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(54) Title: SUBCUTANEOUS ANTI-HER2 ANTIBODY FORMULATION

(57) Abstract: The present invention relates to a highly concentrated, stable pharmaceutical formulation of a pharmaceutically active anti-HER2 antibody, such as e.g. Trastuzumab (HERCEPTIN™), Pertuzumab or T-DM1, or a mixture of such antibody molecules for subcutaneous injection. In particular, the present invention relates to formulations comprising, in addition to a suitable amount of the anti-HER2 antibody, an effective amount of at least one hyaluronidase enzyme as a combined formulation or for use in form of a co-formulation. The said formulations comprise additionally at least one buffering agent, such as e.g. a histidine buffer, a stabilizer or a mixture of two or more stabilizers (e.g. a saccharide, such as e.g.  $\alpha$ , $\alpha$ -trehalose dihydrate or sucrose, and optionally methionine as a second stabilizer), a nonionic surfactant and an effective amount of at least one hyaluronidase enzyme. Methods for preparing such formulations and their uses thereof are also provided.



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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER  
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ADD.  
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A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)  
EPO-Internal, BIOSIS, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	Examples 18-21, [0433],[0558], examples 25, 26; claims, especially claim 52; [0482]	1-26
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X	US 2007/071675 A1 (WU CHENGBIN [US] ET AL) 29 March 2007 (2007-03-29)	1,2,4-9, 12-26
Y	[0111], [0112],[0184],[0180]	1-26
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See patent family annex.

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
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Y	BOOKBINDER ET AL: "A recombinant human enzyme for enhanced interstitial transport of therapeutics", JOURNAL OF CONTROLLED RELEASE, ELSEVIER, AMSTERDAM, NL, vol. 114, no. 2, 28 August 2006 (2006-08-28), pages 230-241, XP005625403, ISSN: 0168-3659, DOI: DOI:10.1016/J.JCONREL.2006.05.027 Abstract, page 232 item 2.9; page 233, item 3.3 to page 237, item 3.6; page 239, item 4.1; the whole document -----	1-26
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