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TABLET DIVISIBILITY STRENGHT MEASUREMENT AND OBSERVATIONS ON DIVISIBILITY ISSUES OF TABLET BREAK LINES

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ABSTRACT

Performance assessment of tablet division using break lines has evaded at all levels by the personnel involved in the drug industry. No test for the measurement of tablet divisibility strength is available. Specifications for the divided parts of a tablet in the European Pharmacopoeia are not implemented by the industry. Studies are wanting on the performance of tablet division in the hands of consumers, many of whom are senior citizens with multiple morbidities. In this study experiments were designed in relation to divisibility contributing parameters of a tablet. New attachment part, the Tablet Divisibility Chuck was designed to be fitted in to the electronic tablet hardness tester facilitating the measurement of the new parameter, the Tablet Divisibility Strength. The availability of this quantified test will greatly facilitate the industry to monitor and address the tablet divisibility issues. A model 'tablet divisibility dash board' displaying all of the tablet divisibility contributing parameter was introduced. It facilitates the industry to manipulate the multiple parameters associated with the tablet divisibility to favorable values. In the tableting operation, the compression pressure adjustment together with excessive pressure release mechanism should be judiciously fine- tuned with tablet divisibility in mind. The Tablet Divisibility Strength and the pharmacopoeia Uniformity of Weight requirements for the divided tablet parts should be an integral part of a tablet product dossier. Since an acceptable validated tablet divisibility strength of a given product is both mechanical and community based, it has a good prospect of replacing the current tablet hardness test.

KEYWORDS: Tablet break line, tablet break valley, Tablet Divisibility Chuck, Tablet Divisibility Strength, Tablet Divisibility Dash Board, double curvature convex tablets, disclets, globelets.

INTRODUCTION

The new solid dosage form at the time of its invention could have looked much like a miniature table and presumably it was therefore termed a tablet, meaning a diminutive table (circa 1500). The tables in that era occurred naturally among rock formations and were of solid structures. The physical attributes of this solid table constitute the foundation for all shapes of tablets that followed and being manufactured thereafter. At a later date a need must have arisen to break the tablet into two for the easy administration in to younger patients. Then came the idea of providing a break line to facilitate the division. This can be conceived as the birth of the flat tablet with a break line and serves as the fulcrum around which easily divisible tablets should be designed.

With time biconvex tablets were introduced for the purpose of sugar coating. Uncoated biconvex tablets were introduced to give an additional shape to distinguish different medications from too many flat shaped tablets. The break line was later introduced in to biconvex tablets too. It is possible in the early days and followed to the present day, that the curved surface features unfavorable for gripping the convex tablet and comparatively much thicker center of the tablet were not taken into consideration in providing deeper break lines. The concept of 'diminutive solid table' was overlooked.

There are many biconvex tablets currently made with comparatively shallow break lines that resist division. Subconsciously, most product information leaflets limit the claim on these tablets to "one side with a break line" with no claim of equal division, with only one product claiming that the "tablets can be divided in to two equal halves Biconvex tablet may be imagined as a flat tablet on to which two additional parts in the form of slices of a sphere have been cemented over the two sides of flat surfaces. The product is more "globular" than "tabular". In other words, the original flat tablet design is hidden within the convex tablet.

Figure 1: Drawings displaying formation of a convex tablet hiding the flat tablet within.

From a mechanical engineering point of view, one should designate this product as a 'Globelet' or 'spherelet' that will put everything in perspective including why the convex tablets resist division. Shallow convex tablets may be better described as 'disclets'.

It has become a trend in the industry to provide shallow break lines (BL) for tablet division merely for the sake of making an impression on the consumers. The pharmaceutical manufacturers need to interacted closely with the tablet tool manufacturers explaining and demonstrating the purpose of break lines. The tool manufactures should be provided with feedback as to the divisibility performance of the tablets made with break line embossed punches. In many instances it is not possible to divide tablets along the BL particularly among biconvex tablets. Some resort to risky division with the knife. The problem is not addressed apparently as it lies in a gray area between engineering and healthcare fields where overlaps are quite rare. It is also important to implement the uniformity of weight test under subtitle 'Subdivision of tablets' of the Eur. Pharm.

Depending on the tablet shape, currently the BLs are provided for tablet division in to 4, 3 or 2 equal pieces so that 0.25, 0.33, 0.5, 0.66, 0.75, 1.25, 1.5 or 1.75 dose of the intact tablet could be administered, an arrangement of great benefit in pediatric extemporaneous dosing practice and where patient titration is required.

Dose flexibility may be important for drugs with highly patient-dependent potency or a narrow therapeutic index.(van der Steen et al., 2010) Pediatrics and geriatrics often use doses that may not be available in marketed strengths. Flexibility of dosage is also important when tablets are prescribed "if needed" and the experienced patient may wish to dose a part of a tablet.(van Santen et al., 2002).

An advantage of scored tablets is the ease of swallowing by dividing in to two parts. This is especially important on large tablets. (Carr-Lopez, n.d.).

Another advantage of scored tablets is the cost savings. Break line on the tablets reduces the number of tablet strengths required, also reducing manufacturing as well as pharmacy and patient costs.(van Santen et al., 2002)(Ciavarella et al., 2016). Many manufacturers charge the same or similar prices for different-strength tablets of the same drug, so buy higher-strength tablets and split them up to use as cheaper lower-strength tablets.(van der Steen et al., 2010).

Difficulty in breaking scored tablets is the most common drawback of scored tablets, especially for the elderly.(van Santen et al., 2002)(Wilson et al., 2001). A recurrent problem with the scored tablets was that they broke unevenly.(Wilson et al., 2001). Unevenly broken tablets can lead to dose variability. Splitting tablets beforehand can increase the risk of dose variation, as there is a risk of taking lighter or heavier tablets later. A poor score line that produces unequal parts may also be experienced as a quality defect by the patient and this might have consequences for the reliance on the drug-product and the compliance. (van Santen et al., 2002), (Barends et al., 2006). Sometimes, unevenly breakage of scored tablets may only be considered a problem if the drug has a narrow therapeutic index.(van Santen et al., 2002).

It has been reported that tablet mass loss results due to crushing and fragmentation at the score line when the tablet breaks. Mass loss leads to patient dose loss, contamination, and health hazards.(van Santen et al., 2002),(Barends et al., 2006), (Verrue et al., 2011).

The project was carried under two branches, a technical investigation and a community study. The study was duplicated in two areas, one consisting of samples from the open market and the other from the manufacturing facility of the State Pharmaceutical Manufacturing Corporation where tableting operation could be manipulated if required for the study. An assessment was made on the 'resistance' to divisibility under the divisibility affecting parameters of shape, diameter, thickness, break line depth, break line depth: thickness ratio and hardness. The study included test for uniformity

of weight of divided tablets. The above variables were assessed with the volunteers in the age groups of 45-59, 60-70 and >70 years. Uniformity of weight of divided halves were determined according to the Eur. Ph.

An important development of the study was the design and fabrication of a pair of new attachments in the form of a divisibility chuck. The chuck can be attached to the existing tablet hardness testers to measure the 'Tablet Divisibility Strength". Units of measurements are the same as for that of hardness testing. It is important to remember that the tablet divisibility stength is a life science related measure and that the tablet hardness test is a mechanical science related measure. With the availability of this measurement, the industry has a new monitoring tool on tablet divisibility and should encourage them to have a fresh look at the issue.

The proposed "Tablet Divisibility Dash Board" displays in the form of curves, all the variables contributing to the divisibility performance. The industry will be able to manipulate the physical parameters of the tablets with the aid of these curves in order to produce divisibility friendly tablets.

If a break line is provided for a tablet, it should without fail divide it in to intended equal parts complying with the compendial requirements. Given the sophistication of the pharmaceutical manufacturing technology there is no reason why hassel free divisible tablets could not be made. A close dialogue between the tabletting tool manufacturers and the pharmaceutical manufacturers will go a long way in providing divisibility effective break lines. A general observation is the need for a greater groove depth. Punch tip design features need changes with enhanced deeper break line forming embossing. The divisibility failure of convex tablets is so adverse that it is felt that break lines may have to be replaced with wider and deeper 'break valleys' as in Betaserc tablets (Figure 2).

Figure 2: Betaserc tablet displaying break valley.

Effortlessly divisible tablet design should commence at the product development stage. Established products already being manufactured can effect improvement by manipulating divisibility contributing parameters towards favorable values. A close study of the "Tablet Divisibility Dash Board' appearing under Discussion can be helpful in drawing up an optimum curve for a product.

Apart from the multiple divisibility deciding factors accessible to the present experiments for evaluation, the internal grain structure of a tablet may have an influence on the subject. All the ingredients, particularly the binder, whether the tablets are wet or dry granulated may have an influence. This is an area that falls entirely under the responsibility of the manufacturer.

MATERIALS AND METHODS

Scope of the Study

Tablet samples consisting of circular shape with a single break line were selected for the study since the divisibilty issues are mainly found in the round tablets. The physical parameters that contribute to the divisibility are the shape, diameter, thickness, break line depth and break line depth: tablet thickness ratio and hardness. These parameters were compaired with.

a) Uniformity of Weight of divided tablet halves,
b) the tablet divisibility percent success rate among the volunteers in three age groups and
c) with the new parameter Tablet Divisibility Strength.

Other studies with selected divisibility parameters were also carried out as required. Samples from the open market and those from the State Pharmaceutical Manufacturing Corporation (SPMC) were separately assessed since running changes could be effected to the SPMC tablets that are being compressed during the study period for additional studies. All tablets met quality control standards and were within the expiry dates. From the open market sixteen scored tablet varieties with different brands were purchased from registered pharmacies. [Manufacturer, address, country of all products required] They were Folic acid BP 100mg

[SPMC], Domperidone BP 10mg [CADILA], Prednisolone BP 5mg [SPMC], Gliclazide BP 80mg [SPMC], Propranolol BP 40mg [SPMC], Frusemide BP 40mg [SPMC], Co-Trimoxazole BP 80mg/40mg [L-Trim], Atorvastatin calcium BP 5mg [Atorva 5], Verapamil Tablets BP 40 mg [SPMC], Cetirizine Hydrochloride BP 10mg [Alerid], Famotidine USP 20 mg [SPMC], Betahistine Dihydrochloride 16mg [Betaserc 16], Spironolactone BP 25mg [SPMC], Ascorbic acid BP 100mg [MSJI], Metformin BP 500mg [SPMC], Salbutamol BP 2 mg [SPMC].

Details of the seven SPMC tablets subjected to experiments are as follows. Losartan Potassium BP 50 mg, Cetirizine BP 10 mg, Prednisolone BP 5 mg, Verapamil BP 40 mg, Spironolactone USP 25 mg, Enalapril Maleate USP 5mg, Mebendazole USP 100mg.

Following instruments were used in the experiments. Electric Weighing Balance (RADWAG, Model-AS220.R2 PLUS,), (SHIMADZU, Model-ATX224), Vernier Caliper (0.05mm), Tablet hardness tester (Electro lab, Model-EHT-5PR India Friability Tester (ERWEKA, Model-TAR 220P, Tableting Machines (HATA,Model-HT-X55LD-U and HT-AP-38MS-U), Abrasives Paper (ENGLISH ABRASIVES-p280D), Double tape (3M Attachment Tape-12mm), Newly designed Tablet Divisibility Strength Measuring Chuck.

Break Line Depth Measurement

Diameter and thickness of tablets were measured simultaneously with the built-in facility of the electronic tablet hardness tester during hardness measurement. Break line depth was measured as follows. One side on the break line was carefully ground with abrasive paper down to the pit of the break line. (Fig 3a,3b). Break line depth was calculated by deducting original thickness with reduced thickness after grinding and using average of three readings. Break line depth: thickness ratio was also calculated.

Uniformity of Weight for manually Divided Tablets

Ten half tablet units were tested first. No additional testing was done if the product met the acceptance criteria of the Ph.Eur 2020, "Subdivision of Tablets".

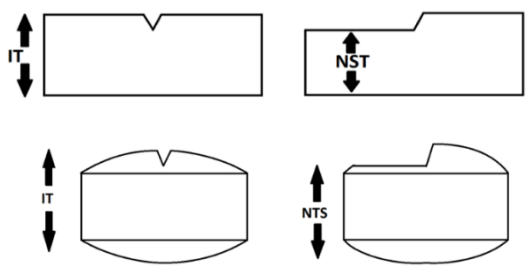

Figure 1: Diagrammatic representation of tablet break line depth measurement by grinding one side on the break line to the pit of the break line.
3a, Flat tablet; 3b, Convex tablet; IT, Initial thickness; NST, New surface thickness

Ten tablets were randomly selected from each drug and weighed individually by electronic analytical balance. Then tablets were broken in half by the two-hand method (Manual Method). In this method, tablets were broken in between the fingers with or without the use of the nails. Tablets were held between the forefinger and thumb in each hand with break line in a vertical position facing away from the body. Pressure was applied with the thumbs at the center of the tablet to break it. (Fig. 4).

Figure 4 Manual division of a flat bevelled tablet.

Each subdivided half tablet was marked/ separated as A and B and weighed. The average weight of part A (Mean), standard deviation (SD) and percentage relative standard deviation (RSD%) were obtained using Microsoft- Office Excel. If at least two results from the ten individual weights of Part A were outside the limits of 85 percent to 115 percent of the average weight (Mean) or if one individual weight was outside the limits of 75 percent to 125 percent of the average weight (Mean), the drug did not meet the Ph.Eur criteria. Then repeat the test with twenty additional tablets.

Percentage Weight Loss

The percentage of weight loss due to fragmenting or powdering during the braking process was calculated for each table. The initial individual tablet weight (W0) was noted. Then, the tablet was broken in half, and the weight of the two divided halves (W1) was determined. Ten tablets of each drug were tested.

$$Percentage\ Weight\ Loss = \frac{W0 - W1}{W0} \times 100$$

Up to now, no Ph.Eur criterion or pharmacopeial definition for the limit on the loss of mass upon breaking exists. Similar researchers and journals indicate it should be less than 1% which is considered in this investigation.

Tablet Divisibility Chuck and the Tablet Divisibility Strength Measurement

Details of the new design tablet divisibility strength measuring chuck are as follows. (Fig 5a, 5b, 5c).

Figure 5a Tablet divisibility chuck, the stationary part on top and the moving part below.

Figure 5b: Divisibility chuck with the.

Figure 5c.Divisibility chuck ready for measurement with a flat tablet placed against the stationary part. Note break line placed vertically facing away from the moving part.

It consists of two pieces, one to be attached to the moving jaw and the other attached to the stationary jaw of the tablet hardness tester. The attached parts should not touch the tablet resting surface of the hardness tester. The moving part has a V-shaped projection facing stationary jaw. The tip of the V in the moving part apply pressure on the tablet sample to be tested. The stationary part has a compromising V-shaped space to hold the tablet in position. Here the two faces of the V are slightly curved and is more acute (smaller radius of curvature) towards the open end of the V shape.

These curved lines for V shape in stationary part in figure 5a top were preferred as it hold small diameter tablets in position better than straight line V-shape where tablets tend to slip. The chuck could be adopted to any hardness testing machine provided the angle of the V-shaped moving part and the variable curvature of the stationary part are retained so that the tablet is held in position until it breaks when pressure is applied. A rough surface with a mild knurling may further help in holding the tablet in position.

Contrary to hardness testing with tablet lying horizontally, the sample tablet was placed on the stationary part perpendicularly with the tablet edges leaning against two arms of curved V. The break line faces the stationary jaw and it is positioned perpendicularly. (Fig 5c). When the machine is switched on, the tip of the V in the moving part presses on the center of the tablet surface opposite to the break line, splitting the tablet in two. The device was designed to mimic the manual division of tablets by the patients. The instrument display registers the Tablet Divisibility Strength.

Community Study on Tablet Divisibility Success Rate

In the community study, selected marketed tablet samples were given to fifteen volunteers, 9 men and 6 women in the Western Province of Sri Lanka, who were divided in to three different age groups, ages 45- 59, 60 - 69 and ≥ 70. Five volunteers, three men and two women consist of each group. Clear instructions were given to volunteers about the acceptable method for tablet division. The two- hand method (Manual Method), was used and one participant received three randomly selected tablets from a given batch of a drug. (Fig 4)

Percentage of tablet divisibility success was calculated according to their divisibility and the weights of the divided halves were also documented. All the volunteers were in good physical condition. Exclusion criteria were dementia, vision impairment and sensorineural or motor peripheral neuropathy.

Tablet Divisibility Dash Board

Multiple parameters that affect the divisibility of a tablet are quite complex. To overcome this a Tablet Divisibility Dash Board was introduced where all parameters are visible. In different tablets the displayed parameters are subjected to variation in unit values. Values favorable to tablet division are placed at the top of the dash board. Two curves are displayed, one representing favorable parameter values of a tablet [xx tab] with 100% divisibility and the other with unfavorable values resisting division with uu% divisibility. (Fig 6).

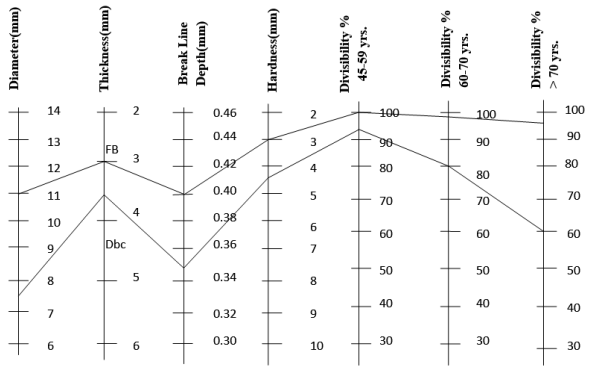

Figure 2: Model divisibility dashboard with imaginary top curve with 100 % divisible flat tablets and bottom curve for divisibility failing double convex Verapamil Tablets in Item. KP-Kilo Ponds, FB-Flat Bevelled, Dbc-Double Concave, Yrs.-Years.

Referring to the dash board, the manufacturers can manipulate the parameters of less than 100% divisible tablets to favorable 100% divisibility value region of the problematic parameter. Tablet tool manufactures may have to involve if the punch tip design needs changes, especially to provide a deeper break line, in worse cases, a break valley.

RESULTS AND DISCUSSION

Market Products

Results of the 'market products' for tablet divisibility parameters against Uniformity of Weight (UOW) of divided tablet halves and divisibility success rates in the community study are given in table 1.

Even at a glance it is evident that all flat tablets, items 1-7 have a divisibility success rate of 100% for all three volunteer groups. However, UOW of ½ tablets for all three volunteer groups have failed for item 1 that has a very low hardness of 1.39 Kp. For the item 6 too, similar results are seen for the tablet with a very shallow depth of the BL, 0.12 mm. For the FB tablets, among the three age groups, UOW of ½ tablets show a higher failure rate as the group age advances for items 2, 3 and 7.

Items 8-16 covers convex tablets where all items except 8 and 12 show failures in all age groups either in divisibility, UOW of ½ tablets or both. Similarly, the divisibility success rate falls with advancing age as evident from 45-59 age group to >70 years age group.

Item 15 as the hardest tablet at 16.01 Kp fails to meet 100% divisibility in all three age groups. The 100% divisibility of all FB tablets carry BL depths ranging from 0.12-0.31 mm. In the case of convex tablets, item 9 with 0.33 mm, item 13 with 0.43 mm and item 15 with 0.38 mm deep BLs show poor divisibility success rate in all three age groups. Thus, even with shallower BLs the FB tablets appear to split easily pointing to the difficulty in dividing convex tablets. In the item 8, despite being a shallow convex tablet and comparatively less favorable divisibility parameters in hardness and BL depth, it shows a controversial 100% divisibility success rate in all age groups. The solid grain structure of the tablet may have favored the divisibility, an inaccessible parameter in this study. The manufacturers themselves may not be aware of the details of this chance success.

UOW failures are noted for three 5.5-6.5 mm small diameter tablets in items 1, 2 and 3. Medium diameter 9 mm item 14 also fails in UOW test, so that there are factors other than diameter contributing to divisibility disrupting any clear relationship of diameter to divisibility.

SPMC Products

Results of the SPMC products for tablet divisibility parameters against Uniformity of Weight (UOW) of divided tablet halves and divisibility success rates in the community study are given in table 2. Each product was compressed at the regular and reduced compression pressures to study the comparative effects. Last item was compressed at an increased pressure for the same purpose.

On tablet shape, there is a larger number of failures in NC shape compared to FB shape. In item a. all three age groups have failed to reach 100% divisibility with only 40% success in >70 yr group of volunteers. Under reduced pressure percent success has improved in all age groups, 60-70 yr group reaching 100%. Item b. shows 100% divisibility success except in >70 yr age group. BL depth of 0.3 mm and BL depth: tablet thickness ratio of 0.08 appear to have favored the tablet divisibility. In items d. and e. of NC tablets, all age groups have failed to reach 100% divisibility success under both regular and reduced hardness.

Following reduced compression force, the results of the UOW of divided tablet halves had essentially remained the same as under regular compression. Two different levels of hardness in first two rows in item g, show improved divisibility in lower hardness second row for all age groups. Higher pressure in third row has resulted in UOW failures in two younger age groups. Smallest and the largest diameter tablets in items c and f, too had yielded nearly similar outcomes of UOW under two pressures.

Following can be summed up for decreased compression pressure tablets. No product has reached 100% success in all three age groups as they fail in either in equal divisibility or in UOW. Three FB tablets show better divisibility compared to convex tablets. In general divisibility has improved following reduced pressure, except in convex tablet, item d. UOW of SPMC products comply better than market products with Eur. Ph. requirements. In both tables 1 and 2 it can be seen that the divisibility failure percent increases with the increase in age group. Loss of weight resulting from tablet division in all tested samples was found to be in the range of 0.13 – 1.1%. No upper limit is prescribed in the Eur. Ph.

Table 1: Results of the Uniformity of Weight of ½ tablets and percentage divisibility in the community study in relation to divisibility parameters of market products.

Tablet Sample/ Shape	Diameter / Thickness (mm)	BL Depth(mm) / Ratio Of BL Depth: Thickness)	Av.Hardness, regular / reduced pressure (KP) (n=10)	Uniformity of weight of half a tablet (Eur.Ph.)	Tablet Divisibility Success % by age group Tablet $\frac{1}{2}$ Uniformity of Weight fails (x)		
Tests by adult,21 yrs.					45-59 yrs.	60-70 yrs.	>70 yrs.
1/ FB	5.5/2.26	0.21 /0.09	1.39	Pass	100(x)	100(x)	100(x)
2/ FB	7.0/2.53	0.31 /0.12	2.67	Pass	100	100	100(x)
3/ FB	6.5/2.85	0.20 /0.07	3.69	Pass	100	100(x)	100(x)
4/ FB	8.0/2.59	0.28 / 0.11	6.02	Pass	100	100	100
5/ FB	8.0/2.83	0.20 / 0.07	4.78	Pass	100	100	100
6/ FB	8.0/3.16	0.12 / 0.04	2.98	Pass	100(x)	100(x)	100(x)
7/ FB	12.5/4.00	0.30 / 0.08	10.68	Pass	100	100(x)	100(x)
8/ DbC	7.0/2.61	0.20 / 0.09	7.66	Pass	100	100	100
9/ DbC	7.0/3.85	0.33 / 0.09	6.97	Fail	60	26.66	13.33
10/ DbC	8.0/3.38	0.31 / 0.09	9.95	Pass	100(x)	86.66	73.33
11/ DbC	8.0/4.61	0.10 / 0.02	6.96	Fail	53.33(x)	46.66(x)	6.66
12/ DbC	8.5/4.09	1.10 / 0.27	6.82	Pass	100	100	100
13/ DbC	9.0/4.45	0.43 / 0.1	8.80	Pass	53.33	33.33	13.33
14/ DbC	9.0/3.73	0.45 / 0.12	4.59	Pass	100(x)	100(x)	100(x)
15/ DbC	11.5/6.14	0.38 / 0.06	16.01	Fail	60	40(x)	6.66
16/ DbC	6.5/3.63	0.21 / 0.06	2.07	Pass	100(x)	100	93.33(x)

1.Folic acid BP 1mg, 2.Domperidone BP 10mg, 3.Prednisolone BP 5mg, 4.Gliclazide BP 80mg, 5.Propranolol BP 40mg, 6.Frusemide BP 40mg, 7.Co-Trimoxazole BP 480 mg (L-Trim), 8.Atorvastatin calcium BP 5mg [Atorva 5], 9.Verapamil BP 40 mg, 10.Cetirizine Hydrochloride BP 10mg [Alerid], 11.Famotidine USP 20 mg, 12.Betahistine Dihydrochloride 16mg [Betaserc 16], 13.Spironolactone BP 25mg, 14.Ascorbic Acid BP 100mg, 15.Metformin BP 500mg, 16.Salbutamol BP 2 mg. Av: Average, BL: Break line, KP: Kilo Ponds, FB: Flat Beveled, Dbc :Double Convex, Yrs:Years.

Table 2: Results of the Uniformity of Weight of ½ tablets and percentage divisibility in the community study in relation to divisibility parameters of SPMC products under regular (1st row) and reduced (2nd row) compression pressures.

Tablet Sample Shape /	Dia. Thickness (mm)	BL Depth (mm) (Ratio of BL Depth: Thickness)	Av.Hardness regular / reduced pressure (KP) (n=10)	Uniformity of weight of half a tablet (Eru.pt.)	Tablet Divisibility Success % by age group Tablet $\frac{1}{2}$ Uniformity of Weight fails (x)		
Tests by adult,21 yrs.					**45-59 yrs.**	**60-70 yrs.**	**>70 yrs.**
a./Dbc	8.0/4.18	0.30 /0.07	4.95	Pass	66.66	66.66	40
	8.0/4.38	--	3.36	Pass	93.33	100	80
b./Dbc	8.0/3.72	0.30 /0.08	4.85	Pass	100	100	86.66
	8.0/3.79	--	3.16	Fail	100	100	93.33
c./FB	6.5/2.81	0.20 /0.07	2.90	Pass	100(x)	100(x)	93.33(x)
	6.5/2.93	--	2.75	Pass	100	100(x)	100(x)
d./Dbc	7.5/3.72	0.35 /0.09	4.15	Fail	93.33	80	60
	7.5/3.69	--	3.82	Pass	80	60	33.33
e./Dbc	9.0/4.26	0.25 /0.06	7.55	Fail	40	33.33	0
	9.0/4.26	--	7.44	Fail	53.33	53.33	6.66
f./FB	10.0/2.92	0.25 /0.09	6.15	Pass	93.33	100	93.33(x)
	10.0/2.98	--	5.94	Pass	100(x)	100	86.66(x)
g,f,g Positions Changed/ FB	8.5/3.35	0.20 /0.06	6.79	Pass	100	93.33	73.33
	8.5/3.36	--	6.21	Pass	100	100(x)	93.33
	8.5/3.30	--	7.86	Pass	100(x)	93.3(x)	53.33

a.Losartan potassium BP 50mg, b. Cetirizine BP 10mg, c. Prednisolone BP 5mg, d. Verapamil BP 40mg, e. Spironolactone USP 25mg, f. Mebendazole USP 100mg, g. Enalapril maleate USP 5mg. Av: Average, Dbc: Double Convex, FB: Flat beveled. KP: Kilo Ponds. First and second rows of samples a.-g are results for regular and reduced compression pressures. Third row of sample g is for increased compression pressure over regular pressure.

Tablet Divisibility Strength Measurements

Results of the tablet divisibility strength measurements in relation to tablet divisibility deciding parameters are given in Table 3. Tablet divisibility strength measurements were carried out with units assigned same as for tablet hardness is a new quality parameter introduced in this study. It is evident that the tablet divisibility strength was found to be less than the conventional tablet strength in all samples tested. Tablet divisibility strength of mebendazole tablets is as low as 1/3rd that of its hardness and is a large 10 mm diameter tablet. For the 8.5 mm diameter and 4.45 mm thick betahistine tablets, it stands at 90.5% that of the tablet hardness. Incidentally this tablet carries a Break Valley for tablet division. No clear indication can be given to these divisibility patterns. A larger number of tablets have to be studied coupled with the community study similar to what was undertaken here. Such a study will help in arriving at the cut- off tablet divisibility strength for each product required for 100% divisibility in patients over 70 years of age.

Table 3: Results of Tablet Divisibility Strength in relation to divisibility. Deciding parameters.

Tablet Sample	Shape	Diameter (mm)	Thickness (mm)	BL Depth (mm)	Av.Tablet hardness KP (n=10)	Av.Tablets Divisibility Strength (KP) (n=10)	Tablet divisibility strength as a % of tablet hardness
1	Flat Bevelled	8.0	2.29	0.28	6.02	3.668	60.93
2	Flat Bevelled	8.0	2.83	0.20	4.78	3.732	78.08
3	Flat Bevelled	8.0	3.16	0.12	2.98	2.283	76.61
4	Flat Bevelled	10.0	2.92	0.25	6.15	2.034	33.07
5	Flat Bevelled	12.5	4.00	0.12	10.68	4.171	39.05
6	Double Convex	8.0	3.38	0.31	9.95	4.503	45.26
7	Double Convex	8.5	4.45	1.10	6.82	6.172	90.05

1. Gliclazide Tablets BP 80mg, 2. Propranolol Tablets BP 40mg, 3. Frusemide Tablets BP 40mg, 4. Mebendazole Tablets USP 100mg, 5. Co-Trimoxazole Tablets BP 80mg/40mg (L-Trim), 6. Cetirizine

Hydrochloride Tablets BP 10mg [Alerid], 7. Betahistine Dihydrochloride Tablets16mg [Betaserc 16]. BL: Break Line, KP: Kilo Ponds, Av: Average, Dbc: Double Convex, Dia: Diameter.

CONCLUSION

The main outcome of this study is the need for deeper divisible break lines especially in convex tablets. The BLs of the convex tablets subjected to the experiments are too shallow so that the values of BL depth: tablet thickness ratios are too small to favor the tablet divisibility. When convex tablets were first introduced, the underline changes to the flat tablet geometry had not been fully realized leading to the failure in providing effective deeper BLs. (Figure 1). In convex tablets currently in use, BLs with end to end even depth should be better than the BLs where midpoint has the greatest depth and then shallow down progressively towards the two the ends. Tablet tool manufacturers and tablet manufacturers must closely coordinate in providing effective BLs having the vulnerable elderly patients in mind. Deeper BLs, Break valleys or butterfly shaped surface tablets are bound to improve divisibility of convex tablets. Tablets that resist division lead to a range of unexpected problems. The binding agent used, its dry weight: tablet dry weight proportion and wet or dry granulation methods employed is bound to effect the divisibility. These parameters were not accessible during the present study. In any case this part of the study will be very complex.

Adoption of tablet divisibility strength measurements in quantified terms with the newly introduced device ‘tablet divisibility chuck’ will provide an understanding about the favorable changes to the divisibility dependent parameters. Together with the ‘tablet divisibility dash board’, the industry will no longer work in the dark on the potential divisibility problems of their products. There is also the prospect of replacing tablet hardness test with tablet divisibility strength measurement since it reflects tablet hardness as well.

The study points to a conclusion that it is a combination of these divisibility factors that determine the results of divisibility and the UOW test of ½ tablets. There is a need for the assistance of a ‘tablet divisibility dash board’ displaying all the possible divisibility determining factors in graphic form (Figure 6). The industry can make use of these curves for their tablets to revise unfavorable parameter units to favorable range. Tablets that fail in the UOW requirements apparently has no relation to tablet divisibility success rates.

In the community study with SPMC products, item a. fails to achieve 100% divisibility in all three age groups, worse being the group >70 yrs. Here the tablet hardness is high at 4.95 Kp and the thickness to diameter proportion is more than 50%. At reduced compression force with tablets of less than 3.36 Kp hardness, the divisibility has improved in all age groups. In items b. and c., two lower age groups show 100% divisibility success, with failure to achieve 100% success in >70 yr age group. Curiously, the failure had increased with lower hardness tablets in item d. pointing to complexity of tablet divisibility. Poor divisibility may be attributed to higher hardness of over 7 Kp for the 9 mm diameter tablets. Item g shows best divisibility at lowest pressure and increasing failure with the advancing age. Overall, the worst failure rates can be seen in the >70 yr age group. Three FB tablets c., f. and g. in SPMC study comes closest to 100% divisibility compared to convex tablets.

Divisibility failure tend to increase with the advancing age, worse at >70 yrs. The industry is duty bound to provide 100% divisible tablets to this age group when it can be expected to be successful at all younger age groups.

In all tablets tested under tables 1 and 2 almost all convex tablets are thicker than 3.5 mm and FB tablets are thinner than 3.5 mm irrespective of their diameters. This again points to the unrealized disadvantage of the geometric proportions of convex tablets. Double curvature convex tablets may favor the divisibility since the design tend to reduce the thickness of convex tablets.

Cross score tablets can be tested first as for single score tablets. The resulting half tablets can also be tested similarly by placing the original circumference of the tablet half on the test surface and the broken surface facing up. The score mark is to be kept perpendicular similar to other tests.

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