formulation was liquid in nature and appearance of the formulation was opaque nature. The spreadibility of the APS-III is observed better because it take less time travel the 7cm. Volatilization test was performed to check volatile nature of solution there is no change in the solution when it kept at room temperature, and the 0.1ml change was observed in APS-II & APS-III, in F1 0.2ml change was observed when it kept in hot air oven at 50oC. All the three antiperspirant solution showed significant different activities. Based on the result all three formulations ASP-I, ASP-II, ASP-III, were stable. On the basis of comparative studies ASP-II formulation is most suitable and compatible. The antiperspirant is safe to use & it can be used as the provision of a barrier to protect skin.

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