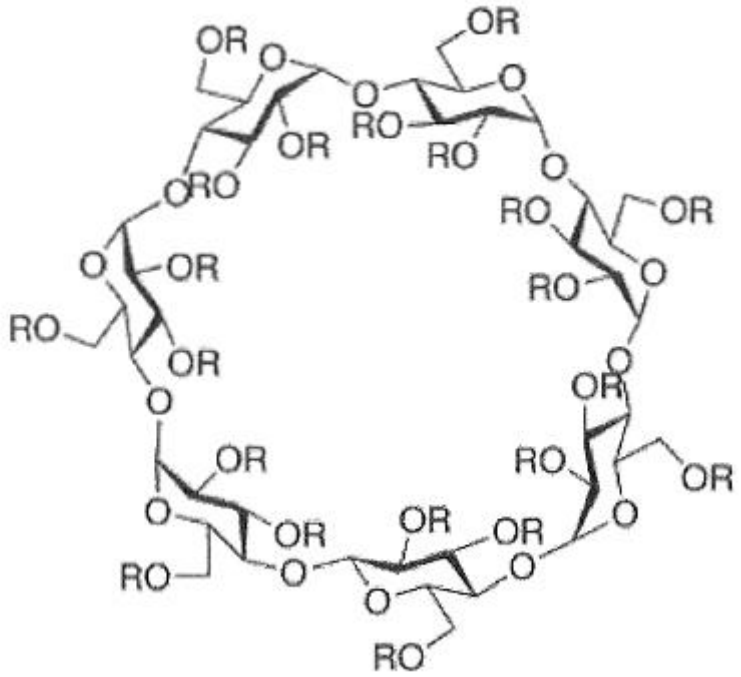
Claims

1. A formulation comprising dantrolene, or a pharmaceutically acceptable salt thereof, and a cyclodextrin in a molar ratio of 1:3 to 1:12 and also comprising polyethylene glycol (PEG) with an average molecular weight in the range 1500 to 6000.
2. The formulation as claimed in claim 1, wherein said pharmaceutically acceptable salt of dantrolene is the sodium salt, optionally the sodium hemiheptahydrate salt or the anhydrous sodium salt.
3. The formulation as claimed in claim 1 or claim 2, wherein said cyclodextrin contains between 5 and 10 glucose subunits and wherein said glucose subunits of said cyclodextrin are optionally substituted with a C_{1-6} alkyl group, which is itself optionally substituted with a hydroxyl group or a sulfo group.
4. The formulation as claimed in claim 3, wherein said glucose subunits of said cyclodextrin are substituted with a C_{2-4} hydroxyalkyl group, preferably a 2-hydroxypropyl group.
5. The formulation as claimed in claim 3 or claim 4, wherein on average, each cyclodextrin molecule contains between 4 and 8 substituents, preferably 5 substituents.
6. The formulation as claimed in any preceding claim, wherein said cyclodextrin contains 6 glucose subunits (α-cyclodextrin), 7 glucose subunits (β-cyclodextrin) or 8 glucose subunits (γ-cyclodextrin), preferably wherein said cyclodextrin contains 7 glucose subunits (β-cyclodextrin).
7. The formulation as claimed in any preceding claim, wherein said cyclodextrin is a β-cyclodextrin of Formula I:



wherein each R substituent is independently selected from the group consisting of H, $–CH_3$, $–CH_2CH(CH_3)OH$, $–(CH_2)_4SO_3Na$ and hydroxyethyl, preferably wherein each R substituent is independently selected from the group consisting of H and $–CH_2CH(CH_3)OH$.

8. The formulation as claimed in any preceding claim, wherein said dantrolene or a pharmaceutically acceptable salt thereof and said cyclodextrin are present in a molar ratio of 1:5 to 1:10, preferably 1:6 to 1:9.5, more preferably 1:8.3 to 1:8.6.
9. The formulation as claimed in any preceding claim, wherein said PEG has an average molecular weight in the range 3000 to 4000, preferably wherein said PEG is PEG3000, PEG3350 or PEG4000.
10. The formulation as claimed in any preceding claim, wherein said PEG is present in an amount such that the w/w ratio of PEG to cyclodextrin is 1:3 to 1:15, preferably 1:5 to 1:12, more preferably 1:8 to 1:10, most preferably 1:8.5 to 1:9.
11. The formulation as claimed in any preceding claim, which comprises dantrolene sodium hemiheptahydrate and 2-hydroxypropyl-β-cyclodextrin in a molar ratio between 1:8.3 to 1:8.6 and which also comprises PEG3350 in an amount such that the w/w ratio of PEG3350 to 2-hydroxypropyl-β-cyclodextrin is between 1:8.5 and 1:9, and wherein, on average, each 2-hydroxypropyl-β-cyclodextrin molecule is substituted by 5 hydroxypropyl groups.

12. The formulation as claimed in any of claims 1 to 11, which is a dry formulation, preferably wherein said dry formulation is a lyophilized formulation.
13. A dry formulation comprising 100-130 mg dantrolene sodium, 3000-4000 mg 2-hydroxypropyl-β-cyclodextrin and 350-450 mg PEG3350.
14. A liquid formulation prepared by dissolving a dry formulation as claimed claims 12 or claim 13 in a pharmaceutically acceptable solvent.
15. The liquid formulation as claimed in claim 14, wherein the pH of said formulation is greater than 7.0, preferably wherein the pH of said formulation is between 8.0 and 10.0.
16. A formulation as claimed in any one of claims 1 to 15, for use as a medicament.
17. Use of a formulation as claimed in any one of claims 1 to 15, in the manufacture of a medicament for the treatment of malignant hyperthermia.