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Skip to content Japan introduced the new JSQI, new permitted quasi-drug additives list and new quasi-drug application rules on March 25, 2021. JSQI 2021 specifies 2,647 active quasi-drug ingredients and 84 test methods. The new permitted quasi-drug additives list deleted one ingredient, modified 13 ingredients' name and made content corrections. The new quasi-drug application rules changed the previous requirements for the application for quasi-drugs manufacturing and marketing licenses. On March 25, 2021, Japan Ministry of Health, Labour and Welfare (MHLW) issued four documents, including the new Japanese Standards of Quasi-drug Ingredients (hereafter referred to as JSQI 2021), new List of Permitted Additives in Quasi-drugs, new Pre-market Application Rules of Quasi-drugs and a Collection of FAQs. In the above four documents, the ingredient standards are revised, and the corresponding pre-market application requirements of quasi-drug products are adjusted.The four documents took effect on March 25, 2021. A grace period of 1.5 years until September 30, 2022 was granted to allow the industry to prepare for new compliance requirements. During the period, the previous quasi-drug ingredient standards and application rules still apply.Compared with the existing regulations, the major revisions are as follows: 1. Revisions to the JSQIJSQI 2021 amended multiple ingredients and test methods in JSQI 2006, replacing it as a new overarching technical standard for quasi-drugs.ItemsMajor ChangesIngredients1. Combines the original two attached active ingredient lists into one list, and sorts them according to the kana syllabary;2. Modifies the specifications of 1453 ingredients;3. Deletes the ingredient Ethanol (96). After the deletion, JSQI 2021 includes 2,647 ingredients.* Note: After deleting Ethanol (96), "Ethanol" specified in JSQI 2021 only refers to "dehydrated ethanol" and "denatured alcohol".Test methods1. Adds two general test methods, bringing the total to 84 ; 2. Revises 17 test methods.2. Revisions to the List of Permitted Additives in Quasi-Drugs1. Change all the expressions of "JSQI 2006" in the previous additives list to "JSQI 2021";2. Delete the ingredient No. 255 "Ethanol (96-96.5 degrees)" in the previous additives list. Notably, this ingredient can be considered as a permitted quasi-drug additive until September 30, 2022;3. Clarify that the specification reference of ingredient No.1003 "Bis(Ethoxydiglycol) Cyclohexane-1,4-Dicarboxylate" shall be JSQI 2021 rather than Collections of Quasi-drugs Additives Standards;4. Modify 13 additives' English names in the previous additives list (see Table 1);Previous Additive ListCurrent Additive List (2021 Version)No.IngredientsNo.Ingredients106Alcailgenes Polysaccharides106Alcaligenes Polysaccharides132Althea Extract132Althaea Extract161Hestnut Rose Extract161Chestnut Rose Extract283Tetra (Polyoxyethylene Polyoxypropylene) Ethylene Diamine282Tetra(Polyoxyethylene/Polyoxypropylene) Ethylene Diamine470α-Olefine Oligomer469α-Olefin Oligomer976Neopentyl Glycol Di(2- Ethyl Hexanoate)975Neopentyl Glycol Di(2-Ethylhexanoate)977Di-2-Ethylhexylamine976Di(2- Ethylhexyl)amine(Dioc tylamine)1396Diglyceryl Sorbitan Tetra-2- Ethylhexanoate1395Diglyceryl Sorbitan Tetra(2- Ethylhexanoate)(Digly ceryl Sorbitan Tetraoctanoate)1777Grape Extact1776Grape Extract2269Mukurossi Peel Extract2268Mukorossi Peel Extract23251,1'-Methylene-bis (4- isocyanatocyclohexane)· Polypropylene Glycol Copolymer23241,1'-Methylenebis(4- isocyanatocyclohexan e)· Polypropylene Glycol Copolymer2740Romanchamomile Extract2739Roman Chamomile Extract2745Resin2744RosinTable 1 13 Renamed Additives3. Revisions to the Pre-Market Application Requirements of the Quasi-DrugsAlong with the revisions to the quasi-drug ingredient standards, relevant application requirements for the manufacture and sale of quasi-drugs have been modified accordingly.For quasi-drugs newly manufactured in line with JSQI 2021, applicants are required to write "JSQI ('外原規' in Japanese)" in the "Ingredient and Content" column in the application form, instead of filling in the specific specification of ingredients;For quasi-drugs that contain any of the revised ingredients in JSQI 2021 and have already obtained a manufacturing or marketing license as per the old specifications, related companies shall apply for a slight modification to change the specific specification listed in the "Ingredient and Content" column to "JSQI ('外原規' in Japanese)".Notably, the obtained manufacturing and marketing licenses will remain valid until September 30, 2022. But starting from October 1, 2022, related companies shall comply with new application rules and re-apply for new manufacturing and marketing licenses.4. FAQs about the Pre-Market Applications of Quasi-DrugsTo facilitate enterprises' applications for the manufacture and sale of quasi-drugs, MHLW also released a FAQs collection, which includes 29 questions relating to the marketing/manufacturing approval of quasi-drugs/cosmetics, formula and test methods, etc.Quasi-drug and cosmetic enterprises shall pay attention to the FAQ, and conduct business in line with the latest requirements. To provide the best experiences, we use technologies like cookies to store and/or access device information. Consenting to these technologies will allow us to process data such as browsing behaviour or unique IDs on this site. Not consenting or withdrawing consent, may adversely affect certain features and functions. Functional Functional Always active The technical storage or access is strictly necessary for the legitimate purpose of enabling the use of a specific service explicitly requested by the subscriber or user, or for the sole purpose of carrying out the transmission of a communication over an electronic communications network. Preferences Preferences The technical storage or access is necessary for the legitimate purpose of storing preferences that are not requested by the subscriber or user. Statistics Statistics The technical storage or access that is used exclusively for statistical purposes. The technical storage or access that is used exclusively for anonymous statistical purposes. Without a subpoena, voluntary compliance on the part of your Internet Service Provider, or additional records from a third party, information stored or retrieved for this purpose alone cannot usually be used to identify you. Marketing Marketing The technical storage or access is required to create user profiles to send advertising, or to track the user on a website or across several websites for similar marketing purposes. In 2021, MHLW revised its approval standards for feminine care products, hair colouring products, permanent wave products, and medicated toothpastes, and issued a new notice. In addition, the standard for quasi-drug raw materials was revised as "the quasi-drug raw material specification 2021." In July 2019, PMDA revised the mockup for the application for marketing approval for quasi-drugs (cosmetics for pharmaceuticals) and added an illustration on how to treat the standard of the appended ingredients and the test method in the case where the standard is the same as the appended standard of the approved item. Along with these developments, progress has been made in improving the simplification and speed of application and examination operations. In addition, in order to facilitate the review process, a briefing for personnel in charge of the application for quasi-drug approval is held every year, and reviews are conducted based on the materials provided at the briefing sessions. However, the positioning of the materials is not clearly indicated. As a recent topic, the Council for Promoting Regulatory Reform has asked the MHLW to consider transitioning to garbage and eye washes, which are thought to have less effect on the human body, in light of the need for the transition to quasi-drugs for some of the Group III Pharmaceuticals, and asked for a conclusion within FY2026. Recommendations For quasi-drugs deemed to be identical and similar to approval quasi-drugs, the review period should be continued to be shortened. When modifying the review approach, the changes should be clearly announced during the briefing session for practitioners applying for quasi-drug approval. Additionally, applicants should receive clear and concise explanations to ensure they fully understand the updates. Skip to content Local Title: 医薬部外品原料規格 2021 Competent Authority: Ministry of Health, Labour and Welfare Implementation Date: 2021-03-25