

User Manual: Protocol for Making the Tissue and Blood Mimicking Materials

Tool Reference

RST Reference Number: RST24TU01.01

Date of Publication: 09/24/2023

Recommended Citation: U.S. Food and Drug Administration. (2023). *Tissue and Blood Mimicking Materials for High Intensity Therapeutic Ultrasound* (RST24TU01.01). <https://cdrh-rst.fda.gov/tissue-and-blood-mimicking-materials-high-intensity-therapeutic-ultrasound>

For more information

[Catalog of Regulatory Science Tools to Help Assess New Medical Devices](#)

Disclaimer

About the Catalog of Regulatory Science Tools

The enclosed tool is part of the Catalog of Regulatory Science Tools, which provides a peer-reviewed resource for stakeholders to use where standards and qualified Medical Device Development Tools (MDDTs) do not yet exist. These tools do not replace FDA-recognized standards or MDDTs. This catalog collates a variety of regulatory science tools that the FDA's Center for Devices and Radiological Health's (CDRH) Office of Science and Engineering Labs (OSEL) developed. These tools use the most innovative science to support medical device development and patient access to safe and effective medical devices. If you are considering using a tool from this catalog in your marketing submissions, note that these tools have not been qualified as [Medical Device Development Tools](#) and the FDA has not evaluated the suitability of these tools within any specific context of use. You may [request feedback or meetings for medical device submissions](#) as part of the Q-Submission Program.

For more information about the Catalog of Regulatory Science Tools, email RST_CDRH@fda.hhs.gov.

Protocol for Making the Tissue and Blood Mimicking Materials

Recipes for Tissue and Blood Mimicking Materials

Materials	Function	TMM % (w/v)	BMM % (w/v)
Degas/DI Water	Substrate/Thermal property	100% (v/v)	100% (v/v)
Gellan Gum	High temperature matrix	0.8%	n/a
Polyurethane Powders	Absorption/Attenuation	12%	5%
Hollow Glass Beads	Scatter/Attenuation	0.2%	0.02%
Calcium Chloride	Mechanical strength	0.1%	n/a
1-propanol	Sound speed	10% (v/v)	10% (v/v)

Protocol for making the Tissue Mimicking Material (500 mL)

1. Weigh out all the ingredients to within a 0.1 g accuracy.
2. Add calcium chloride (0.5 g) and hollow glass beads (1.0 g) to a beaker with 20% (100 ml) of total degassed water (< 3 ppm), along with a magnetic stir bar. This solution is mixed on an electric stir plate under 27 in. Hg vacuum in a bell jar. This mixture is allowed to mix and degas for the duration of the TMM construction process.
3. Mix the polyurethane powder (60 g) and 1-propanol (50 mL) into 80% (400 ml) of total degassed water using a magnetic stir bar. This solution is mixed on a separate electrical stir plate while under 27 in. Hg vacuum in a bell jar for 1hr.
4. After 1 hr, add the Gellan Gum powder (4.0 g) slowly to the polyurethane solution (step 3) by sprinkling it from a spoon as close to the surface of the liquid as possible. This solution is further mixed and degassed under 27 in. Hg vacuum for another 1 hr.
5. Start heating the above Gellan Gum solution and keep stirring. At the same time, heat the calcium chloride solution (step 2) to 80 °C on another hot plate.
6. Heat the Gellan Gum solution to boiling for 2-3 minutes until no visible clumps.
7. Cool the Gellan Gum solution gradually down to 80 °C by stirring on the plate and then add the heated calcium chloride solution. Gently stir and cool the final milky solution on a stir plate
8. At 70 °C, pour the gel solution into the designated phantom holder. Tap the side wall of the holder to allow any trapped large air bubble flow to the top surface.
9. This gel solution will start to solidify around 60 °C and will form a solid TMM in 3-4 hr for a total volume of 500 mL.

Protocol for making the Blood Mimicking Material (500 mL)

1. Measure out all ingredients up to 0.1g accuracy
2. Add 500 ml of degassed and deionized water to an empty glass beaker.
3. Start stirring the water on a magnetic stirring hotplate and dissolve polyurethane powder (25 g) and hollow glass beads (0.1 g) slowly and uniformly.
4. Add 50 ml 1-propanol into the solution.
5. This solution is further mixed and degassed under 27 in. Hg vacuum for another 1 hr until all additives disperse uniformly.
6. After the mixing process, pour the fluid slowly into mold for measurement or use.

Property comparison between TMM vs. soft tissue, and BMM vs. human blood

Physical Properties	TMM	Soft Tissues	BMM (20 °C)	Human Blood (37 °C)
Thermal Diffusivity, mm^2s^{-1}	0.14	0.10 ~ 0.15	0.14	0.1 ~ 0.12
Thermal Conductivity, $\text{Wm}^{-1}\text{K}^{-1}$	0.57	0.47 ~ 0.57	0.60	0.5 ~ 0.58
Acoustic Attenuation, dB/cm	$0.61 f^{1.20}$	$(0.5-1.0) f^{(0.9-1.44)}$	$0.20 f^{1.06}$	$(0.16-0.24) f^{(1.19-1.23)}$
Speed of Sound, m/s	1532	1540 ~ 1590	1560	1540 ~ 1590
Elasticity, kPa / Viscosity, cP (mPa*s)	11 ~ 400	10 ~ 100	4.2	3 ~ 4 @ 37 °C
BSC (@3.5 MHz), $\text{cm}^{-1}\text{sr}^{-1}$	0.25 e^{-3}	$0.1 \sim 1.5 \text{ e}^{-3}$ (duck)	1.26 e^{-5}	$2 \sim 5 \text{ e}^{-5}$
Density, g/cm^3	1.03	1.0 ~ 1.07	1.02	1.054 ~ 1.068