Accepted Manuscript

Formulation and optimization of controlled release powder for reconstitution for metoprolol succinate multi unit particulate formulation using risk based QbD approach

Piyush K. Mundada, Krutika K. Sawant, Veenu P. Mundada

PII: S1773-2247(17)30550-6

DOI: 10.1016/j.jddst.2017.09.001

Reference: JDDST 461

To appear in: Journal of Drug Delivery Science and Technology

Received Date: 5 July 2017

Revised Date: 13 July 2017

Accepted Date: 1 September 2017

Please cite this article as: P.K. Mundada, K.K. Sawant, V.P. Mundada, Formulation and optimization of controlled release powder for reconstitution for metoprolol succinate multi unit particulate formulation using risk based QbD approach, *Journal of Drug Delivery Science and Technology* (2017), doi: 10.1016/j.jddst.2017.09.001.

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.



ACCEPTED MANUSCRIPT

		Formulation attribute					
Drug Product CQA		API particle size	Core pellet size	Core pellet quantity	Drug layering technique	Extent of CR coating	Drug: Polymer
	Dissolution	Low	Medium	Medium	Medium	High	High
Initial	Assay	Low	Low	Low	Low	Low	Low
	Initial strategy	No investigation	Investigate	Investigate	Investigate	Optimize by DoE	Optimize by DoE
Final	Dissolution	Low	PAR identified	PAR identified	PAR identified	Critical PAR identified	Critical PAR identified

Initial and Final Risk assessment by Failure Mode and Effects Analysis (FMEA)

other the second

Download English Version:

https://daneshyari.com/en/article/5548077

Download Persian Version:

https://daneshyari.com/article/5548077

Daneshyari.com