

Comparative Evaluation Data on Haemostatic Dressing

Axiostat v/s SpeedM v/s Quickclot



Introduction

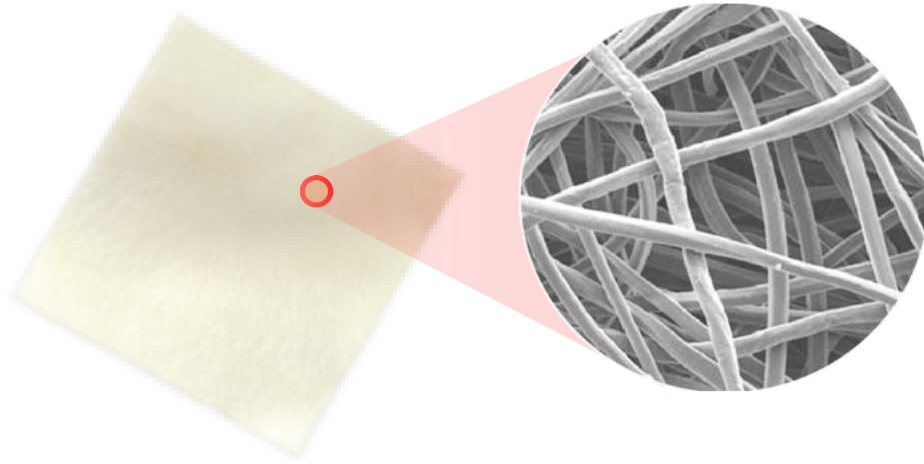


Parameter	Axiostat Gauze	SpeedM Gauze	Quikclot Combat Gauze
Description	100% Chitosan based advanced haemostatic gauze, active on all sides and available in z fold . Non leachable, No coating or printing or impregnation with granules or powder or particles	Cellulose nonwoven fabric partially printed with Halloysite nanotubes and X ray detectable material with acrylate based binding agent and color dye. Risk of leaching of printed Halloysite particles and washing of color dye in severe bleeding	Polyester non-woven gauze impregnated with Kaolin particles and attached with X ray detectable thread. Available in z fold form. Risk of particles leaching in severe bleeding and embolism or thrombosis risk is associated
Active Ingredient	100% Chitosan -A natural biopolymer, core structure of the dressing fiber made up of entirely chitosan	Halloysite, an inorganic aluminosilicate nanoclay	Impregnated Kaolin particles (Aluminium Silicate- Inorganic mineral clay material)

Mechanism of Haemostasis Action

Axiostat Gauze	SpeedM Gauze	Quikclot Combat Gauze
Multi-aspect haemostasis mechanisms Based on Protonated Bioadhesive Technology (PBT) ▪ Charge-based interaction with blood components, ▪ Platelet activation via TLR receptor, ▪ Coagulation cascade activation (Factor X) ▪ Robust fibrin plug formation at bleeding site [1].	Single aspect haemostasis Based on only physical phenomena: plasma absorption and Charge based interaction between negatively charged HNT and positively charged platelet (Non inert material) However, the platelet has negative surface charge (-10.7 mV) due to presence of sialic acid . So, the proposed electrostatic mechanism for hemostasis action scientifically not valid [1,2]. Activation of Factor XII may help in hemostasis	Single aspect haemostasis Based on blood coagulation cascade activation. Kaolin activates Factor XII to initiate coagulation cascade. Inert material , No proven scientific mechanisms for charge-based interaction and platelet activation [3].

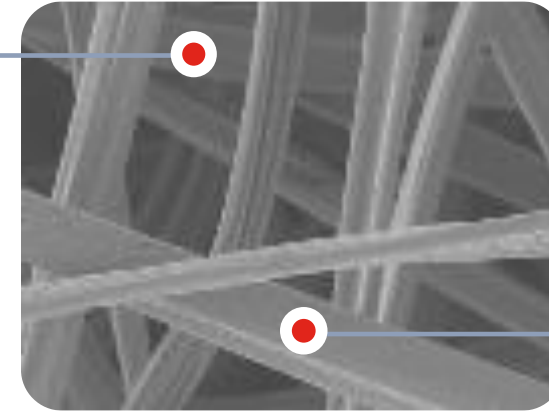
Microscopical Structure of Axiostat Gauze



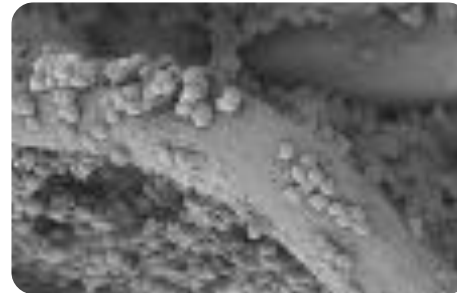
Overview

- 100% Chitosan Nonwoven
- Fibers average diameter ~15–20 μm
- No Powder or Granules, No Mineral

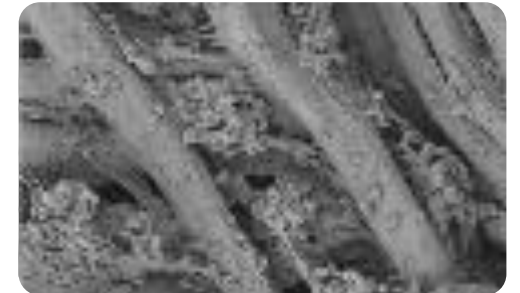
Capturing of **Blood Clotting** Components



Highly Interconnected
Nonwoven network structure



Charge-based adhesion of
blood cells on dressing fibers

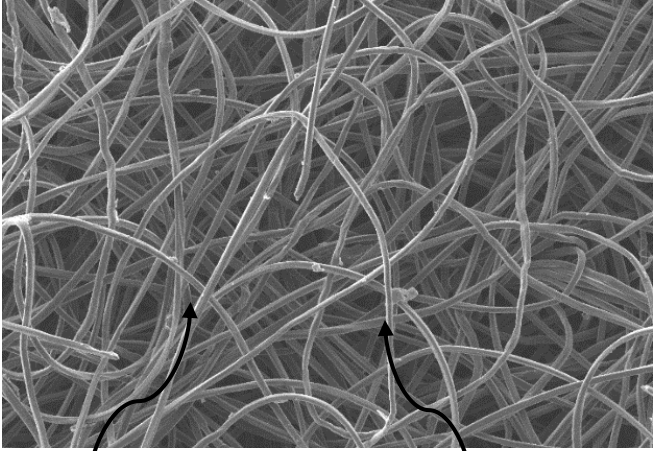
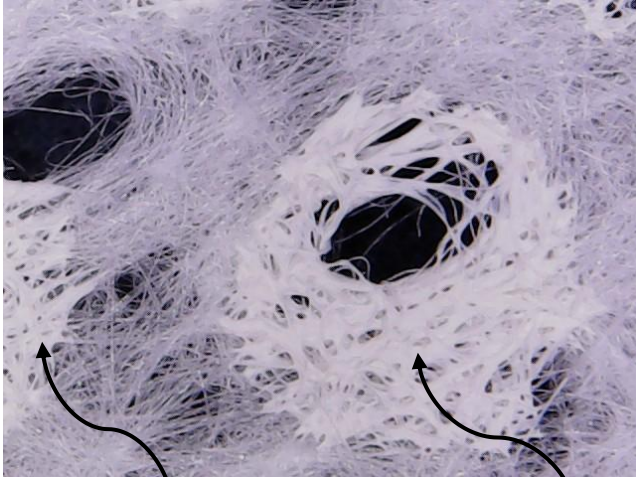
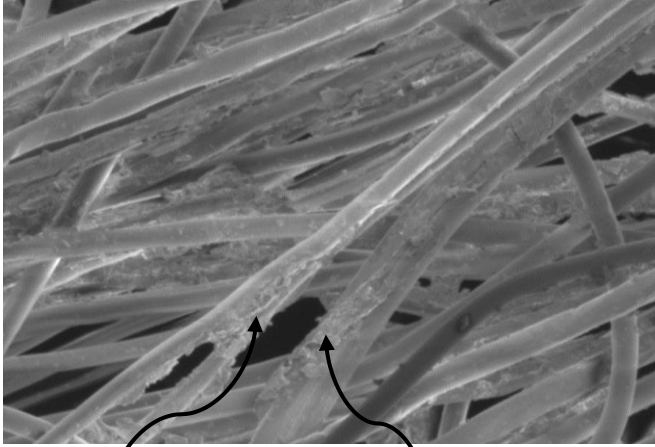


Fibrin generation and blood clot
formation on dressing fiber

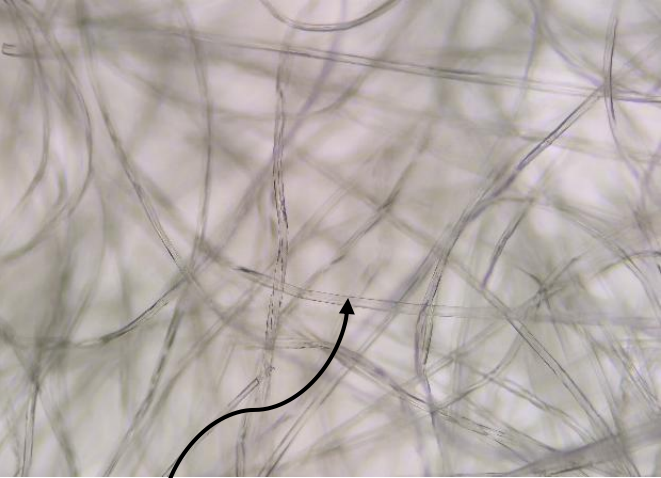
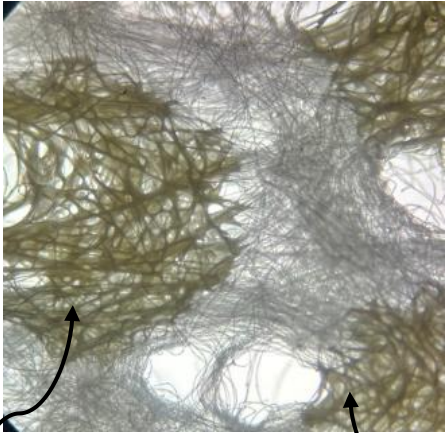
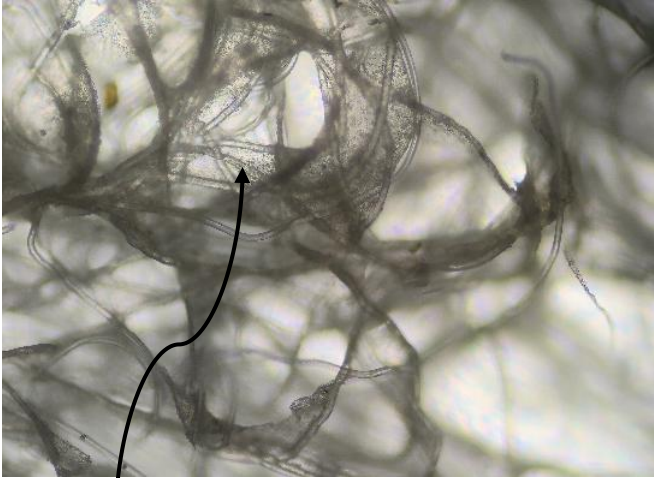
Bench Performance Test (Non-Clinical)

Parameter	Axiostat Gauze	Speed M	Quikclot Combat Gauze
GSM	106	74	85
Absorbency (Times of dressing weight)	30 (3x more than speed and Quick clot)	8.06	10
pH	5.4 (Skin friendly)	6.2	6.1
Tensile strength (Wet)	26.01 N/25mm . High mechanical strength in wet condition helps in one piece removal.	24.27 N/25 mm	~14.2 N/25 mm
In vitro blood clotting (BCI Value)	0.14, less BCI Value indicates more robust and stable blood clot formation.	2.35	1.64
In vitro blood clotting time	Complete blood clotting under 2 minutes (Stable haemostasis, no blood leaking)	Partial blood clotting observed under 5 minutes (Blood leaking observed)	Partial blood clotting observed under 5 minutes (Blood leaking observed)
Integrity/ Dispersion test	Product remain intact, with no product residues, no fibers and no particles observed. Dispersion solution remains clear, no particles observed under microscope.	Color dye leaching from X ray detectable paste, tiny particles observed in the dispersion solution under microscope.	Product remain intact but dispersion solution becomes turbid, demonstrates leaching of tiny kaolin particles under microscope
Particle Release	No	Yes	Yes

Microscopic Analysis (SEM & Digital)

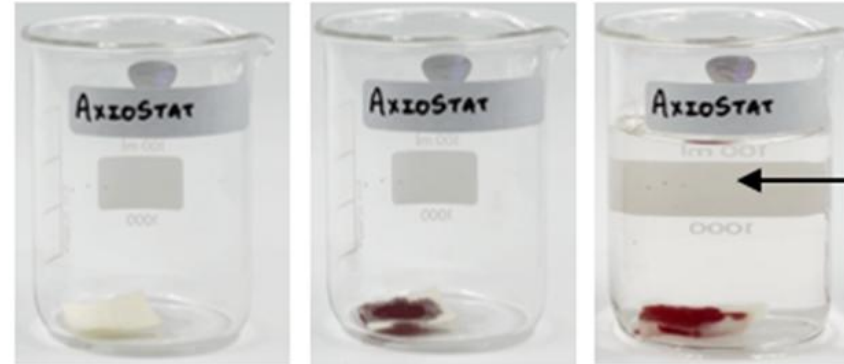
Axiostat Gauze (SEM Image)	SpeedM Gauze (Optical Image)	QuikClot Combat (SEM Image)
 Clear fiber surface was observed, with no particle coating or no granular layer present	 Screen Printed layer of clearly visible Halloysite particles was observed on the dressing fiber surface	 Impregnated layer of clearly visible kaolin particles was observed on the dressing fiber surface

Microscopic Analysis (Optical)

Axiostat Gauze (Optical)	SpeedM (Optical)	Quikclot (Optical)
 Clear fiber surface was observed, with no particle coating or no granular layer present	 Screen Printed layer of clearly visible Halloysite particles was observed on the dressing fiber surface	 Impregnated layer of tiny kaolin particles were observed on the fiber surface of dressing

In vitro Blood Clotting test

Axiostat gauze



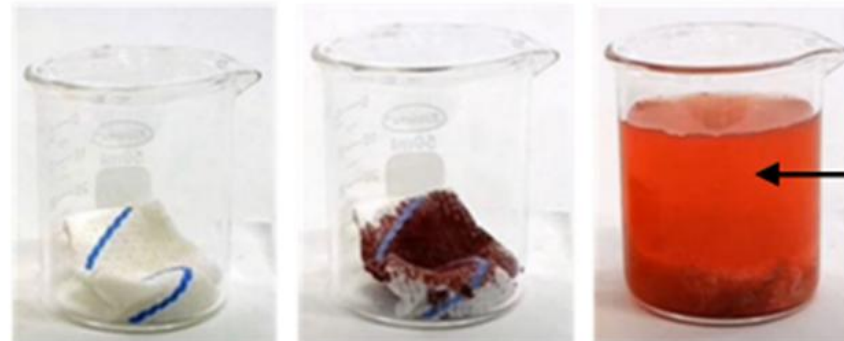
Strong blood clotting, no blood leakage

SpeedM gauze



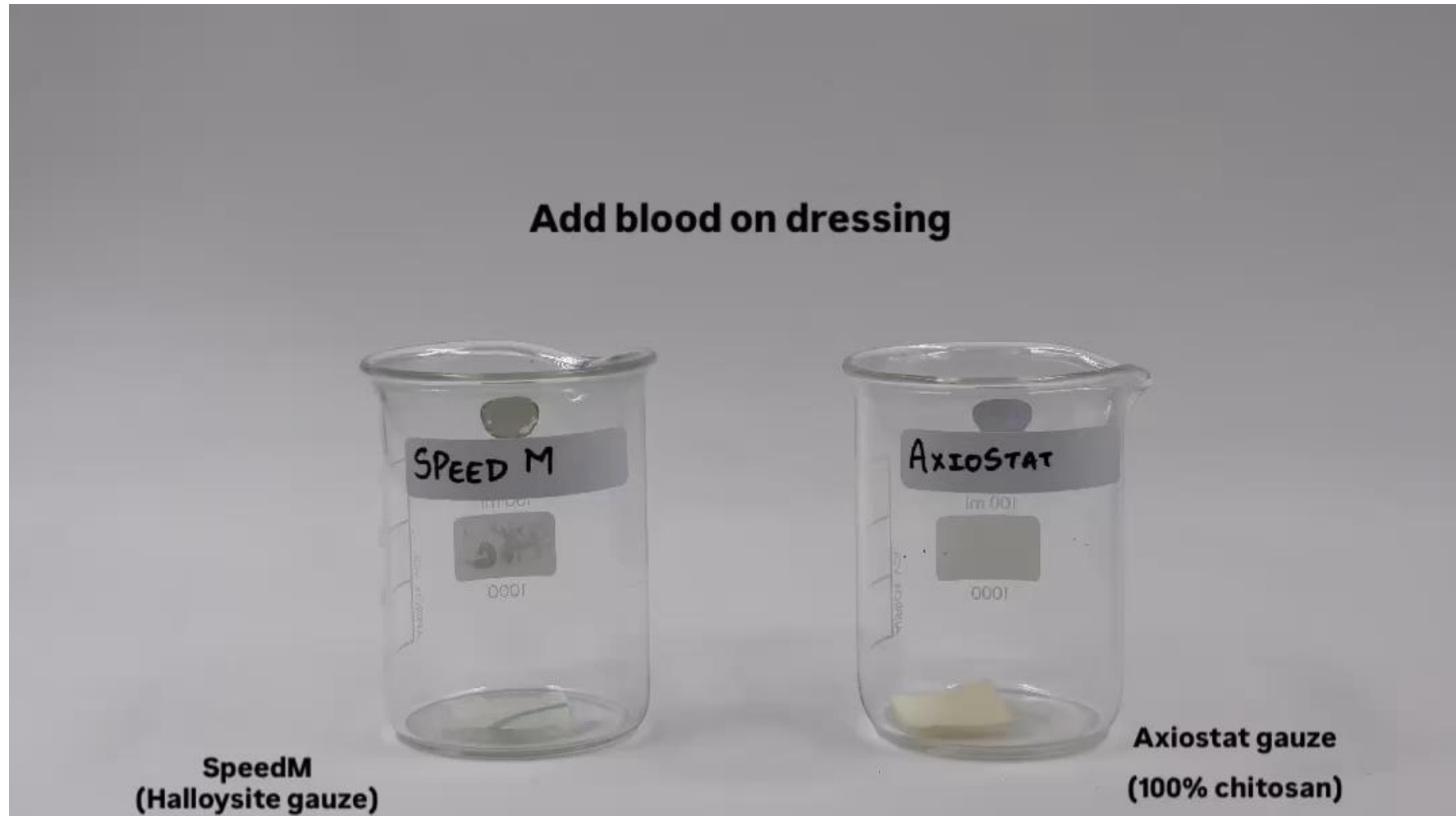
Unclogged blood leaking

Quikclot Gauze

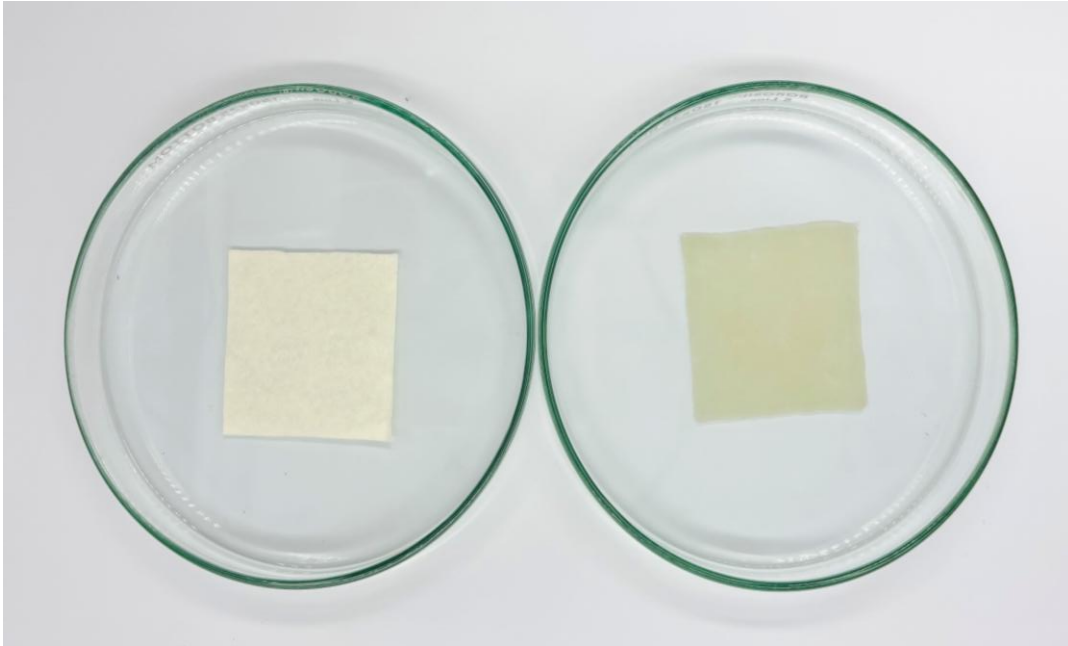


Unclogged blood leaking

In vitro Blood Clotting test (Video)



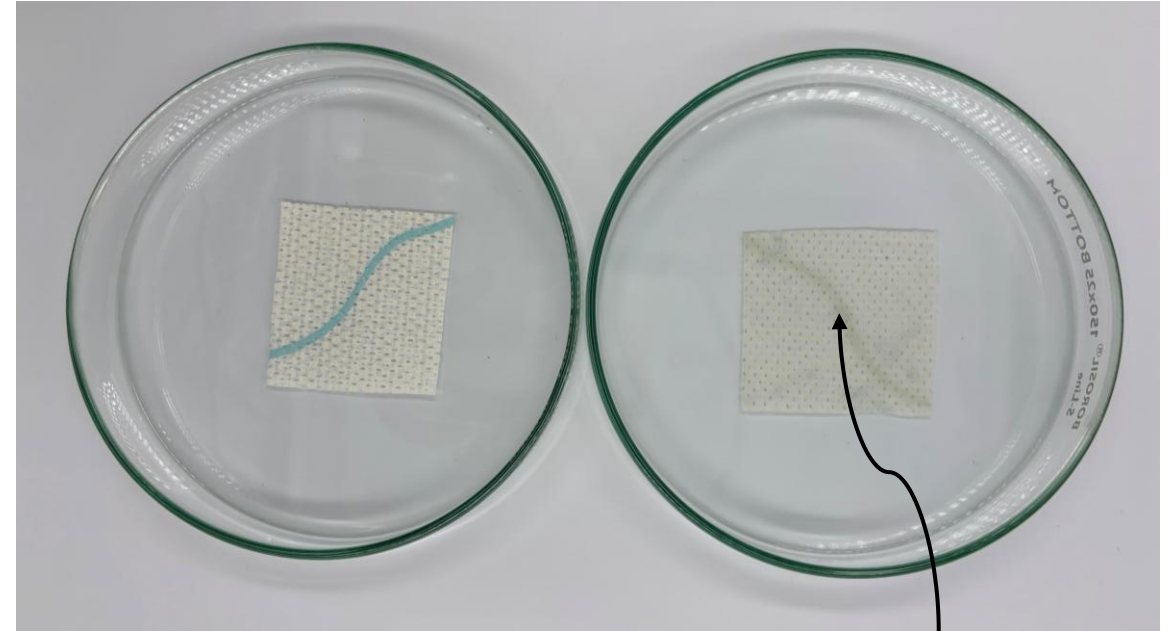
Dispersion / Integrity Test



Axiostat gauze
(Before Dispersion)

Axiostat gauze
(After Dispersion)

Product remain intact, with no product residues, no fibers and no particles observed. Dispersion solution remains clear, no particles observed under microscope.



SpeedM gauze
(Before Dispersion)

SpeedM gauze
(After Dispersion)

Color dye leaching from X ray detectable paste, marker becomes invisible to naked eye. Tiny particles observed in the dispersion solution under microscope.

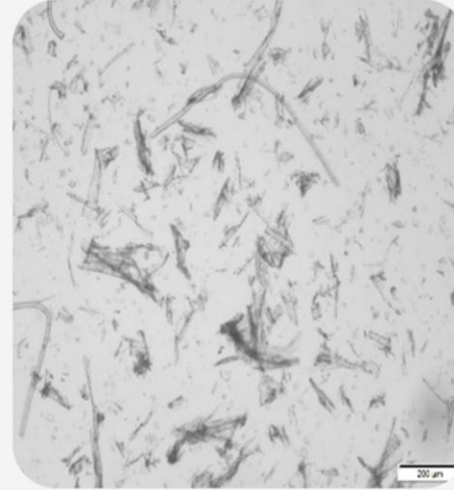
Particle Leaching Test

Visual Microscopic Evaluation



axiostat[®]
GAUZE

Dispersion solution remains clear, no particles observed under microscope.



Quikclot Gauze

Tiny particles with fibers (very high) are observed in the dispersion solution under microscope.



SpeedM

Tiny particles with fibers are observed in the dispersion solution under microscope.

Comparison of Safety, Antimicrobial and other parameters

Parameters	Axiostat Gauze	SpeedM Gauze	Quikclot Combat Gauze
Leaching into blood stream & risk of embolism	No leaching and no risk of embolism, as it has no powder, granules or coated particles [4].	Halloysite particles , color dye, acrylate binder may leach into blood stream in severe bleeding and cause embolism or risk of thrombosis	Kaolin particles leach into blood stream in severe bleeding and cause embolism or risk of thrombosis. [4].
Safety / Limitations	Complete biocompatible, Non-toxic, non-leachable, no powder or granules, inorganic mineral free [4]	Acylate may release to systemic circulation and may cause systemic toxicity , Halloysite particle may cause embolism or risk of thrombosis	Kaolin particles demonstrated genotoxicity [5] , Kaolin particulate can enter bloodstream, risk of thrombogenesis, exothermic reaction reported [6].
Antimicrobial Efficacy	Yes, has antimicrobial and barrier to bacteria property [4]. It showed more than 99.99 % (>4 log reduction) microbial reduction at 24 hours.	Halloysite has no antimicrobial activity	Kaolin has no antimicrobial property [7]
Shelf Life (Years)	5	5	5
Size Available (cm)	7.6 x 300, 7.6 x 370	7.6 x 370	7.6 x 370
Sterilization	Gamma sterile	gamma sterile	Gamma sterile

References

1. Lee, Vivian K., et al. "An architecturally rational hemostat for rapid stopping of massive bleeding on anticoagulation therapy." *Proceedings of the National Academy of Sciences* 121.5 (2024): e2316170121.
2. Feng, Yue, et al. "Systematic studies on blood coagulation mechanisms of halloysite nanotubes-coated PET dressing as superior topical hemostatic agent." *Chemical Engineering Journal* 428 (2022): 132049.
3. Zhu, S. and Diamond, S.L., 2014. Contact activation of blood coagulation on a defined kaolin/collagen surface in a microfluidic assay. *Thrombosis research*, 134(6), pp.1335-1343.
4. Kumar A, Agrawal A, Bharani KK, Mavely L. Evaluation of Hemostatic Effectiveness in a Standard Swine Hemorrhage Model of Severe Bleeding: A Comparative Study of Chitosan Gauze and Kaolin Gauze. *International Journal of Health Technology and Innovation*. 2024 Aug 20;3(02):38-47.
5. Kawanishi, Masanobu, et al. "Genotoxicity of micro-and nano-particles of kaolin in human primary dermal keratinocytes and fibroblasts." *Genes and Environment* 42.1 (2020): 16.
6. Wang, Mingtao, et al. "Hemostatic and antibacterial calcium–copper zeolite gauze for infected wound healing." *RSC advances* 14.2 (2024): 878-888.
7. Tamer, Tamer M., et al. "Hemostatic and antibacterial PVA/Kaolin composite sponges loaded with penicillin–streptomycin for wound dressing applications." *Scientific Reports* 11.1 (2021): 3428.