March 24, 2020

Submission of Review Data on Novel Pharmaceutical Excipients

Pharmaceuticals and Medical Devices Agency

For the review data on novel pharmaceutical excipients, the ”Submission of review data on pharmaceutical excipients (Pharmaceuticals and Medical Devices Agency, dated June 23, 2017)” has been an effective document that explains how to organize and submit the application data using the eCTD format. This document supersedes the above document and exempts the applicant from submitting a hard copy of the data in the eCTD format for reviewers. Please refer to the following for your future submission.

[Common matters for CTD format and non-CTD format]

For a highly novel excipient, expert discussions will be held. Please check with the reviewer in charge of the review team (hereinafter referred to as the "reviewer in charge") about whether or not an expert discussion on excipients will be held, as well as the number of copies of documents for the expert discussion, timing of submission, and place of submission.

[How to submit data on novel pharmaceutical excipients in CTD format]

1. Original and duplicate copies of CTD

Data on a novel excipient should be included in "CTD 1.13.4.1 Documents (copies) to be submitted to PMDA" in the following order:

(1) List of submission data on a novel excipient
(2) Tabulated summary of products for individual review
(3) Approval application form (copy)
(4) Summary of a novel excipient
(5) Data on a novel excipient

Of note, please ensure that all items to be included in the data are listed in: (1) List of submitted data on a novel excipient so that the list can be used as a table of contents.

If the data are stored in other locations in the CTD (e.g., (3) Approval application form (copy), (4) Summary of a novel excipient, and (5) Data on a novel excipient), a document referring to the storage location of the data may be inserted in the above relevant location. For the data in (4), locations of the data on each of the background of development (purpose and merit of mixing), specifications, stability, and safety should be separately referred to in a more specific manner (section title, page number in CTD Module 2). For points to note when using the eCTD, refer to “4. Points to note when preparing eCTD.”

2. Review data

If the original copy of the data attached to the approval application form is submitted in the eCTD format, submission of a hard copy of the data for reviewers may be omitted based on “Submission of Hard Copy of Data Attached to Approval Application Form for New Drugs for

Reviewers” (Administrative Notice of the Office of Review Management, Pharmaceuticals and Medical Devices Agency dated March 29, 2019).

3. Data for expert discussion

A hard copy of the data will be required for expert discussions on a novel excipient. Please submit the data listed in above 1. (1) to (5) for the expert discussions.

4. Points to note when preparing eCTD

For the above 1 (3) Approval application form (copy), (4) Summary of a novel excipient, and (5) Data on a novel excipient, the corresponding data files or PDF files with links to the storage locations should be stored in the m1/jp folder. Please refer to the example provided in the attachment. In the PDF file, a link should be created as specified in the eCTD notification, in principle.

[How to submit data on novel pharmaceutical excipients in non-CTD format]

1. Review data

When an application for a drug containing a novel excipient is filed, the review data on the novel excipient should be submitted along with the original and duplicate copies of the attached data for the drug product. One copy of the review data is required for the application. The number of copies, timing of submission, and place of submission of the review data required for the start of the review of the novel excipient will be notified by the reviewer in charge.

2. How to organize review data

The review data should have the contents and be organized as specified in above 1. (1) to (5) under **[How to submit data on novel pharmaceutical excipients in CTD format]** and be filed wherever possible. Each file should have the cover page with the product name, etc.

3. Submission of the original copy

After completion of the review is notified by the reviewer in charge, the original copy of the review data (with the statement and signature of the sponsor) should be submitted. All written responses should be attached to the front of the original copy.

(Attachment)

Example of description

-[m1-13] Others	
[m1-13-01] Data related to approved drugs	
+ [m1-13-02] Clinical trial consultation record (copy)	
[m1-13-03] Inquiries (copy) and responses to the inquiries (copy)	
-[m1-13-04] Other data	
-[m1-13-04-01] Data submitted to PMDA (copy)	
-[m1-13-04-01-01] Submission data on a novel excipient *	
[01] List of submission data on a novel excipient▼	Relative Filename=../../../0000/m1/jp/m1-13-04-01-01-01.pdf
[02] Tabulated summary of products for individual review▼	Relative Filename=../../../0000/m1/jp/m1-13-04-01-01-02.pdf
[03] Approval application form (copy)▼	Relative Filename=../../../0000/m1/jp/m1-13-04-01-01-03.pdf
[04] Summary of a novel excipient▼	Relative Filename=../../../0000/m1/jp/m1-13-04-01-01-04.pdf
[05] Data on a novel excipient▼	Relative Filename=../../../0000/m1/jp/m1-13-04-01-01-05.pdf
[m1-13-04-02] Data submitted to MHLW (copy) **	
[m1-13-05] Points to note for the eCTD format	

* If multiple novel excipients are contained, new content-blocks (e.g., M1.13.4.1.1 Submission data on novel excipient A, M1.13.4.1.2 Submission data on novel excipient B) may be created and stored.

** This example includes 1 file of “[05] Data on a novel excipient,” but if the “Data on a novel excipient” consists of multiple data sets, multiple doc-content elements should be created to include these data sets.

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<content-block param="m1-13-04">
  <block-title>Other data</block-title>
  <content-block param="m1-13-04-01">
    <block-title>Data submitted to PMDA (copy)</block-title>
    <content-block param="m1-13-04-01-01">
      <block-title>Submission data on a novel excipient</block-title>
      <doc-content xlink:href="../../../0000/m1/jp/m1-13-04-01-01-01.pdf">
        <title>List of submission data on a novel excipient</title>
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        <property name="checksum" info-type="jp-regional-m1-toc">bd53c77685a0545d587788addf09aacd</property>
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        <property name="sequencenumber" info-type="jp-regional-m1-toc">01</property>
      </doc-content>
      <doc-content xlink:href="../../../0000/m1/jp/m1-13-04-01-01-02.pdf">
        <title>Tabulated summary of products for individual review</title>
        <property name="operation" info-type="jp-regional-m1-toc">new</property>
        <property name="checksum" info-type="jp-regional-m1-toc">2c9cd67b1fd57d7a45d0d973f0981d61</property>
        <property name="checksum-type" info-type="jp-regional-m1-toc">md5</property>
        <property name="sequencenumber" info-type="jp-regional-m1-toc">02</property>
      </doc-content>
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        <doc-content xlink:href="../../../0000/m1/jp/m1-13-04-01-01-03.pdf">
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        </doc-content>
        <doc-content xlink:href="../../../0000/m1/jp/m1-13-04-01-01-04.pdf">
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