

EUROPEAN PATENT OFFICE  
U.S. PATENT AND TRADEMARK OFFICE

CPC NOTICE OF CHANGES 459

DATE: JANUARY 1, 2018

PROJECT MP0385

**The following classification changes will be effected by this Notice of Changes:**

<u>Action*</u>	<u>Subclass</u>	<u>Group(s)</u>
<b>DEFINITIONS:</b>		
Definitions Modified:	A61K	47/00

**No other subclasses/groups are impacted by this Notice of Changes.**  
*[Remove if not used]*

**This Notice of Changes includes the following** *[Check the ones included]:*

1. CLASSIFICATION SCHEME CHANGES

- A. New, Modified or Deleted Group(s)
- B. New, Modified or Deleted Warning(s)
- C. New, Modified or Deleted Note(s)
- D. New, Modified or Deleted Guidance Heading(s)

2. DEFINITIONS

- A. New or Modified Definitions (Full definition template)
- B. Modified or Deleted Definitions (Definitions Quick Fix)

3.  REVISION CONCORDANCE LIST (RCL)

4.  CHANGES TO THE CPC-TO-IPC CONCORDANCE LIST (CICL)

5.  CHANGES TO THE CROSS-REFERENCE LIST (CRL)

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## 2. A. DEFINITIONS (modified)

### A61K47/00

**Delete** the existing statement and **insert** the following:

**Medicinal preparations characterised by the non-active ingredients used, e.g. carriers, inert additives**

#### Definition statement

This place covers:

**Insert** a period on the end of the last line:

#### A61K47/00 - A61K47/46

Pharmaceutical compositions characterised by the excipients, i.e. the non-active ingredients.

New excipients per se.

**Insert** a period at the end of the line:

#### A61K47/50

Conjugates, i.e. compounds comprising a non-active ingredient chemically bound to the pharmaceutically active ingredient.

#### Relationships with other classification places

**Insert** the following paragraph at the beginning of Relationships with other classification places:

It should be noted that in A61K 47/00 the invention resides in the use of at least one particular compound as a biologically inert additive or excipient, for example to enhance the stability of a pharmaceutical formulation or to enhance the bioavailability of a biologically active ingredient in the body. The invention therefore does not reside in what the active ingredient does but in what at least one of the biologically inert ingredients does. It may be that this inert ingredient is a separate chemical entity from the biologically active ingredient or it may be that the inert ingredient is chemically bound to the biologically active ingredient. Thus any novelty that resides in the said inert compound per se will warrant classification in the appropriate area in class C01 for

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inorganic compounds or classes C07 or C08 for organic or polymeric compounds respectively.

**Insert** a period at the end of “New excipients per se are (in addition) classified in A61K47/00”:

Galenic aspects of pharmaceutical compositions are classified in A61K9/00 and in A61K47/00. The last place rule does not apply between A61K9/00 and A61K47/00 - A61K47/46.

Excipients can be classified in A61K47/00- A61K47/46 or in A61K9/00, depending on the situation: A61K47/00 is used to classify excipients in compositions for which A61K9/00 does not provide information on excipients. No A61K47/00 is given if A61K9/00 already provides information on excipients (e.g. tablet excipients are only classified in A61K9/20...). New excipients per se are (in addition) classified in A61K47/00.

Conjugates, i.e. compounds comprising a non-active ingredient bound to the active ingredient, are classified in A61K47/50. Pharmaceutical compositions comprising conjugates may in addition be classified in A61K9/00.

The active ingredients in pharmaceutical compositions are classified in A61K31/00 - A61K45/00, or A61K48/00 - A61K51/00.

**Delete** the existing Special rules of classification and **insert** the following:

### **Special rules of classification**

Classified are concrete, well-defined pharmaceutical compositions disclosed in the examples. Also classified are independent claims defining galenic aspects of a pharmaceutical composition or a medical use.

In principle all examples are classified, also 'standard' examples in documents describing e.g. a new medical use.

However, systematically classifying all excipients in the examples is not necessary, and often undesirable. In any case classified are excipients which are described as being important for the invention, or which the reader can identify as having an important function, e.g. for sustained release. For 'standard' compositions the examiner should choose one or a few excipients to classify.

Animal tests are not classified, unless it is absolutely clear that they represent the intended mode of administration.

The description and dependent claims are not classified. However, if the document as a whole focuses on one clearly preferred embodiment, this embodiment may be classified, even in the absence of relevant examples or independent claims.

In general, information relating to the invention is classified using invention information symbols, while additional information is classified using additional information symbols.

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This is largely up to the discretion of the examiner. Please note however the following special situations:

Normally only final compositions are classified, not intermediates. However, it may be useful to classify intermediates as additional information (e.g. a tablet comprising microcapsules; a multicoated microparticle). If the intermediates are claimed separately, they must be classified as invention information.

If, in the classification scheme, a group refers out to another group, an additional information symbol may still be given for the first group (e.g. oral mucoadhesive film).

A61K 47/02 covers inorganic compounds but does not cover polymeric inorganic materials, which are covered by A61K 47/30 - macromolecular (organic or inorganic) compounds – e.g., inorganic polyphosphates.

A61K 47/06 covers hydrocarbon materials of both natural and synthetic sources. Natural examples include petrolatum, mineral oil and ozokerite – i.e., there are no functional groups present in such materials, i.e., ester, ketone, hydroxyl or carboxylic groups. A61K 47/06 also covers mixtures of hydrocarbons as well as pure hydrocarbons.

A61K 47/10 covers alcohols such as aliphatic alcohols, phenols or salts thereof; polyalkylene glycols [PEG], [PPG]; poloxamers; PEG/POE alkyl ethers. This subgroup does not cover sugar alcohols (A61K 47/26) or copolymers comprising polyalkylene glycols or poloxamers (A61K 47/34).

A61K 47/34 does not cover polyalkoxylated compounds, which are classified according to the compounds being derivatised. The following list gives examples of such polyalkoxylated compounds together with the relevant group.

POE alkyl ethers - A61K 47/10

PEG fatty acid esters – A61K 47/14

Poloxamines – A61K 47/18

Polysorbates – A61K 47/26

POE castor oil – A61K 47/44

A61K 47/44 covers materials that comprise mixtures of chemically distinct components, i.e., more than one of the groups A61K 47/02 to A61K 47/42, i.e., carboxylic acids and esters. Materials that comprise such mixtures may include natural or modified oils, fats or waxes such as olive oil, castor oil, montan wax, lignite, shellac, lanolin and beeswax. Materials that comprise only a mixture of different carboxylic acids – i.e., of different carbon chain lengths or a mixture of aromatic and aliphatic carboxylic acids – will be classified in A61K 47/12.

A61K 47/64 covers the situation where peptides, proteins or polyamino acids are chemically bonded directly to drugs or are chemically bonded to the drug via a linker.

A61K 47/62 is more appropriate where peptides, proteins or polyamino acids are bound

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or complexed to special galenical forms of a drug, e.g., a liposome or a nanoparticle modified on its surface by a peptidic modifying agent. In these latter situations, classification in A61K 47/69 would also be appropriate.

If the modifying agent in the conjugate is some kind of inclusion complex, e.g., a cyclodextrin, then classification in A61K 47/69 will be appropriate. If cyclodextrin is used as a simple excipient then classification in A61K 47/40 will be required.

## **Insert** new Glossary of terms:

### **Glossary of terms**

*In this place, the following terms or expressions are used with the meaning indicated:*

Targeting agent	Natural or artificial substances that enhance absorption of a biologically active agent in a particular part of the body – i.e., in a particular organ or to a particular cell type.
Pre-targeting system	An example of this is an immuno-conjugate that has a part that recognizes a target antigen and a part that recognizes a further substance to which a therapeutic agent is attached. When said conjugate is administered it binds to target cells, furnishing said cells with binding sites for the therapeutic agent.
Modifying agent	Natural or artificial substances that enhance the physio-chemical properties of a biologically active agent – i.e., that improve long term storage stability or enhance bioavailability when delivered orally.
Macromolecular	A chemical moiety (organic or inorganic) that is linked to identical sub-units in numbers of greater than 5. Thus, polysiloxanes are classified in A61K 47/34, polyphosphazines in A61K 47/34 and inorganic species such as polyphosphate A61K 47/30
Chemically bound	When two distinct chemical entities are linked to one another by co-valent bonds. An alternative situation may arise when both chemical entities are linked using ionic bonds, for example using organic/inorganic ions that complex with one another, e.g., see A61K 47/52

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Codrug	A dimer, oligomer or polymer of one or more pharmacologically or therapeutically active compounds. e.g. polyaspirin
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