

(b)(4)

Sample Preparation

-(b)(4).

Results

-(b)(4).

-(b)(4).

-----). The results from SRM and control met all assay validity criteria and that from the three lots of products are within the specifications for - (b)(4)- content and -----(b)(4)-----, proposed in the BLA.

Conclusion

We find this method to be suitable for the assessment of content and (b)(4) in NovoEight, and hope this information is helpful for your development of a validated procedure for these product quality attributes. Dr. Lokesh Bhattacharyya may be contacted through me should you have questions.

If you have any questions, please contact me at (301) 827-6116.

Sincerely,

Leigh Pracht
Regulatory Project Manager
FDA/CBER/OBRR/DBA/RPMB

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