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Impact of Particles Size Distribution on Diazepam 5mg Tablets Dissolution

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Diazepam is one of most frequently prescribed benzodiazepines. It is classified as a class I substance according to the Biopharmaceutics Classification Scheme (BCS). Diazepam tablets were prepared using different API raw-materials. Before the formulation, we measured particle size distribution on Malvern Instruments Ltd Mastersizer 2000. The tablets were prepared by employing conventional wet granulation. The formulations were evaluated for hardness, friability, content uniformity, in vitro disintegration time (DT), release profiles. The dissolution profile testing is performed on the two formulations with different particles size distribution.

Test parameters were: medium 0.1 mol / l hydrochloric acid, 900 ml, temperature 37°C ± 0.5°C, Mixing Speed 100 rpm, Number of tested tablets 12, Testing Cycle 10, 15, 20, 25 and 30 min. Instrument: Varian Van Kel VK7025, Varian Cary 50. We used the spectrophotometric method with absorbance measuring on 242 nm for quantification.

Results for particle size distribution for first Diazepam API particle distribution were d (0.10): 88.743 µm; d (0.50): 305.231 µm; d (0.90): 655.911 µm, and for the second raw-material of API was d (0.10): 1.998 µm; d (0.50): 4.419 µm; d (0.90): 8.845 µm. The results of diazepam dissolution for two formulations and f2 value with reference drug are presented in Table 1:

Tab. 1.

	Formulation A					Formulation B				
minutes	10	15	20	25	30	10	15	20	25	30
S.V.	85.34	99.05	100.79	100.39	99.88	99.08	98.49	97.90	97.36	96.89
SD	4.65	2.57	3.20	3.34	3.31	1.32	1.32	1.28	1.27	1.28
RSD	5.45	2.60	3.17	3.32	3.31	1.33	1.34	1.31	1.31	1.32
f2					68,15					99,44

It was concluded on the basis of formulation tests that Formulation B, for which micronized API was used, has a similar dissolution profile for API as compared to the reference medicine (f2=99.94) in comparison to Formulation A (f2=68.15)

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