**Development of an oral dispersible tablet for mucosal delivery of edaravone to MND patients**

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**Background and aims.** Edaravone slows motor neurone disease (MND) progression (1,2), and is commercially available as IV solution and oral liquid suspension (3). Both forms have poor clinical uptake (4). We aim to develop rapidly disintegrating oral mucosal tablet formulations to resolve the challenges of high cost and inconvenient dosing (IV solution) (5), short shelf life, poor bioavailability and administration difficulties (oral liquid) of current edaravone products. This report describes a gelatine-based freeze-dried edaravone tablet.

**Methods.** To a stirred homogeneous mixture of 0.50 g gelatine, 0.20 g glycine, 0.20 g sorbitol, 0.22 g simethicone and 12 mL water was added an aqueous suspension of edaravone (<150 µm, 1.71 g in 8 mL of water). The final suspension was dispensed at 0.8 g (60 mg edaravone) into troche moulds and lyophilised. The demoulded tablets were evaluated for weight uniformity, drug content, drug dissolution, moisture, and friability (6-8) immediately, and after storage at ambient conditions and 40°C, 75% RH.

**Results.**

The tablets weighed 104 ± 5 mg (n = 90) and contained 61.7 ± 2.0 mg (n = 12) edaravone. Within 5 min in simulated saliva, the tablet disintegrated and released 98.4 ± 0.3% of the edaravone load. This was substantially faster than pure edaravone powder (control), which showed only 73.2 ± 7.3% dissolution after 60 min. Tablets were intact after friability testing, showing low weight loss (0.252 ± 0.022%). Moisture content was comparable immediately after preparation (5.49 ± 0.76%) and after 2 weeks storage. Drug content was 100% and 88% of baseline levels after one week storage at ambient conditions and at 40°C, 75% RH, respectively.

**Conclusion/Discussion.** A novel gelatine tablet of edaravone with potential for sublingual administration in MND patients was successfully developed. It significantly enhances edaravone solubility in simulated saliva, and was durable, demonstrating physical and chemical stability on storage.

**References:**

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