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EXPLORING EXTRUDABILITY: DESIGN, DEVELOPMENT ANDCOMPARATIVEANALYSIS OF MEASUREMENT METHODS.

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Abstract:
Objective: The main objective of our study was to design, development and compare the present method to measure extrudability and novel developed apparatus for extrudability measurement of semi solid dosage form.
Methods: Traditional method to measure extrudability and apparatus based extrudability testing method.
Results: The novel apparatus is developed for measuring extrudability of semi solid formulations which showed easy, fast, accurate and precise results.
Conclusion: In field of pharmaceutical industry, the evaluation of extrudability has limited set of techniques do not have specific process and not shows accurate, precise results. To overcome the limitations of traditional method novel apparatus designed and developed which gives more promising option and for accurate, precise, reliable determination of extrudability.

1.Introduction: [1,2,3,11,15]

Pharmaceutical semi solid preparations may be defined as topical products intended for application on skin or assessable mucous membranes to provide localized and sometimes systematic effects at the site of application. In general, semi solid dosage forms are complex formulations having complex structural elements.

Semi solid are characterised by three-dimensional structure that is sufficient to impact solid like character to the undisturbed system but that is easily broken down and realigned under applied force. Semi solid dosage forms include creams, gels, ointments and many more. There are many evaluations performed for semi solid formulations like its pH, viscosity, spreadability and extrudability. Extrudability is the power required to push or force something out of something. A compression- extrusion test consist of applying force to a product until it flows through an outlet (or number of outlets) that may be in one or more slots or holes that in the test cell. The product is compressed until the structure of product is disrupted and extrudes through outlets.
The development of methods for extrudability determination was intensively conducted from past which is traditional method to measure extrudability. Using this method at the time and the

available assortment of excipients, relevant techniques for evaluation of this chrematistics was developed and extrudability optimums that are still used in development of semi solid dosage form. However, a significant expansion of excipient for pharmaceutical technology and improvement for analytical and technological methods makes it necessary to review and validate the methods for measuring the extrudability for their use in modern dosage forms. The study aims to analyse the Comparision between existing method and novel developed apparatus for determining the parameter "extrudability", by using two most popular pharmaceuticals in form of semi solids.

2.Material and Methods: [4,5,6,8,10]

The samples of the semi solid dosage form were selected as objects of the study.

Material for traditional method testing aluminium collapsible tube were taken from pharmaceutics lab whereas material like iron stand, fitting nob, holder plate, pressure applying tool from workshop of mechanical department and weighing balance DT600 from pharmaceutics department.

The traditional method for extrudability measuring in semi solid dosage forms. It should be considered that each two different persons will apply pressure on aluminium collapsible tubes to measure extrudability count that means how much quantity of dosage form get extrudes whereas for newly developed instrument-based method should be considered to take results by applying fixed pressure on tubes containing dosage form and results were calculated and compared.

Two semi solid dosage form formulation:

2.1 Formulation of cold cream: [5]

Table 1. Formulation of cold cream

Ingredients	**Quantity taken(10gm)**	**Use of ingredients**
Bees wax	1.6gm	Emulsifying agent
Borax	0.08gm	Emollient
Methyl paraben	0.02gm	Preservative
	5ml	Laxative

Liquid paraffin		
Water	3ml	Diluent
Perfume	0.31	Fragrance

2.2 Formulation of ointment: [13,16]

Table 2: Formulation of ointment

Ingredients	**Quantity**
Propylene glycol	1.8gm
Lanolin	1.4gm
Petroleum	6ml
Paraffin	0.5gm
Span 83	0.2gm

2.3. Traditional method: [**7,8,9,10,11]**

The most common method for measuring the extrudability is tube pressing method. This method is used in most of pharmaceutical labs to measure extrudability count of semi solid dosage form. This method is messy and time consuming.

During the measurements using the tube pressing method, 10gm of sample prepared before the test and it filled in tube then it will place on platform the pressure has applied of 500gm and extrudability has been calculated in grams and the results.

Fig No. 1: Traditional method for extrudability measurement

2.4. Limitations of previously used method: [11,12]

The previously used slide method, also known as the universal tube filling technique, has been a widely used method for extrudability detection. However, it has certain limitations:

1.Subjectivity and human error.
2.Time-consuming process.
3.Limited throughput.
4.Potential for sample contamination.
5.Lack of automation.
6.Limited storage and shelf life.
7.Difficulty in detecting accurate extrudability count.

2.5. Novel apparatus to measure extrudability:

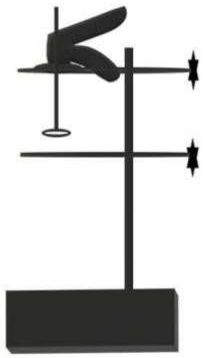

Fig No.2: Novel apparatus for extrudability measurement

2.6. Novel apparatus for extrudability measurement:

The instrument made of materials like iron stand, fitting nob, holder plate, pressure applying tool etc.

Iron stand: this is provided to attach all tools on it and gives support to instrument. It is made of iron.

Holder plate: holder plate holds the tube containing 10gm semi solid formulation.

Pressing piston: this is main part of instrument which has fixed amount of weight(500gm).

Piler like press: this is made of iron and works to press.

Screw knob: fitting is provided to attach pressure applying tool to iron stand.

2.7. Method/ Process:

15mm aluminium tube containing 10gm semi solid has placed on tube holder.

↓

Pressure of 500gm weight applied by pressure applying piston.

↓

Semi solid extrudes through tube as pressure applied.

↓

Extruded amount collected in petri dish and weighed on weighing balance.

↓

As per the criteria extrudability rated as poor (if sample extruded <1), good (if sample extruded >1) or excellent (if sample extruded >2).

Table 3: To rate extrudability of semi solid formulation:

Extruded amount of semi solid	Extrudability
<1	Poor
> 1	Good
>2	Excellent

2.8. Advantages of novel apparatus for extrudability measurement:

1. It's easy to apply fixed and uniform pressure on container having semi solid formulation.
2. Extruded amount is same as pressure is fixed and uniform.
3. Accurate results will get with instrument.
4. Instrument is easy to handle and operate.
5. It's useful for lab level evaluation testing of semi solid formulations.
6. Calculation of results is easy.

Table 4: Comparision of traditional method novel apparatus for extrudability testing

Traditional method for extrudability testing	**Novel instrument based extrudability testing**
No fixed and uniform pressure has applied on container.	Fixed and uniform pressure has applied on container.
Extruded amount varies as pressure varies.	Extruded amount is same as pressure is fixed and uniform.
No accurate results were found.	Accurate results were found.
Messy process.	Instrument is easy to handle.
Result calculation is not easy.	Results calculation is easy.

3.Fabricated device:

Fig No.3: Fabricated device

4.Results:

Prepared formulations were evaluated for measuring extrudability with traditional method and novel apparatus. The results obtained by traditional method were repetitive and with errors whereas with novel apparatus the results were non repetitive, accurate and precise.

Table 5: Extrudability results using tube pressing traditional method

Sample	Weight extruded with 500gm weight
Cold cream	1gm
Ointment	0.8gm

It observed that there was discrepancy between expected and observed results in traditional method of measuring extrudability. This method claims that when 500 gm pressure applied on tube containing 10gm semi solid dosage form extrudes 80% semi solid but actually it found that only 10% to 15% semi solid extrudes through tube. So, it is lacking the accuracy, repetitive results and this could be due to inconsistent pressure application which varies results of extrudability.
To overcome limitations of traditional method a novel apparatus to measure extrudability developed and pressure of 500gm fixed on it which applied with pressure piston. So, the results of extrudability found accurate, precise and apparatus is easy to handle and extrudability count found for semi solid formulations.

Table 6: Extrudability results using novel apparatus based extrudability testing method

Sample	Weight extruded
Cold cream	1.57gm (Excellent)
Ointment	0.60 gm (Poor)

Results for cold cream: results for cold cream showed that 1.57gm amount extruded and it was rated as good extrudability as it is >1gm.

Results for ointment: results for extrudability testing with novel apparatus showed 0.60gm amount extruded. So, it was rated as poor extrudability as it is <1gm.

Results for marketed formulation: results for extrudability with novel apparatus showed 3.02gm amount extruded. So, it as rated as excellent extrudability as it is >2gm.

Table No. 7: Results for various lab formulation and standard marketed formulation

Sample	Extrudability with traditional method (gm)				Extrudability with novel apparatus (gm)
	R1	R2	R3	Mean	
Cold cream	1	0.7	1.3	1	1.29
Ointment	0.5	0.8	1.2	0.83	1.57
Colgate tooth paste	1.6	1.4	2.1	1.7	1.53
Iodex gel	1.2	1.5	1.9	1.53	1.26
Clindamycin gel	0.9	1.1	1.6	1.2	1.59

Conclusion:

In field of pharmaceutical industry, the evaluation of extrudability for semi solid dosage forms has limited set of techniques. Traditional method has been used from so long to measure extrudability testing which varies the results for same dosage form and leads to non-precise results. So, for more promising option and for accurate, precise, reliable determination of extrudability is by using "novel method for extrudability measuring method." It uses the various tools for suitable measuring of extrudability and allows comprehensively evaluating extrudability parameter.

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