

Corporation obtaining approval, the name of its representative, and the address of its main office

Name: Kobe University Hospital

Applicant: Masato Kasuga, Director (Seal)

Address: Kusunoki-cho 7-5-2, Chuo-ku, Kobe City

Approved Type 1 Use Regulation

Name of the Type of Living Modified Organism	Nonproliferative and genetically modified human adenovirus type 5 containing the gene sequence of Herpes simplex virus thymidine kinase (Ad-OC-TK)
Content of the Type 1 Use of Living Modified Organism	Used in clinical facilities for human gene therapy, including storage, transportation, disposal and acts incidental to them
Method of the Type 1 Use of Living Modified Organism	<p>Address: Kusunoki-cho 7-5-2, Chuo-ku, Kobe City, Hyogo Prefecture Name: Kobe University Hospital</p> <ol style="list-style-type: none">(1) The Ad-OC-TK solution should be sealed in containers, transported to a clinical facility in the frozen state, and stored in a freezer in a P2 level laboratory at the facility.(2) Thawing, dilution and dispensing of the frozen Ad-OC-TK solution has to be performed in a safety cabinet in a P2 level laboratory. Storage of the diluted Ad-OC-TK should be kept in a freezer in the P2 level laboratory. Note that when the diluted Ad-OC-TK or its frozen form is transported to another P2 level area through an open area, it should be kept inside a container that is doubly sealed.(3) When disposing of the Ad-OC-TK solutions (including dilutions), these should be sterilized and then disposed of according to the medical waste management protocol defined by the facility (hereinafter referred to as "the medical waste management protocol").(4) The administration of Ad-OC-TK to a subject should be performed in a single room that has appropriate containment measures (hereinafter referred to as "clean room") by injecting the diluted Ad-OC-TK into the bone metastasis or the local reoccurrence of advanced prostate cancer. Syringes, etc., used for the administration of Ad-OC-TK should be disposable ones, and after use, these should be appropriately inactivated in the clean room, followed by disposal in accordance with the medical waste management protocol.(5) The subject should be cared for in the clean room until the third day after administration. When the subject enters the open area outside the clean room for examinations, etc., viral leakage prevention measures, including the wearing of a mask and a gown must be compulsory. The excreta, etc. (including blood, body fluids, urine and feces) of the

	<p>subject during the period of being taken care of in the clean room should be appropriately inactivated in the clean room and disposed of in accordance with the medical waste management protocol. Note that the excreta, etc., from the subject that are to be used as clinical samples should be handled in accordance with the handling of the Ad-OC-TK solution.</p> <p>(6) During the period of being taken care of in the clean room, invasive devices that have been used in the subject and those that have been in contact with excreta, etc., should be appropriately inactivated in the clean room and then disposed of in accordance with the medical waste management protocol, or be washed sufficiently in the clean room.</p> <p>(7) Before releasing the subject from being taken care of in the clean room, confirm that Ad-OC-TK is negative in the blood and urine of the subject. If Ad-OC-TK is detected, the subject should continually be cared for in the clean room.</p> <p>(8) If Ad-OC-TK is detected in the blood or the urine of the subject after releasing the subject from the clean room, immediately transfer the subject back to the clean room, and take the same measures as in (5) to (7) above.</p>
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