

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** ensuring compliance with 21 FCR part 211.1  
**Date:** Tuesday, June 02, 2015 2:19:07 PM

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Good afternoon –

It is best to send your email with your compounding questions directly to the Center for Drugs (CDER) at [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov).

Kind regards,

Doreen M. Kezer, MSN  
Senior Health Policy Analyst  
Office of Good Clinical Practice  
Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

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**From:** [REDACTED]  
**Sent:** Tuesday, June 02, 2015 1:14 PM  
**To:** OC GCP Questions  
**Subject:** ensuring compliance with 21 FCR part 211.1

Hello, I have a few questions about the compounding of [REDACTED] capsules and matching placebo while remaining compliant with 21 FCR part 211.1.

The protocol that has been presented to pharmacy has received NIDA funding, and calls for the over-encapsulation of lorcaserin tablets in size 00 opaque gelatin capsule shells. I would be compounding them for each patient for use within 7 days.

1. Is this manufacturing (if done per patient, and not a large batch), and do I need to validate dissolution and disintegration, etc.? If so, would you share best practices for that process?
2. Does the need to do validity testing decrease if I do not back fill the lorcaserin caps (provided that method can still maintain the blind)?
3. The gelatin caps we have are very easy to pull apart and tampering would not necessarily be detected. What is your suggestion for compounding tamper evident capsules to comply with FDA regulation?

Best regards,

[REDACTED]