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FORMULATION DEVELOPMENT AND EVALUATION OF MICONAZOLE NITRATE EMULGEL

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Abstract: Topical Emulgel containing Miconazole Nitrate can be used in treatment of many skin infections such Jock Itch, Athlete's Foot, Ring worm and Tinea Versi color. This hydrophobic drug was incorporated to emulgel for application to skin. Stable emulgel was formulated in terms of physically and chemically stability, for drug delivery. Experimental designs are used for the selection of optimized batch. Formulation was evaluated for viscosity, % Drug content, % Drug release, Spreadability and pH.

Keywords: Emulgel, phytochemicals.

Introduction*:* It is topical drug delivery system which hasmore efforts towards drug delivery and most effective formulations that has been proved by dermatological and cosmeticology.

This may be either O/W or W/O type gelled by mixing the gelling agents. Incorporation of emulsion in gel base increases stability and make dual controlled release system. Due to excess oily base and insoluble Excipients shows better drug release in comparison of other dosage form. Gel phase makes the formulation non-greasy and good patient compliance. When bothgel & emulsion are combined thus forms emulgel. O/W or W/O emulsion used as vehicle to deliver the drug to skin. They have ability to penetrate to skin. This is promising drug delivery system for hydrophobic drugs. There are major advantages of gel but limitation for delivering hydrophobic drug [18]. Have favorable properties such as thixotropic, greaseless, and easily spreadable.[19]

Incorporation of hydrophobic drugs: Not incorporated directly in gel base because of solubility and problem occurs during drug release. Incorporation of hydrophobic drug in oil phase and oily globules dispersed in aqueous phase (O/W) and mixed in gel base. Provides better stability and release drug.[20]

Better loading capacity: Niosomes & Liposomes are nano sized and due vesicular structure there may be chance of leakage and result in less erentrapment efficiency. Gel shave betterl oading capacity.

Better stability: Other topical dosage form is less stable than emulgel. Powders are hygroscopic in nature, creams shows phase separation & ointment shows rancidity.[21]

No intensive sonication: Vesicular molecules needs sonication and cause drug degradation and leakage.

Controlled release: Used for prolonged period effect of drug which possess short half-life.[22]

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Material & Methods:

Table No. 1.: List of Equipments:

Name of equipment's	Make and Model
Digital weighing balance	Shimadzu ATX224
Mechanical stirrer	Remi Lab
Rectangular water bath	Rolex
Franz diffusion cell	Fabricated by Barod a glass work, Vadodara
UV Visible spectrophotometer	LABINDIAAnalyticalUV-VIS3000+
Digital pH meter	Chem line CL-110
Brookfield Viscometer	DV-II+
Pro Stability chamber	Phoenix Lab Instruments
FTIR spectrophotometer	Bruker

Table No. 2.: List of Excipients

Excipients	Uses	Name of supplier
Miconazole Nitrate	Drug	Mars Remedies Pvt. Ltd
Carbopol 934	Gelling agents	Chiti-chem corporation
Carbopol 947	Gelling agents	Balaji drugs
HPMCK100M	Gelling agents	Chemdyescorporation
Light liquid paraffin	Oil phase	Qualikems finechem. Pvt. Ltd.
Propylene glycol	Oil phase	Suvid hinath laboratories
Span-20	Surfactant	Qualikems finechem. Pvt. Ltd.
Peppermint oil	Penetration enhancers	Aaturinstru.Chem.
Triethanolamine	Neutralizing agent	Chemdyes corporation
Methyl Paraben	Preservatives	Oxford lab.

Table No. 3. Formulation Table of Emulgel

Ingredients (%W/W)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Miconazole Nitrate	1	1	1	1	1	1	1	1	1
Carbopol 934(%)	1	1.5	2	-	-	-	-	-	-
Carbopol 947(%)	-	-	-	1	1.5	2	-	-	-
HPMCK 100 M(%)	-	-	-	-	-	-	1	1.5	2
Light liquid paraffin (ml)	6	6	6	6	6	6	6	6	6
Propylene glycol (ml)	5	5	5	5	5	5	5	5	5
Span-20(ml)	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Peppermint oil(ml)	2	2	2	2	2	2	2	2	2
Methyl Paraben(ml)	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03
Triethanolamine	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s
Water	50	50	50	50	50	50	50	50	50

Method of Preparation For Emulgel:

Step 1: Formulation of emulsion O/W or W/O.

Step 2: For mulation of gel base.

Step 3: Incorporation of emulsion into the gel base with continuous stirring.

Preparation of Emulgel Completed in 3 Steps: Emulgel is prepared either O/W or W/O. Emulsion is two phase system which is essential to permeate hydrophobic drug in skin.Some Excipients used in the preparation of emulsion (oil phase and liquid phase). Aqueous phase prepared by using emulsifying agents in distilled water and oil phase prepared by using surfactant dissolve in oil phase having drug in methanol. Both phases heated at 70-80°C aqueous phase added to oily phase with continuou sstirring at normal room temperature. Second step to prepare gel base by using different types of gelling agents in water. And then to incorporate emulsion in gel base with continuous stirring and pH is adjusted by using neutralizing agents (Triethanolamine).

Preformulation Studies:

Identification of Drugs: Melting point of Drug (Miconazole Nitrate) carried outbyusingmeltingpointapparatus.Compoundwastakeninopencapillarymethod.Small amount of sample was transferred in capillary tube. Then it was placed in melting point apparatus and temperature was noted down at which the drugs start to melt.

Calibration curve of Miconazole Nitrate:

Calibration curve in Ph 5.5 phosphate buffer:

Miconazole Nitrate (about100mg) dissolved in phosphate buffer of pH5.5.Volume was made upto100 ml in volumetric flask by using phosphate buffer pH 5.5. 10 ml stock (1 mg/ml) diluted with solvent up to 100 ml. 100 mcg/ml diluted with solvent to obtained solution 5, 10, 15, 25, 30 mcg/ml. measured at 220 nm by using UV visible spectrophotometer by phosphate buffer pH5.5 as blank media.

Preparation of pH 5.5 phosphate buffer solution: 13.61gm of potassium dihydrogen was dissolved in water to produce 1000 ml and 35.81 gm of disodium hydrogen phosphate was dissolved in water to produced 1000 ml mix both solution by taking 96.4 ml

potassium hydrogen phosphate & 3.6 ml of disodium hydrogen phosphate to produce 100 ml solution adjust the pH if necessary.

Organoleptic characteristics of drug: Drug was examined for organoleptic

Characteristics such as colour, odour which were reported in descriptive terminology.

Solubility determination: Carried out in different solvent by adding excess amount of drug in solvent and kept in screw capped tubes containing solution onmechanical shaker for 24 hours. After solution transferred in other test tubes andcentrifuges at 2000 RPM for 30 minutes at room temperature. 1 ml solution takenfrom each test tube and was placed in 100 ml volumetric flask and diluted the media and was filtered through whatman filter paper. Absorbance was taken at 220nm.

Post formulation studies:

Physical appearance: Observed for visual inspection for their colour, homogeneity & smoothness. [62]

pH: Formulation were inspected visually by their colour & pH. 1gm of formulation was weighed and dissolved in 100ml of distilled water and was soaked for 1 hour. pH value of 1% aqueous solution of emulgel was measured by digital pH meter.

Spreadability: Determined by using modified spreadability apparatus which ismade up of wooden block provided by pulley at one end. Ground slide fixed onblock. About 1 gm of formulation placed between slide and ground slide was provided with hook. Weight putted on top slide and for 5 minutes to remove excess amount of air present in the formulation and thus provides a uniform layer of emulgel between the slides. Excess of amount of formulation was removed from the edges. Top plate subjected to pull with string attached to hook time required by top slide to cover the distance was noted down. Short interval of time indicated better spreadability.

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Result and Discussion:

Organoleptic Properties:

Table No 4. : Organoleptic Properties of Miconazole Nitrate

Properties	Results
State	Solid
Description	Whiteoroff-white crystalline powder
Odour	Odourless
Color	White to offwhite

Physical properties of drug:

TableNo.5 : Melting point of Miconazole Nitrate

Experiment	ReportedMelting point	Observed Melting point
Melting point	159-163°C	160-165°C

Solubility

Table No.6 : Solubility of Miconazole nitrate

Experiment	Parameter	Observation
Solubility(mg/ml)	Solubility in distilled Water (mg/ml)	0.095±0.02
	Solubility in phosphate Buffer pH 5.5(mg/ml)	0.407±0.05
Each observation value are expressed as mean±S.D.n=3		

Characterization of Preliminary Batches From F1to F9

TableNo.7 characterization of preliminary batches F1 to F9

Formulation batch	Viscosity (CPS)± S.D(n=3)	Spreadability (gm.sm/sec)± S.D(n=3)	pH±S.D(n=)	Drug Content (%) ±S.D(n=3)
F1	9325±1.52	9.24±0.7	5.6±0.05	98.87±0.05
F2	9588±1	5.45±0.1	5.7±0.05	98.96±0.06
F3	9897±1	16.65±0.8	5.3±0.04	99.23±0.05
F4	7147±1.52	7.29±0.1	5.5±0.1	98.54±0.05
F5	8745±1.52	5.19±0.2	5.6±0.04	98.59±0.03
F6	9245±1.52	3.87±0.05	5.6±0.05	98.89±0.05
F7	1354±1.52	4.98±0.3	5.6±0.1	97.67±0.1
F8	2568±1.52	8.64±0.5	5.7±0.05	97.98±0.05
F9	5241±1.52	5.54±0.8	5.5±0.1	97.94±0.05

IN-VITRO DRUG RELEASE STUDY OF PRELIMINARY BATCHES F1 TO F9

Table No.8:In-Vitro drug release study

Time (hr)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0.5	6.16	8.69	9.53	6.51	8.68	9.67	5.93	8.68	8.85
1	10.34	12.04	16.81	9.61	12.76	15.99	9.57	11.94	13.78
2	16.17	18.85	24.56	15.40	17.65	21.35	17.18	18.76	22.16
3	21.94	26.29	31.09	19.86	22.13	28.41	22.47	27.89	31.79
4	30.59	34.61	40.63	29.70	32.79	38.29	32.38	37.06	39.71
5	40.74	43.98	53.64	37.82	40.58	46.60	38.99	45.06	45.97
6	52.27	55.02	64.40	49.50	51.42	55.74	51.54	53.64	55.87
7	63.41	64.76	75.31	59.66	62.37	66.32	59.47	61.80	64.20
8	74.60	76.64	85.15	74.47	78.22	79.73	72.25	78.13	79.06

Table No. 9: Characterization of Optimized Emulgel Batches

Formulation batch	Viscosity (CPS)±S.D(n=3)	Spreadability (gm.sm/sec)± S.D(n=3)	pH±S.D (n=3)	Drug Content (%)±S.D(n=3)
E1	9641±1	13.49±0.23	5.6±0.05	97.12±0.07
E2	9823±1.52	13.33±0.35	5.2±0.1	96.6±0.1
E3	8798±2.51	10.89±0.12	5.1±0.05	97.05±0.03
E4	9029±2.08	12.69±0.26	5.2±0.11	98.6±0.07
E5	9598±1.52	15.75±0.28	5.2±0.05	97.08±0.03
E6	9542±2.64	13.45±0.23	5.4±0.05	97.12±0.02
E7	9209±2	10.66±0.11	5.4±0.05	98.64±0.05
E8	9682±2	14.89±0.55	5.7±0.17	98.6±0.07
E9	**9922±1.52**	**15.22±0.17**	**5.7±0.15**	**99.86±0.03**

Conclusion:

Emulgel is promising topical drug delivery system and better suitable for delivery of hydrophobic drug to skin. Miconazole Nitrate was successfully formulated in emulgel to deliver the drug to the skin.From the screening process the parameters and preliminary study concluded that all evaluation parameter like physical appearance, viscosity, pH, spreadability, % drug content determination, in-vitro drug release study should have optimum result for proper formulation for emulgel. From the above study emulgel shows maximum viscosity, spreadability, % drug content determination, in-vitro drug release study was found in carbopol 934 and liquid paraffin were selected for formulating the emulgel.From in-vitro drug release study E9 shows maximum drug release 99.28% in 8 hours with good physical properties.

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Errata

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The authorship of the article titled should be corrected as follows and the article will be considered as corrected authorship:

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