



Work Instruction

WI No.: R - 301

Title: Investigational Products: Storage and Accountability

Referenced SOP: 301-01

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Signature: _____ Date: _____

Intended Audience: Methods Centre

Procedures

1. The Methods Centre (MC), under the direction of the Sponsor, is responsible for supplying the research sites with the investigational product for the REDOXS study, i.e. Dipeptiven, Enteral REDOXS formulas and Micro-Selenium/Selenase.
2. The MC will work in conjunction with the following external parties to manage inventory.
 - Calea Ltd.: for all REDOXS study supplement distribution in Canada
 - Fresenius Kabi : for Dipeptiven and EN REDOXS formula distribution in the European Union
 - Biosyn: for Selenase distribution in the European Union
 - Colorado Lab: for Dipeptiven and EN REDOXS formula distribution in the United States
 - Individual US Pharmacies: for Selenium inventory at individual sites in the US
3. The MC will not supply a research site with investigational product until all required regulatory documentation, including research ethics board approval, has been submitted and received.
4. The MC will ensure that the research site is provided with written procedures concerning investigational product storage conditions, shipping and handling instructions, product dispensing and product destruction or return instructions. These are outlined in the Pharmacy Manual which is provided to all sites at initiation.
5. The MC will ensure that research sites maintain, and when requested, provide written documentation concerning the following:
 - Handling and receipt of investigational products: refer to specific WI
 - Inventory product storage for temperature: refer to specific WI
 - Investigational Product delivery refer to relevant WI
 - Investigational product use records, including accountability and inventory logs: refer to specific WI
 - Training of staff involved with these processes: refer to the pharmacy delegation of authority training/logs
 - Investigational product transfer or return: refer to specific WI
6. The MC will maintain documentation concerning investigational product stability, specification conformance and batch sample analysis and this will be filed in the central study files binder "Fresenius-Kabi".

