STUDY ON MENSTRUAL HYGIENE MANAGEMENT PRODUCTS FOR ITS EFFICACY AND BIOCOMPATIBILITY CRITERIA

K G Geetha[+1], Gopika P Kumar[2], Dr. V Manju[1*]

Abstract

Menstrual hygiene in India has become synonymous with disposable sanitary pads and these products are considered as the most hygienic and safest option. The main role of sanitary napkins is to absorb menstrual blood and to maintain a standard level of hygiene. A comparative efficacy and safety performance of product included four - disposable non compostable menstrual pads, one disposable compostable, one reusable compostable, and one reusable non-compostable product widely available in India. The efficacy studies included - total absorption property such as absorption capacity, retention capacity, wetback properties and absorption rate at different volumes. Safety study included the biocompatibility by cell viability testing in L929cells. The absorption capacity of pads depends on the dimensions of the sanitary napkins. The total absorption property of sanitary pads were evaluated by studying maximum fluid (NS/B) absorbed or absorption capacity, retention capacity or the amount of fluid retained after applying pressure and the fluid lost from the pads on the application of pressure as wetback capacity. Prolonged exposure of sanitary pads to blood simultaneously transforms into a breeding zone of pathogens which can further cause major health concerns in women. The L929 cells are highly preferred to study cytotoxicity. These are mouse fibroblast cells. Cell viability or cytotoxicity assay are designed to evaluate the general toxicity of materials or medical devices. Testing involves extracting materials and then exposing the extract fluid to mouse fibroblast cells (L929). The cells are allowed to grow in cell media with different concentration of the extracts for a specified amount of time. These tests are generally performed on medical devices or personal care products and its raw material to identify any possible underlying toxicological risk. The results showed that all these products had varied level of efficacy and safety properties when exposed to normal saline or blood. Study finding suggests that there is a potential risk for women using disposable sanitary pads. When pads are exposed for longer durations, women experience rashes and irritability. Users of pads are constantly at risk for allergies, which may be brought on by the chemicals in them. The continuous use of these pads can cause fungal infections, reproductive tract infection, UTI etc. Majority of these concerns arise only when a female is exposed to sanitary pads for prolonged hours thereby indicating poor menstrual hygiene. Regulation needs to be mandatory in testing these products like class 1 medical devices as these products are exposed to vaginal tissue or mucosal layer and can impact the health of women.

Keywords – Menstrual hygiene management, biocompatibility, efficacy, L929 cells

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I INTRODUCTION

Disposable sanitary pads are synonymous with MHM products (Menstrual Hygiene Management), because of supportive policy initiatives, market evolution, and the positioning of these products as the most hygienic and safest option [1]. There are many policies undertaken by the government such as distribution of disposable sanitary pads to encourage MHM, improving feminine hygiene. Governmental agencies on their part have also continued to drive policy initiatives towards the same objective. States like Gujarat, Tamil Nadu, Kerala, and Telangana have rolled out schemes for large-scale distribution of sanitary napkins to girls in schools, while some other state governments have ensured that their MHM programs include a component of sanitary pad distribution. The impetus provided by both the government and private players has led to a change in mindsets around menstruation and has increased the use of sanitary napkins among women. Studies showed that it has been estimated that around 1 billion pads are used in India per month [2]. There are innumerable data related to MHM awareness programs and distributions of sanitary napkins, but no proper evaluation is conducted to understand the depth of safety and efficacy of MHM products in India. Though standards are available to practice MHM and disposing of pads, the implementation of safety and efficacy testing of the products are rarely performed or published. This was the concern that led to a thought-provoking topic for the study.

Vaginal exposure to chemicals could have local effects on vaginal and cervical tissue, in addition to their systemic effects. Given the quick absorption that happens in the vagina and the cumulative exposure to pads over a woman's reproductive life, if pads contain dangerous substances, their usage might be a major source of toxic chemicals via the vaginal route. It may also influence on the epithelial integrity of the cervical cells and the vagina, making them more vulnerable to sexually transmitted diseases [3]. Phthalates, bisphenols, parabens, and triclocarban (TCC) are compounds that have been linked to endocrine disruption. As plasticizers and antimicrobials, these compounds are widely employed in a range of industrial and consumer applications. Exposure to phthalates, parabens, bisphenols, and TCC has been associated with impact to the endocrine system and female reproductive disorders in epidemiological research. Elevated exposure to phthalates has been associated with precocious puberty, endometriosis, female genital tumors, and ovulation disorders. Although the utilization of antimicrobials and plasticizers in feminine hygiene products is common, (e.g., pads, pantyliners, tampons, wipes, bactericidal creams and solutions, deodorant sprays and powders, and other vaginal lotions), exposure to endocrine disrupting chemicals due to the use of such products is not known. Female hygiene products are an everyday necessity that cater to the requirements of women. Some feminine hygiene items are not just used during menstruation periods but also throughout a woman's reproductive cycle [4]

Sanitary pads are constructed of synthetic plastic components that may leach into the environment. The level of volatile organic compound (VOC) and phthalates in sanitary pads was assessed. VOC and phthalate contents differed 5,900 and 130 times across different types of sanitary pads. The VOC levels in sanitary pads were comparable to those in the environment. Phthalates concentrations in sanitary pads, on the other hand, were much greater than in conventional commercial plastic items. Because sanitary pads come into close contact with the external genitalia for such a long time, a significant amount of VOCs or phthalates may be absorbed into the reproductive system and may result in something more deadly [5]. To achieve the white appearance of sanitary pads, chlorine bleaching of paper, cotton, and wood pulp is required. This produces dioxins and furans as an undesired by-product, which are commonly discharged into the environment due to incomplete waste incinerator combustion. Dioxin is a carcinogen with a range of harmful consequences which can affect reproductive system , neurodevelopmental, immune system , thyroid hormones, liver, and tooth development [6]. Pesticides used on cotton plantations developed in an inorganic manner include furans, BPA and BPS, two other plasticizing compounds, damage embryonic development and have been related to heart diseases and cancer [7].

According to the current data available [1] its well understood that producers and manufacturers have poor knowledge and implementation practices on effectiveness and safety requirements of these products. Numerous types of sanitary napkins are commercially available in India. However, its efficacy and safety are not well determined other than its dimensional information. The purpose of this study is to evaluate various feminine hygiene products (MHM) available in India for these criteria.

II COMPONENTS OF MHM PRODUCTS

A. COMPOSITION OF SANITARY PADS

A sanitary napkin has up to seven different components. Since the first manufacture in 1896, the functional layer design has remained mostly

unchanged [8]. The addition of superabsorbent gel particles in the absorbent core resulted in a significant increase in absorption capabilities. Typically, a sanitary napkin is made up of the following layers:

1. Top sheet - The top sheets are thin, water-permeable layers that are in contact with the skin [9]. This layer's primary role is to swiftly transport fluids to the layer underneath it. Functional effectiveness requires a high level of wicking ability [10].
2. Absorbent core - This layer's job is to absorb and store fluids that flow through the upper sheet [11]. Fluid is basically trapped inside the core once absorbed, preventing leakage from applied pressure [12].

To aid absorption, the absorbent component may or may not be encased in a layer of cellulose.

However, the fluid retention rate of the compounds used in the core has to be high [13]

3. Bottom sheet - Bottom sheets serve as a water-resistant barrier, preventing leakage completely. This layer comes with adhesives and appendages to help with fastening. Bottom sheets function as a water impermeable barrier to ensure complete leakage prevention. Adhesives/winged appendages are provided with this layer for fastening purposes and skin contact is negligible [14].
4. Miscellaneous components - Depending on the product class, emollients on the top layer and an extra acquisition layer above the absorbent core may be present. Emollients are used to protect the skin from becoming irritated. Additional acquisition layers are included to ensure that fluids are evenly distributed throughout the absorbent core while preventing reflux [15]

B. Menstrual cups – Made of medically graded silicon or latex. These are the one of the proven sustainable MHM practices. The cups can be reused for about 10 years, although they have a higher one-time investment in comparison to other sanitary products. They are more environmentally friendly as well. Menstrual cups have been available since decades but their use is limited.[34]

C. Cotton pads – Made from cotton fibers, typically hold water up to 24–27-fold their own weight. Cotton pads can be reusable, usage can be for few years and pads are biodegradable. These pads are widely used by common people in India.[35]

II MATERIALS AND METHODS

1) Test materials: 7 different types of menstrual hygiene products were evaluated in this study. This included a) 2 different disposable sanitary pads of different company and sizes such as XXL, WBN-brand and XL size, SFDM-brand. b) 2 different disposable sanitary pads with different sizes and did not have superabsorbent material in it i.e., regular size SFS -brand and XL size, SOFBFEL brand. c) a disposable sanitary pad of regular size and claimed biodegradable, this had superabsorbent material component d) a reusable cotton pad and e) a menstrual cup. A pictorial representation of the disposable menstrual hygiene sanitary pads and reusable menstrual hygiene products are given in Figure1.

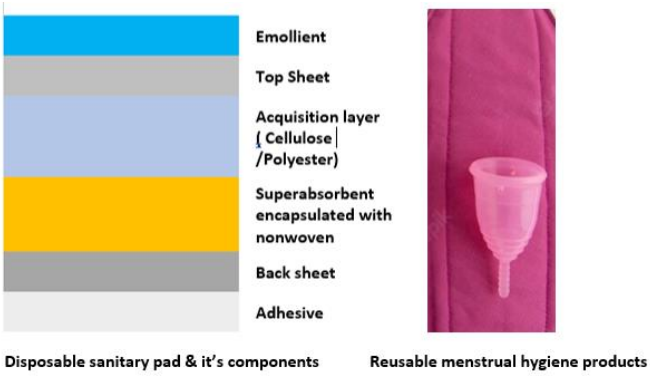

Figure1

2) Methods

A) Dimensions, Total Absorption properties and pH

i) Dimensions: The length was measured using a ruler to cross verify with the label claims. As shown in Table 1 the sizes chosen were in the range from regular to XXL. Centre width of the sanitary napkins in the centre was also measured. Thickness was measured using a micrometer.

ii) Total Absorption property: Total absorption property of pads were studied by different parameters such as absorption capacity, retention capacity, wetback analysis

Absorption capacity: In general performance studies use saline solution to measure the absorption capacity. However, in the real case scenario that is not what takes place. Thus, this study aims at testing sanitary napkins with saline solution and blood so as to compare the results and see if the studies conducted using saline solutions were appropriate [17] [18]. Quantitation of amount of blood lost during menstruation might be difficult. Methods for estimating menstrual blood loss include a graphic blood loss evaluation chart, weighing used pads, and an alkaline hematin test of extraction from used pads. However, in a clinical environment, these procedures are either cumbersome or overly complicated [19]. Clinical comparative evaluation of variety of sanitary napkins available in the Indian market is

changeling. This study aimed to measure blood absorption capacity of MHM products as similar to a true condition and make it available to the consumers. According to the Indian standards (IS 5405) [21]and articles published by UNICEF, the absorbency or absorption capacity of sanitary pads were calculated as the total weight of solution (saline /goat blood) in gram (gm) per pad. Absorption capacity of 6 different sanitary pads were studied [22] for absorption capacity as the amount of normal saline (NS) or goat blood (B) absorbed in gm/ cm2 . Pads were exposed to (NS/B) for 30 minutes, in an upside manner for maximal absorption. Excess fluids (NS/B) were drained, and weight of the remaining fluid (NS/B) was weighed. The total weight of the fluid (NS/B) absorbed by the pad was calculated. The absorption (Ab) capacity was calculated as the total weight of the fluid (NS/B) absorbed divided by the area of the pad and expressed as gm/cm2

Wetback Analysis: Leakage is a common concern in women while using sanitary napkins. This parameter was considered to examine the difference in the performance when 1kg of external pressure was applied according to IS 5405:2019 [20].Wetback was measured as the weight of the fluid (NS/B) in gm drained from the pad when applying 1kg of weight for 10 min and calculated as gm/cm2.

Retention capacity: This parameter allows the users to understand the performance of the sanitary pad. As different brands have different claims when it comes to locking the fluid. A pad's retention (RT)capacity was studied [23] which refers to the weight of the retained fluid (NS/B) in gm /cm2 that can withstand the pressure.

Absorption rate: Absorption rate of the pads are not generally studied. This parameter is generally studied for performance evaluation of wound dressings. Absorption rate was studied [24] as the time taken in sec for the disappearance of fluid (NS/B) from the surface of the pad. This was measured after dispensing 1,5 and 10ml to the center of pads. The time in seconds for disappearance of respective volume of NS/B from the surface was measured [25]. This parameter corelates with the wicking property of MHM products and is an important one. However, it is not much considered under performance standard criteria of sanitary napkin.

iii) pH: pH of all menstrual products were studied at 10% w/v in NS and recorded using pH meter [16]

B) Exposure and extraction: Seven MHM products were exposed to 30 ml each of NS & B. The exposure time of 5 hours was considered based on an average wear-time. After exposure, the products were extracted in the ratio of 1:10 with water (hydro) for both NS and B exposed [27] products. The B exposed products were also extracted with water-alcohol/ hydro alcohol (1:1). All three extracts were evaporated using a rota-vapour and a semi-solid residue was obtained (Yield <1%).

C) Biocompatibility

Biocompatibility by cell viability study were conducted for hydro extract of NS exposed, Blood exposed hydro (BH) and Blood exposed hydro-alcoholic (BHA) extracts of 7 different type of menstrual hygiene products. Cytotoxicity studies were performed using mouse fibroblast L929 cell line by SRB assay [4].Cells were grown in culture flasks containing the growth medium of Dulbecco's Modified Eagle's Medium (DMEM, Invitrogen, CA, USA) supplemented with 10% fetal bovine serum and antibiotics (200 µl/ml penicillin G, 200 µg/ml streptomycin, and 2 µg/ml fungizone). Cells were maintained at +37°C in a humidified 5% CO_2 atmosphere and monitored daily by using an inverted microscope. Subcultures were performed twice a week, when an 80% of confluence was observed. When the cells reached confluence, they were detached using 0.2% (w/v) trypsin and transferred to new culture flasks. After sufficient growth for experimentation, the cells were trypsinized and plated in 96-cluster well culture plates at a concentration of 1×10^5 cells/well. Each well contained 100 µl of cell suspension in the growth medium, and the plates were incubated for 24 h at 37 °C under 5% CO_2 to obtain a monolayer culture. After 24 h of incubation, the old medium was removed from each well. Then, a 100-µl volume of growth media with seven different filter sterilized concentrations of saline expose extract, B expose hydro extracts and hydroalcoholic extracts of 7 menstrual hygiene products were plated in replicates to evaluate cell viability using SRB assays [28]. Two sets of experiments were conducted in triplicates.

Following a 24-h incubation period at 37 °C under 5% CO_2, the cell viability of both plates was assessed.

SRB assay is used for cell density determination, based on the measurement of cellular protein content. The method described here has been optimized for the toxicity screening of compounds to adherent cells in a 96-well format. After an incubation period the cell monolayers were fixed with 10% (wt/vol) trichloroacetic acid and stained with 0.04% SRB for 30 min; then, excess dye was removed by washing the cells repeatedly with 1% (vol/vol) acetic acid. The protein-bound dye was

dissolved in 10 mM Tris base solution for optical density (OD) determination at 510 nm using a microplate reader. Cell viability was expressed as a percentage of the control values [29].

III RESULTS

Dimensions Total Absorption properties, and pH All the tests performed were in 6 replicates and the mean results are provided in Table 1.

Dimensions

Total length of all the 6 sanitary pads were ranging from 40 to lowest 23 cm, however the length of absorbing materials of the pad were lower than the total length except for PS R and CRP R. Width of the pads in cm were ranging from 8 to 6.6 cm. The total area of the pads was from 280 to 140.5 cm2. Thickness of pads was between 3 to 4 mm, except for CRP R which had the highest of 8 mm. The dry weight all the disposable pads were in the range of 6.7 to 14 gm, however the CRP cotton pad had the highest weight of 39gms.

Total Absorption properties

Total absorption property was studied using both NS and B. Absorption capacity of the pads was calculated as gm/cm2 and it ranged from 0.4 to 0.17. Wet back(gm/cm2) of the pads were from 0.03 to 0.01 gm/cm2. Absorption rate of the pads at 1 to 5 ml volume varied from 1 sec to 12.75 seconds. Retention capacity was calculated in gm/cm2 and it ranged from 0.4 to 0.18 pH
pH of the 6 different types of sanitary pads were close to neutral range i.e., 6.6 to 7.1 and was as defined in the Indian standard IS 5405.

Extraction yield

The extraction yield of the menstrual hygiene products ranged from 0.005-0.4gm/ pad for normal saline hydro leachable extract (NS) , Blood hydro leachable extract and Blood hydroalcoholic leachable extract the individual yield are provided in the Table 2

Biocompatibility

Each 7 concentrations of the 3 extracts were tested in triplicates for cell viability in two sets of different experiments and its mean values as percentage of the control values are provided in Table 3. Among the menstrual hygiene products, extracted leachables of MHM products exposed to blood had higher impact on L929 cell viability compared to leachable extracts from normal saline extracts.

IV DISCUSSION

Studies showed that there were different components in the commercially available disposable pad in comparison to old conventional reusable cotton pads. All the pads studied had neutral pH. There were difference in dimensions like length, width and thickness and also in its absorption, retention, wetback capacities and absorption rates with respected to NS and B exposures. It was observed that the absorption capacity of pad was lower for blood (B) in comparison to normal saline (NS) except for SFDM XL sanitary pad. b) More or less the absorption capacity or retention capacity in gm /cm2 was similar for all the products studied and pad having SAP had a better retention capacity . Product with higher area would have a higher absorbency. The cotton pad had the highest thickness and hence comfort during wear would be minimal for it. Wetback was higher for product which had higher cotton in its components. This could result in leakage under pressure unlike pad having SAP. Lower the absorption rate , better is the performance. The cotton pad has highest absorption rate compared to all the other products studied. pH of the 6 different types of sanitary pads were in the neutral range and as defined in the Indian standard IS 5405, all the extracts were semi solid in nature. There was a higher yield in hydro-alcoholic extracts when compared to hydro extracts of menstrual hygiene products.

According to Graph 1, As compared by the ANOVA (*$P < 0.05$, **$P < 0.01$ and ***$P < 0.001$) : SFDM XL : NSAb capacity and RT capacity was higher VS B Ab capacity and RT capacity (***$P < 0.001$) and with respect to all the pas studied, : CRP R : NS Ab capacity and RT capacity + B Ab capacity and RT capacity was similar (and higher (***$P < 0.001$) than all pads except SFDM XL, WBN XXL, SFS R and SOFBFEL XL: NS and B Ab capacity and RT capacity was similar($P > 0.5$) :PS R: : NSAb capacity and RT capacity was higher VS B Ab capacity and RT capacity (***$P < 0.001$) and was lowest among all the pads studied. According to Graph 2 , As compared by the ANOVA (**$P < 0.01$ and ***$P < 0.001$):Wetback was higer (***$P < 0.001$) for all pad exposed to NS than B except for WBN XXL :SFDM XL : Wetback was lowest for both NS and B (***$P < 0.001$) among all the studied pads , CRP R , SOFBFEL Xand SFS R : Wetback was higher for B compaired to all other products :PS R : Wetback was lowest (***$P < 0.001$) for B According to Graph 3 , As compared by the ANOVA (**$P < 0.01$ and ***$P < 0.001$) :WBN XXL and SFDM XL : NS Ab rate was lower at all tested volumes VS B Ab rate was increasing with volume (***$P < 0.001$) :SFS R: NS and B Ab rate

was similar, and it was increasing (***P < 0.001) with higher volume :PS R: NS and B Ab rate was similar, and was not increasing with higher volume (P> 0.5) however it was higher than all tested pad except CRP R :SOFBFEL XL: NS and B Ab rate was similar, and was not increasing with higher volume (P> 0.5) and was least : CRP R : NS and B Ab rate was increasing with higher ((***P < 0.001) volumes and was among the higest (***P < 0.001) According to Graph 4 As compared by the ANOVA (*P < 0.05, **P < 0.01 and ***P < 0.001); All MHM products exposed to NS ie WBN XXL NS =SFDM XL NS= SFS R NS= SOFBFEL XL NS had no significant effect on L929 cell viability (P >0.5) .However, pads with SAP exposed to B and lechable hydroalcoholic extract and lechable hydro extract had significant effect on cell viability.It was such that WBN XXL BHA > SFDM XL BHA > WBN XXLBH> SFDM XL BH>SFS R BHA= SOFBFEL XL BHA> SFS R BH= SOFBFEL XL BH.

According to Graph 5 , As compared by the ANOVA (*P < 0.05, **P < 0.01 and ***P < 0.001); All pads & menstrual cup exposed to NS and its leachable hydro extract had no much affect on cell viability of L229 cells i.e. PS R NS =CP NS= MC NS and B exposed hydro& hydro acholoic leahable of cotton pad and menstrual CP BHA= CPBH= MC BHA=MCBH had no sigificant effect on cell viability however the PS R pad claimed for biodegradability and natural matrial had significant effect on L929 cellviability.

CONCLUSION

Efficacy and safety testing of menstrual hygiene products which included four disposable, non compostable menstrual pads as claimed in the packaging (WBN XXL, SFDM X, SFS R , SOFBFEL XL), and one disposable compostable (PS R) and one reusable compostable (CRP-R) and one reusable noncompostable product .The study results showed that all these products had varied level of efficacy properties in term of absorption properties such as total Ab capacity ,Rt capacity , wetback properties ,Ab rate at different volumes . Efficacy properties was different when the pad were exposed to NS and B. Hence when testing these type of products it is important to include mandatory testing with realistic condition than giving users a choice of testing fluid selection as NS or any artificial blood or goat or sheep blood as mention in BIS 5405 . There were dimensional difference between the disposable pads studied however pH of all the pads had neutral pH as defined in the BIS 5405 standard .Some parameters of efficacy tests are included as a part of product verification however safety studies of these products are done as a part of product validation only. Our study showed that all seven products studied from Indian market was passing the cytotoxicity testing as mentioned by standards i.e., saline treated hydro extracts. However, it was a new finding that both hydro and hydro alcoholic leachable extracts of disposable menstrual pad which contained SAP and cellulose components showed dose depended cytotoxic potential by SRB assay in L929 cells. But blood exposed hydro and hydroalcoholic leachable extract of reusable cotton product nor the menstrual cup did not affect the cell viability of L929 cells. This shows that there are some potential safety concerns on leachable materials related to disposable menstrual pad especially higher in disposable pads when exposed to blood. Our study showed that reusable products are safer than disposable products. None of the standards mention to test safety parameters in a realistic condition, however the quality parameter testing mentions to test either saline, fluid, goat, or sheep blood for efficacy parameters. Our study suggests that standard needs to consider testing products for safety in more in vivo conditions to define its safety potential similar to medical devices are very much essential as these products are routinely used by women and it get exposed to vaginal tissue & mucosal layer and can lead to untoward feminine health issues

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TABLES & GRAPHS

Code of menstrual pad Components of Pad	WBN XXL	SFDM XL	SFS R	SOFBFEL XL	PS R	CRP R
Total length in cm	40	23	24	28	23	23
Length of the pad in cm	35	21.3	21	24.5	23	23
Width in cm	8	6.6	7.4	7.4	8	8
Area in cm2	280	140.5	155.4	181.3	184	184
Thickness in mm	4	3	3	4	3	8
pH	6.6	7.1	6.9	6.8	6.9	7.1
Dry weight in gm	14.11	7.4	6.68	8.77	8.96	39
Top Sheet	Non-woven cotton	Non-woven cotton and rayon	Non-woven cotton	Nonwoven cotton	Non-woven cotton	Single cotton material
A thin layer	Non-woven absorbing sheet	Non-woven absorbing sheet	-	-	Cottony non-woven	
Absorbent core	Cottony material and SAP	Cottony material and SAP	Cottony material	Cottony material	Cottony material and SAP	
Impermeable bottom sheet	PE/PU	PE/PU	PE/PU	PE/PU	PE/PU	-
Packaging	Individually wrapped PE	Individually wrapped PE	Common PE cover only	Common PE cover only	Individually wrapped cellulose	_
Ab Rate @1ml- NS in sec	1	1	3	1	5	3
Ab Rate @5ml- NS in sec	1	1	4	1	5.5	5
Ab Rate @10ml- NS in sec	1	1	5	1	6	7.5
Ab Capacity gm/cm2-NS	0.21	0.4	0.21	0.18	0.2	0.25
RT Capacity gm/cm2-NS	0.2	0.4	0.18	0.17	0.19	0.22
Wetback gm/cm2- NS	0.01	0.01	0.03	0.02	0.02	0.03
Ab Rate @1ml B in sec	1	1	3	1	5.5	12.5
Ab Rate @5ml B in sec	3	2	4	1	6.5	13
Ab Rate @10ml B in sec	3	3	5	1	7	14
Ab Capacity gm/cm2-B	0.215	0.252	0.224	0.211	0.152	0.268
RT Capacity gm/cm2 -B	0.204	0.25	0.205	0.198	0.152	0.257
Wetback gm/cm2- B	0.011	0.002	0.019	0.013	0	0.011

Table 1 : Total Absorption Properties – Dimensions and pH of MHM products

Yield in gm/pad

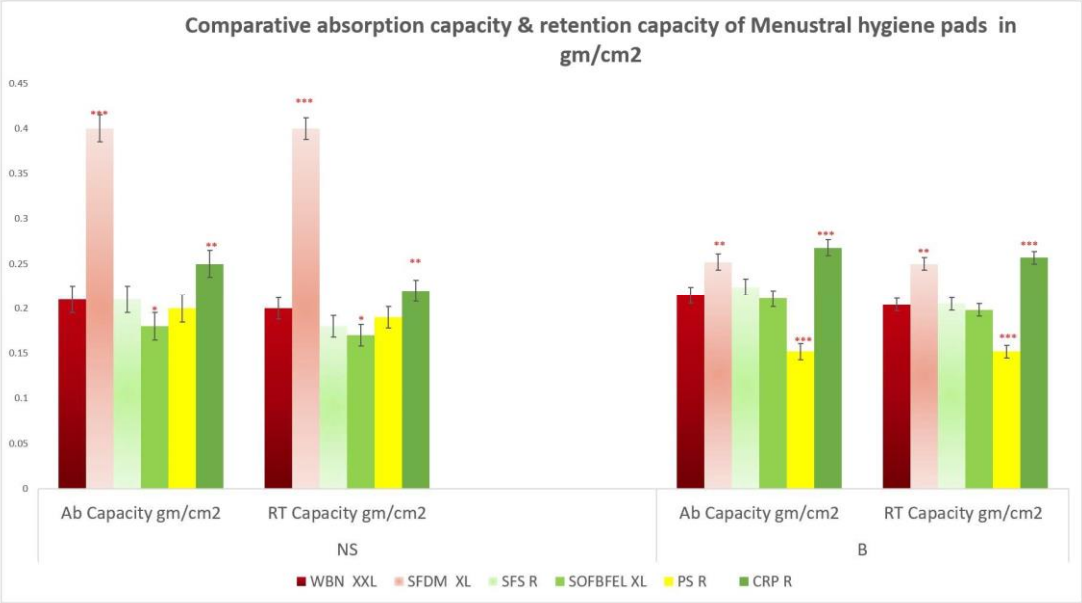
	WBN XXL	SFDM XL	SFS R XL	SOFBFEL XL	PSR	CP	MC
NS	0.07055	0.037	0.02004	0.02631	0.03584	0.076	0.005
B-H	0.16932	0.0888	0.0668	0.0877	0.10752	0.19	0.025
B-HA	0.36686	0.1924	0.10688	0.14032	0.15232	0.418	0.05

Table 2: Yield of extracts

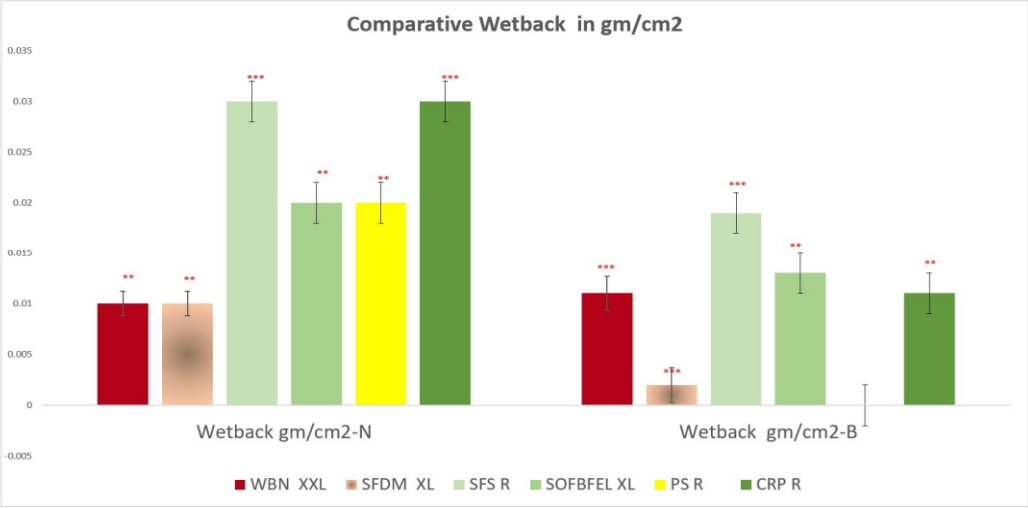
Conc. (mg/ml)	WBN XXL			SFDM XL			SFS R XL			PSR		
	NS	B-H	B-HA	NS	B-H	B-HA	NS	B-H	B-HA	NS	B-H	B-HA
0.01	99.4	100	95.1	99.2	100	98.1	99.1	100	100	99.4	100	98
0.04	100	83.4	45.8	100	91.2	65.6	100	89.3	82.2	100	94.1	70.1
0.12	99.5	43.6	31.5	100	60.6	45.3	99.2	70.4	68.3	100	65.3	51.5
0.37	98.8	34.1	23.6	99.1	45.9	30.1	98.1	48.1	35.4	99.6	48.2	34.5
1.11	100	28.3	14.3	99.6	35.3	22.4	100	35.2	23.1	99.5	38.3	26.6
3.33	99.6	19.6	10.9	100	20.1	15.6	99	23.1	20.5	100	24.6	19.9
10	100	10.1	0	99.6	18.4	8.1	100	25.8	18.2	100	23.1	14.2

Conc. (mg/ml)	SOFBFEL XL			CP			MC		
	NS	B-H	B-HA	NS	B-H	B-HA	NS	B-H	B-HA
0.01	99	100	100	98.4	100	98.2	100	100	100
0.04	100	91.9	84.3	100	99	100	100	100	100
0.12	100	73.3	70.6	100	100	99.3	100	98.1	99.1
0.37	99.2	51.1	40.1	99	100	100	99.5	100	100
1.11	99.9	38.2	26.6	99.3	98.6	100	100	100	100
3.33	100	28.3	20.2	100	99.1	99.5	100	98.6	100
10	99	25.4	18.3	99.1	100	100	99.2	100	100

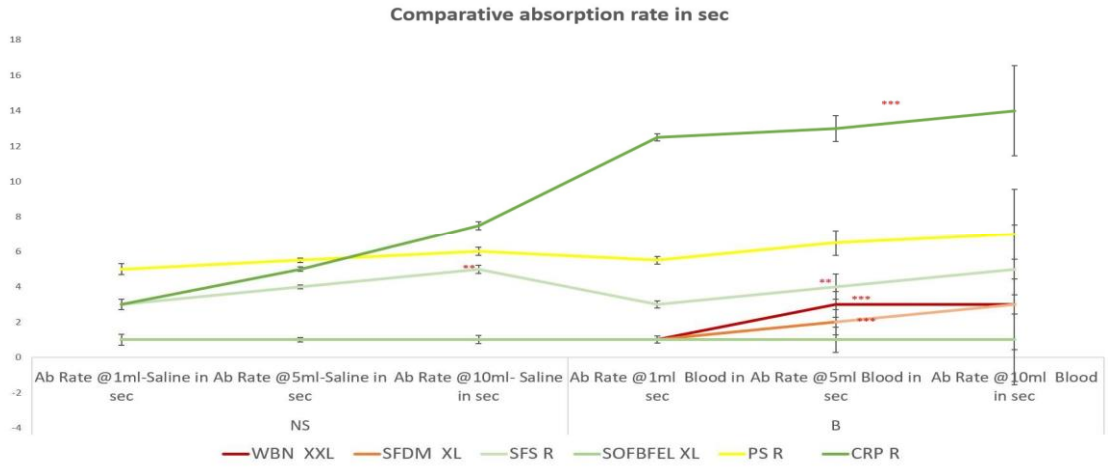
Table 3: % Cell viability/ Biocompatibility assay



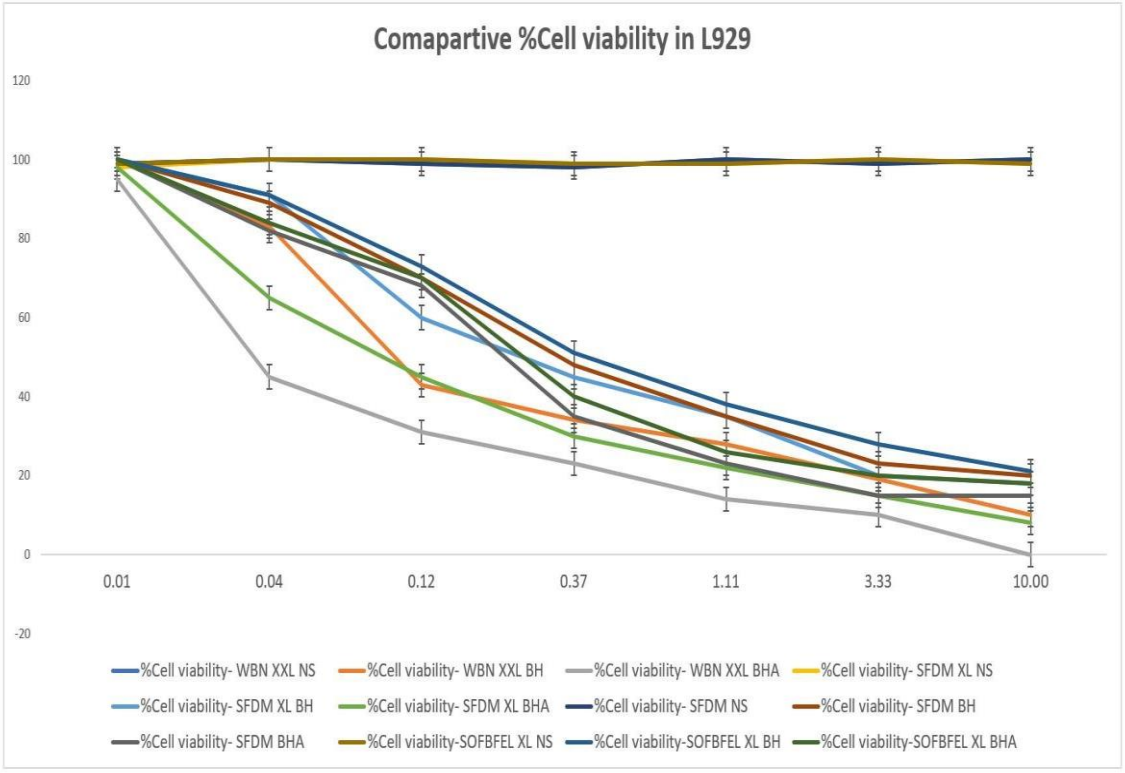
Graph 1



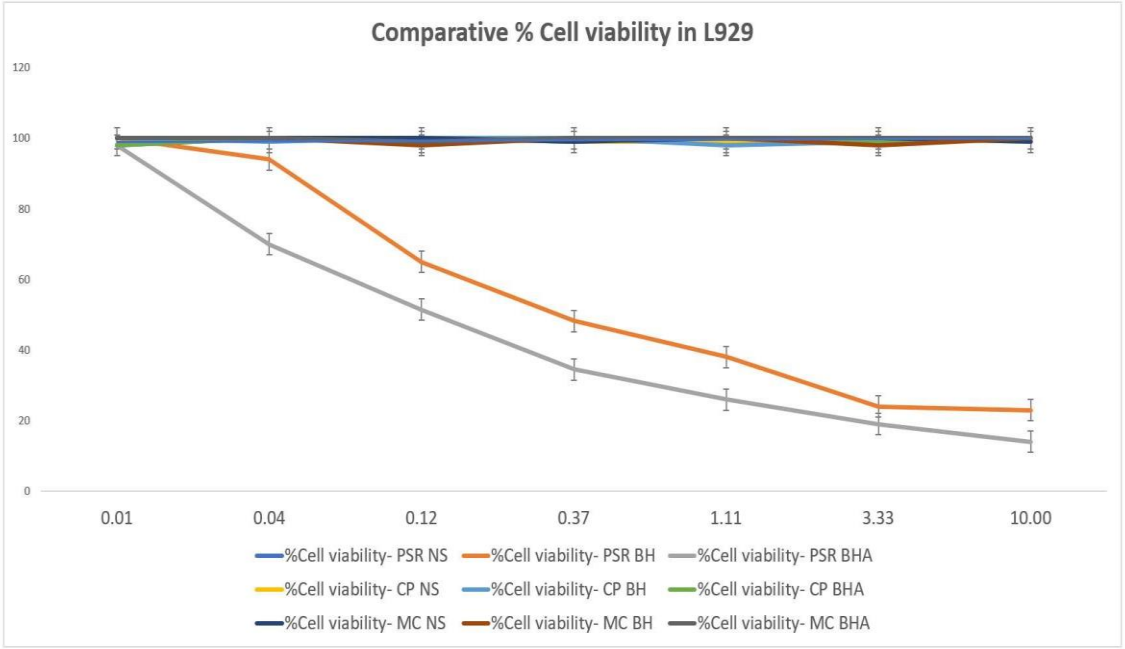
Graph 2



Graph 3



Graph 4



Graph 5

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