BRAZIL

EXAMINATION GUIDELINES OF PATENT APPLICATIONS ASPECTS RELATED TO THE EXAMINATION OF PATENT APPLICATIONS IN THE CHEMICAL AREA

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1. INTRODUCTION

These Guidelines address particular aspects of the examination of patent applications in the Chemistry area, complementing the general aspects of patentability and formalities found in the INPI Patent Application Examination Guidelines, Block I (Resolution INPl / PR N.124 / 2013 - RPI 2241 , dated 12/17/2013) and Block II (Resolution INPl / PR N.169 / 2016 - RPI 2377, of 07/26/2016). Since it is a complement to the INPI Guidelines, the Guidelines must be read together. Seeking to help understand the text, the chapters and paragraphs of Blocks I and II are identified throughout the document.

2. CHEMICAL COMPOUND

2.1 NEW AND INVENTIVE ACTIVITY

The technical examination of the patentability requirements of patent applications claiming chemical compounds follow the same procedures applicable to products in general and are detailed in Block II of the Patent Application Examination Guidelines. It is only to be remembered that in compound patent applications in which the composition, formulation and/or physical form is also claimed, it is considered that the novelty and inventive activity of the compound will be extended to the composition (Paragraph 7.6 of Block II of the Patent Application Examination Guidelines), formulation and/or physical form (accessory inventions).

2.2 CLARITY AND ACCURACY OF CLAIMS

The most precise way of claiming a chemical compound is the one that defines it in terms of its chemical structure (general formula), nomenclature (according to IUPAC rules) or another name that defines it unequivocally. Only in those cases where it cannot be defined as previously described, the compound may be characterized by its production process, as determined in Paragraphs 3.60 and 3.61 of Block I and in Paragraphs 4.17 of Block II of the Guidelines for Examination of Patent Applications, provided that it meets the patentability requirements.

Claims that define the compound by its process of obtaining are only possible in extreme cases where it is not possible to define it in another way and where the process itself is sufficiently precise in order to avoid ambiguities as to what is being protected. This is because, insofar as the product resulting from the process includes, for example, the by-products thereof, such claims tend not to be clear as to the material they protect.

Independent claims that define the compound solely by its physical, physicochemical or biological properties are not accepted, since such characteristics alone do not identify the compound in question, jeopardizing the clarity and precision of the claimed matter, contrary to art. 25 of Law 9,279/96 (Industrial Property Law, LPI). For example, an independent claim of the type "Compound characterized by having the property Y" would not be accepted, as the term "compound" is undefined, and may refer to any compound having the Y property.

Likewise, independent claims defining a compound by its applications or use, for example, "Compound characterized as being used for X" are

not accepted, insofar as they represent an indefiniteness as to the subject matter to be protected, Art. 25 of the LPI (Guidelines for Examination of Patent Applications, Block II, Paragraph 4.16).
The clarity of a claim of chemical compound may also be compromised by the use of generic expressions often employed in order to broaden the scope of protection to encompass the derivatives of the compound. This is the case of claims of chemical compound which claim, in addition to the compounds per se, their stereoisomers, hydrates, solvates, prodrugs, ethers and esters or other derivatives. These expressions alone do not identify the derivatives of the compound clearly and precisely since they only define the derivatives by their chemical class or chemical function. If the report of the patent application sufficiently describes these objects, the claim may be reformulated so as to better define the claimed subject matter.
On the other hand, claims of compounds which contain generic expressions, such as "pharmaceutically acceptable salts" and "agriculturally acceptable salts", may be accepted, since: 1) the compound is responsible for the activity, the salt being a release agent of the active fraction of the compound and; 2) the person skilled in the art has knowledge of the salts commonly used in his area of operation.

2.3 COMPOUNDS DEFINED BY MARKUSH-TYPE FORMULAS

Claims of compounds defined by the Markush-type formula are examined according to the Patent Application Examination Guidelines, Block I, Paragraphs 3.38 and 3.126 to 3.128 and Block II, Paragraphs 6.1 to 6.14.

2.4 SALTS, N OXIDES, ESTERS AND ETHERS

Salts, N-oxides, esters and ethers of known chemical compounds of the prior art are usually employed to provide the compound with properties which enable conditions more appropriate to its industrial application, such as solubility, dissolution, stability and suitable organoleptic properties.
Technical analysis of patent applications claiming salts, N-oxides, esters and ethers follows the same guidelines applied to chemical compounds in general. In order to be considered novel, the claimed salt / N-oxide / ester / ether could not have been anticipated in the prior art. Where the prior art generically anticipates salts / N-oxide / esters / ethers of known compounds, the claimed salt / N-oxide / ester / ether may not have been specifically disclosed (See

Item 2.8 of these Guidelines and Guidelines for Examination of Applications of Patent, Block II, Paragraphs 4.16 to 4.25 and 5.31 to 5.34). For example, the patent application claims protection for the mesylate salt of compound A. The prior art document discloses compound A and salts thereof, listing as preferred salts mesylate, fumarate and hydrochloride. In this case, the claimed mesylate salt of the compound A is considered to be specifically disclosed in the prior art and is therefore not novel. On the other hand, if the patent application claims the succinate salt of compound A, said salt will be considered novel since it was not specifically mentioned among the preferred ones of the prior art document.

In the possibility of a particular salt, N-oxide, ester or ether altering the properties of the base compound in a manner not obvious to a person skilled in the art, this salt, N-oxide, ester or ether will be considered endowed with inventive activity. On the other hand, the mere description of an alternative salt / N-oxide / ester / ether of a known compound, when disassociated with a property not obvious or of an unexpected technical effect to the prior art, has no inventive activity.

Usually, the process of obtaining a salt, N-oxide, ether or ester involves the combination of known and standard procedures of the prior art, since all the reactions of obtaining these classes of compounds are described in the literature and, therefore, obvious to a person skilled in the art.

However, if the salt, N-oxide, ether or ester is considered to be patentable, the processes for obtaining it can be analyzed as analogous processes (Item 8 of these Guidelines) and, as a result, will also be endowed with patentability requirements.

It will be appreciated that the use of the generic expressions "their ethers" and/or "esters" in claims pertaining to a compound per se do not identify the ethers and esters derivatives of the compound clearly and precisely, since they only define derivatives by means of its chemical class or chemical function. If the patent application report sufficiently describes these objects, the claiming frame may be reformulated so as to better define the claimed subject matter.

On the other hand, compound claims containing generic expressions, such as "pharmaceutically acceptable salts", "agriculturally acceptable salts", "immunologically acceptable salts" and "N-oxides" may be accepted, since: 1) the compound is responsible for the activity, the salt or N-oxide being a release agent of the active fraction of the compound and; 2) the technician in the subject has

knowledge of the salts commonly used in their area of operation.

2.5 PRODRUGS

The chemical compounds may function as prodrugs, i.e. compounds that require prior biotransformation to exhibit their pharmacological effects. Also inactive compounds (or substantially less active than the drug) may be considered, which, after administration, undergo biotransformation to give pharmacologically active compounds.

Pro-drugs are generally developed from derivatives of certain functional groups of a particular compound, in order to optimize the physicochemical, biopharmaceutical or pharmacokinetic properties of the pharmacologically active compounds, overcoming any barriers relating to the formulation and release of drugs, such as low solubility in water, chemical instability, poor oral absorption, pre-systemic metabolism, inadequate central nervous system penetration, toxicity and local irritation.

The technical analysis of this subject follows the same guidelines applied to chemical compounds in general. Especially with regard to the analysis of the inventive step requirement, it is important to note that in certain instances, a known strategy for improving the pharmacological or pharmacotechnical properties of drugs may lead to an effect that would not be obvious to a person skilled in the art.

It is emphasized that the use of the generic term "its pro-drugs" in claims pertaining to a compound per se, does not identify the prodrugs of the compound clearly and accurately. If the patent application report sufficiently describes these objects, the claiming frame may be reformulated so as to better define the claimed subject matter.

2.6 INTERMEDIATE COMPOUNDS OF REACTION

Intermediates, in the narrow sense, are chemical compounds (or groups of chemical compounds) that are used in the route of production of another chemical compound (or group of chemical compounds), through chemical and/or physical change(s), losing their identity. For the sake of simplification, the reference to "chemical compound" will encompass "group of chemical compounds". In the context of these Guidelines, intermediates may be intermediates per se or starting materials (precursors).

Of course, there may be chemical compounds which, in addition to functioning as precursors (intermediates) of a particular chemical compound, also have end uses, such as pesticides, pharmaceuticals, dyes, etc. However, in this case, when they are in their function as

pharmaceuticals, etc., they will no longer be "intermediaries" within the meaning of these guidelines and should be analyzed according to the previous item.
With the above explanations in mind, two situations may occur:
(1) the intermediate is the main invention;
(2) the intermediate is conventionally referred to as an "accessory invention" in which the main invention may be a final chemical compound or a process for obtaining a chemical compound.
In cases where the intermediate compound is not the main invention, it should be assessed whether the intermediate and the preparation thereof belong to the same inventive concept of the main invention, which is a compound (final product) and/or the process of its preparation. Here, the guidelines contained in the Guidelines for the Examination of Block I - Paragraphs 3.119 to 3.125 apply.
It will be appreciated that in both cases the claims relating to the intermediate(s) are necessarily product claims and should be treated as such by applying the most appropriate guidelines set out in these Guidelines. Also, in both cases, claims are accepted for the process of obtaining the intermediate(s).

2.6.1 Intermediate compounds as main invention

The claims relating to the intermediate(s) are necessarily chemical compound claims and the technical analysis of this subject follows the same guidelines applied to chemical compounds in general.
The inventive activity of an intermediate must be judged on the basis of its application as an intermediate, and of its differences in relation to the compounds of the prior art. Thus, if the closest prior art discloses compounds similar to the claimed intermediate but does not suggest its application in obtaining other compounds, i.e., their application as intermediates, it is understood that it would not be obvious or apparent to a person skilled in the art to use compounds similar to those of the prior art as synthetic intermediates.
In the case where the compounds of the closest prior art have the function of intermediates, the differences between the claimed (intermediate) compound and those of the prior art must be observed, in order to evaluate whether or not these differences are obvious, considering the intermediate function of the claimed compound.

2.6.2 Intermediate compounds as accessory invention

Where the intermediate is an accessory invention in a patent application relating to another compound as the main invention, it is

not possible to extrapolate the novelty and the inventive step of the main invention to the intermediate, since the effects / activities / purposes of the main invention and intermediate are different.
In cases where the intermediate compound is not the main invention, it should be assessed whether the intermediate and the preparation thereof belong to the same inventive concept of the main invention, which is a compound (final product) and/or the process of its preparation. Here, the guidelines contained in the Guidelines for the Examination of Block I - Paragraphs 3.119 to 3.125 apply.

2.6.3 Process for the obtaining intermediate compounds

A process for obtaining an intermediate may constitute the main invention of the patent application, but the most common one is an accessory invention for a main invention of the final compound or even of an intermediate.
In the former case, in which the process of obtaining the intermediate is the invention, the process claims of intermediate must define.
(1) the starting material, the product obtained and the means of transforming the first into the second and;
(2) the various steps required to achieve the proposed objective.

2.7 CHEMICAL COMPOUNDS FOUND IN NATURE

Chemical compounds found in nature are not considered inventions, according to the provisions of art. 10 (IX) of the LPI.
Synthetic chemically obtained compounds having naturally occurring counterparts, not being able to distinguish them from the compounds found in nature, are also not considered as an invention. This aspect has been addressed in greater detail in the Patent Application Examination Guidelines, Block II, Paragraph 1.43, and in the Guidelines for Examination of Patent Applications in the Biotechnology Area, Item 4.2.1.1.

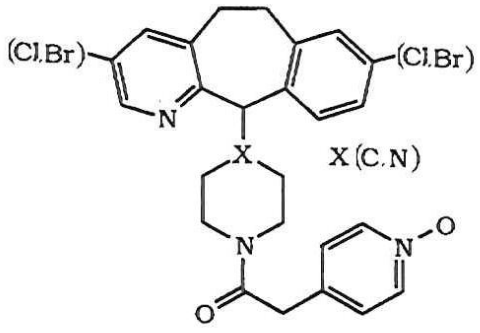
2.8 PATENT APPLICATIONS OF SELECTION OF CHEMICAL COMPOUNDS

Some patent applications may address a selection of compounds of a broad class of compounds described in the prior art, for example, compounds defined by Markush type generic formulas. Usually, the above document refers to a new class of chemical compounds.
The procedures for the technical examination of the patent applications for the selection of chemical compounds are detailed in Block II of the Guidelines for the Examination of Patent Applications, paras. 4.19 to 4.25 and 5.31 to 5.34.

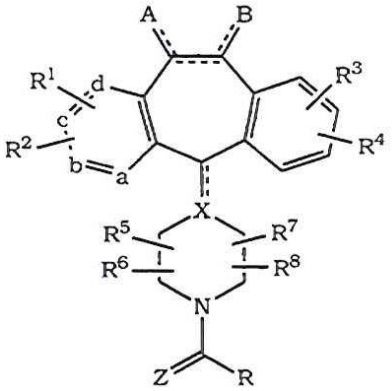
In general, to be considered novel, the selected chemical compound may not have been specifically disclosed in the prior art in the form of examples, tests, results, lists, tables, nomenclature, individualized structural formula or method of preparation. With respect to the inventive step, the selection of said compound can not be obvious or apparent to a person skilled in the art from the teachings of the prior art. Invariably, because it is a selection of compounds already described generally in an earlier document, the evaluation of the inventive step requirement of the patent for the selection of compounds involves the presentation of comparative data in relation to the prior art. As defined in Block II of the Guidelines for Examination of Patent Applications, Paragraphs 4.19 and 5.32, the comparison must be made in relation to the state of the closest technique, which, in this case, corresponds to the compound(s) of highest similarity structurally disclosed in the prior art.
The following are some examples that illustrate three situations that may occur in the technical examination of patent applications for the selection of chemical compounds: 1) Selected compounds devoid of novelty and inventive activity; 2) Selected novel compounds, but devoid of inventive activity and; 3) Selected new and inventive compounds.

Example 1: Compounds devoid of novelty and inventive step
Invention
Useful tricyclic amide compounds in the treatment of proliferative diseases
Prior art
The prior art document discloses tricyclic amide or urea compounds also used in the treatment of proliferative diseases.

Invention



Prior Art



Technical analysis

The selected chemical compounds represent a restricted group among the compounds generally disclosed in the Markush formula of the prior art document. Such compounds selected in the application under analysis do not correspond to the compounds exemplified in the prior art document; however, have been described among such preferred compounds in said document. Accordingly, the claimed compounds are considered to be specifically disclosed in the prior art (Patent Application Examination Guidelines, Block II, Paragraphs 4.21 to 4.23) and do not fulfill the novelty requirement.

In order to demonstrate the inventive step, the applicant presented a series of biological tests comparing the selected compounds with the compounds of higher structural similarity specifically disclosed in the prior art. However, in view of the fact that the claimed compounds are not new, they also do not meet the requirement of inventive step.

Example 2: New compounds, devoid of inventive step

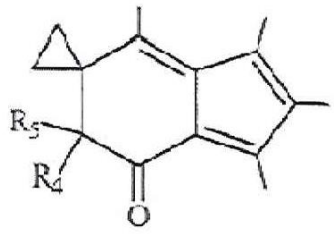
Invention

The application relates to analogous compounds of iludins with antiproliferative activity for the treatment of tumors in mammals.

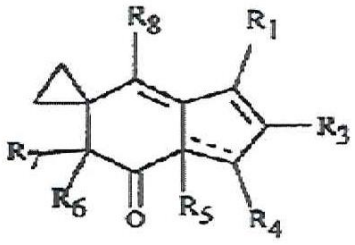
Prior art

The prior art generically describes, in the Markush formula, analogous substances of illudin useful as antiproliferative agents.

Invention



Prior art



Technical analysis

The compounds selected represent a restricted group among the compounds generally disclosed in the prior art document, but as not specifically disclosed (Patent Application Examination Guidelines, Block II, Paragraphs 4.21 to 4.23), are considered novel.

The applicant presented test results comparing the antiproliferative activity between the claimed compounds and the compounds of higher

structural similarity specifically disclosed in the prior art. The results presented did not demonstrate an unobvious effect with respect to the prior art, since the antiproliferative activity of the claimed compounds was very similar to the compounds disclosed in the prior art (Patent Application Examination Guidelines, Block II, Paragraph 5.33). Thus, although the claimed compounds are considered novel, they do not meet the requirement of inventive step.

Example 3: Compounds provided with novelty and inventive step

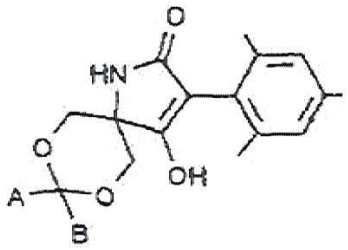
Invention

The patent application relates to phenyl-substituted cyclic ketoenols, processes for their preparation and their use in pesticidal and herbicidal compositions.

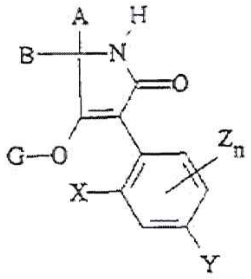
Prior Art

The prior art discloses a generic description of cyclic ketoenols with pesticidal and herbicidal activity encompassing the compounds selected in the patent application under review.

Invention



Prior art



Technical Analysis

The compounds claimed in the selection patent application were considered novel since, although they are generally chemically provided derivatives in the Markush formula in the prior art document, they have not been specifically disclosed (Patent Application Examination Guidelines, Block II, Paragraphs 4.21 to 4.23).

To substantiate the inventive activity of the subject, test data have been presented which clearly demonstrate the unobvious technical effect of the claimed compounds as compared to the compounds of higher structural similarity specifically disclosed in the prior art. In this way, the selected compounds were considered not obvious to a person skilled in the art (Patent Application Examination Guidelines, Block II, Paragraph 5.34).

3. STEREOISOMERS

lsomers are compounds that have identical molecular formulas but differ in nature, in the sequence of the bond or in the spatial arrangement of their atoms. Enantiomers, atropisomers and diastereoisomers, which will be defined below, are members of the class of isomers that have the same molecular formula but differ in the spatial position of their atoms.

The enantiomers are molecules that have chiral centers and have non-overlapping mirror images of each other. Diastereomeric compounds are stereoisomers which are not mirror images of one another and have different physicochemical properties.

Atropisomer is a subclass of conformational isomers, which may be isolated as a pure chemical species and arising from a restricted rotation of a single bond (usually due to very bulky substituents).

A stereoisomeric mixture is a mixture of stereoisomers, in any ratio.

A racemic mixture is a mixture of equimolar stereoisomers.

3.1 DESCRIPTIVE SUFFICIENCY

The clear and sufficient description of the stereoisomer in pure form lies in the characterization of the absolute configuration of its chiral center at the time of the filing of the patent application.

Analytical techniques, such as circular dichroism, nuclear magnetic resonance (with or without addition of chiral displacement reagent), circular birefringence, optical rotational dispersion, chromatography (with chiral column), polarimetry and single crystal X-ray diffraction can be used for characterization of the enantiomer / atropisomer / diastereoisomer claimed.

The parameters of the process of obtaining the stereoisomer, either by asymmetric synthesis or by the purification process after the synthesis of the compound, must be specified in the descriptive report, in order to guarantee its reproducibility by a person skilled in the art. Due to the possibility of racemization of the chiral compounds during the production process, it is important that the descriptive report reveals the reagents used (mainly in the chiral center formation stage), the reaction conditions, the isolation and purification methods of the stereoisomer obtained by said process. The report should also describe the possible enantiomeric excess obtained and the method of analysis used for its measurement.

3.2 CLARITY

Stereoisomers must be defined by the official nomenclature (IUPAC) or

other system that identifies them unequivocally.
It is emphasized that the use of the generic term "stereoisomers" in claims pertaining to a compound per se does not identify the stereoisomers of the compound clearly and accurately. If the patent application report sufficiently describes these, the framework of claim may be reformulated so as to better define the claimed subject matter.

3.3 NOVELTY

The stereoisomer compounds will be considered novel in cases where the prior art does not describe the claimed enantiomer / atropisomer / diastereoisomer. Novelty will also be attributed to cases where there has been described in the prior art enantiomer / atropisomer / diastereoisomer isolated from nature and the antipode thereof is now claimed.
However, since in the prior art the compound has already been disclosed in a stereoisomeric mixture, such as a racemic mixture, the pure enantiomerically or atropisomerically pure compounds are not considered novel since the stereoisomeric mixture already has both stereoisomers. It is emphasized that when the prior art does not specify the absolute configuration of the chiral centers of the described compounds, nor is any chiral influence observed in the synthesis process of such compounds, it will be considered that the distribution of the enantiomers occurs in an equitable manner, that is, it is a racemic mixture.
In the case of patent applications dealing with diastereoisomers, the novelty will be proven when the prior art does not specifically describe the claimed diastereoisomer. In some cases, the assessment of the novelty of the claimed diastereoisomer is only possible by the presentation of characterization data of the known compound so that a comparison can be drawn between the claimed diastereoisomer and the prior art. In this case, the same analytical techniques employed for the characterization of the claimed diastereoisomer should be applied to samples of the stereoisomer disclosed in the prior art.
The composition containing only one of the stereoisomers is considered novel even though the prior art describes a composition containing the compound in the form of a racemic mixture or other stereoisomeric mixture. In this case, the wording of the composition claim must necessarily exclude the possibility that the protection also falls on the racemic composition or other composition containing stereoisomers already described in the prior art. Particularly, the use of the term

consists, as it is considered a restrictive term, limits the constituents of a composition only to those defined in the claim (Patent Application Examination Guidelines, Block I, Par. 3.48). For example, a claim of the type *"Composition consisting of the R-enantiomer of compound X and vehicles"* excludes the presence of any other stereoisomer other than that defined in the claimed composition. Note that the term "vehicles" (excipients, adjuvants, carriers, etc.) is related to carrier substances of the R-enantiomer and therefore does not include the S-enantiomer (even if it is an inactive component). On the other hand, the use of the term comprises makes the scope of protection of claims of composition wider, compromising novelty. For example, the wording of a claim of the type "Composition comprising the R-enantiomer of compound X and vehicles" does not limit the constituents to only those elements defined in the claimed composition, which may comprise, in addition to the stereoisomer R, other constituents, including the stereoisomer S (Patent Application Examination Guidelines, Block I, Paragraph 3.49). However, a "composition of the type comprising the R-enantiomer of compounds X and vehicles, wherein said composition is free of the S-enantiomer of compound X" could be considered novel in view of the fact that it excludes the presence of the S-enantiomer of the claimed composition. A composition consisting of a stereoisomeric mixture of definite constitution (determined stereoisomeric excess) will be considered novel, provided that it has not previously been disclosed in the prior art. For example, a claim of the type "Composition comprising the R-enantiomer of compound X and vehicles, wherein the enantiomeric excess is greater than 70%" could be considered novel.

The use of an isolated enantiomer / atropisomer is not new if the prior art already discloses the use of its racemic mixture for that purpose. The same is considered for the the claim that deal with diastereomers of a compound, when the prior art anticipates the claimed use for said compound.

If the application concerns a new use of an isolated stereoisomer compound, the examination should be based on the Patent Application Examination Guidelines, Block I, Paragraphs 3.73 to 3.76 and Block II, Paragraph 4.18 and in the Guidelines for Examination of Patent Applications - Chemistry, Item on New Uses of Known Products.

3.4 INVENTIVE ACTIVITY

When the purpose of the compound of the prior art is known, it is expected that the pure stereoisomer of this compound will exhibit the

same purpose. Thus, it is considered that the person skilled in the art would be motivated to obtain this stereoisomer with the purpose of identifying the most suitable industrial use, for example, the most active stereoisomeric form. The same reasoning should be applied to the analysis of inventive activity of compositions containing stereoisomers.

If the application concerns a new use of an isolated stereoisomeric compound, examination should be based on the Patent Application Examination Guidelines, Block I, Paragraphs 3.73 to 3.76, and Block II, Paragraphs 5.40 to 5.45 and in the Examination Guidelines for Patent Application - Chemistry, Item on New Uses of Known Products.

4. POLYMORPHS

Polymorphism refers to the ability of a chemical compound to exist in one or more crystalline phases having different arrangements and/or conformation of the molecules in an ordered crystal lattice. Amorphous solids consist of solids with disordered arrays of the molecules and do not have a defined crystal lattice.

4.1 DESCRIPTIVE SUFFICIENCY

For the characterization of the crystalline form, the descriptive report should contain, on the date of filing of the application, identification data obtained by physico-chemical characterization techniques of solids, such as those exemplified below or by alternative techniques validated that best identify it:

a. Single crystal X-ray diffraction (Monocrystal XRD);
b. Diffraction of X-rays by the Powder Method (XRD by the Powder Method);
c. Solid State Nuclear Magnetic Resonance Spectroscopy Carbon 13 (^{13}C NMR);
d. Spectroscopy in the Infrared Region;
e. Raman spectroscopy;
f. Electron Microscopy;
g. Thermal Analysis: Differential Scanning Calorimetry (DSC), Thermogravimetry (TG) and Differential Thermal Analysis (DTA).

It should be noted that the single crystal XRD technique is sufficient for the perfect characterization of the crystalline structure of the solid. If single crystal XRD data are not provided, the XRD technique should be used by the indexed powder method, associated with other methods of physicochemical identification of solids, provided that the set of techniques is sufficient for the unambiguous identification of crystalline form. It should be noted that more advanced solid characterization techniques not provided for in these Guidelines will be evaluated as to their relevance for the identification of the crystalline solids claimed. In the absence of the characterization data of the crystalline solid, it will be considered that the descriptive report does not clearly and sufficiently describe the object. Note that it will not be allowed to present characterization data of the claimed solid after the filing of the patent application, since it would be considered an addition of matter.

The parameters of the process of obtaining the crystalline form must be specified in the descriptive report, in order to guarantee its reproducibility by a person skilled in the art. Essential parameters

in these processes are considered, for example, the indication of the solvent(s) and their concentration(s), rates of addition of solvents, rates of heating and cooling, description of the process obtaining any seeds used in the crystallization process and other parameters that may be considered critical.
It should be noted that the crystalline form claimed is considered part of the preparation process, i.e., so that the process can be considered sufficiently described so as to enable its reproduction by a person skilled in the art, the polymorph obtained by such a process should be duly characterized in the descriptive report.

4.2 CLARITY AND ACCURACY OF CLAIMS

The identification of a crystalline form is made by means of physicochemical parameters that define its structure. The simple denomination by designations such as alpha or beta form, form I or II, does not clearly and precisely define the crystalline form. The following are examples of claims of crystalline forms with clear and precise wording.

Example 1:
Crystalline form of compound X characterized by having a melting point of 151°C as measured by differential scanning calorimetry (DSC 2K min^{-1}) to present reflections (2-theta) at 7.5, 10.1, 12.0, 12.4, 13.7, 15.0, 16.0, 17.3, 17.7, 18.0, 19.2, 19.8, 20.7, 21.0, 22.2, 22.7, 22.9, 23.6, 24.1, 25.6 and 30.5, with respective relative intensities 11.4, 63.0, 19.0, 21.0, 7.6, 15.2, 9.5, 7.6, 5.7, 14.3, 5.7, 23.0, 11.4, 11.4, 61.0, 100.0, 13.3, 7.6, 28.6, 9.5 and 7.6, in its X-ray diffractogram;
exhibit maximum peaks at 3338, 1708 and 1431 cm^{-1} in their infrared spectrum, exhibit maximum peaks at 107.9, 118.2 and 135.0 ppm in their ^{13}C solid state NMR spectrum, and exhibit maximum peaks at 3080 , 1580 and 122 cm^{-1} in its Raman spectrum.

Example 2:
Crystalline form of compound X characterized in that it presents reflections (2-theta) at 7.5, 10.1, 12.0, 12.4, 13.7, 15.0, 16.0, 17.3, 17.7 , 18.0, 19.2, 19.8, 20.7, 21.0, 22.2, 22.7, 22.9, 23.6, 24.1, 25.6 and 30.5, with the respective relative intensities 11.4, 63.0, 19.0, 21.0, 7.6, 15.2, 9.5, 7.6, 5.7, 14.3, 5.7, 23.0, 11.4, 11.4, 61.0, 100.0, 13.3, 7.6, 28.6, 9.5 and 7.6 in its monocrystal X-ray diffractogram.

4.3 NOVELTY

The distinctive characteristics of crystalline forms are based on physico-chemical parameters. In general, the closest prior art is that which reveals the obtaining of the compound, which, for the most part, is not characterized as to its crystalline structure. In such cases, for the purpose of evaluating the novelty of the claimed crystalline form, physico-chemical characterization data of the solid compound described in the prior art may be presented at the time of the filing of the patent application or during the technical examination.

If the prior art already reveals the claimed crystalline form, although in admixture with other forms, regardless of its concentration, the crystalline form claimed is not considered novel.

In the event that the prior art describes the compound in a non-solid state (e.g. liquid, pasty or oily), the physico-chemical characterization data of the compound of the prior art is dispensable, since, under these circumstances, there has been no doubts as to the novelty of the claimed polymorph.

4.4 INVENTIVE ACTIVITY

Even if it is a single chemical substance and the possibility of formation of different crystalline networks is a peculiar property of solids, the polymorphic forms may have different physicochemical properties both in the product preparation processes and in the shelf life or still in terms of chemical effects.

However, it is important to note that the search for crystalline solids of a compound is a common practice of the industry to improve the physicochemical characteristics of compounds in general. Thus, the mere description and characterization of an alternative crystalline solid of a known compound, when disassociated with a property not obvious to the solid or a technical advance against the prior art, has no inventive step.

5. SOLVATES, CLATHRATES, CO CRYSTALS

In some crystalline solids, the solvent may be incorporated into the crystalline network of the compound in stoichiometric or non-stoichiometric proportions. These molecular adducts are called solvates, also called pseudopolymorphs. When the water is the solvent of crystallization, the resulting solid is called hydrate.

When a solvate loses the molecules of the solvent incorporated into the crystalline lattice (purposely or not) and the crystal retains the structure of the solvate, the obtained solid is called desolvate. This matter should be evaluated as discussed in the item on Polymorph of these Guidelines, since it refers to the crystalline form composed only of one type of molecule.

In turn, clathrates are inclusion compounds wherein a molecule (guest) is entrapped in a cavity of the host molecule or the host molecule network (e.g., cyclodextrin inclusion complexes).

In general, solvates, clathrates and co-crystals have the following common features:

1) all are formed by at least two molecules;

2) all may assume different crystalline forms;

3) all may have different characteristics according to the structure and constituents of the crystal.

In a patent application the invention of which is any of these products, it must be considered that:

1) for the clear and sufficient description of a solvate, clathrate, crystalline or co-crystal complex, the chemical identification of the molecule and stoichiometry is mandatory, which can be determined by means of thermogravimetric analysis techniques (TG), Karl Fischer or other validated techniques that provide such information;

2) if the invention to be protected is a solvate, the Chemical Compound item of this Guideline and the INPI Patent Application Examination Guidelines should be consulted for evaluation of the subject matter, since the solvate is considered a different chemical compound of its correspondent without solvation or anhydrous;

3) if the invention to be protected is a crystalline form (clathrate, co-crystal or crystalline form of the solvate), it must be physicochemically characterized by the techniques described in the item on Polymorph of this Guideline, in addition to the Patent Application Examination Guidelines of INPI, in order to define both the constituents and the structure of the crystalline form.

4) the use of the generic terms "solvates thereof", "hydrates", "their clatrates" and/or "their co-crystals" in claims referring to a

compound per se, do not identify solvates, hydrates, clathrates and co- crystals of the compound clearly and accurately. If the patent application report sufficiently describes these objects, the claiming frame may be reformulated so as to better define the claimed subject matter.

6. COMPOSITIONS, FORMULATIONS AND PHYSICAL FORMS OF COMPOSITIONS

Claims of compositions, formulations and physical forms of compositions are examined according to the Patent Application Examination Guidelines, Block II, in its Paragraphs 7.1 to 7.15.

6.1 CLARITY AND ACCURACY OF CLAIMS

As discussed in the Patent Application Examination Guidelines, Block II, Paragraphs 7.1 to 7.15, a composition is usually defined only by its constituents. However, the compositions may further be defined by mixed characteristics so as to encompass physical or application characteristics, so long as they are qualitatively and/or quantitatively defined by their constituents. In the following, complementary examples of compositions are presented, with emphasis on the clarity and accuracy analysis of the claims (article 25 of the LPI).

Example 1:

Claim 1: Pharmaceutical composition, characterized in that it comprises compound A and excipients B and C.

Claim 2: Pharmaceutical composition according to claim 1, characterized in that it is for oral administration.

According to art. 25 of the LPI, since the composition is defined by the constituents thereof in claim 1 and the administration form is an additional feature restricting the claimed matter to the field of compositions for oral use (tablets, capsules, syrups, etc.).

Claim 3: Pharmaceutical composition according to claim 1, characterized in that it is in capsule form.

According to art. 25 of the LPI, since the composition is defined by its constituents in claim 1 and the expression "it is in capsule form" is a further feature of the claimed subject matter.

Claim 4: Pharmaceutical composition according to claim 1, characterized in that it is for the treatment of asthma.

According to art. 25 of the LPI, since the composition is defined by its constituents in claim 1 and its application is an additional feature, which restricts the claimed matter to the field of the useful products to the treatment of asthma.

Claim 5: Pharmaceutical composition according to claim 1, characterized by releasing eighty percent (80%) of component A in less than thirty minutes.

According to art. 25 of LPI, since the composition is defined by its constituents in claim 1, and the release of component A is an

additional feature, which informs the properties of the claimed material.

Example 2:
Claim 1: A pharmaceutical composition characterized in that it comprises the compound A and excipients B and C for oral administration.
According to art. 25 of the LPI, since the composition is defined by its constituents. Information on the form of administration is an additional feature, which restricts the subject claimed to the field of compositions for oral use (tablets, capsules, syrups, etc.).

Example 3:
Claim 1: Pharmaceutical composition for oral administration characterized in that it comprises compound A and excipients B and C.
According to art. 25 of the LPI, since the composition is defined by its constituents. The information on the method of administration is an additional feature, which restricts the subject claimed to the field of compositions for oral use (tablets, capsules, syrups, etc.).

Example 4:
Claim 1: A pharmaceutical composition characterized in that itcomprises compound A and excipients B and C to treat asthma.
According to art 25 of LPI, because the composition is defined by its constituents. The information on the use of the composition represents only an additional characterization of the composition, which restricts the claimed matter to the field of the useful products to the treatment of asthma.

Example 5
Claim 1: Pharmaceutical composition comprising compound A and excipients B and C characterized in that it is for the treatment of disease Y.
Not acceptable for lack of clarity (article 25 of LPI), because the composition is not characterized by its constituents but by its application. In this case, to comply with art. 25 of the LPI, it is possible to rephrase the claim, by shifting the constituent elements of the composition to the characterizing part. (Patent Application Examination Guidelines, Block I, Paragraphs 3.04 to 3.09).
If the composition is known in the prior art, the claim would also not be new, since the feature relating to the use of the composition

does not confer novelty to the product.

Example 6:
Claim 1: A composition characterized by releasing eighty percent (80%) of the active ingredient in less than thirty minutes.
Not acceptable for lack of clarity (article 25 of LPI), because the composition is not characterized by its constituents. The released percentage of the active principle does not define the claimed matter.

Example 7
Claim 1: An insecticidal composition characterized in that it is in the form of a spray.
Not acceptable for lack of clarity (article 25 of LPI), because the composition is not characterized by its constituents and the form of application does not define the claimed matter.

Example 8:
Claim 1: Pharmaceutical composition characterized in that it comprises compound A and its excipients B and C to be used as sustained release tablets capable of releasing eighty percent (80%) of component A in less than thirty minutes.
According to art. 25 of LPI, since the composition is characterized by its constituents and the pharmaceutical form and the properties of the product are additional characteristics of the composition.

Example 9:
Claim 1: A tablet characterized in that it comprises compound A and excipients B and C.
According to art. 25 of the LPI, since the tablet is characterized by its constituents (in this case, the elements of the composition that constitute the invention)

Example 10:
Claim 1: Pharmaceutical form characterized in that it is in the form of a tablet consisting of 100 mg of A, 220 mg of B and 200 mg of C.
According to art. 25 of LPI, since the pharmaceutical form is characterized by its constituents and by the physical form of tablet.

Example 11:
Claim 1: A pharmaceutical composition characterized in that it

comprises the compound A and its excipients B and C.
Claim 2: Pharmaceutical composition according to claim 1, characterized in that the dosage of A ranges from 45 to 90 mg per kg of the patient.
Not acceptable for lack of clarity (Article 25 of the LPI), since the additional feature of the dependent claim refers to the method of administering the pharmaceutical composition, which is part of a therapeutic regimen and is not related to the product. The added feature does not add information about the product per se, which creates an inconsistency with the claimed material.
Claim 3: Pharmaceutical composition according to claim 1, characterized in that it is administered twice daily.
Not acceptable for lack of clarity (Article 25 of the LPI), since the additional feature of the dependent claim relates to the method of administering the pharmaceutical composition, which is part of a therapeutic regimen and not a product. The added feature does not add information about the product per se, which generates an inconsistency with the claimed material.

Example 12
Claim 1: A composition characterized in that it comprises a compound A and a compound B.
Claim 2: A composition according to claim 1, characterized in that it optionally comprises other active ingredients.
Not acceptable for lack of clarity (Article 25 of the LPI), since the term "and optionally other active ingredients" does not define said active ingredients. If the application report provides a sufficient description of the so-called "active ingredients", the claim may be reformulated in order to restrict the active ingredients to those described in the descriptive report.

Example 13:
Claim 1: A gray-colored soda-lime glass composition characterized in that it comprises an element A and an element B at concentrations x and y, respectively, present as coloring agents, the glass having a total light transmission of <20% for a glass having thickness of 4 mm.
Claim 2: A gray-colored soda-lime glass composition according to claim 1, characterized in that the glass has a total light transmission of <10% for a glass having a thickness of 4 mm.
According to art. 25 of LPI, since the composition is characterized

by its constituents and their respective concentrations. The luminous transmission (physical parameter) is an additional feature of the subject matter.

Example 14:

Claim 1: Fertilizer composition characterized in that it comprises the raw material A (eg ammonium nitrate) and the raw material B (eg calcium sulfate), in the concentrations X and Y, respectively.

Claim 2: Fertilizer composition according to claim 1, characterized in that it contains the nutrient Z (eg total nitrogen) at a concentration of 80% by weight and the nutrient W (eg calcium) at a concentration of 10%, in Weight.

According to art. 25 of the LPI, since the composition is characterized by its raw materials and their concentrations. The nutrients and their concentrations are further characteristics of the composition.

Example 15:

Claim 1: Fertilizer composition characterized in that it consists of elements X, Y and Z (ex: carbon, hydrogen, nitrogen, phosphorus, potassium ...).

Not acceptable for lack of clarity (article 25 of LPI), because the composition is not characterized by the raw materials that contain such elements, nor does it specify their concentrations.

7. COMBINATIONS OF CHEMICAL COMPOUNDS

A combination is the association of two or more compounds targeting a particular final product. The combination may be contained in a single form or in separate forms for simultaneous application. For the examination of combinations, Paragraphs 5.24 to 5.30 and 7.16 to 7.23 of the Guidelines for Examination of Patent Applications, Block II, should be considered.

In the particular case of inventions relating to combinations, the interaction between the associated compounds should produce a non-obvious effect, for example a synergistic or supra-additive effect, which does not correspond to an additive effect, ie the mere sum of the effects of each compound composing said combination.

Thus, when the result of the association of two or more known compounds is a sum of the effects that would be expected for each compound used alone, the claimed combination will be considered devoid of inventive step, since said combination corresponds to a predictable combination of compounds known to generate an expected technical effect.

Evidence of the unobvious effect of a combination often involves the presentation of data that would allow a comparison between the effects observed with the respective compounds when used alone and those obtained from the combination of these compounds under the same experimental conditions.

It should be noted that the alleged unobvious effect can not be suggested in the prior art, for example in combinations of compounds of the same class as the compounds of the combination under analysis (Patent Application Examination Guidelines, Block II, Paragraph 7.19).

7.1 DESCRIPTIVE SUFFICIENCY, CLARITY AND ACCURACY OF CLAIMS

7.1.1 Combination comprising compounds defined by "Markush formula"

When the invention relates to a novel combination of two or more compounds, wherein at least one of the compounds is defined by a formula of the type "Markush", for example,

"A combination characterized in that it comprises a compound as defined by general formula (I) in association with compound A"

Special attention should be given to the clarity and precision of the wording of the claim and Patent Application Examination Guidelines, Block II (paragraphs 6.13 and 6.14) should be consulted.

7.1.2 Combinations which comprise one or more classes of chemical compounds

The invention relates to a combination comprising one or more groups of compounds defined by their chemical class or by their mechanism of action, for example,

“A pesticide combination characterized in that it comprises a pyrethroid compound and an enzyme inhibitor compound X ".

The definition of the compounds of the combination by their chemical class or their mechanism of action in a generic manner, without specifying which are the exact compound(s) comprised in the combination, is not sufficient to clearly define the matter to be protected, contrary to the provisions of art. 25 of the LPI.

If the report of the application provides a sufficient description of the compounds which fall within the classes of compounds according to the invention, the claims may be reformulated so as to restrict the compounds to those described in the descriptive report.

7.1.3 Combinations which optionally comprise other active ingredients

Requests for a new combination may comprise, in addition to the main claim relating to the combination, accessory claims of the type:

”A combination characterized in that it comprises compound A and B and optionally other active ingredients”.

In such situations, particular attention should be given to the clarity and precision of the wording of the claim of combination, since the mere mention of the term "and optionally other active ingredients" is not sufficient to clearly define the claimed subject matter, contrary to the provisions of art. 25 of the LPI.

If the report of the application provides a sufficient description of the compounds which are framed as the other active ingredients according to the invention, the claimed framework may be reformulated so as to better define the material to be protected.

7.1.4 Combination in which the compounds are in separate forms

In applications relating to combinations in which the compounds are in separate forms, the descriptive report shall provide evidence that such combinations are obtainable in the form of a product for simultaneous application, even if it is sought through a kit (Patent Application Examination Guidelines, Block II, Paragraph 7.11).

Example:

Descriptive Report:

The patent application relates to a combination comprising herbicides A and B. In the descriptive report, the synergistic effect of the combination was demonstrated when the compounds were applied to the plants separately, but simultaneously.

Claims Chart

Claim 1: "A synergistic herbicidal combination characterized in that it comprises compound A and compound B."

Claim 2: "A method for controlling weeds characterized in that the plants are treated with the combination as defined in claim 1."

Claim 3: "A method according to claim 2, wherein compound A and compound B are applied simultaneously or sequentially."

Technical analysis:

Claims 1 and 2 may be accepted provided they meet the patentability requirements. In contrast, claim 3 can not be accepted, since it includes the possibility that the application of compounds A and B occur sequentially. Since a combination refers to a combination product of two or more compounds for simultaneous application, the possibility of sequential application would be inconsistent with the material to be protected.

8. ANALOGOUS PROCESSES

Analogous processes comprise starting materials and/or final products which are novel and inventive in view of the prior art, although such processes involve the combination or use of procedures known in the art.

In identifying novelty and inventive step for the starting materials and/or final products, it is not necessary to investigate such requirements for their respective claims to analogous processes, provided that they are interconnected with the main claim of starting material and/or final product.

Accordingly, claims of analogous processes can be interpreted generally as accessory claims, since, by definition, the assignment of novelty and inventive step is a function of the presence of these requirements in the product and/or starting material. In addition to the analogous processes relating to the synthesis of chemical compounds having novelty and inventive activity, the concept can also be extrapolated to those processes relating to the production of pharmaceutical compositions, agrochemicals, medicaments, catalysts, lubricants, pesticides or herbicides, among others.

If the technical examination considers that the starting materials and/or end products have no novelty and/or inventive activity, the analogous processes claimed will not be accepted for lack of novelty and/or inventive step in the prior art.

In another situation, if the technical examination considers that the starting materials and/or end products have no novelty and/or inventive step, but considers that the claimed processes involve novel and/or inventive steps, such process claims should be examined as process claims, that is, it was no longer an analogous process claim.

Because the steps involved in the analogous processes are generally well known to one skilled in the art, it may suffice to mention them generally in the descriptive report.

9. NEW USES OF KNOWN PRODUCTS

This item deals with particularities of the technical examination of inventions of new uses of known products, especially new medical uses, in addition to the Guidelines for Examination of Patent Applications, Block I, Paragraphs 3.73 to 3.76 and Block II, Paragraphs 4.18 and 5.40 to 5.45.

The protection of the claim for new use is given to the whole use of the known substance for a new purpose. In this way, the report should clearly and sufficiently describe the new use sought.

In the event that the application seeks protection for a new use of various compounds, for example, identified in a "Markush formula", only the use of the compounds which has been effectively demonstrated in the descriptive report will be considered sufficiently described, in order to prove the claimed use . Although, theoretically, the compounds defined by a particular "Markush formula" may exhibit similar activities, it is not possible to extrapolate the new use of a single compound to all others unless tests are shown to prove this equivalence of effect.

The application dealing with a new use of a group of compounds will have the unity of invention if said compounds are structurally related (Markush formula, for example) or have the same mechanism of action.

In the pharmaceutical area, the application which deals with a new medical use intended for a group of diseases of the same etiology will also have a unity of invention.

9.1 NEW MEDICAL USE

9.1.1 Novelty

To be considered novel, the invention of new medical use should disclose the application of a pharmaceutical product already known to produce a medicament for treating or preventing a disease other than that for which this product was already employed in the prior art.

Characteristics related to the use of the compound, such as the therapeutic scheme (dosage, route of administration / application, dosage range) and/or group of patients do not give novelty to the known use of the compound. For example, if the prior art discloses the "use of compound X to manufacture a medicament for treating disease Y" and the application claims the "use of compound X to manufacture a medicament for treating Y disease in diabetic patients", the pleaded use is not considered new.

9.1.2 Inventive activity

In the case of new medical use inventions, some aspects must be observed to assess the inventive activity requirement:

1. The mechanism of action of the compound involved in the new use should not be understood from its mechanism of action for medical use already disclosed in the prior art.
2. The new use shall relate to the treatment of a disease whose etiology is different from the etiology of the disease related to the use disclosed in the prior art.
3. The new use can not be deduced from the structure-activity relationship of the drug in comparison with structurally related molecules, i.e., from the structural analogy with other compounds that present the same activity now claimed, already disclosed in the prior art.
4. The novel use can not be understood from the disclosure of adverse effects known from the prior art to the drug in question.
5. The novel use can not be understood from the use of the compound for the treatment of a symptom of a disease already disclosed in the prior art, although the claimed use refers to a different disease.

9.1.3 Sufficiency of the descriptive report and substantiation of the claims

It is to be understood that the protection of the claim for new medical use is to the entire use of the substance known to manufacture a medicament for a new therapeutic use. In this way, the report should clearly and sufficiently describe the new use sought.

The descriptive report must present evidences that prove the new use pleaded at the filing of the application. In the absence of proof of such use, it is considered that this essential technical feature of the claim is not supported in the descriptive report and thus, the subject matter is not sufficiently described. Results of in vitro tests may show indications of new therapeutic use, however, they are often not confirmed "in vivo", due to the pharmacokinetic aspects, among others related to the behavior of the drug within the organism. Thus, it is not always possible to extrapolate the results of the in vitro assays to a real therapeutic application, unless additional information is provided to prove this equivalence of effect. In the case of animal studies, the models adopted should present the possibility of extrapolation

for the humans or animals to be treated.
In the event that the application seeks protection for a new medical use of compounds defined by a "Markush formula", only the use of the compounds which have been effectively demonstrated will be considered as grounded. Although, theoretically, the compounds defined by a particular Markush formula may have similar applications, it is not possible to extrapolate the use of a single compound to all others unless evidence is provided to prove this equivalence of effect.
In accordance with Paragraph 3.89 of Block I of the Guidelines for the Examination of Patent Applications, the burden of proving the support of the claims lies with the applicant and for this, additional evidence is accepted in the course of the technical examination, provided that they are intended exclusively for information already contained in the application as originally filed.

9.1.4 Clarity and precision of the claims

The claims of new use for preparing a drug must specify the disease being treated. Claims of new use that refer to disorders, syndromes, symptoms or any other generic terms, such as "gastro-intestinal disturbances", "respiratory syndromes", will not be accepted, because they cause indefiniteness regarding the matter to be protected.
Claims of new medical use which refer to the condition treated in terms of the mechanism of action, for example, "use of compound X to prepare a medicament for treating a disease by the selective occupancy of a serotonin receptor" or "use of the compound X to prepare a serotonin reuptake inhibitor medicament", will not be accepted, since they do not define the disease in question clearly and accurately.
Excerpts contained in the claims for new medical use related to the therapeutic scheme and group of patients also do not define the use of a compound to prepare a medicament and thus are not accepted as causing indefiniteness to matter. The following are complementary examples related to new medical use.

Example 1:
Claim: "Use of the product (or compound or active ingredient) X characterized in that it is in the preparation of a medicament for treating the disease Y."
According to art. 25, because the use of the product is characterized in a clear and precise manner for the preparation of a medicament for

treating a defined disease.

Example 2:
Claim: "Product X characterized in that it is used as a medicament."
Not acceptable for lack of clarity (Article 25 of the LPI), since the product is defined by its use and not by its technical characteristics.
In addition, since the product is known from the prior art, it would not present novelty (Patent Application Examination Guidelines, Block I, para. 3. 74).

Example 3:
Claim; "Product X characterized by the fact that it is for the treatment of disease Y."
Not acceptable for lack of clarity (article 25 of LPI), since the product is being defined by its use and not by its technical characteristics.
In addition, since the product is known from the prior art, it would not present novelty (Patent Application Examination Guidelines Block I, para. 3. 74).

Example 4:
Claim: "Use of the product X characterized as being in the treatment of disease Y."
Not acceptable, since, as written, it refers to a therapeutic method (Patent Application Examination Guidelines, Block I, para. 3.76).

Example 5:
Claim: "A process for treating disease Y characterized by the administration of the product X."
Not acceptable, since, as written, it refers to a therapeutic method (Patent Application Examination Guidelines, Block I, para. 3.76).

Example 6:
Claim: "Use of compound X to prepare a Y receptor inhibitor medicament."
Not acceptable for lack of clarity (article 25 of the LPI), because it refers to the condition to be treated in terms of mechanism of action and does not define a disease clearly and precisely.

Example 7:
Claim: "Use of compound X to prepare a medicament for treating CNS disorders or syndromes."
Not acceptable for lack of clarity (article 25 of the LPI), because it refers to the condition to be treated in generic terms and does not define a disease clearly and precisely.

Example 8:
Claim: "Use of the product X for the preparation of a medicament for treating the disease Y which consists in administering the medicament 3 times a day orally."
Not acceptable for lack of clarity (Article 25 of the LPI), since the additional feature of the claim ("... consists in administering the drug 3 times a day orally") is inconsistent with the pleadings, since it refers to the method of administration (part of a therapeutic regimen) and not to the use (method for preparing a medicament for treating disease Y).